Informed Consent for Elective Abortion:
A Policy Analysis for North Carolina.

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Abstract:

Abortion is a divisive issue. People on both the pro-life and pro-choice sides of the debate hold strong beliefs about the morality of abortion and how available it should be to women with unintended pregnancies. Its controversy not withstanding, it is an extremely common occurrence. More than a million women had an abortion in 2005, and estimates suggest that one in four women in America will have an abortion in her lifetime. Therefore, abortion services are a significant component of women's health care.

The informed consent process for elective abortion is an important element in the quality of medical care women receive. The purpose of pre-procedural counseling is to help the woman make an informed decision and to provide her with emotional support if it is needed[3] .This process should inform the woman of the risks, benefits and alternatives to the procedure, and the risks and benefits of the alternatives. Shared decision making requires that the consent procedure should also allow time for the woman to ask questions and provide a medium for the woman and her physician to discuss her values and beliefs in an effort to make the best decision for her. The prevalence of abortion, and the imperative to provide high quality care combine to make the informed consent process a matter of public health.

The political and social tensions surrounding abortion have engendered numerous regulations on the provision of abortion services. This paper focuses on regulation of the informed consent process for elective abortion. Supporters of proposed regulations argue that the regulations help women by ensuring that they are given the information that they need to make informed decisions, and time to think over their decisions[4] . Two bills currently before the NC legislature, the Woman's Right to Know Bill and the Ultrasound Before an Abortion Bill, would mandate additional requirements for the informed consent process for elective abortion,.

This paper is an analysis of the content of these bills, with evaluations of the risks of abortion stated in the materials, and of the implications of the regulations for women's health. The paper progresses through a history of abortion politics and social attitudes towards abortion; a discussion of the intention of informed consent and the ethical principles it was designed to uphold; a review of the evidence for the harms of abortion to women's health, focusing on the psychiatric health consequences of abortion; and a presentation and discussion of data from a series of elite interviews. The paper concludes with policy recommendations.

The research and analysis indicate that the content and requirements of the two proposed bills violate the principles of the informed consent process, and could have a negative effect on women's health by causing unnecessary delays in obtaining an abortion. The informed consent process for elective abortion should help women, contributing to high quality of care and helping them make informed decisions. The two bills analyzed here are counterproductive to those two women's health goals. Countering these legislative attempts can be achieved through public education about the safety of abortion and the current practices of informed consent for elective abortion.

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Introduction:

Abortion is a legal medical practice in the US. A woman's right to have an abortion is protected under the right to privacy, according to the 1973 Supreme Court ruling *Roe v. Wade*[5]. It is a common procedure; based on current practice, one in four women in America will have an abortion in her lifetime[1]. However, vocal objection to the legality and practice of abortion has never abated in the United States. Since *Roe v. Wade*, politicians and activists who oppose abortion have passed legislation, primarily at the state level, placing special regulations on abortion that are different from those applying to other elective surgical and medical procedures. One type of legislation that has seen particular success is regulation of the informed consent process for elective abortion.

The informed consent process for an elective abortion involves pre-procedural counseling. Informed consent is considered separate from *options counseling*, where women with unintended pregnancies may discuss with a health care provider whether they want to keep the pregnancy and raise the child, keep the pregnancy and give the child up for adoption, or terminate the pregnancy. If a woman decides to terminate the pregnancy after options counseling, she then undergoes a pre-procedural informed consent process. The purpose of pre-procedural counseling is to inform the patient of the risks and benefits of the procedure and any alternatives to the procedure as a part of the informed consent process. Two categories of "alternatives" include those covered in options counseling, which include the alternative of carrying the pregnancy to term and either giving the child up for adoption or maintaining custody of the child, and those covered after a woman has decided to terminate the pregnancy, with alternatives depending on the gestational age of the fetus and the types of available medical and surgical abortion. Some states mandate special requirements for the informed consent process for elective abortion. Thus, the medical and legal professions, and the political process, may treat the

procedure differently from other procedures receiving routine pre-procedural counseling. Although I present informed consent and options counseling as separate entities in this paper, it is important to note that they overlap. In most clinical situations it is difficult to separate the elements of counseling and consent from one another.

Both the practice of abortion and the informed consent process related to the procedure are critical issues for women's reproductive health, and as such have significant implications for public health. Despite the overall decline in the abortion rate since the 1980s, abortion is still one of the most commonly performed medical procedures in the United States[2, 6, 7]. With approximately 1.2 million abortions performed in 2005, minimizing the physical and psychological risks for women who choose to terminate their pregnancies is of clear public health importance [2, 7]. When abortion was legalized, counseling a woman prior to the abortion became an essential component of the abortion procedure[3]. The purpose of this counseling is to help the woman make an informed decision and to provide her with emotional support if she needs it[3]. The informed consent process for a woman considering pregnancy termination can have an effect on her decision; it can influence the decisions women make and their feelings about those decisions[3]. If women are not fully informed, or are unsure about what will happen during the procedure, they may have an unnecessarily traumatic experience or feel dissatisfied with the quality of care[3]. Therefore it is imperative that the informed consent process for elective abortion meets standards for informed consent and serves as a helpful tool in women's decision making processes. It is also important that the informed consent process contributes to high quality medical care for women, improving the health of women by helping them make informed decisions.

This paper is a policy analysis exploring the informed consent process for elective abortion in North Carolina (NC). Two bills are currently being debated in the NC legislature that would enact further regulation on the informed consent process for elective abortion. The primary research question is: Do the current bills being proposed in NC fulfill the ethical principles of informed consent in medical practice, and will they support women in making informed decisions about their reproductive health?

This paper progresses through an analysis of the social and political history of reproductive health policies in NC and compares the social and political climate for elective abortion in NC to that of other states in the Southeast. Included in this discussion is an analysis of current policies for the informed consent process for elective abortions in the US, the presentation of two bills being proposed in the NC legislature that would regulate the informed consent process for elective abortion, and a review of the existing medical literature to evaluate the content of the identified policies. The paper includes a systematic summary and analysis of review articles on psychiatric consequences associated with elective abortion to investigate the quality of the available evidence on this topic. An essential component of this evaluation and analysis is interviews with elite stakeholders, including experts in the fields of reproductive health services, reproductive health policy, women's health advocacy, and political analysis. All of the information gathered contributes to the evaluation of the two proposed bills in NC. The bills are evaluated based on whether they fulfill the ethical principles of the informed consent process and whether they will benefit the health of women in the state of NC. The paper concludes with a discussion of the public health implications of the proposed bills and recommendations for future policies and research into the effects of regulation of the informed consent process for elective abortion on women's health.

This study provides readers with an analysis of the social and political factors that influence reproductive health policies in the Southeast, and in particular NC. The study offers readers a full discussion of the risks of abortion for women's health, and a review of the ethical issues that arise when materials mandated for the informed consent process for abortion are motivated by non-medical purposes or beliefs.

Historical Background of Abortion in the United States

In the US, abortion received federal protection with the 1973 Supreme Court decision in *Roe vs. Wade*. However, the legal status of abortion is not always an indication of its practice, safety, or availability. Abortion can be illegal, but still widely practiced, and when it is legal, it may not be equally accessible to all women[8]. In the US, abortion "before quickening" (i.e., abortion before the pregnant mother senses fetal movement) was commonly practiced prior to the founding of the American Medical Association (AMA) in 1847[8]. Up until this point, little moral objection to the practice was expressed and there was no legislation restricting access to the procedure[8]. Abortion was commonly performed by lay health workers and was not always safe for women. With the intent of increasing professional autonomy medicine and improving physician's status, the AMA launched an anti-abortion campaign to emphasize the lack of safety associated with the practice of abortion at the time[8]. The AMA was joined by members of the religious sector—largely led by Catholics and fundamentalist Protestants—in the 1860s in speaking out against abortion, [8]. By 1900, abortion was illegal in the US and, although Colorado and NC liberalized their abortion laws in 1967 (Schoen), abortion remained illegal in the rest of the country until 1973[8]. In 1973, the confluence of multiple factors in the social and political environment facilitated the passage of *Roe v. Wade*[9].

In the 1960s, women were entering the workforce and college at an increasing rate and yet still held the primary caretaking role for children[9]. These increasing demands and the imbalance of responsibility made the need for safe and reliable fertility control paramount. In the absence of safe and legal abortion, and with limited availability of effective contraception, women in need of fertility control resorted to illegal abortions[9]. Illegal abortions became commonplace. These practices undermined the legitimacy of government policies, but also endangered the lives of the women who were using them[9]. Although sometimes performed safely, illegal abortion was often dangerous to the life of the woman[9].

In the late 1960s, the increasing prevalence of illegal abortions prompted the AMA to shift its position and begin supporting legalization of abortion procedures when performed by physicians.[9] Analysts of the political climate and motivations underlying this shift present two contrasting views. In one of these analyses, observers attribute the AMA's change in official policy to members witnessing the suffering of women from complications of illegal abortion[9]. According to this theory, many doctors drew the conclusion that these complications were unnecessary and tragic[9]. A second theory attempting to explain the transition within the AMA holds that physicians wanted to take control of abortion away from others and keep it under their sole supervision and authority[10]. During this time, some medical professionals and concerned citizens banded together to provide illegal—but medically safe—abortions[9]. One of the most famous of these was the Chicago-based group called Jane, a group that started with volunteer doctors, who then trained lay women to perform the procedure safely. This organization delivered illegal but safe abortion services to thousands of women[9].

The discussion of women's rights and the threat to women's health presented by widespread illegal abortion provided a framework for exposing the dangers associated with

existing laws limiting reproductive freedom. In addition, the legitimacy of American law was actively threatened by the disregard for the illegality of abortion[9] . This disregard was demonstrated by those who were willing to perform abortions, even under the threat of arrest and loss of license. The philanthropist and activist John D. Rockefeller III called for abortion law reform in the 1970s. He made the argument that abortion was inevitable and unstoppable and that, at the time, its prohibition was leading to large-scale disrespect for the law. He argued that abortion should be legalized for the sake of maintaining social order and stability[9] .

By the 1970s, the Women's Movement, abortion activities and criticism of ineffective policies had generated a climate ripe for change in reproductive health policies[9] . Promotion of the AMA's interests and concern for the sanctity of American social order were not the only factors driving the need for change. Pro-eugenics policies also played a role. Pro-eugenic policies that began in the 1920s and continued through the 1970s supported state-funded, selective abortions and the sterilization of poor women and women with non-white racial backgrounds[11] . One example is the NC Eugenics Board. In 1929, NC passed a state eugenics law that allowed for the sterilization of individuals found to be mentally diseased, feeble-minded or epileptic and whose sterilization was in the interest of the mental, moral or physical improvement of the patient or inmate or of the public good. NC established a state Eugenics Board in 1932. The board received petitions for sterilization from penal institutions, charitable institutions and from county welfare superintendents. Eugenic scientists believed that feeblemindedness was a hereditable condition, and that it was responsible for poverty, promiscuity, criminality and alcoholism and illegitimacy. According to this notion, sterilization was seen as a way to prevent these undesirable social outcomes.

Starting in the 1920s, research began that eventually undermined the assumptions of eugenic science, but many eugenics-related policies were not challenged directly until the 1940s. Most states saw a decline in the number of state-ordered sterilizations in the 1940s, but there was an expansion of the program in Georgia, NC and Virginia. The program in NC promoted sterilization as one of several solutions to poverty and illegitimacy and increasingly targeted Black women. The focus in the 1960's on the "culture of poverty" replaced hereditary theories as justification for eugenic sterilization. In the 1960s, the availability of better contraception, passage of voluntary sterilization laws, and the reform of abortion laws contributed to a decline in pro-eugenics policies for abortion and sterilization. Above all, by the late 1960s, organized feminist activities raised women's right to control their own fertility to the public agenda[11]. The Women's Movement, actively introducing into the discussion the belief that control over one's own reproductive autonomy is a basic human right, was both necessary and sufficient to the shift in political culture from acceptance of general prohibitions on abortion to acceptance of abortion as part of what came to be known as reproductive rights [9].

These forces culminated in *Roe vs. Wade*. With this decision, the US Supreme Court held that women have a Constitutional right to privacy that encompasses the decision to terminate a pregnancy. The case held unconstitutional any statute that prohibited abortion and statutes that imposed requirements that were so stringent as to make abortion unavailable[12]. The core holding of *Roe vs. Wade* was that states cannot outlaw abortion before a fetus becomes viable (defined as able to survive independent of the mother and legally as 24 weeks gestational age) and can do so thereafter only when the life or health of the pregnant woman was not threatened by the pregnancy[6, 13]. A legal implication of this belief was that the state cannot favor the life of the fetus over the life or health of a pregnant woman. By connecting abortion to the

Constitutional right to privacy under the Due Process Clause of the 14th Amendment of the United States Constitution, the Supreme Court's decision in *Roe vs. Wade* defined abortion as a Constitutionally protected practice.

Since *Roe vs. Wade*, anti-abortion advocates have been increasingly involved in challenging the legality and administration of reproductive health services. Although Supreme Court rulings have consistently upheld *Roe vs. Wade* since its inception, abortion opponents have successfully limited abortion in both social and political arenas[13]. The first major success was the passage of the Hyde Amendment in 1977. This amendment cut of the availability of federal funds for most abortion services and thereby significantly decreased the accessibility of abortion for poor women [9].

Challenges to the legality of *Roe vs. Wade* have come from within and without the political realm. "Pro-Life" groups have organized public demonstrations and encouraged the obstruction of abortion providers' actions through both violent and non-violent means. In addressing their constituents' interests and their own beliefs, elected officials and interest groups have introduced specific legislation with the intent of limiting access to abortion services.

Anti-abortion tactics have changed significantly over time. Tactics that opponents began using in the mid-1990s have been particularly successful in generating limitations on abortion access. Prior to this time, violence against abortion providers and patients was the most pronounced anti-abortion tactic. Since 1977, 80,000 acts of violence or disruption have been reported at abortion clinics, including 7 murders of providers, 17 attempted murders, 41 bombing of clinics, 166 cases of arson, and 125 assaults[6]. The trend in violent acts has been decreasing since the early 1990s, but this record represents the violent history of the anti-abortion movement[6]. Much of this violence is justified by using a "fetus-centered" approach, whereby

protesters reason that they are acting to protect the unborn from abortion providers and from women who are willing to end the lives of innocent children. The fetus-centered argument implies that women make a rational and autonomous choice to have an abortion, and in doing so demonstrate selfishness and a lack of morals or values[14].

The administration under George W. Bush has aggressively attempted to grant rights to fetuses. It has extended coverage to fetuses under the State Children's Health Insurance Program (SCHIP); expanded the mission of the federal Advisory Committee on Human Research Protection to include embryos; and expressed support for the Unborn Victims of Violence Law, a law that criminalizes harming fetuses separately from harming the pregnant woman[6].

In the mid-1990s, anti-abortion leaders changed their tactics from overt violence and an emphasis on the fetus' right to life to anti-abortion messages emphasizing a desire to protect women's health[15]. The "woman-centered" anti-abortion campaign endorses and promotes the belief that abortion places a woman's health at risk. This approach cites medical literature that supports links between abortion and poor health outcomes like breast cancer, depression, and high-risk future pregnancies.

The woman-centered approach demonstrates a shift in the representation of anti-abortion advocates' attitudes toward the procedure. In effect, this focus re-positions anti-abortion advocates as defenders, rather than critics, of pregnant women who have had or who are considering abortions. Woman-centered discourse around abortion focuses on depicting women who are considering abortions as confused and in despair, and argues that women in this position cannot make rational or autonomous decisions about whether or not to have an abortion[14].

Woman-centered anti-abortion activists contend that physicians who provide abortions dismiss or

exploit this inability to make an appropriate decision in order to profit by providing the procedure [14].

The woman-centered anti-abortion strategy is actively seeking the enactment of several key policy changes on both the State and Federal level. These include laws requiring abortion providers to counsel women, using specific materials developed by the state, on the potential harms of abortion to their health; laws mandating the use of materials that describe details of abortion procedures for both early and late term abortion; laws requiring the provision of materials that describe fetal development throughout pregnancy as a part of the informed consent process for elective abortions; and laws requiring waiting periods (usually 24 hours) after the materials have been presented prior to the procedure [16]. The new anti-abortion strategy has been extremely effective in changing policy, and many states have adopted special policies for the informed consent process for elective abortion[17]. Examples of success with this approach include the groundbreaking 1992 US Supreme Court decision in *Planned Parenthood of Southeastern Pennsylvania vs. Casey*, where additional state restrictions on the provision of abortions were deemed Constitutional with the exception of a policy that would require women who were married to notify their husbands of their decision to terminate the pregnancy[18]. Another example is the passage of the Federal Abortion Ban, first signed into law by President George W. Bush in 2003 and deemed Constitutional by the Supreme Court in April of 2007, and the 2007 Supreme Court decision in *Gonzales vs. Carhart*. Both decisions deemed a ban on late-term abortions constitutional, even though it does not provide an exception for cases in which the procedure is necessary for the health of the mother[19].

Ideologies & Social Attitudes towards abortion in the US:

Social attitudes towards abortion in the US: US public opinion about abortion is diverse. A public opinion poll in 2003 reported that 60% of Americans think that it has become too easy to obtain an abortion[20]. However, most people in the US believe that patients should have access to legal treatments, even in situations where the physician may be troubled by the moral implications of those treatments[21]. About 49% of US citizens consider themselves more "pro-choice" and 45% consider themselves more "pro-life"[20]. Fifty-five percent of Americans support a woman's right to a first trimester abortion, and 75% support increased public funding for family planning services and counseling.[20]

Social attitudes and acceptance of abortion for any reason (i.e. abortion on demand) have declined since the mid-1980's; but the general public opinion towards abortion indicates that it is an accepted practice, especially for women with a health indication or with psychosocial reasons for seeking a termination. By the age of 45, 43% of all US women will have had an abortion[6]. This large percentage of the population indicates that abortion is accepted and used by women in the US, even if they may not report being "pro-choice" or in favor of abortion on demand.

"Pro-choice" and "Pro-life" ideologies: Abortion is one of the most divisive issues in the US. Differences in opinion exist about the morality of abortion in general and under specific circumstances, but disagreements usually stem from a deeper source. People on opposite sides of this issue often differ in the way that they think about women's roles in society and in the way they perceive sex and sexuality.

Data from the National Fertility Study (NFS), the National Opinion Research Center (NORC) and several public opinion polls indicate differences in the demographic characteristics of people on the two sides of this issue. These data show that attitudes towards abortion are

closely related to religious affiliation, and that liberal attitudes toward abortion are positively correlated with high educational level, low parity, and support for female equality [8].

Based on these survey results, individuals who disapprove of abortion can be characterized as typically Roman Catholic or fundamentalist Protestant and strongly committed to organized religion; on the conservative or traditional end of the spectrum with regard to women's role in life, premarital sex, sex education and civil liberties; and have no more than a high school or some college education[8]. Individuals who approve of the legality of abortion tend to be non religious or Jewish; not strongly committed to organized religion; they are likely to think of women's role in more liberal terms and to have college or graduate level degrees[8].

Although these data describe the general population's attitudes and beliefs, it is also important to investigate the beliefs and attitudes of people who are activists in the "pro-life" and "pro-choice" movements. A sociological study of over 200 activists on both sides of this issue finds that activists from opposing camps are very different from one another in sociodemographic characteristics and overall values. Differences in sociodemographics reflect the same trends as in the general population described above[8]. More important differences were between the values of activists. Pro-life activists felt that men and women were intrinsically different, that a women's place was in the home, and that the primary purpose of sexuality is procreation. Consequently, this group is generally opposed to most forms of contraception, and consider an unanticipated pregnancy not as unwanted but unexpected[8].

According to this same study, pro-choice activists believed that women and men were similar in rights and responsibilities. They focused on the emotional rather than procreative aspects of intercourse, wanted to be able to plan conception when they were emotionally and

financially prepared for parenthood, and wished to limit family size to conform to their social and economic goals. Therefore, they perceived contraception as very important and useful.

While pro-choice activists approved of abortion for family planning, most did not approve of abortion as a form of birth control[8]. Family planning is the ability to decide when one wants to have children and the spacing of those children. Birth control—the practice of using some method to decrease the likelihood of getting pregnant—is one element of family planning. All methods of birth control have failure rates and may be used inconsistently; thus, unintended pregnancies are possible even for a woman using birth control. It appears that activists on both sides of this debate have deeply vested interests, not only in the outcome of the pregnancy, but in much wider issues including the role of women in society. Because of these deeply rooted interests, the abortion debate is likely to remain heated[8].

Informed Consent:

The woman's health-centered anti-abortion movement relies heavily on the concept of informed consent, a critical component of ethical interaction between patients and their providers. This movement seeks to pass legislation that requires doctors to follow specific guidelines in the informed consent process for elective abortion, using the justification that women having abortions need to be informed about the risks of abortion to their health and about available alternatives to abortion such as adoption. Because the concept of informed consent is central to this strategy, it is important to understand the definitions and intentions of the informed consent process as they apply to current thinking and application of medical ethics.

Many ethicists and organizations have defined the principles of medical ethics. The basic principles accepted and currently promoted among US physicians are beneficence, nonmaleficence and patient autonomy. According to Doyal et al, current medical ethics practice

is guided by the duty of practitioners to protect the life and health of their patients (beneficence and nonmaleficence) and to respect patient autonomy[22]. Faden and Beauchamp define patient autonomy as the right of competent patients to make informed choices about their medical options, intentionally and without controlling influences or coercion[22-24].

Legal doctrine, ethical theories and contemporary understandings of the patient-physician relationship all underscore the importance of full patient comprehension as a means to support patient autonomy[23]. Many researchers with an interest in the ethics of informed consent conclude that consent is an essential component of doctor-patient interactions because it is a means by which ethical ideals of respecting patients' autonomy can be realized[25-28].

Consent is understood and defined by different theoretical models[27]. "Real" consent is the understanding of consent that is used in the fields of Medicine and Law. This model assumes positivist concepts to define the parameters of consent[27]. Positivism distinguishes factual concepts through defining dichotomies (informed vs. ignorant, free choice vs. coercion)[27]. Informed consent in the positivist framework has the benefit of encouraging health professionals to know and explain clearly what they plan to do and why[27]. Basic information standards as established by the Nuremberg Code (1947) and the Declaration of Helsinki (1964) require physicians to discuss the following as part of the informed consent process: the nature and purpose of the intervention; intended effects and possible side effects; risks, harms and benefits; and any reasonable alternatives. Furthermore, the process must be voluntary, meaning that the consent process took place free from force, fraud, deceit, duress or other form of restraint or coercion, and with the patient's knowledge about the right to refuse or withdraw without future negative effects on health care and the patient's right to ask questions and negotiate aspects of

treatment[29, 30]. Respect for patient's consent reflects an appreciation of the physical and mental integrity of patients and defends them from unwanted interventions, deception or coercion[27]. A patient's thoughts, feelings and values are important elements of the consent process because they influence the choices that a patient perceives as acceptable. Social pressures, anxiety or distress can inhibit a patient's ability to make an informed decision free from coercion, and for this reason it is assumed that these pressures should be reduced or eliminated by presenting accurate information in a neutral manner[27]. These principles culminate in the Informed Consent Doctrine, a basic legal rule for medical practice that states that a procedure cannot occur without first obtaining consent from the patient[12].

For medical interventions, it is accepted that consent means a voluntary, un-coerced decision made by a competent and autonomous person on the basis of adequate information and deliberation[31]. Conceptually, the informed consent process requires several steps: assigning the person decision-making capacity, disclosing relevant information about the procedure, ensuring that the patient understands the information s/he has been given, ensuring that the patient is making a voluntary choice, and authorizing the participant's decision[32].

A necessary element to the consent process is the patient's ability, or competence, to make an informed decision. Roughly, competence can be determined by a patient's Mini-Mental Status Exam Score (MMSE) or Intelligence Quotient (IQ), but these are imperfect measures[27]. Competence to make an informed decision can be difficult to determine, because truly informed consent involves being able to inform a patient fully about a medical decision[27]. The ability to inform a patient relies heavily on that patient's medical literacy. The consensus is that fully informed consent is the goal, even though it may not always be attained, and unless a person is

mentally handicapped, severely emotionally disturbed, or very young, there is little question that he or she is competent to make an informed decision[3].

According to these standards, informed consent involves knowing about the nature and purpose of the intervention; the intended effects and possible side effects of the intervention; the risks, harms and potential benefits for the procedure; and any reasonable alternatives to the procedure. Voluntary consent involves freedom from force, fraud, deceit, duress, overreaching or other ulterior forms of constraint or coercion; knowing about the right to refuse or withdraw without punishment; and the right to ask questions and to negotiate aspects of treatment[29, 30].

Medical decision making is an essential component of medical ethics and risk management[28]. The process of medical decision making is based on patient autonomy and informed consent[28]. Shared decision making is an important part of informed consent because it facilitates communication between physician and patient. That communication helps to bridge the gap between medical knowledge of the possible risks and benefits of an intervention and the consequences that matter the most to a patient based on his or her values and beliefs[27]. The need for shared decision making is in part driven by pressures from the bioethical and legal fields to move away from paternalism and respect patient autonomy[33]. Ideally, medical decision making is informed by the best evidence about the risks, benefits, and alternatives, it also encompasses patient-specific characteristics and values[34]. A fundamental goal in enhancing patient choice is to enable patients to come to an autonomous decision which reflects personal preferences. Consent is promoted as a means by which these ideals can be achieved[32, 33].

Informed consent and shared decision making are mechanisms that can fulfill the ethical duty of physicians to support patients in making informed decisions about their medical care[32]. The fundamental belief that the patient has a right to make medical decisions without coercion is

embodied in the basic standards of the leading professional medical associations[16]. All states require health care providers to obtain consent from patients prior to performing non-emergency procedures. These requirements generally mandate that providers give patients information on the risks and alternatives to the procedure. The rules that govern what is included in the risks and benefits vary, but generally rest on the best medical evidence to provide patients with the risks and benefits of the procedure and all the reasonable alternatives to that procedure, including the consequences of non-treatment[34].

Informed Consent for Elective Abortion:

Two controversial elements of legislation related to the informed consent process for elective abortions are requirements regarding the content of pre-abortion educational materials and the use of mandatory waiting periods following the delivery of these materials prior to the abortion.

Of these, the former most directly interferes with the concept of informed consent. Some of these policies require the discussion of materials that are not consistent with the intent of the informed consent process for all other elective procedures. An example of deviation from routine informed consent is the provision of materials that may not be relevant to the decision of the woman[35]. Some of the materials describe multiple abortion procedures, including late-term abortions, and may include descriptions of fetal development throughout gestation through a term pregnancy. However, ninety percent of abortions are performed before 12 weeks of gestational age[16]. As more than 90% of women who receive abortions do so in the first trimester, the descriptions of fetal development and late-term abortion procedures are irrelevant to their care[16]. Similarly, materials requiring doctors to inform women about child support laws

and pregnancy support services may not be relevant to a woman seeking an abortion, especially if financial concerns are not the primary motivation for the choice to terminate[35].

In another example of policies inconsistent with the fundamental elements of informed consent, Richardson et al.'s analysis of pre-abortion counseling materials presenting health risks associated with abortions found that the content of some of the materials was misleading, inaccurate, or provided incomplete information[35]. These materials often contain misinformation about the risks of abortion to a woman's health. Examples include a link between elective abortion and an increased risk for breast cancer, infertility or complications with future pregnancies, and negative mental health outcomes. None of these health risks has been clearly linked to elective abortion by the body of available evidence[35]. One of the most statistically rigorous studies on the abortion-breast cancer link, published in the *New England Journal of Medicine* in 1997, found no connection between abortion and breast cancer[36]. In 2003, the National Cancer Institute (NCI) conducted a systematic review of the evidence and concluded that there was clearly no link between abortion and breast cancer[15]. No systematic review of the evidence has linked legal and safe abortions to loss of future fertility[35]. Finally, the best predictor of a woman's mental health after an abortion is her mental health prior to the abortion; there is no currently accepted body of evidence that abortions cause mental health problems in women[15, 35-37].

Concerns about these materials include the notion that they are not intended to inform women of the true risks and benefits of the procedure, but rather that the policies are intended to mislead and dissuade women from having abortions by misrepresenting and exaggerating possible negative health risks[16, 6].

The second legislative tactic mentioned above involves mandatory waiting periods for abortions, a now common policy approach for activists and legislators opposed to abortion[4]. Those who support this legislation argue that it is intended to educate women seeking abortions and give them time to consider their decisions[4]. This argument makes the assumption that most women seeking abortions have not given their decision enough thought prior to making an appointment for an abortion[14].

Mandated waiting periods are typically 24 hours. Some mandates allow for women to be given the consent materials over the phone or by mail, but others require that the woman receive the consent materials in person, necessitating at least two visits to the clinic[17, 38]. Critics of mandatory waiting periods, particularly those that require two visits to an abortion clinic, assert that they cause women to have abortions later in pregnancy, which increases the risks associated with the procedure[38]. Waiting periods can also create additional costs for women in the form of lost time working and the possible costs of travel and childcare[4]. Another concern is that requiring more than one visit may threaten a loss of confidentiality if the woman has to justify her absence from work with a note from a physician[4].

For abortion consent, many states have detailed and specific requirements for the informed consent process[16]. The 1992 Supreme Court Decision in *Planned Parenthood of Southeastern Pennsylvania vs. Casey* let stand a state statute mandating a 24-hour waiting period following counseling of women seeking an elective abortion with state-mandated counseling materials, stating that it did not impose an "undue burden" on a woman's right to an abortion[39]. Since that decision, 24 states have adopted legislation that requires a waiting period, usually 24 hours, following receipt of state-mandated counseling materials. Seven of these states require that the counseling be done in person, necessitating two visits to the abortion clinic[17, 38].

Currently, 32 states have enacted abortion counseling laws under the banner of informed consent, detailed in Table 1.

Table 1: State Laws with Informed Consent Procedures Specifically for Elective Abortion[17]

State	Waiting period	Description of all common abortion procedures	Description of fetal development throughout pregnancy	Ability of a fetus to feel pain	Inaccurately portrays risk to future fertility	Inaccurately asserts possible link between breast cancer and abortion	Describes negative emotional responses only	Accessing ultrasound services
Alabama	24 hr	W	W					
Alaska		W	W	W		W		
Arkansas	Prior day	W	W	V,W				
Georgia	24 hr	W	W	V,W				V
Idaho	24hr	W	W					
Kansas	24hr	W	W			W		
Kentucky	24hr		W					
Louisiana	24hr	W	W	V				
Michigan	24hr						W	W
Minnesota	24hr	W	W	V,W				
Mississippi	24hr					W		
Nebraska	24hr		W				W	
North Dakota	24hr		W					
Ohio	24hr		W					
Oklahoma	24hr	W	W	V,W		W		V,W
Pennsylvania	24hr	W	W					
South Carolina	1hr	W	W					
South Dakota	24hr	W	W	W			W	
Texas	24hr	W	W	W	W		W	
Utah	24hr	W	W				W	V
Virginia	24hr	W	W					
West Virginia	24hr	W	W			W	W	
Wisconsin	24hr	W	W					V,W

* Key: W= written materials, V= materials delivered verbally, Source: Guttmacher Institute. *Allan Guttmacher Institute State Policies in Brief.* 2008.

Many states in the Southeastern United States have policies mandating that certain topics are covered as a part of pre-abortion counseling. For example, Georgia has a policy that requires the discussion of fetal pain and abortion alternatives and support services for those alternatives. South Carolina, Tennessee and Virginia have policies that require the discussion of alternatives to abortion and support services for those alternatives[16].

As of May 2008, NC did not have a policy that applies specifically to the informed consent process for elective abortion. However; two bills awaiting debate in the NC legislature

would require material to be included as part of the pre-abortion consent process. The first bill, "Woman's Right To Know" (House Bill 1552), would mandate that providers would be counsel women about the medical risks of abortion, including the alleged risk of psychological harm; provide detailed information about fetal development throughout gestation, using conception instead of a woman's last menstrual period (LMP) to date the pregnancy; present materials describing the abortion procedures available at all stages of pregnancy, and present materials discussing financial support services available to a woman if she decides to keep her pregnancy. This bill would also require physicians, if they perform a prenatal ultrasound, to inform the woman that she has the right to view the ultrasound image. The bill includes the requirement that any woman considering abortion who calls a clinic where abortions are provided has a right to speak with a physician over the phone. If a physician failed to adhere to the policy, he or she would be at risk for legal punishment including having to pay civil remedies to the plaintiff (who could be the patient, or the father of the fetus who was aborted).

The other pending bill, "Ultrasound Before an Abortion" (House Bill 1782), would require a physician to perform an ultrasound prior to performing an abortion and to review the image with the woman prior to her giving informed consent. This bill would allow women to refuse to see the image. Both bills are attached in the Appendix to this document.

The fate of these bills in North Carolina is unknown at the time of this writing. North Carolina's history with women's reproductive health has at times been a progressive one, and at times very conservative. The opinions of the state's population and politicians on the topic are also quite diverse. Partly due to a culture that was highly concerned generally with public health and specifically with maternal and child health, North Carolina became one of the first states in the nation to have public birth control services provided to women on welfare, starting with the

nation's first state-supported birth control program in 1937, the condom project in 1940, and reforming the illegal status of abortion in 1967[11]. In contrast, many neighboring states did not have widespread public health programs that supported public birth control programs and did not reform their abortion laws prior to the Supreme Court decision, *Roe vs. Wade*, in 1973[10]. Currently, North Carolina stands out among southeastern states by not having a waiting period for abortion services and not having special informed consent processes required by law for elective abortion.

The next section addresses the following questions: What are the social and political factors in North Carolina's history that may explain this difference between NC and its neighboring states? Are the current bills to enact policies that direct the informed consent process for elective abortion in NC likely to pass? What are the medical and ethical implications if these bills are adopted in NC?

Systematic Review:

Introduction: Many supporters of mandated informed consent procedures for elective abortion argue that abortion carries significant risks for women's health and that women should have the right to know about these risks prior to consenting to have an abortion[4, 38, 40]. Supporters of the mandatory waiting period that follows mandatory counseling argue that a woman needs adequate time to think about her decision prior to having an abortion[4]. The medical evidence that supports the health risks of abortion has questionable quality, and most studies that have examined the effect of a waiting period on a woman's satisfaction with her choice to have an abortion have found that waiting periods do not offer any benefit to a woman's decision making process[4, 38].

The controversy surrounding abortion creates conflicting views of the risks of abortion for women's health, and many review articles have evaluated the bodies of evidence about these

risks. Care should be taken when reading any review article to determine if the authors used rigorous standards of inclusion, exclusion, and evaluation of existing evidence; and if the authors were transparent about how they weighed the available evidence to draw any conclusions. Elements of high quality review articles include using a systematic approach to identifying studies, and a transparent system of evaluating those studies, and including a thorough description of methodology and reasoning supporting both evaluation and conclusions. Lower quality studies tend to be less transparent and the conclusions are not always well justified. Review articles on the health risks of abortion are of varying quality. Some have significant sources of error and bias, while others are of high quality. Many studies on abortion have limitations of study design or the tools used to measure outcomes, and high quality review articles will discuss those limitations in their evaluation of the evidence.

One of the requirements in the pending laws in North Carolina is mandatory waiting periods after the informed consent procedure has taken place prior to the abortion. Supporters of mandatory waiting periods argue that they are intended to inform women seeking abortions and give them time to consider their decisions[4]. This legislation implies that a woman needs time after the counseling to make an informed decision, and to participate in a healthy decision-making process. For this reason, the issue of the quality of evidence for the mental health sequelae of elective abortion is particularly pertinent.

In this review I will evaluate the quality of several review articles on the risks to women's mental health associated with elective abortions. The guiding question for this review is: What is the quality of existing literature reviews of the evidence for mental health risks of elective abortion?

Methods: To identify review articles for inclusion in this review, I searched the databases of PubMed, ISI Web of Science, CINAHL, and PsychInfo using the keywords or MeSH terms (induced abortion OR therapeutic abortion OR elective abortion) AND (stress disorders, post-traumatic OR post-traumatic stress disorder OR depressive disorder OR depressive symptoms OR adjustment disorder OR major depression OR post abortion syndrome OR anxiety disorder) AND (informed consent OR decision making). Searches for the risk of poor mental health outcomes yielded 23 articles. I read the abstracts of all of these articles, and included articles that met the selection criteria in my review. I also included references found in articles included in the review if they were review articles and met the other inclusion and exclusion criteria. The selection criteria include that the article is a review article or meta-analysis and that the article topic is the risk of mental health outcomes associated with elective or induced abortion. My inclusion criteria were any review articles that discuss the evidence linking elective abortion to poor mental health outcomes conducted since 1970. My exclusion criteria were articles that are not review articles, and that do not discuss the risks or incidence of the negative mental health outcomes associated with elective abortion. A single reviewer (L.K.P.) read all abstracts and decided which articles fulfilled the inclusion and exclusion criteria.

Using the inclusion criteria, I identified 23 articles. After reviewing the abstracts and excluding articles that did not meet selection criteria, I was left with four articles addressing the risk of psychiatric disorder from abortion yielded four articles. One article reviewed the evidence for many health outcomes associated with elective abortion, and was included for the section about mental health outcomes. I conducted a systematic evaluation of the review articles.

Each article was defined as being systematic or descriptive, and evaluated according to standards for high quality systematic reviews. The quality of the articles was evaluated using the

following criteria: the type of review (systematic or descriptive), the presence of a focused key question (defining the population of interest, the intervention in the study, the control group used for comparison, and the outcomes of interest), whether a comprehensive search strategy was used, whether a thorough method for appraisal of the quality of the included articles was applied to all of the articles in the review, analysis of any heterogeneity between articles in the review, whether publication bias was assessed, the strength of the evidence presented, and the use of statistical analysis when appropriate. Each article was assessed using these criteria to determine if the quality of the article was poor, fair, or high.

Review articles are of two types, systematic and descriptive. Systematic reviews use a comprehensive search strategy and reproducible inclusion and exclusion criteria. Article selection should ideally be conducted by more than one author in order to decrease selection bias in the review. Together, these processes help to eliminate the bias of the author in the selection of articles for the review. Narrative or descriptive reviews tend to ask broader questions, with the author selecting the evidence to be included in the review. These articles tend to not have a methods section describing the selection process for the articles that are reviewed, are prone to having bias, and are difficult to reproduce.

The methods that the authors use to evaluate the quality of the articles included in the review should be consistent and thorough. If they are not, bias is introduced into the review. Also, any heterogeneity among the articles in the review should be discussed in order to offer a full analysis of the existing literature. Evidence should be presented similarly for all the articles included in the review, so that comparisons can be made about the quality of the cumulative evidence on the topic. Finally, statistical analysis in the form of a meta-analysis should only be done when appropriate; that is, only when the articles in the review are similar enough in their

population, intervention, control, and outcome to be combined for analysis as a whole. The content of the articles and the conclusions from the evidence from each article, along with the quality of the article, are described in Table 2 of the Results section.

Results: The systematic review article by Thorp et al. found that induced abortion increased the risk for mood disorders strongly enough to provoke attempts at self-harm[41] . The article had no focused key question, and asked broad questions about the evidence for negative health outcomes associated with elective abortion. The authors conducted a comprehensive literature search, and detailed their search strategy in their methods section. However, one major review article was excluded that did fit the inclusion criteria, and did not fit the exclusion criteria. The reason given for the exclusion of this article was that the authors did not believe that it had any additional information to add to the other articles included in the review. The articles were abstracted by a single author, which can lead to bias.

The authors clearly describe the results of their review, but the strengths and weaknesses of each article, details about the study design and control or comparison population, and overall validity of each article were not discussed. Instead, the strengths and weaknesses of descriptive studies were discussed in general. As with the validity of the individual articles, differences between articles were not discussed in detail. Heterogeneity among articles was discussed briefly, citing that differences in reference population and measurement tools could account for some of the differences. No detailed explanation was offered about the differences in articles with positive and negative findings, although articles with positive findings were given more weight in the discussion and conclusion sections of the article. The authors addressed the possible existence of publication bias, but there was no formal, objective assessment of whether or not it was present among the articles included in the review.

The strength of the evidence and statistical analysis of the paper is moderate. The evidence from the included articles was presented in an evidence table. No statistical analysis was done. This is appropriate considering the possible heterogeneity of the studies included in the review. While the evidence table gives details about the type of study and the amount of time for follow-up for each study, the table does not list the control or comparison group for each study, nor the quality of the individual studies. The comparison group is important because it influences the meaning of a study's results and the comparison groups for many studies on the mental health consequences of abortion vary from study to study. Most of the evidence presented by Thorp et al. indicates that poor mental health outcomes are associated with elective abortion. This is concerning, and a detailed analysis of the included articles needs to be done in order to ascertain if the studies that are included are valid.

The overall quality rating for the article by Thorp et al. is poor. This study had an initially sound method of identifying articles to include in the review, but did not adhere to the inclusion and exclusion criteria by excluding one article based on neither criterion. There is a lot of potential for bias in the inclusion of the articles that are reviewed because they were abstracted by only one author, without a method for ensuring minimization of bias. In the analysis and conclusions, more weight was given to studies that found associations between negative mental health outcomes and elective abortion; although no methodology or reasoning for this additional weight was given.

The article by Morris et al. found that most research on early term abortions indicates lower psychosocial stress post-abortion than pre-abortion, and that there are certain psychosocial variables that indicate a small population of women is more likely to have negative mental health outcomes following abortion. This population includes women who lack strong social support;

feel conflicted, ambivalent, or coerced into making the decision to terminate; and women having late terminations for reasons of fetal anomaly. Most research on late-term abortions is on abortions for fetal anomalies and finds negative mental health symptoms following the abortion, but these symptoms tend to improve with time and that they may be due to the psychosocial stress of having the diagnosis of a fetal anomaly[42].

This article was a descriptive review and asked the key question: What is the role of psychiatrists in pregnancy terminations? This question is inadequately focused; it does not specify a population, intervention, control and outcome. The authors did not conduct a systematic review, and therefore did not conduct a comprehensive literature search. They do not describe the methods of their literature search and how they selected articles, making selection bias a possibility and decreasing the validity of their conclusions. However, there were articles in the review that had both positive and negative findings in looking for associations between elective abortion and poor mental health outcomes.

Most of the articles included by Morris et al. were appraised individually. The strengths and weaknesses of some articles were combined in the analysis of the quality of the studies reviewed. Heterogeneity among the findings of the articles was described in detail. Reasons for differences in findings were described thoroughly as being due to differences in control populations, different measures used to assess mental health, and different follow-up times.

The strength of the evidence provided in the article is fair. The authors chose to report findings in terms of the percent of the study population with the outcome of interest, and did not use comparative statistics like risk ratios, odds ratios, or absolute risk. The evidence was not presented in an evidence table, and so a comprehensive look at all the articles reviewed was

difficult. The authors did not conduct a quantitative analysis on the cumulative data, but this is appropriate considering the heterogeneity among the studies included in the review.

The quality rating for Morris et al.'s article is fair. The article is not systematic, and there are no details about the methods that the authors used for selecting articles. However, most articles that are included are analyzed for quality, and the strengths and weaknesses of the articles are described.

The Turrel et al. article is also a descriptive review.[43] This article asked a focused key question about the primary outcome of interest, negative mental health outcomes, and a focused key question about secondary outcomes, the psychosocial variables that affect whether or not a woman is at elevated risk for negative mental health outcomes following an abortion. The article found that most women feel relief following an abortion for an unintended pregnancy and see the experience as an opportunity for emotional growth and learning. The variables that seem to make some women more prone to negative mental health outcomes include the demographic variables of: younger age, not having any other children, having an abortion later in pregnancy, and having strong religious beliefs that abortion is wrong. The psychosocial variables that seem to be associated with poor mental health outcomes include not having adequate information, feeling coerced into having the abortion by family/friends, and not feeling comfortable with the decision making process.

This article was not a systematic review, and did not include a methods section on the search strategy, inclusion and exclusion criteria, and article selection process. However, the articles included in the review are appraised thoroughly for their quality, validity, strengths, and weaknesses. The limitations of all of the articles are also described. The authors state that since the articles only pertain to women in the US, the data are not generalizeable outside of the US.

They also remark on the limitations of descriptive studies and the potential sources for bias due to retrospective and prospective cohort study designs. Differences in the article findings were discussed and possible reasons suggested, including (as in the Morris et al. article) differences in study design, control or comparison population, differences in measurement tools used for the outcomes, and differences in follow-up times. Publication bias was not assessed formally in the article. The evidence is presented in a qualitative evidence table that gives a comprehensive overview of the studies used in the review.

The overall quality rating for the article by Turrel et al. is fair because the article is not a systematic review, and therefore has the potential for bias in the inclusion of articles. However, the authors use thorough and consistent measures to appraise the articles included in the review, and a complete discussion of the strengths and weaknesses of the articles, as well as of the review article, is offered.

The fourth article, a dissertation by Martucci et al., was only available as an abstract at the time of this review and not available in print through the University Library[44]. At this time I am attempting to obtain a complete copy of the dissertation. This dissertation is a meta-analysis of the data available on the psychosocial predictors of psychological sequelae of induced abortion. This study found that abortion subjects have lower prevalence of psychiatric symptoms post-abortion than prior to the abortion and that the variables of education level, number of children, level of perceived support, and decision making behaviors were predictors of psychological sequelae of abortion. The quality of the literature selection process, literature analysis, and data analysis cannot be assessed at this time.

Limitations of this review: This review is a small-scale systematic review, where the inclusion and exclusion criteria are defined, but may be subject to some bias because the author

used her discretion in defining those criteria. The evaluation of the quality of the articles was also based on criteria chosen by the author and was conducted by the author, which can also introduce bias. However, the author attempted to be as systematic as possible in selecting the review articles to be included and in evaluation of those articles for quality. The same definitions were applied to all articles to determine what type of study, whether or not the study used a focused key question, and the quality criteria for the analysis that each article presented for the articles included in the review.

Table 2: Summary of the review articles analyzed:

Author & Type of article	Main results	Focused Key Question?	Comprehensive literature search strategy?	# of articles reviewed	Were articles appraised using standard methods for validity?	Differences in article findings explained thoroughly?	Publication Bias assessed?	Strength of evidence of negative mental health sequelae	Quality rating
Thorp, J.M., Hartmann, K.E., Shadigan, E.. Systematic Review[41]	Induced abortion increased the risk for mood disorders	No.	Yes.	10	No.	No	No.	Low	Poor.
Morris, K., Orr, F. Descriptive Review[42]	Poor mental health outcomes not associated with elective abortion.	No.	No.	27	Yes.	Yes.	No.	Fair	Fair.
Turrell, S.C., Armsworth, M.A., Gaa, J.P. Descriptive Review.[43]	No evidence supporting a traumatic post-abortion syndrome for most women.	Yes.	No.	9	Yes.	Yes.	No.	Fair	Fair.
Martucci, J.. Systematic Review[44]	Abortion subjects have fewer psychiatric symptoms post-abortion than pre-abortion.	Yes.	N/A	10	N/A	N/A	N/A	N/A	N/A

Discussion: The results of this review of the existing review articles on the evidence for mental health sequelae associated with elective abortion indicate that the evidence supporting an increased risk of negative mental health outcomes due to elective abortion is weak. Current review articles indicate that some women are at higher risk for negative mental health outcomes,

and three out of four indicate that the women who are likely to experience poor mental health outcomes can be identified by certain demographic and psychosocial variables and counseled accordingly. The article by Thorp et al. drew the conclusion that since poor mental health outcomes might occur in some women, and since elective abortion is a very common procedure in the United States, all women seeking elective pregnancy terminations should be counseled about the possible negative mental health outcomes. It is not clearly explained why the authors drew this conclusion and gave more weight to the evidence supporting risks for poor mental health outcomes than to articles that did not support the association. The only explanation given in the discussion is that some articles found evidence for poor mental health outcomes, and that poor mental health consequences associated with abortion cannot be ruled out. However, the authors do not provide adequate descriptions of the quality of the articles that reported poor mental health outcomes to support the reasoning behind their conclusions.

The other articles conclude that the majority of women seeking elective abortions have a positive mental health status after the procedure. The general consensus is that women who might be at higher risk for experiencing negative mental health outcomes can be identified through adequate pre-abortion assessment and pregnancy options counseling. Red flags to identify women who might be at increased risk for poor mental health outcomes include women who are feeling conflicted, who are without support, or who are being coerced into having the abortion. These articles were vulnerable to bias because they were not systematic reviews. However, the evidence presented in these articles had both positive and negative findings for the associations between elective abortion and mental health, and each article that was included was thoroughly appraised for quality, strengths and weaknesses, which bolsters the validity of these conclusions.

It appears from this evidence that women may need to be assessed during pregnancy options counseling to see if they may be experiencing conflict, lacking support, or subject to coercion and therefore be at higher risk for negative mental health outcomes, and that women at higher risk might benefit from more detailed counseling and facilitation of their decision making process. For most women seeking abortion, there is little threat of a poor mental health outcome. From the evidence presented, it appears that women may experience both positive and negative mental health sequelae, and that the likelihood of a positive outcome is high. If counseling about mental health sequelae associated with elective abortion is to be included in the informed consent process for abortion, both the positive and negative mental health outcomes that are possible should be included in this discussion.

Elite Interviews:

Introduction: In my investigation into the social and political climate for abortion in NC, it was essential to include interviews with elite stakeholders. Elite interviews are interviews with people who hold important or exposed areas of expertise in a particular arena[45]. Elite interviews are useful when one wants to know what a group of people think, or how they interpret a series of events, and his or her beliefs and ideologies[46 45]. The goal of interviews is not to establish "the truth", but to provide insight into the mindset of those who have played a role in shaping the society in which we live, and to assess for agreement between different stakeholders[45]. Interviews can help in interpreting documents, interpreting personalities and beliefs of people .who are advocating for a certain cause, provide information that is not recorded elsewhere, and help the researcher understand the context, tone and atmosphere of the area of research[45].

Some of the limitations of elite interviews are that they are not always done with a representative sample of stakeholders in a particular area. This may be due to some elites not being as willing to participate in interviews as others, or being more difficult to contact[45]. The

reliability of the respondent can be questionable, if for no other reason than forgetfulness. Therefore, the responses need to be taken in light of the fact that they are all subjective and may not be completely factually accurate[45]. Respondents can also change their minds or give different answers at different points in their life, and so their responses are not always reproducible[45].

I was interested in the perceptions of people invested in reproductive health policy regarding the practice of abortion, the practice of informed consent for abortion, and the two bills being proposed in the NC legislature at the time of writing this paper. I wanted to elicit responses from people who were both opposed to abortion and from people who were invested in maintaining access to abortion services because I feel that it is important to understand the perspectives of people on both sides of the issue. I also wanted a deeper understanding of the motivations and beliefs that people had in developing their position and advocacy either to promote or decrease abortion access for women. Interviewing these stakeholders is a method whereby subtleties in their beliefs and attitudes can be drawn out through conversation [46].

Methods: I obtained IRB approval from the University of North Carolina at Chapel Hill prior to the start of identifying respondents for participation in this study. Respondents were identified as people occupying elite stakeholder positions using publicly available data. An additional list of potential respondents was provided by a person identified as an elite stakeholder. Requests for study participation were sent to nine identified stakeholders, and I received nine responses from the original nine requests. One person did not have time to participate, and two others no longer held the position from which I had identified them. I conducted six structured interviews with the remaining elite stakeholders. The characteristics of the respondents are presented in Table 3. I conducted two interviews over the phone, and conducted the other four in person, at the location of choice of the respondent. Each respondent granted his or her consent to be interviewed and to have the interview recorded. Interviews were from 20

to 60 minutes in duration and were guided by an interview questionnaire that had been approved by the IRB. Additional questions were asked if clarification was needed. All interviews were recorded using a digital recorder and I transcribed all interviews. Following transcription, I erased the digital copies of the interviews. I had taken notes during the interviews in case of recorder malfunction and to note additional observations during the interview. I analyzed the transcripts to identify major themes in the interviews, and then I coded them. These themes and illustrative quotes from the interviews are presented in the Results section of the paper. The accuracy and validity of the themes and coding were checked by discussing the analysis with my adviser, Dr. Trude Bennett.

Table 3: Characteristics of Respondents

Interview number	Respondent sex	Generational age*	Occupation	Setting of interview
1	Female	Post-Roe v. Wade	Physician and Abortion provider	Phone
2	Male	Pre- Roe v. Wade	Physician and Abortion provider	Phone
3	Female	Pre-Roe v. Wade	Politician in NC, President of NC Democrats for Life	Phone
4	Female	Pre-Roe v. Wade	Executive Director of Pregnancy Support Services	In person, at her place of work
5	Female	Pre-Roe v. Wade	Lawyer, special interest in Reproductive Health	In person, at her residence
6	Female	Post- Roe v. Wade	Public Relations director for Planned Parenthood	In person, at her place of work
* Generational age indicates whether the respondent personally experienced social and political events leading up to the 1973 Supreme Court decision of Roe v. Wade.				

Results: Out of the six transcripts, I identified nine major themes, with sub-themes emerging within five of those major themes. The dominant themes I identified were: women's understanding and knowledge about abortion; abortion services; women's health; morality; stigma of abortion; mistrust; role of abortion regulations; political climate for abortion; and leadership.

Women's understanding and knowledge about abortion

Under the major theme of women's understanding and knowledge, I identified three sub-themes. These sub-themes are (1) factual knowledge about the abortion procedure; (2) understanding of the consequences of the abortion procedure; and (3) decision-making abilities of women seeking abortions.

All respondents recognized that women need to have a full understanding of the abortion procedure and its consequences, as well as time to use their decision-making skills to come to a

comfortable decision. However, within these sub-themes, there are striking differences between respondents who were providers or advocates for abortion services, and respondents who were opposed to the procedure of elective abortion.

Factual knowledge about the abortion procedure: Respondents who were directly involved with the provision of abortion services or advocates for abortion rights held the opinion that women seeking abortions were generally well informed about the details, risks, and alternatives to the procedure when they made an appointment for an abortion. One respondent reported that when she asked women to describe the risks and alternatives to abortion, they were usually able to do so.

Respondents who were opposed to abortion did not specifically address whether women had adequate knowledge about the actual procedure, but expressed a belief that women needed to be told about the risks and alternatives to abortion and implied that this was not currently the practice of abortion providers, and that women generally were unaware of the risks and alternatives to abortion unless physicians informed them.

Understanding of the consequences of the abortion procedure: Respondents who were opposed to abortion expressed concerns that women had not had time to think through or did not understand the full implications of the abortion procedure. This observation is illustrated by the following quotes:

> Respondent: "I think that people should see the, the realization of what they are intending to do… it is a human life and that if you are going to dispose of that human life…you should understand that that is what it is."

> Respondent: "having an abortion is an extremely final decision, I mean, you can't backtrack on it, once it's done it's done… and I think people should understand that."

In contrast, respondents who were involved in the provision of abortion services stated that patients requesting abortion services had a clear understanding of the consequences of the abortion procedure.

> Respondent: "[women] do not change their mind when they're presented with a picture on an ultrasound, they're very aware that they are ending a pregnancy."

Decision-making abilities of women seeking abortion: All respondents conveyed that there are different stages of decision making that a woman goes through in her decision to have an abortion. A few respondents indicated that this decision making process was on a continuum. They believed that women could interface with abortion providers or pregnancy support services at any point along this decision making spectrum, and where they were on the spectrum would influence their decision making process. At one end of the decision making spectrum are women who are facing the realization that they have an unintended pregnancy. Respondents differed in their expressed beliefs about where in the spectrum of the decision making process the majority of women seeking abortion can be found. The respondents who were opposed to abortion indicated that most women considering abortion services are in distress about their situation and may not be thinking about their options clearly. They felt that most women seeking abortion were at an early stage in the decision making process. These respondents indicated that women at this stage were not in an appropriate frame of mind to make rational decisions about whether or not to have an abortion:

> Respondent: "We find often with the women that we work with when they first find out that they have a positive pregnancy test the immediate reaction is shock, disappointment, all kinds of emotions tend to rise to the top there… but as… time goes on… I also think we should have a waiting period within the informed consent...just to let emotions settle down… with the passage of time our, our thought processes… tend to settle down a little bit and we can sometimes make decisions that… we might not regret later on."

At the other end of the spectrum are women who have thought through all of their options, weighed the risks and benefits and consequences, assessed their available support systems and consulted the people they feel they need to consult. Some of the respondents felt that most of the women they encountered who had scheduled abortions were at this stage in the decision making process. While there was a recognition among some of these respondents that women may be driven by concerns about the cost or demands of having a child, this factor did not make these respondents feel that women in this situation were in despair or unable to think rationally about their decision.

> Respondent: "I think some of the legislation assumes that women haven't...really thought about this decision… That's not our experience in serving women, our experience is that when women come in, they're facing unintended pregnancy and they've weighed their options and… they've thought very carefully, they've consulted the people in their life that support them… They've really given this thought…

> It's not taken lightly, and they have reached the conclusion that they do not want to maintain the pregnancy."

As these quotes illustrate, the respondents see women as being in different stages of the decision making process, having different levels of understanding about the full consequences of having an abortion, and that their general knowledge level about the risks and alternatives of the abortion procedure differ. One respondent indicated that the differences in opinion about where women are in the decision making process might be due to differences between women who go to crisis pregnancy centers with the suspicion that they are pregnant and women who make appointments for abortions:

> Respondent: "Right under 50%...of women faced with an unintended pregnancy will maintain the pregnancy, period...those are just decisions women make... I don't know…if [crisis pregnancy center workers] have just caught women ... in the early stages of trying to figure out what they are going to do and...they haven't really made a decision… it's not firm yet... But women who come in for a pregnancy test and women who...schedule an appointment and come in for an abortion are...women at very different times and under very different circumstances in terms [of] their thinking about what they are doing."

Abortion Services:

This theme includes respondents' descriptions of their perceptions of abortion providers and current abortion practices. The subthemes are: (1) attitudes of abortion providers and current practices of abortion, and (2) perceptions of an "abortion industry". There were major discrepancies between the perceptions about the attitudes of abortion providers toward their patients described by respondents who were opposed to abortion, and the attitudes towards patients that were described by abortion providers.

Attitudes of abortion providers & current practices of abortion: The respondents who were abortion providers described what they did for the informed consent process for women, and expressed their concerns about making sure that the women they served were well-informed and had the opportunity to ask questions and be as involved during the abortion procedure as they wanted to be.

> Respondent: "I think the important things are to make sure that a patient understands the procedure, at a level where they can understand what is actually going to happen…They need to understand the alternatives that are available to them… They need to understand the risks and benefits of the procedure and they need to have an opportunity to ask questions… it's…routinely…what I go through with any procedure that I do, and its what I teach my staff…and… what I require of all our procedures, regardless of what type of procedure that is…I think that people deserve to know what the procedure is… exactly what's going to happen. They need an opportunity to ask questions, I think that's really, really important…One of the parts of… appropriate provider-patient relationships is that they are given the opportunity to know exactly what is going on and when, and also given the opportunity to *not* know if they don't want to."

Multiple respondents also mentioned the importance of making sure that a woman coming in for an abortion was not being coerced by another person into making that decision. Providers recognized that sometimes, because pregnancy can involve multiple people and not just the woman, the woman may be under pressure from other people in her life to make a decision one way or another.

> Respondent: "We provide individual counseling and so, if a woman comes in with her partner… if she wants him to be with her for the procedure, we can accommodate that. But we require that we provide individual counseling, that she speak with us separately so that we can talk to her about her decision and make sure that it's her decision and that she's not being coerced or pressured."

One respondent also indicated that abortion providers were highly committed to providing abortion services to women because it is a service that women need. She highlighted how committed abortion providers were to women's health by discussing how abortion services are as inexpensive as possible to decrease the barrier of cost for women.

> Respondent: "The fact is that people who are committed to providing abortion care… have for years collectively really kept the cost down, so that women are able to… pay for this care… the reality is that if you compare abortion to any other medical procedure, the fact that it's as affordable as it is, and is accessible… as it is, is completely about the commitment of people who provide abortion care to keep it at a cost that women can afford… if it were market driven, like any other procedure… it would be so much more expensive than it is…and that's just a decision on the part of providers to keep the cost down um, rather than to drive up the cost… knowing that women cannot wait, because… the risks increase as women wait and I think… everyone wants for women who are faced with an unintended pregnancy and have decided they don't want to keep that unintended pregnancy to come in as soon as possible… to make that happen… we need to keep the cost down because that's a major barrier."

Perceptions of an "abortion industry": Respondents who were opposed to abortion had a very different perception of abortion providers, and referred to or described an "abortion industry" where abortion providers were encouraging women to have abortions hastily, without giving their decision much thought, in order for financial gain. These respondents believe that abortion providers are highly unethical in their practice of medicine and were purposefully withholding information from women seeking abortions in order to be able to perform abortions on them.

> Respondent: "And the other thing, this may just be an aside, but, in…pregnancy care centers, we don't charge for our services, so we don't stand to gain or lose money, by whatever decision she makes. That potentially could be… different… in the abortion industry, because they are making money."

> Respondent: "I would hope that [abortion providers] would operate on a highly ethical plane...They would have to approach this issue ethically, and looking at what might or might not be the best for the woman, rather than what might or might not be best for their pocketbook."

> Respondent: "We want to protect [the patient]... We're not going to coerce her one way or the other, by saying 'Oh you're a student. You need to have this abortion because there's no way you can finish your education'. Certainly, there's lots of ways to finish your education… Just quickly snuffing out a life—to me—isn't fair to the girl."

Respondents who were opposed to abortion also stated that the absence of a 24-hour waiting period may unfairly burden abortion providers with an obligation to perform the procedure on patients who have not fully grasped the implications of their actions.

> Respondent: "I think [abortion providers] would feel better [if there was a mandatory waiting period] because it takes more of the responsibility off of them and puts it on the person who's having the abortion... I think that [currently]… what you're doing is almost putting [abortion providers] in the position of being facilitator, whether they want to or not"

One respondent described abortion services as only being provided in abortion centers, by a minority of physicians willing to participate in this service.

> Respondent: "I understand that ...abortion providers… they've already come to that place, and this...generally its done in a ...place where...that's the main...thing that's being done, so its not like… we're talking about … doctor's offices here there and yon...the majority of physicians in North Carolina do not do...abortions"

Women's Health

Under the major theme of women's health, I identified two sub-themes. These sub-themes are: (1) concern about the effects of the bill contents and requirements; and (2) concern for the mental and physical health of women.

Concern about effects of additional regulation and bill contents on women's health: Respondents who opposed the additional regulation of abortion proposed in the two bills expressed concerns about the effects that this kind of additional regulation may have on decreasing access to abortion services, and the requirements introduce barriers to care that may result in a delay in abortion and therefore expose a woman to unnecessary increased risks to her health.

> Respondent: "The 24 hour waiting period, that's nothing but a way to cut down on the number of women who can get abortions, because a lot of them can't take 2 days off work."

> Respondent: "I can tell you what the experience has been in other states [who have passed similar legislation], and what it has done is delayed abortions, and [a] delay of any source, whether it be administrative, logistic, travel, financial, all have the same net effect of driving up the morbidity and mortality risk, and the expense...From a public health point of view—this has been well-established with … 35 years of good documentation from the CDC—such legislation will have an adverse effect on the health of women.'

> Respondent: "[State-mandated, scripted counseling materials and waiting periods] hurt women, so we as clinicians have to reject them, because they violate the fundamental principle of beneficence...These hurt patients, thus we as clinicians…oppose them."

Respondents who did not support the additional regulations also expressed concerns about the risks to a woman's mental and physical health from the contents of the bills.

> Respondent: "The definition of 'medical emergency' is very distressing... Roe versus Wade says you have to have a health exception, and [the proposed legislation has] something that's a very long way from simply a health exception... [With the proposed legislation, a medical emergency] has to be... 'serious risk of substantial and irreversible impairment of major bodily function' ... When I looked at that I thought…its not even just physical health, it goes so far beyond that, its terrifying, really…[and] part 2E says… you've got to inform the woman that she is free to withhold or withdraw her consent to the abortion at any time before or during the abortion, and the point comes [during the procedure] surely where a physician can't stop."

> Respondent: "The piece about information about exactly…where a pregnancy is developmentally... and showing pictures of that, I think is psychologically damaging to women who chose an abortion."

Concern about effects of abortion on women's health: Respondents on both sides of the issue expressed concerns for the mental and physical health of women seeking abortion services. Respondents who supported increased regulation expressed concerns about the risks to a woman's mental and physical health that they believed were linked to abortion.

> Respondent: "[Some women who undergo an abortion] suffer emotionally… and they are tormented by it. Now, lots of women aren't, but for those women who are, is it really fair to them to say: 'Well, honey… get on with it'?"

> Respondent: "There are medical complications [of the procedure]… it's not just like having your hair done… People have died from… abortions, even those that are done under medical procedures… Even though it is a small pool, it is a risk… There might be complications to being able to reproduce again… There are risks to depression."

One respondent expressed concern about the bills' contents requiring that women be told about how unsafe abortion is when her understanding is that it is a safe procedure.

Respondent: "I fully understand that... while there's a perception that abortion is dangerous, its actually one of the...most common... health services provided to American women, and it is, at this point... extremely safe ... My impression is that while its not a happy event—for anyone—though there is a great deal of relief expressed by a lot of people who obtain an abortion... There has been... very little evidence that there are in general significant psychological risks."

Morality:

Morality was a major theme, but it was not addressed by all of the respondents. Concerns about the morality of abortion and of society's acceptance of abortion were important in explaining both the opposition to abortion expressed by two of the respondents, and contributed further explanation for their strong motivation in opposing abortion and supporting further restriction and regulation of this procedure. Two sub-themes of morality were identified: abortion as an immoral act and immoral behavior. Immoral behavior was further divided into descriptions of a lack of personal responsibility for one's actions, and the promotion of sexual activity in our culture.

Abortion as an immoral act:

Respondent: "I believe religiously that abortion is the taking of a human life... You're not gonna change those of us who believe that, biologically, ... life begins at conception...You have a whole group... of people who are voiceless, who are powerless, who can't speak for themselves, and they are being misused in my opinion, their life is not being valued as God values their life"

Immoral behavior:

Personal responsibility:

Respondent: "I watched a slow progression from a community spirit of responsibility to one of 'me-ism'... Does it fit my lifestyle? Will it inconvenience me?... Its all about me, and... you can see abortion, in my mind, went hand in hand with that, and that the farther we got into... self-determination, the farther we got away from responsibility for our own actions...Even today, it always just amazes me that people... don't see a problem with abortion, but they don't want to take responsibility for their own sexual behavior."

Promotion of sexual activity:

Respondent: "In this area, I think elective abortion is...a pretty popular choice. [In this geographic region of NC] we have...3 universities... I think the mindset tends to be much more... toward promoting abortion than promoting life... [University Campuses] tend to be a little bit more liberal, in terms of... what I would consider would be traditional Family Values, that would be- father, mother united in marriage, then having children...We don't always see a strong promotion of marriage, but we see a strong promotion of... sexual activity...at both [the University of North] Carolina and Duke [University], and... NC Central [University] as well...Certainly, sexual activity is rampant. We see lots of girls from that campus...[abortion and sexual activity are being promoted] through...Student Health I think because ... they make the morning after pill very available, and... are well-versed in birth control and contraception...rather than promoting abstinence."

> Respondent: "I also think that there are bigger issues… involved here than just whether you're gonna have a baby or not have a baby… once you have a positive pregnancy test. … Those are issues that we're in a position to be able to deal with, and that would be, sex outside of marriage and…why that might not be the best… decision for… a young couple to make, because there are gonna be consequences, and those consequences will literally be life-changing."

Stigma of Abortion:

Stigma of abortion was another major theme that was only addressed by some of the respondents. Many of those who spoke about stigma shared the ideas that abortion has become something that people are ashamed of having had—and of performing—and that the stigma associated with abortion seems to have increased since the 1980's.

One respondent described several scenarios in which the stigma associated with abortion became apparent to her. One situation took place in her physician's office, where the physician and nurses openly discussed her patient information until the respondent asked the physician if he performed abortions. At that point, the respondent's physician shut the door to the room, and spoke quietly when he said that he did perform the procedure. Another situation that this respondent described involved a vocal pro-choice advocate whose physician husband asked her to be less vocal in her support because of his fears for the reputation of his practice. Finally, this respondent described how she had written a book on the laws surrounding minors who were pregnant in NC; in this book, the respondent stated that she presented and answered factually 150 questions about legal issues for pregnant minors. As a result of the book's contents, one of her funders refused to put their name on the book for fear of being associated with abortion.

Other examples of stigma were given, and a feeling that abortion has a stigma attached to it was described by respondents.

> Respondent: "I do think that we experience… the same sort of national… messaging and stigmatizing of abortion that has happened over the last 2 decades. I think that …we're very far removed from [the time]… when abortion was illegal, [and] that people cannot fathom those days and those people take… legal… and safe abortion for granted, so… we really still face the stigmatization of abortion as a medical procedure and as a life-saving procedure for women."

> Respondent: "[Abortion]… carries more… impact...for the…person who is considering this procedure, not only because of how intimately personal it is, but because of the larger… cultural…viewpoint- the political, the social ramifications of it."

Mistrust:

Respondents on either side of the pro-life, pro-choice debate expressed mistrust for people who were on the opposite side. Respondents who were opposed to abortion seemed to feel that they could not trust abortion providers to follow existing regulations for abortion, and respondents who were in support of abortion rights did not feel that pro-life advocates and politicians who were constructing additional regulations were being honest about their true intentions in designing these bills.

Mistrust of abortion providers/ pro-choice advocates: Overall, antiabortion respondents seemed to be of the impression that abortion providers and abortion rights advocates were not operating abortion services ethically, were coercing women into having abortions, and were not abiding by current regulations of abortion services.

> Respondent: "The other part of [the additional regulation of abortion] is who's going to enforce it... The states that have 'right to know' laws… aren't always abiding by them, so there needs to be...some kind of enforcement provision ... Would people have enough integrity to abide by [a law after it has been passed]? … I don't have an answer for that."

There was also mistrust in the quality of the evidence being used to understand the risks and benefits of abortion for women's health. Much of the current evidence for the effects of abortion on women's health comes from the Guttmacher Institute, a research institute affiliated with the Planned Parenthood organization. Data from this institution are considered scientifically sound by both advocates and opponents of abortion[20] . Despite this, both respondents felt that since the information was coming from an institution affiliated with a pro-choice stance, they did not trust that it was accurate.

> Respondent: "I…want…research to come from… licensed and accredited… universities that are doing research. I would not… want the research to come from those who have a political stake in it…[Biased research will result in] a lack of confidence on my part and other people's parts. …I don't want statistics coming from Planned Parenthood…on the other hand I don't want them coming from the Right to Life either…I would prefer them to come from accredited institutions that…know and follow and have a high regard for neutrality in doing research."

Mistrust of abortion opponents/ pro-life advocates: Respondents who were abortion providers or advocates for abortion rights seemed to mistrust the intentions of those writing the proposed regulations. One expressed reason for mistrust is that these additional regulations for abortion are seen as not coming from a genuine need to improve the health of a population, but instead to achieve further restrictions on abortion services.

> Respondent: "[they're] coming up with a solution to a non-problem, which in my view is perverse...If they can identify a problem, then perhaps we can have constructive talks about ways that we might resolve that problem, or improve the health of women in our state, but I would suggest that they are not proposing any of this legislation will improve the health of women in the state of NC… I think that if you read between the lines these legislative attempts are designed purely to deter women from having abortions and exercising their right to choose."

Respondents also expressed mistrust by describing how proponents of further regulations used "tricks" to increase the susceptibility of abortion providers and women who have had abortions to harassment, and increase the cost of providing abortion services in order to decrease the number of abortion providers available to women seeking abortions.

> Respondent: "The other piece around the Woman's Right to Know bill… is that it also requires that… any woman who calls into a health center that provides abortions… and says she's pregnant and wants to schedule an abortion has the right to speak with the doctor who's going to provide the abortion… The purpose for that part of the bill is simply to tie up doctors who otherwise be seeing patients…You could easily see how... if anti-choice organizations wanted to, as a result of that bill, they could call clinics all day long… They could call and harass doctors all day long, and keep them on the phone."

Respondents also revealed mistrust in the legislators' ability or willingness to provide patients with medically accurate materials in the mandated materials being proposed by current legislation.

> Respondent: "One of the concerns is just misinformation…[For example,] they date the pregnancy differently ...so they'll date it from conception rather than from LMP [last menstrual period] and it makes it misleading...so its those kinds of things that… need to be consistent with what medical practice is, and medical practice always dates pregnancies based on LMP, and never from conception"

One respondent expressed concern about the language in the two proposed bills. She felt that the bills had conflicting requirements within them and also that there were requirements within the bills that conflicted with current medical knowledge and practices. Her concern was that the lack of clarity and agreement within the bills as well as the conflict between the legal requirements to disclose materials in

the informed consent process with current medical opinion would further discourage physicians from providing abortions.

> Respondent: "They talk about...the material shall also convey objective information about the risks associated with each procedure, the possible detrimental psychological effects of abortion ...If I were a physician and didn't believe that there...were... material evidence of...detrimental effects of large groups of people for the psychological effects of abortion, I would not know what to do about this... Every time you make it not only more difficult, just as a matter of... time and money, and staff and whatnot, but where you actually don't know what to do, you're just cutting down on the number of people who are going to do abortions".

One respondent who was opposed to abortion also expressed concern for the motivations of proponents of these bills. She questioned whether or not legislators and pro-life advocates were blurring the lines of science to convince women not to have abortions.

> Respondent: "I know that some people are discussing... increased rates of...breast cancer... Is it informed consent when you are stepping out into... what people would like to believe versus what science actually says?"

Role of Abortion Regulations:

Under the major theme of the role of abortion regulations, I identified three sub-themes. These subthemes are (1) the need for abortion regulation; interference in the physician-patient relationship; and (2) legislative history of abortion regulation.

Need for abortion regulation: The majority of respondents who were abortion providers or abortion rights advocates felt that the regulation of abortion proposed in the two NC bills, the Woman's Right to Know, and the Ultrasound Before an Abortion, was unnecessary, inappropriate, and unprecedented. Most respondents who felt that these bills were not appropriate felt that they were not addressing a public health problem.

> Respondent: "I would ask the legislators who are promulgating such legislation: What is the problem you are addressing, and why do we need a law to correct the problem?"

The majority of respondents opposing this legislation also noted that the involvement of the government in the regulation of medical practice at this level is not seen for any procedure other than abortion. Many respondents also expressed concern about non-physicians being responsible for writing the materials that would be provided and required to be given to women seeking abortions.

> Respondent: "I would suggest that it is an inappropriate intrusion of other people into the practice of medicine. It would be as inappropriate as a bunch of doctors telling the legislature that lawyers should practice their trade differently. We are not competent to—nor do we have any justification for—tinkering outside of our field of competence."

Respondents who oppose this legislation argue that this level of regulation is unnecessary to ensure that women are receiving informed consent because all women that they serve are given all of the information that they need, and are well informed.

> Respondent: "We provide information about the procedures, risks and.. side effects… [we] make sure the woman understands what's going to happen during the procedure…[We] give her an opportunity to ask any questions … we need to also let her know about the… admitting privileges of the provider that's going to do the abortion… and in North Carolina… any pregnant woman who is seeking an abortion also has to have an ultrasound…we have a policy that if any woman comes in for any procedure that involves an ultrasound that we will offer to let her see the ultrasound… That's a Planned Parenthood policy… If the woman comes in and she's pregnant and we're doing an ultrasound in preparation for an abortion… we always offer her the opportunity to look at the picture and see if, if she wants to…I think its completely unnecessary, we are required already to do ultrasounds, we already do offer women… the opportunity to see the picture, if she chooses."

Interference with the physician-patient relationship: Respondents who oppose this legislation also feel that the additional regulations are inappropriate because they interfere with the physician-patient relationship. These respondents felt that scripted counseling materials do not allow for meaningful dialogue to take place as in a normal informed consent process.

> Respondent: "Any time you have state-scripted, mandatory counseling you rob the doctor and the patient relationship... The essence of state-scripted mandatory counseling is that it removes any kind of dialogue between patient and doctor that is based on that woman's individual circumstances and the doctor's concern for that woman, for her individual circumstances… [State-scripted counseling] applies a one-size-fits-all [approach] to every single woman that walks in the door."

Another reason given as to why the bills are inappropriate is that they require physicians to counsel any woman who calls the clinic saying that she wants to have an abortion, even if they have never seen the woman and have no medical information on her.

> Respondent: "I also think it's an issue of ethics in terms of what kind of practice … we expect or want out of doctors. …Do we want doctors diagnosing over the phone without having seen the patient? Do we want doctors to provide advice? Is that really the kind of care that we want for women? Is that the kind of care we want doctors to provide?"

One anti-abortion respondent agreed that the current form of the bills contains materials that are inappropriate for women seeking abortions. Concern was raised by this respondent, as well as by an abortion provider, that the requirement for women to have to look at the ultrasound of their fetus prior to consenting to the procedure resembles a punitive measure for abortion-seeking patients.

Pro-life respondents were in support of additional regulation of the informed consent procedure for abortion. Both of these respondents believed that currently women who are seeking abortions are not undergoing informed consent for the procedure at all, and therefore believed that additional regulation was necessary to ensure that women underwent informed consent prior to having an abortion.

> Respondent: "I am always amazed at... groups that oppose consent altogether... Are you telling me that in something that is going to destroy a human life and may change that woman's life for the rest of her life that you don't have... a responsibility to tell her... what the advantages and disadvantages are?"

> Respondent: "We have seen women who are just devastated because they haven't had the opportunity to... have had a lot of good information before they make the decision to abort."

Legislative history of abortion regulation:

Most respondents agreed that abortion access has become more restricted since the Roe v. Wade decision to make it legal in the US. Many respondents referred to Supreme Court rulings in the past to illustrate when restrictions on a woman's right to an abortion began.

> Respondent: "[Currently proposed legislation] takes place... in the shadow of the Supreme Court... And [with the decision of Casey v. Gonzales], Justice Kennedy has made it abundantly clear that they look forward to further restricting... abortion access for women."

Political climate for abortion:

Some abortion rights advocates felt that the current laws and the history of NC's legislation of abortion reflected a very progressive leadership in support of abortion rights.

> Respondent: "We are absolutely the jewel of the South in terms of reproductive freedom...We are and in some ways a safe harbor... We haven't spent so much of our time trying to dictate what doctors say to patients or trying to create more hoops for women to jump through in order to... have an abortion... We don't have the sort of... barriers that some of the states have put in place ... I think that it's going to continue in this way in the South, [and] that North Carolina will need to stand strong in terms of protecting a woman' right to legal and safe abortion."

> Respondent: "I think we have been fortunate in NC that the NC legislature has not addressed this issue in many decades because it's a non-problem...I think it's a tribute to the citizens and the legislators of NC, this has always been a progressive state in the Southeast and I think it retains that status."

> Respondent: "We have a decent...General Assembly...[and] state legislature, so they're not spending a lot of their time taking up bills that would mandate state-scripted counseling or...mandatory delay periods...I think they are more focused on issues that are more pressing to the people of North Carolina, like high school drop-out rates and transportation crisis... and that sort of thing...So in terms of our political environment I think we're in a really good place."

Other advocates felt that the progressive history of NC was giving way to a more hostile environment towards abortion.

> Respondent: "I've been working in reproductive health... for 30 years, and I do not recall a time in that period when there was a more hostile climate in the US, for abortion, and... I know that North Carolina is not one of the states where it is most severely limited ... but... it's a pretty hostile climate in North Carolina also."

One of the pro-life respondents felt very strongly that NC is not a pro-choice state, but conceded that the NC Democratic Party continues to have strong progressive leadership in favor of upholding abortion rights. This respondent stated:

> "Pro-choice has lost the argument in North Carolina- you can look at the voting records and tell that".

But when asked whether she thought that the current bills would pass and why, she said:

> "No...not now, not at this point...because we have a... very strong core progressive leadership in the political party here in NC".

She then clarified that the state was not as progressive as it may seem:

> "The progressives... are in leadership positions... [they're] pretty strong because they can direct policy, they can determine who will be on committees... so if a person was looking at this just on the... surface... they would, I think, mistakenly say, 'well darn, North Carolina is really a – quote unquote- progressive state on abortion'... that's a misnomer".

The pro-life respondents felt that the climate towards abortion depended on what part of the state you were located in, and that local attitudes towards abortion and sexual activity differ in various areas of the state. Urban areas were perceived as being more liberal and tolerant of abortion and sexual activity and rural areas were perceived as being more conservative.

Leadership:

The final theme I identified was the role of leadership in the making of abortion policies. The role of leadership in shaping the political environment for abortion in the United States and in North Carolina was brought up by several respondents. Respondents indicated that overall, NC has strong progressive leadership in favor of upholding abortion rights in this state.

Although NC has maintained a relatively progressive stance on abortion in the Southeast, there have been some successes with placing restrictions on abortion access in NC. Some respondents indicate that a particular legislator—Paul "Skip" Stam of Wake County —has been highly influential in the successful attempts at restricting access to abortion in NC. Respondents mentioned his significant involvement in sponsoring the two bills that are the subject of this analysis. All of the respondents who spoke about the importance of leadership seemed to feel that this legislator was important in influencing reproductive health policies in NC.

> Respondent: "We had a state abortion fund. It never paid for abortion entirely, it only subsidized the abortions. When Skip Stam was running things in the '95 session they decimated the state abortion fund. [It was decreased from] 1.1 million dollars at some point, its now 50,000 dollars. [To be eligible for these state funds,] you have to… live at or below federal poverty level and not be qualified for Medicaid, which is generally how you qualify for Medicaid… If you can find someone that fits [these criteria], they also have to be a victim of rape, or incest, or face life endangerment to get… the money…With those special provisions that they made in 95, no woman has accessed any of the money from the State abortion fund…I always worry about the Woman's Right To Know bill,...because Skip Stam... is the primary sponsor, and he's been pushing this bill, I mean… he has said publicly that that is the bill that he wants to see passed… if there's one bill that they get… all of the anti-choicers to sign on, that's the bill… and so… I think you would be a fool not to worry about that bill because I know that it's the bill he wants to see passed".

> Respondent: "I noted that they are introduced …as I would expect, by representative Paul Stam. He is the Minority... leader of the House and… he has a number of ... very strong ...programs, but the one I associate him with most strongly is his opposition to abortion… so he's powerful, he's ...determined, he's effective."

But respondents also noted that these bills have not succeeded in the past, and that the legislators who are in favor of increased regulation of abortion have not been highly successful yet.

> Respondent: "We don't tend to have a very organized opposition…our legislature doesn't have a really… vehemently, organized… community opposition to…abortion providers, although there are definitely pockets that are pretty intense."

The respondents agree that the leadership in the NC legislature is very important in determining abortion policies. While most respondents indicated that the climate for abortion in the US is becoming more hostile towards abortion, they also indicated that so far NC has maintained a progressive stance. However, most respondents also indicated that powerful individual leaders who are strongly motivated to limit access to abortion can have a significant effect on policy changes, as seen in the 1995 session where access to the state abortion fund became highly limited, and by the devotion of particular leaders to getting bills like the Woman's Right to Know passed. It appears that while most of the respondents agreed that NC is at least perceived as being progressive on abortion, most of them did not feel certain that this stance would not change.

Limitations: The limitations of this research include the small sample size and the imbalance of respondents on both sides of the abortion debate. The small sample size means that the data presented may not be representative of the thoughts, beliefs, and attitudes of all elite stakeholders who are invested in reproductive health policy in NC. While the sample size was small, representatives of both the medical and legal fields were included, which allows for a broader perspective on the issue of regulations for the informed consent process for elective abortion.

The sample of respondents included 4 individuals who were considered "pro-choice" and 2 individuals who were considered "pro-life". One of the original contacts on the "pro-life" side was no longer in the position that would classify her as elite in the field, and it was difficult to identify and contact other elites who were key stakeholders on the side of opposing abortion.

While the balance of opinion on abortion was not even, the same interview guide was used in all interviews, transcripts from each interview were coded using the same process, and a second reader was consulted in order to minimize bias in presenting information from either side. However, the difference in the number of respondents on each side should be taken into account when considering the spectrum of opinions, thoughts, and beliefs that are presented in this paper.

A final limitation to this research is the potential for bias in the interpretation of the data. As stated above, I consulted a second reader to attempt to minimize bias in data presentation and analysis and present each side of the argument fairly.

Discussion: Opponents to abortion and supporters of abortion rights can agree on several things. They all believe that women need to be fully informed, using unbiased data, about the abortion procedure and the risks and alternatives to that procedure. They also agree that women with unplanned pregnancies should not be coerced into making a decision about whether to terminate the pregnancy. Most of the respondents acknowledged that the bills in their current form were not likely to pass in the state of NC due either to their content, the political climate in NC towards abortion, or both. Finally, all of the respondents evinced a strong concern for the health and well-being of women. These points of agreement are significant because they indicate a common ground for discussion about appropriate informed consent practices for elective abortions. If everyone involved is truly invested in helping women make informed decisions about whether or not to terminate a pregnancy, free from coercion or misleading information, with interest in the woman's well-being, then it should be possible to agree on a policy that supports those goals.

However, it is even more important to consider where respondents disagreed with one another, because some of those disagreements influence how respondents feel the goals of informed decision making can and should be met. Where the respondents disagree reflects differences in opinion about women's decision making process when considering an abortion, differences in understanding about current abortion service practices and informed consent, differences in opinion about the quality of existing evidence regarding the risks of abortion for women's health, whether or not abortion is fundamentally immoral, and the necessity of specific regulation for abortion services.

Women's Understanding and Decision-Making Stage: Respondents had very different perceptions of where women were in the decision making process and how well informed they were about their decision. Respondents who were opposed to abortion perceive women as being in the early stages of decision making when they are considering abortion and that women do not understand that they are ending a life. These respondents felt that a woman needed to be made aware of what she was really doing in terminating a pregnancy. The implication is that women do not realize what it is that they are doing, and if they did, then maybe they would not choose to have abortion. But, according to the respondents who were involved in providing abortion services, and to qualitative research examining women's decision making process, women do recognize that they are ending a pregnancy and have given this decision a lot of thought[1]. While it may be true that women going to crisis pregnancy centers may feel uncertain about what they are going to do, it may also be true that this group of women is a different population of women than those who have already made a decision about what they are going to do and have made an appointment for a pregnancy termination. In addition, women who present to family planning clinics to find out if they are pregnant and are facing unintended pregnancy undergo options

counseling. The respondents who were involved in providing abortion services all stated that they make sure women are fully informed about their decisions and expressed concern that women who decide to have abortions do so free from coercion.

Perceptions about abortion services and providers: It is difficult to reconcile the difference in understanding about how abortion providers are currently providing care between respondents who were opposed to abortion and respondents who were involved in providing abortions. This is because the respondents who oppose abortion conveyed a perception of abortion providers as essentially immoral physicians who were either coercing women into having abortions for their own financial gain, or who felt badly about the services that they were providing. This sentiment was expressed by the respondent who indicated that physicians who provide abortions to women might feel "better" about that service if there was a 24-hour waiting period. Suggesting that physicians might feel "better" about what they do implies that those physicians do not feel good about the care that they are providing to women. This respondent also discussed how "most" physicians in NC do not perform abortions, and that most abortions are performed in settings where abortion is the only health service offered. This implies that most physicians do not feel comfortable performing abortions.

These perceptions also create an image of abortion that sets it outside of regular medical practice, being done in a place where it is the only thing offered by physicians who are not like "most" in that they are willing to perform abortions. If this is indeed the perception of this respondent, it does not reflect a complete understanding of the range of practice of medicine or the range of services provided at most family planning clinics. Many physicians do not perform abortions, but this is not necessarily because they do not agree with the practice of abortion. One recent survey of physician attitudes toward morally controversial practices like abortion found

that 52% of the physicians surveyed objected to abortion for failed contraception[21]. While this is a large percentage of physicians, it does not indicate that most physicians do not provide abortions solely because they object to the procedure. Results from this survey also indicated that even if physicians did not feel like they approved of abortion for failed contraception, 86% felt that physicians who object to certain procedures are obligated to refer the patient to someone else who will provide it[21].

One contributing factor to the small percentage of physicians who provide abortions could be that there are medical specialties that would not include abortion in their typical range of services. Among specialties where abortion services might be provided, there is another consideration in determining if a physician can perform abortions: whether or not they received training in the procedure. Not all residency programs provide training in abortion services [47]. An indication that training is an important determinant of whether or not a physician provides abortions is that physicians who are trained, are more likely to provide abortion services when they go into practice[47]. Therefore, the lack of physicians who provide abortions may be less of a statement about the general opinion of physicians about abortion, and more a reflection of the specialization of medicine into different fields, and differences in the kinds of training available to physicians during their residency.

As for abortions being performed in places where that is the *only* service offered, that description only applies to a select few locations. There are 1,787 facilities in the US that provided medical and surgical abortions as of 2005[2]. Out of the total number of facilities, 381 were classified as "abortion clinics". Abortion clinics are defined as nonhospital facilities where half or more of patient visits are for abortion services[2]. These clinics performed 69% of all abortions in 2005[2]. There were 435 other clinics defined as places where abortion services make

up less than 50% of patient visits[2]. The non-specialized clinics performed 25% of all abortions in 2005[2]. Together, clinics that specialize in abortion and clinics that are non-specialized provide many other important family planning services including contraception services; STD testing and treatment; pre-natal care; and, for many young women, yearly cervical cancer screening[48]. The data from 2005 showed that 604 hospitals and 367 physician offices also provided abortions[2]. Hospitals and private physician offices generally provide a smaller percentage of the total abortions in the US (5% and 2% respectively), but it is important to understand that they do provide abortion services to women[2, 48].

The perception that abortion providers are unethical and are coercing women into having abortions reflects a deep mistrust of abortion providers. This mistrust may stem from the belief that abortion is immoral and, because it is immoral, all those who participate in it are lacking moral integrity and may have poor standards of ethical medical practice. The perception that abortion providers are coercing women into having abortions in order to make money reflects a lack of understanding about the cost of abortion when compared to the cost of medical care in general. It is true that abortions cost money, but, as one respondent commented, it is substantially less expensive than most medical procedures[49]. In fact, the average price for an abortion at 10 weeks gestational age in 2005 was $413, after adjustment for inflation this is $11 less than the cost of the same procedure in 2001[2]. The cost of abortion services is going down, even though the cost of medical care in the US is rapidly increasing. Abortions are a medical procedure and therefore do cost money in order to help finance the cost of care, but abortion providers do not make a profit from their practice. Many abortion clinics depend on donations for support because they do not make a profit from their services and they serve many low-income women[49]. In addition, the lack of reimbursement for providing abortion services, as compared to the large

reimbursements that physicians receive for providing other types of procedures, is a deterrent for physicians to provide abortions[49]. Being an abortion provider is not advertised as a career track for medical professionals seeking a lucrative practice environment.

The perceptions of abortion providers as being unethical or ashamed of their practice were not consistent with the thoughts and feelings expressed by those abortion providers or advocates who worked closely with providers who were interviewed for this study. All of these respondents indicated that they provided patient-centered care, trying to ensure that the patient was not being coerced into the procedure by someone else. They felt that they were providing a service to women who were in need of that service, and adhering to the highest of medical ethical standards in doing so. The descriptions of the type of care provided to women as a part of the typical abortion counseling and procedure indicated that these providers are very conscientious about the health of the women that they serve.

Risks of abortion for women's health & sources of evidence: Issues concerning the quality of the available evidence for the risks of abortion for women's health also stem from mistrust about the evidence from the Guttmacher Institute (GI). Both respondents who were opposed to abortion and who felt that abortion carried significant risks for women's health did not trust this research because GI is affiliated with Planned Parenthood. They both stated that they preferred their information to come from non-biased sources. However, later in the discussion, both of these respondents cited data from organizations affiliated with a publicized pro-life stance. For example, one respondent quoted a figure about the percentage of women who change their minds about whether or not to have an abortion after seeing an ultrasound image of their fetus. Research in the early 1980's indicated that looking at fetal ultrasound images early in pregnancy increases bonding with the fetus in some women, but not all, and this study was not

conducted in a family planning clinic where women were having ultrasounds prior to terminating a pregnancy[50]. The figure that the respondent quoted comes from research conducted in crisis pregnancy centers that have a pro-life stance; therefore there may be other factors influencing the outcome of the pregnancy besides the showing of an ultrasound image[50, 51]. Another respondent reported that the evidence she used to counsel women comes from the Medical Institute and Focus on the Family. Both of these organizations are strongly affiliated with pro-life beliefs[52, 53]. In saying that they wanted unbiased information not coming from an organization affiliated with Planned Parenthood, but then accepting research from organizations affiliated with a pro-life stance, these respondents indicate that they are not willing to accept "biased" information when it comes from an organization that is pro-choice.

The issue of whether or not the research from GI is biased is questionable. The journals that GI produced are peer-reviewed, and many pro-life organizations use data collected from GI to monitor trends in abortion in the US[20, 41]. If these data are rigorous enough to be used by such organizations, it is somewhat contradictory to not trust the rigor of their data on the health outcomes and safety of abortion. Some published data found in medical journals that do not have an association with a pro-choice or pro-life stance indicate that abortion is associated with health risks. However, these same journals have published a body of evidence indicating that abortion is not associated with significant risks to a woman's health. The latter type of data far outnumbers the data indicating adverse health outcomes of abortion. With the increasing availability of medical (medication-induced) abortion for early pregnancy termination, abortion has become even safer. One study looking at the associated morbidity and mortality of abortion found that out of all the medication abortions reported to the CDC in 1999, there was not a single death [54].

Many review articles examine all the existing evidence. These reviews report that abortion is one of the safest medical procedures available. It is also the opinion of ACOG, which closely monitors and assesses the available research on abortion risks, that abortion is a safe medical procedure[7]. Data published by ACOG reported that the overall death rate due to abortion from 1988-1997 was 0.7 per 100,000 procedures[7]. Therefore, data from GI are not discrepant with data from other "neutral" sources in reporting the safety of abortion. If opponents of abortion are unwilling to trust the data from peer-reviewed articles in GI publications, there is also a large body of evidence from "neutral" sources indicating that abortion is a safe procedure. The only data that are discrepant with this overwhelming opinion are data that come from scientifically unsound studies, and data that come from research organizations with a vested interest in the pro-life cause.

Morality of abortion: Respondents who opposed abortion emphasized that abortion is an immoral practice. They expressed feelings about the immorality of society and of women who were "not taking responsibility for their own actions" and resorting to abortion. However, qualitative research into the reasons why women have abortions indicates that women describe a conscious examination of the moral aspects of their decisions, taking into account the weight of their responsibilities to their families, their existing children, and to themselves and children that they might have in the future[1]. A theme in this research was women's responsibility to children and other dependents. Contrary to the perception of one respondent that women choose abortion out of convenience, almost all women in this study cited concern for responsibility to other individuals as a factor in their decision to have an abortion[1]. After giving all of these elements in their life thought, they come to the conclusion that having an abortion is the most responsible choice[1, 55]. For people who are fundamentally opposed to abortion, it will remain an immoral act.

However the assertion that women who are having abortions are doing so without thinking about others does not appear to be accurate in all situations.

Necessity of specific regulation for abortion services: Respondents who were in favor of the proposed regulations cited the reasons that women considering abortions need to undergo informed consent prior to the procedure, free from pressure or coercion on the part of abortion providers. However, respondents who were involved in providing abortion services all stated that they currently undergo a thorough, patient-centered informed consent process with the women they serve. These respondents felt that the informed consent regulations proposed in the two bills would interfere in the physician-patient relationship by requiring the following of a uniform informed consent script. These respondents felt that every woman is unique, and comes to the discussion with her own level of understanding and her own questions about the procedure, and that applying a uniform script to all women would not address all of their concerns, or answer the questions that they have.

Respondents who favored the 24-hour waiting period felt that it would give women additional time to think about their decision. All respondents agreed that women should take as much time as they need to come to a decision. One respondent who works with abortion providers reported that women are already taking at least 24 hours to think about their decision. She remarked that women are thinking about this decision from the moment that they realize that they have an unintended pregnancy. Other respondents raised concerns about the effects of the 24-hour waiting period on delaying access to abortion services. Research has shown that states with 24-hour waiting periods, especially those that require women to make two visits to an abortion clinic, are associated with an increase in later term abortions[38]. Later term abortions are more expensive, and although safe overall, the risk of morbidity and mortality from later term

abortions when compared to early abortions is more than 30 times higher[7, 38]. Based on these figures, ACOG published a policy recommendation that abortion access should be increased, rather than decreased, in an effort to allow women seeking abortions to have procedures earlier rather than later in their pregnancy[7].

Respondents who opposed the regulation also felt that the bills would undermine the trust in a patient- physician relationship by requiring physicians to follow a script rather than participate in a discussion with the patient. Respondents also brought up concerns about the content of the bills and the additional requirements contained in the bill, including the requirement that a physician must speak with *any* woman who calls and has questions about the abortion procedure. This is a legitimate concern, as counseling people over the phone about medical issues without having any relationship with that person or knowledge about their personal history borders on malpractice. The bills also contain contradictory and confusing language that makes the rules for abortion providers unclear, and in some cases places the woman's health in danger (as in with telling her that she can ask to stop the procedure during the procedure, which could place her at significant risk for bleeding or infection). Blurring the rules for physicians about what is and is not legal in providing a health service according to a new regulation raises concern for litigation or malpractice, and discourages physicians from providing that service[49, 56].

Conclusion: In light of these findings, I have concluded that the current bills being proposed to regulate the informed consent process are counterproductive to providing women with high-quality health care. Much of what the proposed bills would require is already being practiced as a part of abortion services. According to the descriptions given by abortion providers and studies on the practice and safety of abortion services, women are receiving high

quality, individualized counseling prior to the procedure. Most abortion service providers agree that women who are having an abortion have given the decision a lot of thought. The 24-hour waiting period is associated with increased risks to women's health because it may cause unnecessary delays in care. In addition, the requirement that physicians discuss only the potential risks of abortion, and to discuss risks that are not substantiated by current medical opinion, are not in keeping with the rules of informed consent. Many of the requirements included in the proposed bills would impede the appropriate informed consent process and may create unnecessary delays for women who are seeking abortions; therefore these proposals are inappropriate because they will decrease the quality of women's health care.

Finally, the core belief that abortion is an immoral act is an irreconcilable difference between those who are opposed to abortion and those who are in favor of providing abortion services to women. This belief is at the heart of the motivation behind why many people oppose abortion. However, whether or not abortion is an immoral practice is an issue separate from ensuring that the informed consent process for elective abortion adheres to the principles of medical ethics and is in the best interest of the patient. Decisions about what is best should be made by individual patients, in collaboration with their loved ones, and guided by their physicians[56]. Patients make decisions based on their own values, desires and beliefs, and legislation has no place in this process[56]. What is consistent with the ethical principles underlying informed consent is that women be given all the necessary information about the risks, benefits and alternatives to this procedure, and the risks and benefits of all the alternatives; and the opportunity to ask questions and participate in shared decision making prior to undergoing an elective abortion. Since this is the current medical practice, it appears that the additional legislation is not necessary.

Policy Recommendations:

The politics of abortion policy making are very complex. Just as there were many factors influencing the social and political climate in the 1970s when Roe v. Wade was decided, there are many factors today that influence the public's willingness to pass legislation that will limit access to abortion. The abortion debate is rooted in morality, and people's opposition or support is closely tied to their beliefs about women's roles in society and their acceptance of women's right to control their reproduction. People on both sides of the issue often think that abortion is fundamentally different from other medical procedures and therefore should be treated differently. In addition, there is a lot of information available to the public on the dangers that abortion poses to women's health, even if that information is not supported by current medical thinking. Many people outside of medicine do not understand how medical practice is regulated, and are not sure that all physicians go through an informed consent process with all of their patients prior to conducting a procedure. Therefore, to many people, legislation that requires physicians to go through the informed consent process with patients, and that includes a waiting period following that process, seems reasonable and in the best interest of the patient. Most people recognize that the decision about whether or not to have an abortion is complicated and takes time. People also generally agree that women need to be fully informed about their decision prior to having an abortion. This helps explain why abortion opponents have been successful in passing legislation that limits access to abortion[20].

The majority of abortions in the US are not performed for medical indications, and are considered to be elective, which implies that patients are making a choice[3]. As abortion currently stands in the US, this choice should be made by a woman and her physician[3]. The choices faced by women with respect to pregnancy termination are not always easy, but the decision to have an abortion is not always a traumatic one and women should be trusted as they are competent to

make this decision[56]. Abortion, like other major decisions in life, requires some support and has an associated amount of stress. The amount of distress experienced with an abortion varies from person to person.

The argument of opponents to abortion that abortion causes irrevocable psychological harm is not supported by the majority of medical evidence on this topic[6]. The small systematic review included in this paper supports the assertion that abortion is not a traumatic experience, and that it is not associated with negative mental health outcomes for the majority of women in the US. Most data suggest a limited sense of loss and guilt and few to no long-term emotional and psychological sequelae[6]. With rare exceptions, psychiatric illness does not occur *de novo* or permanently[57]. For women who feel sad, depressed or guilty, it should be remembered that such feelings are common and that a circumscribed period of mourning after an abortion is considered normal[57]. Finally, the amount of distress that a woman experiences from an abortion may be the same or less than the distress she would experience if she were denied the ability to have an abortion[57]. Studies have examined the effects of compulsory parenthood in countries where abortion laws are more restrictive than in the US, and long-term comparisons made between women who were refused abortion and women who were granted abortion indicated that mandatory motherhood was likely to be harmful to a woman's mental health[57]. Other studies indicate that women who are denied abortions often experience resentment and distrust of the medical system, and that forced motherhood is associated with negative psychological outcomes for both women and their children[6]. One long-term study of the outcomes of children of unwanted pregnancies whose mothers were denied abortion compared to matched controls of pregnancies where abortion was not requested found differences in the rate of negative

psychosocial development and mental well-being between the study and control population up to 35 years after they were born [58].

Although abortion is safe for most women, research has identified certain populations of women for whom the risk of negative psychiatric outcomes are increased. It is important to understand what populations of women are at higher risks for poor mental health outcomes in an effort to prevent them. Most literature suggests that the characteristics that place some women at higher risk include women who are having later-term abortions, abortions for medical or genetic indications, whose choice is less voluntary, and women with a severe, pre-existing or concurrent psychiatric illness[57]. In addition, a woman's personal beliefs about the morality of abortion may place her at increased risk for a negative mental health outcome. The teachings of some religions postulate that human life begins at conception and hold that abortion is murder[3]. Women who are members of these religions but who also decide to terminate a pregnancy may need additional help in coping with the apparent contradiction between their religious beliefs and their life decisions[3]. Some women may feel profoundly guilty about their decision and expect that they may somehow be punished[3]. This type of patient could probably benefit from discussions about her expectations of punishment or her ability to forgive herself or to seek forgiveness[3]. There are religious organizations and literature from Catholics for a Free Choice and the Religious Coalition for Abortion Rights that may help these women feel more at ease with their decisions[3].

Existing research that identifies populations that may be at risk for negative psychological outcomes, in combination with research investigating appropriate screening tools to identify those women, should be used to help providers identify women who are at higher risk. Research should also be conducted on the effectiveness of interventions that apply to these

higher risk populations, and interventions that appear to improve women's health should be promoted. It is important to note that abortion counseling and the informed consent process are designed to inform the woman of her choices and give her support in making her decision, not to ensure that the woman is entirely sure about her decision or to resolve any feelings of doubt or uncertainty[3]. Feelings of doubt and ambivalence are not an indication that the woman is making the wrong decision, but rather that the decision is complex[3]. In addition, the existence of some emotional and psychological distress surrounding abortion and the need for support is not sufficient to categorize it as a psychological or psychiatric problem[57]. A successful counseling session cannot always resolve feelings of ambivalence or guilt, but it can help a woman clarify her feelings, give her an opportunity to ask questions and express her concerns, and provide her with the information she needs to make an informed choice in a non-judgmental atmosphere[3].

The data from the elite interviews indicate that proponents of further regulations for the informed consent process for elective abortion are either not aware of the current practice of informed consent in abortion provision, or do not trust that providers are adhering to the current regulations. Therefore, further regulation seems to them an appropriate solution that is in the best interest of women. However, the current practice of abortion does involve undergoing the informed consent process with every patient, and providers feel that the legislation will impede this process from being as effective and patient-centered as it is currently. It may be that people who support further regulation are being intentionally misinformed about the current practice of abortion by legislators with a vested interest in limiting abortion access. If this is the case, it is important to educate the public and politicians about the current practice of abortion.

It is important that the public be made aware of the truth about current abortion practices. Information about the safety of abortion has changed over time. In the late 1970s and early

1980s, abortion was less safe than it is today. Through legalization of abortion, increased availability of medication abortion, and monitoring of morbidity and mortality, the medical field has improved the safety of this procedure so that today, the risk of death from abortion is less than the risk of death from anaphylaxis resulting from a penicillin shot[6, 54]. If politicians and the public understood that abortion was a very safe procedure; that all physicians are guided by the rules of medical ethics; and that there are already regulations and requirements in place that ensure that patients undergo informed consent prior to having a procedure done, they might question, as one of the respondents did, why is more regulation necessary? What will more regulation accomplish?

The law on abortion has historically been based on two premises: that the law should leave individuals free to make their own decisions without state coercion, and that it should reflect societal values[12]. The current attempts to regulate the informed consent process and require the reading of materials that are designed to dissuade women from having abortions defies the first premise because it is an attempt by the state to coerce women into not having abortions. These attempts violate the second premise because they do not reflect the public's general opinion that patients should have access to legal treatments, which would include a woman's right to choose, without government interference[21]. These are not the first attempts to violate these premises. From 1973-1983, numerous attempts were made to decrease access to abortions[12]. These attempts included imposing 24-hour waiting periods and requirements that the woman be shown pictures of fetuses at different stages of development[12]. At that time, these attempts were struck down by the court systems because they unduly burdened a woman's right to obtain an abortion[12]. In 1983, the Court in the *City of Akron* v. *Akron Center for Reproductive Health* case invalidated regulations requiring physicians to recite a lengthy and fixed list of

abortion risks, stating that the government could not decide what specific information women must be given[12]. These regulations would have also required that an attending physician inform the woman, among other things, that abortion is a major surgical procedure with serious risks, about the availability of assistance if the patient decides to carry the pregnancy to term, that the woman be told about the abortion technique in graphic detail, and that the woman be given information about the physical and emotional complications of abortion and the availability of adoption services[12]. The Court held that these regulations were unduly burdensome and that it is the sole responsibility of the physician to ensure that appropriate information is given to the patient[12]. The Court invalidated the statue, stating that much of the information required was designed not to inform the woman, but to discourage her from having an abortion, and the Court emphasized that states could not place unreasonable obstacles in the path of the doctor and the patient[12]. The regulations included in this statute, which was struck down by the Supreme Court more than 20 years ago, sound remarkably similar to the regulations being proposed in the Woman's Right to Know and the Ultrasound Before an Abortion bills.

The influence of the political environment on reproductive health policy making must not be underestimated.. In the last decade, many restrictions on elective abortion have passed and have been deemed Constitutional by the Supreme Court. This is in part due to the changing composition of the Supreme Court, the dedication of legislators who oppose abortion, and the heavily anti-choice stance of the current Bush administration[6, 19]. One Democratic Congresswoman was quoted as warning not to underestimate the commitment of abortion opponents to their cause. She said, "They are persistent, and they are insistent"[20]. NC House Minority Leader Paul Stam was identified by respondents as being a key legislator in the battle over abortion restrictions in NC. In response to the Supreme Court decision on banning certain

late-term abortions in 2007, he said that he was encouraged, but felt that the state was unlikely to add further restrictions unless there is a change in the state legislature[59]. In a newspaper article, Melissa Reed, the executive director of NARAL Pro-Choice NC at the time of the interview, said that bills restricting abortion access are likely to be introduced in the wake of the Supreme Court decision. She confirmed that although they are unlikely to be passed with the current legislature, but to remember how important elections are to maintain that climate in the state legislature[59]. Both elites quoted in this article reflect the opinion stated by the majority of interview respondents that NC's current legislature is unlikely to pass bills that will further restrict abortion access, but that pressure will continue from pro-life advocates to change the makeup of the current legislature in order to have some success in this area.

Many researchers and analysts who have examined the content of bills like the "Woman's Right to Know" conclude that these initiatives employ scare tactics to persuade women into thinking that abortion is more dangerous than it actually is. The bills do this by mandating the reading of a lengthy list of possible but very rare complications from abortion, but not a corresponding list of possible benefits[6]. One Congressman who is opposed to abortion has stated that until abortion opponents can see the overturning of Roe v. Wade, they are using, "every modest and incremental approach available", including measures that limit access to abortion through regulating the informed consent process[20].

It is also important to recognize the role of unplanned pregnancy in the debate about abortion. Many analysts agree that the abortion rate in the US is high in part because we have a high rate of unintended pregnancies[2]. Slightly more than one in five pregnancies in the US ends in abortion. This indicates that unwanted pregnancy is very common. More needs to be done to help women prevent unintended pregnancy[2].

The current practice of informed consent for elective abortion in NC is in the best interest of women's health. Patients and physicians are able to engage in patient-centered, shared decision making that would not be possible under the proposed regulation for informed consent. If any regulation needs to be passed, it should be regulation that protects the patient-physician relationship from unnecessary interference. Because there is a 38% increase in the risk of death for abortions performed with each additional week of gestation, policies that seek to increase, rather than decrease access to abortion are in the best interest of women's health[7]. Legislators who oppose abortion usually do so on the grounds that it is an immoral practice. They have a right to their personal beliefs. However, it is unethical to distort the truth about the current practice of abortion and seek to enact legislation that would appear to be in the best interest of women, but would actually diminish the quality of care that they receive, in order to limit abortion access.

Public health research has clearly shown that decreased access to abortion services is associated with higher incidences of later term abortion and illegal abortion, both of which threaten women's health and well-being[7, 38, 60]. It is important for the public health field to understand both the current social and political climate for abortion, and to understand the motivations and beliefs of people who support legislation that further limits access to abortion. This understanding will support an effort to educate the public about the potential harmful effects of this legislation and to counter it with policy proposals that will further improve, rather than diminish, women's health.

Preserving women's access to abortion services will require continuous efforts on the part of concerned public health and medical professionals at the federal and state levels and in the courts[6]. Legislators promoting the insertion of the government into the shared decision making

process need to be aggressively countered[6]. Health care providers and educational institutions need to enhance their professional and public education programs to ensure the distribution of scientifically sound information on contraception and abortion[6]. It is the duty of public health and medical professionals to uphold the tenets of informed consent for elective abortion and oppose this type of legislation in the interest of preserving women's health.

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Appendix I: House Bill 1552

GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2007 H 1
HOUSE BILL 1552

Short Title: WRTK-Woman's Right to Know. (Public)

Sponsors: Representatives Johnson, McElraft, Justice (Primary Sponsors); Allred, Almond, Avila, Blackwood, Blust, Boylan, Brown, Clary, Cleveland, Dockham, Dollar, Folwell, Frye, Gillespie, Gulley, Hilton, Holloway, Holmes, Howard, Justus, Lewis, McComas, McGee, Moore, Neumann, Pate, Samuelson, Setzer, Stam, Starnes, Steen, Tillis, Walend, and Walker.

Referred to: Rules, Calendar, and Operations of the House, if favorable, Judiciary I.

April 18, 2007

A BILL TO BE ENTITLED AN ACT TO REQUIRE A TWENTY-FOUR-HOUR WAITING PERIOD AND THE INFORMED CONSENT OF A PREGNANT WOMAN BEFORE AN ABORTION MAY BE PERFORMED.

The General Assembly of North Carolina enacts:

SECTION 1. Chapter 90 of the General Statutes is amended by adding the following new Article to read:

"Article 1H. Woman's Right to Know Act.

90-21.60. Short title.

This act shall be known and may be cited as the 'Woman's Right to Know Act'.

90-21.61. Definitions.

As used in this Article, unless the context clearly requires otherwise, the term:

(1) 'Abortion' means the use or prescription of any instrument, medicine, drug, or any other substance or device intentionally to terminate the pregnancy of a woman known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.

(2) 'Attempt to perform an abortion' means an act, or an omission of a statutorily required act, that, under the circumstances as the actor believes them to be, constitutes a substantial step in a course of conduct planned to culminate in the performance of an abortion in North Carolina in violation of this Article.

(3) 'Department' means the Department of Health and Human Services.

(4) 'Medical emergency' means that condition which, on the basis of the physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function.

(5) 'Physician' means an individual licensed to practice medicine or osteopathy in accordance with this Chapter.

(6) 'Probable gestational age' means what, in the judgment of the physician, will with reasonable probability be the gestational age of the unborn child at the time the abortion is planned to be performed.

(7) 'Qualified person' means an agent of the physician who is a licensed psychologist, licensed social worker, licensed professional counselor, registered nurse, licensed physician, or certified health educator.

(8) 'Stable Internet Web site' means a Web site that, to the extent reasonably practicable, is safeguarded from having its content altered other than by the Department.

(9) 'Woman' means a female human, whether or not she is an adult.

90-21.62. Informed consent to abortion.

No abortion shall be performed upon a woman in this State without her voluntary and informed consent. Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if all of the following conditions are satisfied:

(1) At least 24 hours prior to the abortion, the physician who is to perform

the abortion or the referring physician has orally informed the woman, by telephone or in person, of all of the following:

a. The name of the physician who will perform the abortion.

b. The statistically significant medical risks associated with the particular abortion procedure to be performed.

c. The probable gestational age of the unborn child at the time the abortion is to be performed.

d. If the physician who is to perform the abortion has no liability insurance for malpractice in the performance or attempted performance of an abortion, that information shall be communicated.

e. If the physician who will perform the abortion has no local hospital admitting privileges, that information shall be communicated.

The information required by this subdivision may be provided orally, by telephone or in person, without conducting a physical examination or tests of the patient, in which case the required information may be based on facts supplied by the woman to the physician and whatever other relevant information is reasonably available. The information required by this subdivision may not be provided by a tape recording but must be provided during a consultation in which the physician is able to ask questions of the woman and the woman is able to ask questions of the physician. If, in the medical judgment of the physician, a physical examination, tests, or the availability of other information to the physician subsequently indicates a revision of the information previously supplied to the patient, then that revised information may be communicated to the patient at anytime prior to the performance of the abortion. Nothing in this section may be construed to preclude provision of required information in a language understood by the patient through a translator.

(2) The physician who is to perform the abortion, the referring physician, or a qualified person has informed, by telephone or in person, the woman of each of the following at least 24 hours before the abortion:

a. That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care.

b. That public assistance programs under Chapter 108A of the General Statutes may or may not be available as benefits under federal and State assistance programs.

c. That the father is liable to assist in the support of the child, even if the father has offered to pay for the abortion.

d. That the woman has the right to review the printed materials described in G.S. 90-21.63, that these materials are available on a State-sponsored Web site, and the address of the

State-sponsored Web site. The physician or a qualified person shall orally inform the woman that the materials have been provided by the Department and that they describe the unborn child and list agencies that offer alternatives to abortion. If the woman chooses to view the materials other than on the Web site, they shall either be given to her at least 24 hours before the abortion or be mailed to her at least 72 hours before the abortion by certified mail, restricted delivery to addressee.

e. That the woman is free to withhold or withdraw her consent to the abortion at anytime before or during the abortion without affecting her right to future care or treatment

and without the loss of any State or federally funded benefits to which she might otherwise be entitled. The information required by this subdivision may be provided by a tape recording if provision is made to record or otherwise register specifically whether the woman does or does not choose to have the printed materials given or mailed to her.

(3) If the physician uses ultrasound equipment in the performance of an abortion, the physician shall inform the woman that she has the right to view the ultrasound image of her unborn child before an abortion is performed. If the woman requests to view the ultrasound image, it shall be shown to her.

(4) The woman certifies in writing, prior to the abortion, that the information described in subdivisions (1) and (2) of this section has been furnished her and that she has been informed of her opportunity to review the information referred to in sub-subdivision c. of subdivision (2) of this section and in subdivision (3) of this section. The original of this certification shall be maintained in the woman's medical records, and a copy shall be given to her.

(5) Prior to the performance of the abortion, the physician who will perform the abortion or the qualified person must receive a copy of the written certification required by subdivision (4) of this section.

(6) The information required under this section and under G.S. 90-21.66 is provided to the woman individually to protect her privacy and maintain the confidentiality of the decision and to ensure that the information focuses on her individual circumstances and that she has an adequate opportunity to ask questions. If, at the time the information is provided, the woman is on the premises of the physician who is to perform the abortion, then the information shall be provided in a private room in order to further the protections and purposes of this subdivision.

(7) The woman is not required to pay any amount for the abortion procedure until the 24-hour waiting period has expired.

90-21.63. Printed information required.

(a) The Department shall publish in English and in each language that is the primary language of at least two percent (2%) of the State's population and shall cause to be available on the State Web site established under G.S. 90-21.64 the following printed materials in a manner that ensures that the information is easily comprehensible:

(1) Geographically indexed materials designed to inform a woman of public and private agencies and services available to assist her through pregnancy, upon childbirth, and while the child is dependent, including adoption agencies. The information shall

include a comprehensive list of the agencies available, a description of the services they offer, and a description of the manner, including telephone numbers, in which they might be contacted. In the alternative, in the discretion of the Department, the printed materials may contain a toll-free, 24-hour-a-day telephone number that may be called to obtain, orally, a list of these agencies in the locality of the caller and of the services they offer.

(2) Materials designed to inform the woman of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from the time of conception until full term, including any relevant information on the possibility of the unborn child's survival and pictures or drawings representing the development of the unborn child at two-week gestational increments. The pictures must contain the dimensions of the unborn child and must be realistic and appropriate for the stage of pregnancy depicted. The materials shall be objective, nonjudgmental, and designed to convey only accurate scientific information about the unborn child at the various gestational ages. The material shall also contain objective information describing the methods of abortion procedures employed, the medical risks associated with each procedure, the possible detrimental psychological effects of abortion, and the medical risks associated with each procedure, as well as the medical risks associated with carrying an unborn child to term.

(b) The materials referred to in subsection (a) of this section shall be printed in a typeface large enough to be clearly legible. The Web site provided for in G.S. 90-21.64 shall be maintained at a minimum resolution of 70 DPI (dots per inch). All pictures appearing on the Web site shall be a minimum of 200x300 pixels. All letters on the web site shall be a minimum of 11 point font. All information and pictures shall be accessible with an industry standard browser, requiring no additional plug-ins.

(c) The materials required under this section shall be available at no cost from the Department upon request and in appropriate numbers to any physician, qualified person, facility, or hospital.

90-21.64. Internet Web site.

The Department shall develop and maintain a stable Internet Web site to provide the information described under G.S. 90-21.63. No information regarding who accesses the Web site shall be collected or maintained. The Department shall monitor the Web site on a daily basis to prevent and correct tampering.

90-21.65. Procedure in case of medical emergency.

When a medical emergency compels the performance of an abortion, the physician shall inform the woman, prior to the abortion if

possible, of the medical indications supporting the physician's judgment that an abortion is necessary to avert her death or that a 24-hour delay will create a serious risk of substantial and irreversible impairment of a major bodily function. As soon as feasible, the physician shall document in writing the medical indications upon which the physician relied and shall cause the original of the writing to be maintained in the woman's medical records and a copy given to her.

90-21.66. Informed consent for a minor.

If the woman upon whom an abortion is to be performed is a unemancipated minor, the voluntary and informed written consent required under G.S. 90-21.62 shall be obtained from the minor and from the adult individual who gives consent pursuant to G.S. 90-21.7(a), unless the waiver order of G.S. 90-21.8(e) and (f) has been issued.

90-21.67. Civil remedies.

(a) Any person upon whom an abortion has been performed and any father of an unborn child that was the subject of an abortion may maintain an action for damages against the person who performed the abortion in knowing or reckless violation of this Article. Any person upon whom an abortion has been attempted may maintain an action for damages against the person who performed the abortion in knowing or reckless violation of this Article.

(b) If judgment is rendered in favor of the plaintiff in any action authorized under this section, the court shall also tax as part of the costs reasonable attorneys' fees in favor of the plaintiff against the defendant. If judgment is rendered in favor of the defendant, and the court finds that the plaintiff's suit was frivolous and brought in bad faith, then the court shall tax as part of the costs reasonable attorneys' fees in favor of the defendant against the plaintiff."

SECTION 2. If any provision, word, phrase, or clause of this act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect the provisions, words, phrases, clauses, or applications of this act which can be given effect without the invalid provision, word, phrase, clause, or application, and to this end the provisions, words, phrases, and clauses of this act are declared to be severable. The General Assembly declares that it would have enacted this act and each provision, word, phrase, or clause of this act irrespective of the fact that any one or more provision, word, phrase, or clause be declared unconstitutional.

SECTION 3. The Department of Health and Human Services shall use funds available to cover the costs of implementing this act.

SECTION 4. This act becomes effective October 1, 2007, and applies to claims for relief arising on or after that date.

Appendix II: House Bill 1782

GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2007 H 1
HOUSE BILL 1782

Short Title: Ultrasound Before an Abortion. (Public)

Sponsors: Representatives Hilton, Johnson (Primary Sponsors); Avila, Brown, Cleveland, Current, Gillespie, Moore, Samuelson, Stam, Starnes, and Tillis.

Referred to: Rules, Calendar, and Operations of the House, if favorable, Health and, if
favorable, to the Com on Judiciary I.

April 19, 2007

A BILL TO BE ENTITLED AN ACT TO PROVIDE FOR AN ULTRASOUND BEFORE PERFORMING AN ABORTION.

The General Assembly of North Carolina enacts:
SECTION 1. Article 11 of Chapter 14 of the General Statutes is amended by adding the following new section to read:

14-45.2. Ultrasound before performing an abortion.

(a) Notwithstanding G.S. 14-45.1, except in the case of a medical emergency and in addition to any other consent requirements under the laws of this State, no abortion may be performed unless the following conditions are satisfied:

(1) The licensed physician performing the abortion shall inform the woman of the probable gestational age of the embryo or fetus, verified by an obstetric ultrasound, at the time the abortion is to be performed. The licensed physician performing the abortion shall:

a. Perform an obstetric ultrasound on the woman; and

b. After viewing the images to verify the gestational age, reproduce and review the images with the woman before the woman gives informed consent to have an abortion procedure performed. Nothing in this subdivision shall be construed as requiring the woman to view the ultrasound image. Neither the physician nor the woman shall be penalized if the woman decides not to view the ultrasound image.

(2) The licensed physician performing the abortion shall present the woman with a written form containing the following statement: 'You have the right to review printed materials prepared by the State of North Carolina that

describe fetal development, list agencies that offer alternatives to abortion, and describe medical assistance benefits that may be available for prenatal care, childbirth, and neonatal care.' This form shall be signed and dated by both the licensed physician who is to perform the procedure and the pregnant woman upon whom the procedure is to be performed. The form shall be kept in the woman's medical file, and the medical file shall be maintained for at least three years.

(3) The woman shall certify, in writing, before the abortion that the information and obstetric ultrasound images described in subdivision (1) of this subsection have been provided to and reviewed with her, and that she has been informed of her opportunity to review the information referred to in subdivision (2) of this subsection.

(4) Before performing the abortion, the licensed physician performing the abortion shall determine that the written certification required in subdivision (3) of this subsection has been signed. This subdivision shall not apply in the case where an abortion is performed pursuant to a court order.

(b) No abortion may be performed less than one hour after the woman receives the written materials and certifies this fact to the licensed physician or the physician's agent.

(c) In the event the person upon whom the abortion is to be performed is an unemancipated minor, as defined in G.S. 90-21.6(1), the information described in subdivisions (a)(1) and (2) of this section shall be furnished and offered respectively to a person required to give parental consent under G.S. 90-21.7(a) and the unemancipated minor. The person required to give consent in accordance with G.S. 90-21.7(a), as appropriate, shall make the certification required by subdivision (a)(3) of this section. In the event the person upon whom the abortion is to be performed has been adjudicated mentally incompetent by a court of competent jurisdiction, the information shall be furnished and offered respectively to her spouse or a legal guardian if she is married or, if she is not married, to one parent or a legal guardian. The spouse, legal guardian, or parent, as appropriate, shall make the certification required by subdivision (a)(3) of this section. This subsection shall not apply in the case of an abortion performed pursuant to a court order.

(d) For purposes of this section, the phrase 'medical emergency' means that condition which, on the basis of the physician's good faith judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the risk of her death or for which a delay will create serious risk of substantial and irreversible impairment of major bodily function. The phrase 'probable gestational age of the embryo or fetus' means what, in the judgment of the attending physician based upon the physician's examination and the woman's medical history, is with reasonable

probability the gestational age of the embryo or fetus at the time the abortion is to be performed. The phrase 'licensed physician' means a physician licensed to practice medicine under Article 1 of Chapter 90 of the General Statutes."

SECTION 2. This act becomes effective December 1, 2007.

OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

APPLICATION FOR IRB APPROVAL OF
HUMAN SUBJECTS RESEARCH
Version 3-Oct-2007

Part A.1. Contact Information, Agreements, and Signatures

Date: 01/08

Title of Study: Informed Consent for Elective Abortion: A Policy Analysis for North Carolina.

Name and degrees of Principal Investigator: Lily Pemberton
Department: Public Health Leadership Mailing address/CB #: 2025 S. Lakeshore Dr. Apt. A, Chapel Hill, NC, 27514
UNC-CH PID: 700429299 Pager: N/A
Phone #: (919) 696-1565 Fax #: N/A Email Address: lily_pemberton@med.unc.edu

For trainee-led projects: __ undergraduate _X_ graduate __ postdoc __ resident __ other
Name of faculty advisor: Trude Bennett, PhD
Department: Maternal and Child Health Mailing address/CB #: 7445
Phone #: (919)966-5977 Fax #: (919)966-0458 Email Address: trude_bennett@unc.edu

Center, institute, or department in which research is based if other than department(s) listed above:

Name of Project Manager or Study Coordinator (if any):
Department: Mailing address/CB #:
Phone #: Fax #: Email Address:

List **all other project personnel** including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. **Include email address for each person who should receive electronic copies of IRB correspondence to PI:** Sue Tolleson Rinehart, PhD, Dept. of Pediatrics and Dept. of Public Health Leadership, Mailing Address 231D MacNider Hall, CB# 7220, Phone #: 919 843 9477, Fax #: 919 966 7299, Email Address: suetr@unc.edu
Email addresses of persons to receive electronic copies of IRB correspondence to PI: lily_pemberton@med.unc.edu, suetr@unc.edu, trude_bennett@unc.edu

Name of funding source or sponsor (*please do not abbreviate*):
_X_ not funded __ Federal __ State __ industry __ foundation __ UNC-CH
__ other (specify):
For industry sponsored research (if applicable):

Sponsor's master protocol version #: Version date:

Investigator Brochure version #: Version date:

Any other details you need documented on IRB approval:

RAMSeS proposal number (from Office of Sponsored Research):

Checklist of Items to Include with Your Submission

Include the following items with your submission, where applicable.

- Check the relevant items below and include one copy of all checked items 1-11 in the order listed.
- Also include two additional collated sets of copies (sorted in the order listed) for items 1-7.

→ **Applications will be returned if these instructions are not followed.**

Check	Item	Total No. of Copies
☐	1. This application. One copy must have original PI signatures.	3
☐	2. Consent and assent forms, fact or information sheets; include phone and verbal consent scripts.	3
☐	3. HIPAA authorization addendum to consent form.	3
☐	4. All recruitment materials including scripts, flyers and advertising, letters, emails.	3
☐	5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc.	3
☐	6. Documentation of reviews from any other committees (e.g., GCRC, Oncology Protocol Review Committee, or local review committees in Academic Affairs).	3
☐	7. Protocol, grant application or proposal supporting this submission, if any (e.g., extramural grant application to NIH or foundation, industry protocol, student proposal). This must be submitted if an external funding source or sponsor is checked on the previous page.	1
☐	8. Addendum for Multi-Site Studies where UNC-CH is the Lead Coordinating Center.	1
☐	9. Data use agreements (may be required for use of existing data from third parties).	1
☐	10. Only for those study personnel *not* in the online UNC-CH ethics training database (http://cfx3.research.unc.edu/training_comp/): Documentation of required training in human research ethics.	1
☐	11. Investigator Brochure if a drug study.	1

Principal Investigator: I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

_____ _____

Signature of Principal Investigator Date

Faculty Advisor if PI is a Student or Trainee Investigator: I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

_____ _____

Signature of Faculty Advisor Date

Note: The following signature is not required for applications with a student PI.

Department or Division Chair, Center Director (or counterpart) of PI: (or Vice-Chair or Chair's designee if Chair is investigator or otherwise unable to review): I certify that this research is appropriate for this Principal Investigator, that the investigators are qualified to conduct the research, and that there are adequate resources (including financial, support and facilities) available. If my unit has a local review committee for pre-IRB review, this requirement has been satisfied. I support this application, and hereby submit it for further review.

_____ _____

Signature of Department Chair or designee Date

_____ _____

Print Name of Department Chair or designee Department

Part A.2. Summary Checklist *Are the following involved?*	Yes	No
A.2.1. Existing data, research records, patient records, and/or human biological specimens?	__	_X_
A.2.2. Surveys, questionnaires, interviews, or focus groups with subjects?	_X_	__
A.2.3. Videotaping, audiotaping, filming of subjects, or analysis of existing tapes?	_X_	__
A.2.4. Do you plan to enroll subjects from these vulnerable or select populations: a. UNC-CH students or UNC-CH employees? b. Non-English-speaking? c. Decisionally impaired? d. Patients? e. Prisoners, others involuntarily detained or incarcerated, or parolees? f. Pregnant women? g. Minors (less than 18 years)? ***If yes***, give age range: to years	 _X_ __ __ __ __ __ __	 __ __ __ __ __ __
A.2.5. a. Are sites outside UNC-CH engaged in the research? b. Is UNC-CH the sponsor or lead coordinating center for a multi-site study? ***If yes,*** include the ***Addendum for Multi-site Studies***. ***If yes***, will any of these sites be outside the United States? ***If yes***, is there a local ethics review committee agency with jurisdiction? (provide contact information)	__ __ __ __	_X_ _X_ __ __
A.2.6. Will this study use a data and safety monitoring board or committee? ***If yes:*** UNC-CH School of Medicine DSMB? (must apply separately) Lineberger Cancer Center DSMC? Other? Specify:	__ __ __ __	_X_ __ __ __
A.2.7. a. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc? b. Do you plan to obtain a federal Certificate of Confidentiality for this study?	__ __	_X_ _X_
A.2.8. a. Investigational drugs? (provide **IND #**) b. Approved drugs for "non-FDA-approved" conditions? *All studies testing substances in humans must provide a letter of acknowledgement from the UNC Health Care Investigational Drug Service (IDS).*	__ __	_X_ _X_
A.2.9. Placebo(s)?	__	_X_
A.2.10. Investigational devices, instruments, machines, software? (provide **IDE #**)	__	_X_
A.2.11. Fetal tissue?	__	_X_
A.2.12. Genetic studies on subjects' specimens?	__	_X_
A.2.13. Storage of subjects' specimens for future research? ***If yes,*** *see instructions for* ***Consent for Stored Samples***.	__	_X_
A.2.14. Diagnostic or therapeutic ionizing radiation, or radioactive isotopes, which subjects would not receive otherwise? ***If yes,*** *approval by the* ***UNC-CH Radiation Safety Committee*** *is required.*	__	_X_
A.2.15. Recombinant DNA or gene transfer to human subjects? ***If yes,*** *approval by the* ***UNC-CH Institutional Biosafety Committee*** *is required.*	__	_X_
A.2.16. Does this study involve UNC-CH cancer patients? ***If yes,*** *submit this application directly to the* ***Oncology Protocol Review Committee***.	__	_X_
A.2.17. Will subjects be studied in the General Clinical Research Center (GCRC)? ***If yes,*** *obtain the* ***GCRC Addendum*** *from the GCRC and submit complete application (IRB application and Addendum) to the GCRC.*	__	_X_

Part A.3. Conflict of Interest Questions and Certification

The following questions apply to **all investigators and study staff** engaged in the design, conduct, or reporting results of this project **and/or their immediate family members.** For these purposes, "family" includes the individual's spouse and dependent children. "Spouse" includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other's welfare and shares financial obligations.

A.3.1. Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have:		
(a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study?	__ yes	x no
(b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	_x no
(c) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	_x no
A.3.2. Has the University or has a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team?	__ yes	_x no
A.3.3. Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project?	__ yes	_x no

If the answer to ANY of the questions above is *yes*, the affected research team member(s) must complete and submit to the Office of the University Counsel the form accessible at http://coi.unc.edu. List name(s) of all research team members for whom any answer to the questions above is *yes*:

_____

Certification by Principal Investigator: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of every UNC-Chapel Hill employee or trainee who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above, and that I have instructed any such person who has answered "yes" to any of these questions to complete and submit for approval a Conflict of Interest Evaluation Form. I understand that as Principal Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by University policy.

_____ _____

Signature of Principal Investigator Date

Faculty Advisor if PI is a Student or Trainee Investigator: I accept ultimate responsibility for ensuring that the PI complies with the University's conflict of interest policies and procedures.

_____ _____

Signature of Faculty Advisor Date

Part A.4. Questions Common to All Studies

For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use.

A.4.1. **Brief Summary**. Provide a *brief* non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. *Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.*

Purpose: To examine the health and medical ethical implications of the informed consent process for elective abortion policies in North Carolina. Several proposals for policies regulating the informed consent process for elective abortion will be analyzed using the Bush model of policy analysis to attempt to determine the policy that has the potential to fulfill the ethical and medical intent of the informed consent process as a part of patient autonomy and informed decision making.

Participants: Physician leaders, reproductive health experts, women's health advocates and administrators who have stake in the content of reproductive health policies. These will include physicians, political scientists, policy analysts, public health experts and patient advocates. These professionals will be affiliated with UNC hospitals and/or nationally, regionally or locally recognized organizations with a stake in reproductive health policies.

Procedures (methods): In-depth structured interviews with questions pertaining to the political and social factors that contribute to reproductive health care policies, the political climate for abortion and other reproductive health services, the evolution of these political and social climates in NC and surrounding states, the differences and similarities between NC and its surrounding states, the ethical and medical requirements of informed consent processes for elective procedures and for elective abortion, the ethical and medical implications of the informed consent process for elective abortion and the likelihood that the proposed bills will pass in NC. Interview subjects will be identified by position using publicly available information and contacted for interview availability and scheduling, undergo the consent process using the consent form included in this application, and interviewed either by phone or in person with a digital auditory recording of the interview (if the subject consents) and notes taken during the interview (if the subject consents). I will also conduct informal questioning of key informants, identified by position or by experts in their field to obtain information used to guide further background research for the project. No personally sensitive information or identifiers will be collected or used from key informants who are surveyed. The interviews will be triangulated with analyses of the medical literature; historical and political background readings; existing policies for the informed consent process for elective abortion; the history, meaning and intent of the informed consent process for elective procedures; and other public documents.

A.4.2. **Purpose and Rationale**. Provide a summary of the background information, state the research question(s), and tell why the study is needed. If a complete rationale and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive rationale and literature review, including references.

Special requirements for the informed consent process for elective abortion are mandated by some states. Most informed consent procedures apply to procedures that are done in a non-emergent setting and seek to inform the patient of the potential risks, benefits and harms of having the procedure. The intent of informed consent is to allow the patient to make an autonomous and informed decision about whether or

not to proceed with the procedure. Materials for the informed consent process for elective abortion have created controversy in the medical and ethical fields because some of the materials about health risks are not consistent with current evidence-based professional opinion and are not relevant to all women who are seeking an abortion. The concern about these materials is that they are not intended to inform women of the true risks and benefits of the procedure so that women can make informed decisions, rather they are intended to be misleading and dissuade women from having abortions. There are concerns about the consequences of these materials for women seeking elective abortions and for abortion providers. .

I am interested in identifying the possible health and ethical consequences of policies regulating the informed consent process for elective abortion. I am interested in the situation of North Carolina in particular because it is a state that has differed from neighboring southeastern states with regard to reproductive health policies. In addition, North Carolina currently has two bills that are being proposed that would require mandated pre-abortion counseling. I am interested in how the history, the current social and political climate and the relationship of North Carolina with neighboring states will influence the passage and content of a policy regulating the informed consent process for elective abortions. Through my analysis and triangulation of methods, I hope to determine a policy for North Carolina that would fulfill the intent of the informed consent process as a part of medical ethics facilitating the autonomy of patients by aiding them in the informed decision making process.

A.4.3. **Subjects.** *You should describe the subject population even if your study does not involve direct interaction (e.g., existing records).* Specify number, gender, ethnicity, race, and age. Specify whether subjects are healthy volunteers or patients. If patients, specify any relevant disease or condition and indicate how potential subjects will be identified.

We will interview approximately 20-30 professionals, women's health advocates, or persons involved in reproductive health policy making, of any race or sex, at UNC hospitals or another national, state or local organization with a stake in reproductive health care policies. These organizations will include UNC Institute of Government, Southern Mountain Women's Health Alliance, MAHEC Ob-Gyn residency program, UNC Ob-Gyn residency program, Women's reproductive health care providers, Planned Parenthood of Central NC, NARAL, National Women's Health Organizations, Ipas, Family Health International, El Centro, UNC School of Law, Members of the NC legislative body. The interview subjects will be identified by position using publicly available information.

I will conduct informal surveys with key professionals identified by position to collect information for clarification of existing practices or policies, involved groups or persons and other background information.

A.4.4. **Inclusion/exclusion criteria.** List required characteristics of potential subjects, and those that preclude enrollment or involvement of subjects or their data. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, or age. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided.

The only inclusion criterion for interviews is to be a professional, advocate, activist or lobbyist, with a stake in reproductive health policy.

The only exclusion criterion for interviews is the professional's inability or unwillingness to be interviewed for the project in person or by telephone.

Inclusion criteria for key informants is to be a professional, advocate, activist or lobbyist with a stake in reproductive health policy.

Exclusion criteria for key informants is the informants inability or unwillingness to be questioned for the project.

A.4.5. **Full description of the study design, methods and procedures.** Describe the research study. Discuss the study design; study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other medical treatment if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture,

etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures. If the study involves medical treatment, distinguish standard care procedures from those that are research. If the study is a clinical trial involving patients as subjects and use of placebo control is involved, provide justification for the use of placebo controls.

This research project will analyze current and proposed policies regulating the informed consent process for elective abortions according to the Bush analysis model to determine the policy that fulfills the medical and ethical criteria for informed consent as a part of the informed decision making process for women considering elective abortions. In conducting this analysis and developing policy proposals, current informed consent for elective abortion policies will be analyzed, political and social variables that affect reproductive health policies in the southeast will be analyzed and used to develop policy alternatives for North Carolina, and expert opinions on the health and ethical implications of existing and the proposed policies will be applied to the model in order to determine the most suitable policy for the informed consent process for elective abortions in North Carolina. The study will be triangulated. We will begin with a brief literature search using PubMed, Lexis Nexis, PsychInfo, CINAHL, Thomas, ISI Web of Science, GoogleScholar and Public health databases for background information, using key words "Informed consent, counseling, consent, disclosure, verbal or written communication, state laws, policy, politics, ethics, abortion, therapeutic abortion, induced abortion, mandatory, mandates, required, North Carolina, Southeast, Southeastern United States, South, South Carolina, Tennessee, Georgia, Virginia, breast cancer, breast neoplasm, PTSD, depression, anxiety, mood disorder, infertility, fertility, parity, fetal pain, United States, United Kingdom, Britain, Europe, ethics". In addition, we will review pertinent public records from UNC hospitals and women's health organizations. Finally, we will conduct interviews with key women's health stakeholders affiliated with UNC hospitals, National, State and local women's health organizations and policy analysts. Lily Pemberton, the Principle Investigator of the study, will perform all searches for literature and pertinent documents and conduct all interviews. Mrs. Pemberton will frequently enlist the expertise of her faculty advisors Dr. Trude Bennett and Dr. Sue Tolleson-Rinehart.

Interviews and surveys of key informants will be conducted either via phone or in a private office. They will last up to 1 hour. Participants of surveys will be asked to provide their expert opinions on important aspects of current informed consent procedures for elective abortion in North Carolina, current practices of options counseling for unintended pregnancies in North Carolina, and important events, groups or people that have contributed to reproductive health policy making in North Carolina. Participants of interviews will be asked about the history of reproductive health policy in NC and the USA, the political and social factors that contribute to reproductive health care policies, the political climate for abortion and other reproductive health services, the evolution of these political and social climates in NC and surrounding states, the differences and similarities between NC and its surrounding states, the ethical and medical requirements of informed consent processes for elective procedures and for elective abortion, the ethical and medical implications of the informed consent process for elective abortion and the likelihood that the proposed bills will pass in NC and the likely future of policies regulating the informed consent process for elective abortions in NC. We will not ask nor collect any personal information from participants of any kind, except for their names and public positions. This information will not be linked to data, included in the text or any publication unless the interviewee gives us their permission to do so on the interview consent form provided prior to the interview. Participants' comments will be recorded as written notes by Mrs. Pemberton and, for accuracy, by digital voice recording. Mrs. Pemberton will transcribe the recordings. The interview participants have the right to refuse to be recorded and may do so on the consent form prior to the interview.

A.4.6. **Benefits to subjects and/or society.** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is

no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.

Interviewees and survey participants themselves will not benefit from participation. Society will benefit from an improved understanding of the social and political factors that contribute to reproductive health policy making, in particular the passing of mandatory pre-abortion counseling policies. In particular, readers will gain better understanding of the medical and ethical implications of mandatory pre-abortion counseling policies and the elements that contribute to an ideal mandatory pre-abortion counseling policy. Readers will also gain a better understanding of the evidence surrounding the health consequences of abortion, the intention of informed consent policies, the historical social and political factors that influence attitudes towards and policies involving women's health and reproductive health and the likely future of reproductive health policies in NC.

A.4.7. **Full description of risks and measures to minimize risks.** Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

We do not believe interview or survey participants will incur any harm by participating in the interview or survey. Participants will only sacrifice their time to be interviewed or surveyed. The PI will make all reasonable efforts to prevent a breach of confidentiality from happening.

Unless they consent to do so, interview participants will be identified only by the positions they hold and not by their names. With many people that we intend to interview, it is possible that they could be identified by their position, for example "Director of Central NC Planned Parenthood". Survey participants will not be identified by person or position in the paper. All participants will only be asked to comment on matters concerning reproductive health policy and practice. No personal information will be solicited, only knowledge, attitudes, and opinions about informed consent and abortion policy and possible implications for women's health and provider's practices. We cannot foresee substantial risk if their identity is discovered.

Participants will always be free to refuse to answer questions and to stop the interview at any point in time.

A.4.8. **Data analysis.** Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies).

Interview transcripts will be reviewed and integrated with information from the medical literature and other public documents. Quotes from the interviews will be used to construct hypotheses and illustrate arguments.

A.4.9. **Will you collect or receive any of the following identifiers?** Does not apply to consent forms.

__ No _x_ Yes *If yes, check all that apply*:

a. _x_ Names
b. _x_ Telephone numbers
c. __ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
d. _x_ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
e. _x_ Fax numbers
f. _x_ Electronic mail addresses
g. __ Social security numbers
h. __ Medical record numbers
i. __ Health plan beneficiary numbers
j. __ Account numbers
k. __ Certificate/license numbers
l. __ Vehicle identifiers and serial numbers (VIN), including license plate numbers
m. __ Device identifiers and serial numbers (e.g., implanted medical device)
n. _x_ Web universal resource locators (URLs)
o. _x_ Internet protocol (IP) address numbers
p. __ Biometric identifiers, including finger and voice prints
q. __ Full face photographic images and any comparable images
r. __ Any other unique identifying number, characteristic or code, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

A.4.10. **Identifiers in research data**. Are the identifiers in A.4.9 above linked or maintained with the research data?

_x_ yes __ no

A.4.11. **Confidentiality of the data**. Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

Notes and transcriptions of entire participant interviews will be kept secure on Mrs. Pemberton's password-protected computer. Entire, identified interviews will not be shared outside the research group, except in the case of providing a participant a transcript of his/her own interview.

A.4.12. **Data sharing.** With whom will *identifiable* (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.

__ No one
__ Coordinating Center:
__ Statisticians:
__ Consultants:
__ Other researchers:
__ Registries:
__ Sponsors:
__ External labs for additional testing:
__ Journals:
__ Publicly available dataset:
_x_ Other: If a participant requests a copy of the transcript of their interview, they will be provided with one. No other identifiable data will be shared with anyone except that those experts who consent to be named may have their names and comments presented in research reports.

A.4.13. **Data security for storage and transmission**. Please check all that apply.

For electronic data:

__ Secure network _x_ Password access __ Encryption
__ Other (describe):
_x_ Portable storage (e.g., laptop computer, flash drive)
Describe how data will be protected for any portable device: password protected

For hardcopy data (including human biological specimens, CDs, tapes, etc.):

__ Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above)
_x_ Locked suite or office
__ Locked cabinet
__ Data coded by research team with a master list secured and kept separately
__ Other (describe):

A.4.14. **Post-study disposition of identifiable data or human biological materials**. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

Interview comments will be stored in hard copy in a file cabinet in Dr. Tolleson-Rinehart's office in a secured suite in the UNC School of Medicine.

Part A.5. The Consent Process and Consent Documentation (including Waivers)

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances.

- If you will obtain consent in any manner, complete **section A.5.1**.
- If you are obtaining consent, but requesting a waiver of the requirement for a signed consent document, complete **section A.5.2**.
- If you are requesting a waiver of any or all of the elements of consent, complete **section A.5.3**.

You may need to complete more than one section. For example, if you are conducting a phone survey with verbal consent, complete sections A.5.1, A.5.2, and possibly A.5.3.

A.5.1. **Describe the process of obtaining informed consent from subjects**. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). If non-English speaking people will be enrolled, explain how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. *After you have completed this part A.5.1, if you are not requesting a waiver of any type, you are done with Part A.5.; proceed to Part B.*

Please see the attached Fact Sheet and Consent Form. The Fact Sheet explains the research question and goals. The Consent Form permits participants to consent to be interviewed, to have their interview recorded, to have notes taken on the interview, and to have their responses identified by their name. We are not asking personally sensitive information; as the attached structured interview protocol makes clear, we seek only information and opinions with regard to reproductive health policy. We will obtain written consent from participants who are interviewed in person. We will obtain oral consent (recorded on a digital recorder and transcribed following the interview) from participants who are interviewed on the telephone.

A.5.2. **Justification for a waiver of *written* (i.e., signed) consent**. *The default is for subjects to sign a written document that contains all the elements of informed consent.* Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true. *Chose only one:*

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). _x_ yes __ no

Explain. If the participant does not consent to being identified by name in the final paper, the identifying information included in the paper would be by position only. _x_ yes __ no

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey).

Explain. We anticipate some participants will be interviewed by telephone only. We will begin the telephone interview by reading the Fact Sheet, the four Consent

statements (consent to be interviewed, to having notes taken on the interview, to have the interview recorded and to be identified by name in the paper), and ask participants to provide verbal consent to all four. Participants' oral consent will be part of the recorded, transcribed interview.

If you checked "yes" to either (and you are not requesting a waiver in section A.5.3) consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document.

→ If you have justified a waiver of written (signed) consent (A.5.2), you should complete A.5.3 *only* if your consent process will not include all the other elements of consent.

A.5.3. **Justification for a full or partial waiver of consent.** *The default is for subjects to give informed consent.* A waiver might be requested for research involving only existing data or human biological specimens (see also Part C). More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

__ Requesting **waiver of some elements** (specify; see SOP 28 on the IRB web site):
__ Requesting **waiver of consent entirely**
If you check either of the boxes above, answer items a-f.. To justify a full waiver of the requirement for informed consent, you must be able to answer "yes" (or "not applicable" for question c) to items a-f. **Insert brief explanations that support your answers.**

a. Will the research involve no greater than minimal risk to subjects or to their privacy? __ yes __ no
Explain.

b. Is it true that the waiver will *not* adversely affect the rights and welfare of subjects? *(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)* __ yes __ no
Explain.

c. When applicable to your study, do you have plans to provide subjects with pertinent information after their participation is over? *(e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)* __ yes __ not applicable
Explain.

d. Would the research be impracticable without the waiver? *(If you checked "yes," explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?).* __ yes __ no
Explain.

e. Is the risk to privacy reasonable in relation to benefits to be gained or the importance of the knowledge to be gained? __ yes __ no
Explain.

If you are accessing patient records for this research, you must also be able to answer "yes" to item f to justify a waiver of HIPAA authorization from the subjects.

f. Would the research be impracticable if you could not record (or use) Protected Health Information (PHI)? *(If you checked "yes," explain how* not *recording or using PHI would make the research impracticable).* __ yes __ no
Explain.

Part B. Questions for Studies that Involve Direct Interaction with Human Subjects

→ ***If this does not apply to your study, do not submit this section.***

B.1. **Methods of recruiting.** Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment. *For prospective subjects whose status (e.g., as patient or client), condition, or contact information is not publicly available (e.g., from a phone book or public web site), the initial contact should be made with legitimate knowledge of the subjects' circumstances. Ideally, the individual with such knowledge should seek prospective subjects' permission to release names to the PI for recruitment. Alternatively, the knowledgeable individual could provide information about the study, including contact information for the investigator, so that interested prospective subjects can contact the investigator.* Provide the IRB with a copy of any document or script that will be used to obtain the patients' permission for release of names or to introduce the study. Check with the IRB for further guidance.

Individuals with special knowledge of reproductive health care policy, women's health and abortion procedures will be identified through public information on positions and job descriptions and areas of expertise. These individuals will be contacted by Mrs. Pemberton and asked if they would participate in an interview. If they agree to an interview, at the time of interview they will be given a copy of the attached informed consent form to sign, or have the form read to them and consent recorded over the phone if they are only able to be interviewed by phone. They will be informed about the nature of the study and that their consent is voluntary and that they have the right to end the interview at any point during the process.

B.2. **Protected Health Information (PHI).** If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization*. If this applies to your study, please provide the following information.

a. Will the information collected be limited only to that necessary to contact the subjects to ask if they are interested in participating in the study? No PHI is needed for this study.

b. How will confidentiality/privacy be protected prior to ascertaining desire to participate?
Participants all occupy public positions. Their positions form the basis for their recruitment to participate.

c. When and how will you destroy the contact information if an individual declines participation?
Immediately upon receiving the refusal to participate.

B.3. **Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable.** Include the number of required contacts and approximate duration of each contact.

Each participant will be contacted 1-3 times to establish interview time and mode that is the most convenient for the person. Each interview will take up to 1 hour. Follow-up will include a thank you letter to each participant.

B.4. **Where will the subjects be studied?** Describe locations where subjects will be studied, both on and off the UNC-CH campus.

Participants will be interviewed in their offices, or in the location of their choice, while Mrs. Pemberton is either interviewing them personally or by phone from a private location on the UNC-CH campus or in her residence.

B.5. **Privacy.** Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope).

Phone and office conversations will be conducted in individual private offices.

B.6. **Inducements for participation.** Describe all inducements to participate, monetary or non-monetary. If monetary, specify the amount and schedule for payments and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it. For compensation in foreign currency, provide a US$ equivalent. Provide evidence that the amount is not coercive (e.g., describe purchasing power for foreign countries). Be aware that payment over a certain amount may require the collection of the subjects' Social Security Numbers. If a subject is paid more than $40.00 at one time or cumulatively more than $200.00 per year, collection of subjects' Social Security Number is required (University policy) using the Social Security Number collection consent addendum found under forms on the IRB website (look for Study Subject Reimbursement Form).

None.

B.7. **Costs to be borne by subjects.** Include child care, travel, parking, clinic fees, diagnostic and laboratory studies, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this.

No costs other than their time to participate in the interview.

Informed Consent for Elective Abortion: A Policy Analysis for North Carolina.
A Study by Lily Pemberton, at the University of North Carolina at Chapel Hill

Information Sheet for Consent of Interviewees

IRB Study # **Consent Form Version Date:** January 2008

Principal Investigator:	Lily Pemberton
UNC-Chapel Hill Department:	Public Health Leadership Program
Faculty Advisor:	Trude Bennett Dr. P.H.
UNC-Chapel Hill Department:	UNC School of Public Health Department of Maternal and Child Health.
Advisor Phone #:	(919) 966-5977
Advisor e-mail:	trude_bennett@unc.edu

Study Contact telephone number: (919) 593 3212

Study Contact email: lily_pemberton@med.unc.edu

[Introductory script, embedding fact sheet and consent information]:

Hello, I am Lily Pemberton. Thank you so much for talking with me today. I am an MD/MPH candidate at The University of North Carolina at Chapel Hill. I am conducting research to fulfill the requirements of the Master's of Public Health degree in the Health Care & Prevention program.

I have asked to interview you because of your knowledge and experience with reproductive health policy. I have identified you by searching publicly available websites and information for organizations that deal with reproductive health issues. I am looking into the informed consent process for elective abortions and I am interested in various approaches to this topic, including pending legislation introduced in North Carolina and the impact on women and health care providers

My faculty adviser is Dr. Trude Bennett, who is a faculty member of the UNC School of Public Health. I hope this analysis will help people better understand the implications of social and political variables that influence reproductive health policy making. The results of this study may be published in a scholarly journal. You can choose whether or not you would be mentioned or quoted by name in any reports or publications resulting from this research.

The interview has several open-ended questions. The interview will take a maximum of 1 hour. With your permission, I would like to record this interview on a digital voice recorder, as well as take notes on our conversation, to make absolutely sure that I have an accurate record of your comments. If you grant permission for this conversation to be recorded on cassette, you have the right to revoke recording permission or end the interview at any time.

The audiotapes made of the interview will be kept in a locked cabinet and destroyed after I transcribe them. Transcripts will be entered on my computer which is controlled by a password known only to me. The electronic version and any printed copies of the transcripts that I use for analysis will also be destroyed upon completion of the study.

Your participation in this study is completely voluntary. Your choice of whether or not to participate will not influence your future relations with the University of North

Carolina at Chapel Hill.

If you have any questions about the research now, please ask. If you have questions later about the research, you may contact me by phone at **(919) 593 3212** or by e-mail at **lily_pemberton@med.unc.edu** . You may also contact my faculty adviser, Dr. Trude Bennett, by email at **trude_bennett@unc.edu** or by phone at **919.966.5977.**

Risks and Benefits: The only potential risk associated with this research could be a loss of confidentiality, and I will take all realistic efforts to keep this loss from happening. While you may not benefit personally from completing this survey, I believe that you will be helping the larger health care community by contributing to understand reproductive health policy making in the Southeast.

Can you please sign this consent form and check all relevant boxes if you agree to participate in an interview?

☐ I AGREE to being interviewed.

☐ I AGREE to having notes taken on my statements during the interview.

☐ I AGREE to having this interview tape recorded with a digital voice recorder.

☐ I AGREE to being quoted or mentioned by name.

_____

Name of Participant

_____ _____

Signature of Participant Date

If no, thank you for taking time to listen to my request.

If yes, Thank you for your help with my project! Let's begin.

Informed Consent for Elective Abortions in North Carolina: Interview Guide

1. I would like to discuss the issue of informed consent for elective abortions with you.
2. First, what are the medical and ethical responsibilities of health care providers during the informed consent process for elective procedures?
3. What should be included in the informed consent procedure for an elective abortion?
    a. Probe missing elements relating to the risks/benefits/alternative treatments by saying: "The usual elements of Informed Consent are the risks, benefits and alternatives, you have touched on (what they discussed in their answer to the above question- including risks, benefits and alternative treatments), what about the other elements?"
4. We have discussed what topics should be covered in the informed consent process for elective abortion, what are the best sources of evidence for risks, benefits and alternative treatments?
5. Do you feel that health care providers have any ethical obligations to disclose anything else as a part of the informed consent process for elective abortion?
6. Should the informed consent process for elective abortion be treated differently from the informed consent processes for other elective procedures?
    a. Probe: If "yes"- what is it about elective abortion that warrants this special treatment?
7. Are there any other medical procedures that you think warrant special attention or requirements for the informed consent process?
    a. Probe: If the procedures are not specified- ask what procedures warrant special treatment. If the reason why these procedures are special is not specified- ask why these procedures warrant special procedures.
8. What do you think the current social and political climate is like for elective abortion in North Carolina?
9. How do you think the climate in North Carolina compares to neighboring states in the Southeast?
    a. Probe by asking about specific differences or similarities if either is not discussed in the above answer by saying- "There may be differences and similarities among NC and these neighboring states, you have discussed the (differences or similarities depending on the above answer), what do you think are some of the (differences or similarities depending on the above answer)?
10. There are 33 states in the US that have passed legislation mandating that certain topics are covered as a part of the informed consent process for elective abortion. Are you aware of the pending legislation of this sort in North Carolina?*
    a. If "yes"- will ask, "can you describe what you know about this pending legislation".
        i. Will probe, if not answered, about the following:
            1. Do you feel that this policy fulfills the medical and ethical requirements of the informed consent process?
            2. If passed, what do you think will be the consequences for women's physical and emotional health?
            3. If passed, what do you think will be the consequences for providers of women's health services?
            4. Are there any ethical issues or concerns raised by the content of these bills?

5. Do you think that these bills are likely to pass?
    a. Probe: if the interviewee does not elaborate on why they do or do not think that the bills will pass, will ask "Why do you think the bills (will or will not depending on their answer) pass?

b. if "yes" but the understanding of what the bills contain is not complete, will inform the interviewee of any main elements of the bills that they did not discuss, using the following list of main elements:
    1. Names of the two bills: the NC House Bill 1552, 'Woman's Right to Know' bill, and NC House Bill 1782, the "Ultrasound Before and Abortion" bill.
    2. One would require a 1 hour waiting period, the other would require a 24 hour waiting period.
    3. Require the discussion of financial support services available for carrying the pregnancy to term, in addition to child support laws and printed materials listing support services for pregnant women
    4. Require the physician to inform the woman of her right to view ultrasound images of her womb prior to the abortion
    5. Require written information be given about the characteristics of the fetus at 2-week increments including realistic pictures of each stage of fetal development

    ii. After informing of the main elements, will probe:
        1. Do you feel that this policy fulfills the medical and ethical requirements of the informed consent process?
        2. If passed, what do you think will be the consequences for women's physical and emotional health?
        3. If passed, what do you think will be the consequences for providers of women's health services?
        4. Are there any ethical issues or concerns raised by the content of these bills?
        5. Do you think that these bills are likely to pass?
            a. Probe: if the interviewee does not elaborate on why they do or do not think that the bills will pass, will ask "Why do you think the bills (will or will not depending on their answer) pass?

c. If "no" - will inform the interviewee of the main elements of the bills, using the following list of main elements:
    1. Names of the two bills: the NC House Bill 1552, 'Woman's Right to Know' bill, and NC House Bill 1782, the "Ultrasound Before and Abortion" bill.
    2. One would require a 1 hour waiting period, the other would require a 24 hour waiting period.
    3. Require the discussion of financial support services available for carrying the pregnancy to term, in addition to child support laws and printed materials listing support services for pregnant women
    4. Require the physician to inform the woman of her right to view ultrasound images of her womb prior to the abortion

5. Require written information be given about the characteristics of the fetus at 2-week increments including realistic pictures of each stage of fetal development

ii. After informing of the main elements, will probe:
   1. Do you feel that this policy fulfills the medical and ethical requirements of the informed consent process?
   2. If passed, what do you think will be the consequences for women's physical and emotional health?
   3. If passed, what do you think will be the consequences for providers of women's health services?
   4. Are there any ethical issues or concerns raised by the content of these bills?
   5. Do you think that these bills are likely to pass?
      a. Probe: if the interviewee does not elaborate on why they do or do not think that the bills will pass, will ask "Why do you think the bills (will or will not depending on their answer) pass?

11. What is your opinion about the medical need of the materials required by these bills?
12. Is there anything else that you would like to add?

Final statement:
Thank you for your time!

* If the interviewee requests a more detailed account of what the 2 NC bills say, will provide them with the following statement, verbally if interviewing over the phone, and in writing if interviewing in person:

> There are two bills in the North Carolina legislature that pertain to the informed consent process for elective abortions. The first is the NC House Bill 1552, called the 'Woman's Right to Know'. This bill would require that for all non-emergent elective abortions, the informed consent process would include a 24 hour waiting period after the consent process, the statistically significant medical risks associated with the particular abortion procedure that is being considered, the probable gestational age of the fetus or unborn child at the time that the abortion is to be performed, the name, insurance status and hospital admitting privileges of the physician who will be performing the abortion procedure, the financial support services for prenatal care and adoption services, child support laws requiring the father of the child to support the child, the availability of printed materials listing support services for pregnant women, that the woman can withdraw her consent at any point in the abortion process, that if a physician uses an ultrasound prior to performing the abortion, the woman be made aware that she has a right to view the images and discuss them with her provider, that the woman be provided with printed information about public and private agencies that will support her in her pregnancy, materials to inform the woman of the probable anatomic and physiologic characteristics of the fetus or unborn child at two-week gestational increments from the time of conception until full term including realistic pictures of each stage of development, material on the methods of abortion that exist, the medical risks associated with each

procedure, as well as the risks of carrying the fetus or unborn child to term. These materials will be provided by the State to physicians, free of cost. The second bill is NC House Bill 1782, the "Ultrasound Before and Abortion" bill. This bill would require that, except in the case of a medical emergency, an ultrasound be performed by the physician providing the abortion prior to performing an abortion. The physician must offer to reproduce and review the images with the woman prior to her giving informed consent for the abortion. Women may refuse to view the images. The physician must also present the woman with written information containing the statement, 'You have the right to review printed materials prepared by the State of North Carolina that describe fetal development, list agencies that offer alternatives to abortion and describe medical assistance benefits that may be available for prenatal care, childbirth, and neonatal care', this form must be signed and dated by both the physician and the patient. There must be a 1 hour waiting period after the written materials and offer to review the ultrasound are given to the woman.

OFFICE OF HUMAN RESEARCH ETHICS -- Institutional Review Board

INSTRUCTIONS FOR APPLICATION FOR IRB APPROVAL OF HUMAN SUBJECTS RESEARCH

Version 3-Oct-2007

What is the purpose of this form?

This application is to seek *initial* IRB approval for a research study.

What parts of this application should you submit?

- For ***all studies***, submit Part A, which consists of these sections:
  - Part A.1. Contact Information, Agreements, and Signatures
  - Part A.2. Summary Checklist
  - Part A.3. Conflict of Interest Questions and Certification
  - Part A.4. Questions Common to All Studies
  - Part A.5. The Consent Process and Consent Documentation (including Waivers)

- For ***studies that involve direct interaction*** with human subjects (any contact with subjects including questionnaires, interviews, focus groups, observation, treatment interventions, etc), submit:
  - Part B. Questions for Studies that Involve Direct Interaction with Human Subjects

- For ***studies*** that use data, records or human biological specimens ***without direct subject contact***, submit:
  - Part C. Questions for Studies using Data, Records or Human Biological Specimens without Direct Contact with Subjects

Note: You should submit Parts B or C only as applicable. If the study involves *both* direct interaction *and* data collection without contact, use both Parts B and C in addition to Part A.

Who can serve as principal investigator (PI)?

The PI is the person who will personally conduct or supervise this research study. Under most circumstances, this will be a faculty member. For IRB communication purposes, a trainee/student may be listed as PI. However, a faculty advisor must be identified, who holds ultimate responsibility for ensuring that this project complies with all University, regulatory, and fiscal requirements.

→ *See next page for additional instructions*

---- Instructions – Do not submit this page with your application ----

Complete submission instructions can be found at http://ohre.unc.edu/submission_instructions.php. **All application and consent materials must be copied or printed on one side only**. See the checklist on page 1 of the application itself for items to include and number of copies.

Some applications require additional review prior to the IRB submission. Examples include the General Clinical Research Center (GCRC; http://gcrc.med.unc.edu/investigators/admin/gcrcapp.htm) or the Oncology Protocol Review Committee (PRC; http://cancer.med.unc.edu/research/prc/default.asp). See their web sites for details.

Many schools, departments, centers and institutes in Academic Affairs have local review committees that review before the IRB. See http://ohre.unc.edu/submission_instructions.php for a list of these units or consult your own unit for details.

Address for all Applications and Other Correspondence

IRB
CB# 7097, Medical Building 52
105 Mason Farm Road
Chapel Hill, NC 27599-7097

Types of Review

There are three levels of IRB Review (full board, expedited, and exempt), determined by the nature of the project, level of potential risk to human subjects, and the subject population. *The type of review applicable to a particular study is determined by the IRB.* Regardless of the kind of review, all applications use the same submission form.

Exempt and expedited review can be given to studies that constitute no more than minimal risk to the human subjects, i.e., the risk one experiences in daily living. These reviews are done in the IRB office on a continual basis.

Full board review is required for studies that involve greater than minimal risk or vulnerable populations that require special protection by the IRB. These require review by the convened IRB at the next scheduled meeting. See http://ohre.unc.edu/guide_to_irb.php for additional guidance.

---- Instructions – Do not submit this page with your application ----

Words	Facet	Synonyms	MeSH, APA							
A	Informed Consent	pre-procedure counseling, counseling, consent, disclosure, verbal or written communication	informed consent; consent forms							
B	Abortion	therapeutic abortion, induced abortion, abortion induced, induced abortions, abortions induced, abortion legal	abortion, induced; abortion, legal; therapeutic abortion	database searches	date	database(s) used	Limits	terms used	# found	#used
C	Policy	legislation and jurisprudence, public policy, public policies, health policies, social control policies	public policy, health policy, social control policy; jurisprudence	1	2/1/2008	PubMed				
D	PTSD	stress disorders, post-traumatic; post-traumatic stress disorder	stress disorders, post-traumatic	2	2/1/2008	Google Scholar				
E	Depression	depressive disorder, depressive symptoms; depressive disorder, major; adjustment disorders; dysthymic disorder	depression; depressive disorder; depressive disorder, major; dysthymic disorder, adjustment disorders; dysthymic	3	2/1/2008	Refworks		Purpose- import articles from previous literature searches/paper//research		
F	Mandatory	mandates, required, mandatory programs	mandatory programs;	4	2/8/2008	ISI Web of Science		Informed Consent, state laws	27	2
G	Post-abortion syndrome	post-abortion traumatic syndrome		5	2/8/2008	ISI Web of Science		Informed consent , utilization	64	4
H	fertility	infertility, parity, fecundity; infertility,female	fertility; infertility; infertility, female	6	2/8/2008	Google Scholar		Informed consent, quality, use	260000	3
I	breast cancer	breast neoplasm; breast tumor; carcinoma, ductal, breast	breast neoplasms; breast tumor; carconoma,ductal,breast	7	2/9/2008	PubMed	free full text, humans only, english only	(abortion OR therapeutic abortion OR induced abortion OR abortion, legal OR abortion, criminal OR illegal abortion) AND	42	30
J	anxiety	anxiety disorders; anxiety disorder	anxiety; anxiety disorders	8	2/9/2008	PubMed	free full text, humans only, english only		629	72
K	fetal pain			9	2/9/2008	PubMed	free full text, humans only, english only		84	46
L	North Carolina		North Carolina	10	2/9/2008	ISI Web of Science		abortion (topic) AND policy (topic) AND informed consent (topic)	4	4
M	Southeast	Southeastern United States, South	southeastern united states;	11	2/9/2008	ISI Web of Science			13	0

Description of themes:

1. Women's knowledge/ understanding:
    a. Factual knowledge about the abortion procedure (risks, benefits, alternatives)
    b. Understanding of the consequences of the procedure (ending a pregnancy, possible negative consequences)
    c. Decision-making abilities of women with unplanned pregnancies (having a rational mindset, not being coerced, having thought the decision through)
2. Mistrust:
    a. Of abortion providers/ pro-choice advocates (not abiding by current standards of medical ethics, not abiding by laws already in place to regulate abortion)
    b. Of abortion opponents/ pro-life advocates (not being honest about the true motivation behind regulation of abortion, sneaking extra limitations and avenues for further restriction and harassment of physicians into the proposals)
3. Role of abortion regulations:
    a. Regulations as unnecessary, inappropriate, unprecedented
    b. Regulations needed to ensure that women are going through the informed consent procedure
    c. Attitudes towards regulation (political climate for abortion regulation in the US and in NC)
4. Abortion services:
    a. Attitudes of abortion providers towards their practice and their relationships with patients
    b. Current practice of abortion providers described by those providers
    c. Perceptions of current practice of abortion by people opposed to abortion
    d. Perception of an "abortion industry" and motivations of abortion providers in this context
5. Women's health:
    a. Concern about decreased access to abortion and implications for women's health
    b. Concern for the mental and physical health of women who have unintended pregnancies
    c. Attitudes about the effect of abortion on women's mental and physical health
6. Morality:
    a. Abortion as an immoral act,
    b. Morality of society, social attitudes towards abortion
    c. Morality of society, social attitudes towards sexual activity
7. Leadership:
    a. The role of leadership in the US and in NC in shaping current abortion policies and proposed policies
8. Stigma of abortion:

a. Attitudes towards abortion that reflect a stigmatization of abortion in society