4-2013

Physician satisfaction with informed consent process in psychiatric research

Sushma Polavarapu

Physician Satisfaction with Informed Consent Process in Psychiatric Research

by

Sushma Polavarapu

THESIS

Submitted to the College of Health and Human Services

Eastern Michigan University

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

Clinical Research Administration

Thesis Committee:

Irwin Martin, PhD, Chair

Stephen A. Sonstein, PhD

Clarita S. Ketels, DO

April 2013

Ypsilanti, Michigan

Dedication

This thesis is dedicated to God, who gave me the strength and patience to complete this study.

I lovingly dedicate this thesis to my husband Praveen Krishna, who supported me each step of the way.

I also dedicate this thesis to my parents for their endless love, support, and encouragement.

Also, this thesis is dedicated to my committee members, IRB committee members, physicians for their endless support and encouragement.

Also, this thesis is dedicated to the people who directly or indirectly helped me in the successful completion of this study.

Finally, this thesis is dedicated to all those who believe in the richness of learning.

I am grateful to know all of you.

Acknowledgments

This dissertation would not have been possible without the guidance and the help of several great people, who in one or another way have contributed and extended their valuable assistance in the preparation and successful completion of this study.

First and foremost, it is with immense gratitude that I acknowledge the support as well as the help of my professor and my thesis chair, Dr. Irwin Martin. I will never forget his sincerity and encouragement in the successful completion of this study. He has been my inspiration to cross all the hurdles that I have faced in the completion of this study. Thank you so much for support and continuous encouragement, sir.

Secondly, I would like to express my sincere thanks and gratitude to Dr. Stephen Sonstein, Director of Clinical Research Administration, for his extended, long-term support starting from my first day to final level in accomplishing my master's degree at Eastern Michigan University. Thank you so much, sir, for your persistent help throughout my master's program.

I would like express my special thanks to Dr. Clarita Ketels for her valuable advice, unselfish as well as unfailing support, and friendly help in the start of this research study, who undertook to act as my committee member in spite of her professional commitments.

I would like to express my appreciation to the physicians who have participated in my survey and the organization (Michigan Psychiatric Society) who helped me in forwarding my survey to the physicians.

I would like to thank each and everyone who directly or indirectly helped me in the completion of this study.

Finally, I would like to thank my husband, Praveen Krishna. I don't know how my life would have been without him. He always takes my problems as his problems and directs me in overcoming them. He has always been an inspiration to me. Without him, this thesis would not have been possible. Thank you so much for your faithful love and endless help.

Also, my special recognition goes out to my family for their care as well as the support and also to the omnipresent God, who gave me the strength in completing my thesis by answering my prayers.

Abstract

Informed consent process is crucial in any research. The consent is meaningful only when the subject is capable of using disclosed information in deciding whether to participate in a research study. Decision-making capacity might change in psychiatric patients during the informed consent process. Therefore, there may be some elements which are neglected during the informed consent process in psychiatric research. The purpose of this research study was to determine the perceptions of physicians about what elements of informed consent might be neglected in psychiatric research and what additional elements might be included that would improve the informed consent process for psychiatric trials. There were limitations in this study; response rate was very low. Other researchers have also found very low response rates in physician surveys. Further studies should be done with a larger population having wide range of healthcare professionals who have had experience in psychiatric clinical trials.

Table of Contents

List of Figures

Chapter 1: Introduction

According to ICH GCP (1996), "Informed consent is the process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate." Also, documentation of informed consent is done by means of a written, signed, and dated informed consent form (ICH GCP, 1996).

The consent is meaningful only when the subject is capable of using disclosed information in deciding whether to participate in research or not. According to Dunn (2006), a person is capable of making a decision only when he/she is able to:

- Understand, use and appreciate the information
- Apply it to their situation
- Be consistent in their decision

Cognitive impairment and certain psychiatric or neurological diseases (e.g., schizophrenia, Alzheimer's, severe depression) may affect the decision-making capacity. In addition, some situational factors like complexity of disclosed information, and manner of disclosure can also affect the decision-making capacity.

According to Stanley Milgram (1974), "The social psychology of the century reveals a major lesson: often it is not so much the kind of person a man is as the kind of situation in which he finds himself that determines how he will act."

Milgram's experiment is a classic in psychology that demonstrates the dangers of obedience. The experiment demonstrates that situation plays a stronger role than

personality factors in obedience. The psychologists argue that obedience depends on both internal and external factors such as the overall temperament of the person and his personal beliefs. In Milgram's experiment, subjects are deceived to achieve the research goals and deception of research subjects is essential to prevent subjects from knowing the researcher's insight (McLeod, 2007).

However, it is very important to stick to the ethical code, as we are dealing with humans, and deception of subjects is not correct in all situations. (e.g., psychological disability is a situation where people are not in a position to take correct decisions on their own. Therefore, psychological disability should not be a cause for deception.) Hence, a deception results in violation of individual rights to choose to participate, and it leads to distrust of psychology in community (McLeod, 2007).

According to Appelbaum (1982), description of experimental methods (e.g., randomization, blinding) to subjects was often neglected during informed consent process in psychiatric research. This negligence leads to the gaining of informed consent from psychiatric patients by deception, which causes distress to patients (McLeod, 2007). In addition, in many psychiatric trials, the subjects are primarily treated to advance the goals of the researcher rather than as a person who is respected for his/her own sake (Bernard, 2010).

This research study aimed to determine the perceptions of physicians regarding what elements of informed consent might be neglected in the psychiatric research and what additional elements might be included that would improve the informed consent process for psychiatric trials. The perceptions of physicians who have done psychiatric clinical

trials were to be compared with the work they have actually done. This comparison would have determined if any elements that they identified as their perceptions are neglected by them in their real work. This exercise would have given an idea about whether the elements are actually neglected and could be used to support the hypotheses of the research. If the results of comparison showed congruity between psychiatrists' perceptions and their actual work, then this might have altered the informed consent process for psychiatric patients and included new elements in the informed consent.

Chapter 2: Background

According to Bernard (2010), as per the ethical concerns, restricting subject participation in psychiatric trials is one way to protect them.

According to the Center for Disease Control and Prevention (CDC) statistics, more than 1 out of 20 Americans 12 years of age and older are suffering from serious depression (Depression, n.d.), and nearly 40% of adults in 35 states are suffering from serious psychological disorders (Non-specific Psychological Distress, n.d.).

There has been a drastic increase in the mental illness rate in United States; research with psychiatrically ill subjects is also facing increased scrutiny ("America's State of Mind: A Report by Medco," 2011).

There has been an increase in the use of medications for mental health by both men and women in 2010 when compared to 2001 (Fig.1). There has also been an increase in the use of medications for mental health by boys as well as by the girls in 2010 when compared to the usage of medications for mental health in 2001 ("America's State of Mind: A Report by Medco," 2011).

As shown in Figure 2, there was an increase in the use of ADHD (Attention - Deficit / Hyperactivity Disorder) medications from 2001 to 2010. Women have surpassed men in the usage of medications for ADHD in 2010 compared to 2001. There has also been a continuous increase in the use of medications for ADHD from 2001 to 2010 ("America's State of Mind: A Report by Medco," 2011).

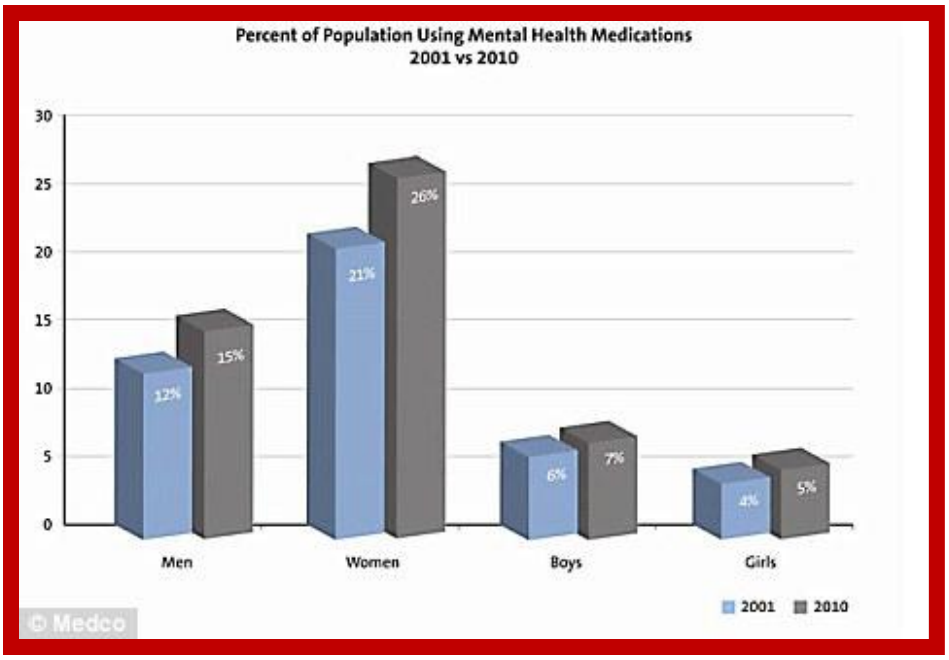

Figure 1. Percent of Population Using Mental Health Medications ("America's State of Mind: A Report by Medco," 2011)

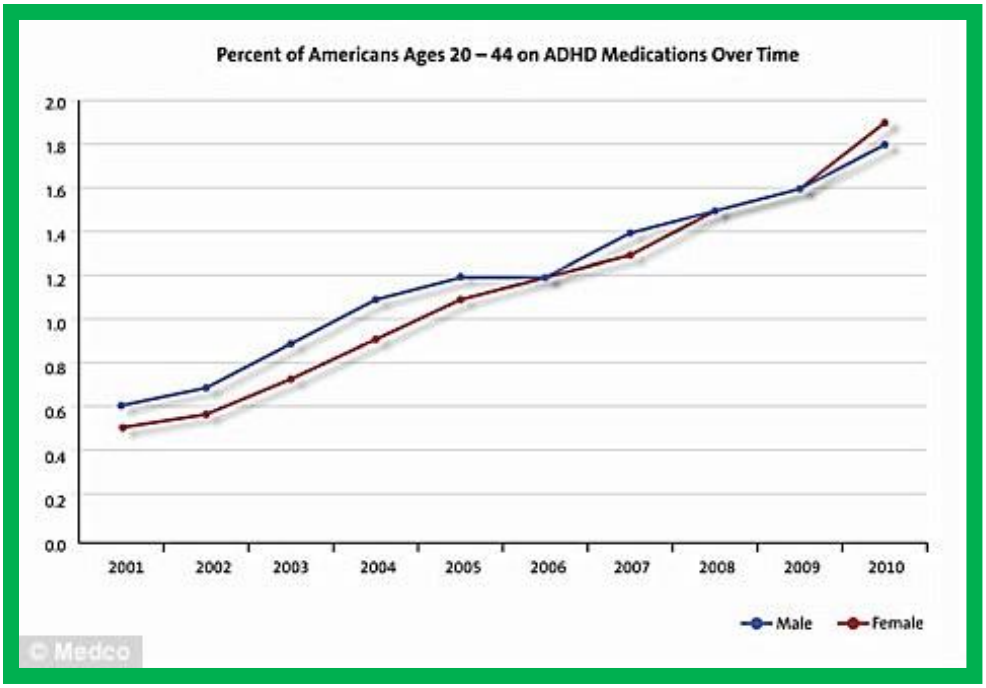

Figure 2. Percent of Americans Ages 20 - 44 on ADHD Medications over Time ("America's State of Mind: A Report by Medco," 2011)

Psychiatric illness should not prevent a patient from understanding what he/she has consented to, choosing whether to participate or not, having the ability to communicate his/her consent, and accepting the need for a medical intervention (Van Staden, 2003). A person should be competent to give his/her consent. Malhotra (2007) stated "Competency refers to some minimal, mental capacity required to perform a specific, legally recognized act or to assume some legal role."

According to the U.S Supreme Court, recruiting psychiatric patients into research without verifying their competency is violating due process rights (Kitamura, 1999). Assessing subject competency is a challenging task. If a competent patient is assessed as incompetent, his/her rights to give informed consent are violated, and if an incompetent patient is assessed as competent, his/her rights to be protected from mental health law are violated. Persons to be determined as incompetent for one condition (financial affairs) may be competent to make a decision about participation in research. Moreover, decision-making capacity is protocol-specific and situational specific (Kitamura, 1999).

According to the National Center for Ethics (2002), "A patient who lacks capacity to make one decision does not necessarily lack the ability to make all decisions." For example, a dementia patient can make a decision, such as whether to take a simple antibiotic treatment for urinary tract infection, but at the same time he/she cannot decide about a complex neurosurgical procedure with many risks and anticipated benefits. Therefore, each decision must be assessed separately while evaluating the decision-making capacity of patients (National Center for Ethics, 2002).

The following factors can help the researcher to determine that the research subject is competent, if they satisfy all of the following (Cady, 2010):

- Patient is aware of surroundings
- Patient can understand the research information provided
- Patient is able to make a decision by himself/herself based on what is best for him/her
- Patient is able to ask a question about the information provided in informed consent
- Patient is able to support his/her decision to refuse to participate in research

Components of Decision-Making Capacity

"Capacity is the dimensional quality of a person" (Karlawish, 2008). Decisional capacity is evaluated under four subparts (Zalta, 2011):

Understanding: This is the first and most basic element required for giving consent. This is the ability to grasp and understand the information provided in the informed consent form.

Appreciation: This is the ability of the decision-maker to determine that this is his or her decision to make and also to evaluate the subject's ability to appreciate the nature and potential alternatives for the future.

Reasoning: This is to determine the ability of the subject to think logically about the treatment options available, compare options, and infer the consequences of treatment options.

Choice: Many authors do not consider choice as an element of capacity. Choice is just the state of expressing their decision. Even a person with a good understanding, appreciation, and reasoning skills cannot express his/her decision if he/she is unconscious. Therefore, expressing choice is added to the list of elements of capacity as choice may compromise the decisional capacity.

Tools Used to Assess the Decision-Making Capacity

According to the National Center for Ethics (2002), there is no standard tool to assess the decision-making capacity in spite of many tools developed. Among the tools developed, the Mac CAT-CR, Informed Consent Survey and Vignette methods are designed to measure all four of the subparts of capacity, as other tools measure understanding in most cases (Dunn, 2006).

1) MacArthur Competence Assessment Tool for Clinical Research (Mac CAT-CR)

This is one of the most commonly used tools to assess the decision-making capacity of patients. This tool is designed by Grisso and Appelbaum (Grisso, 2001). Dunn (2006) stated that Mac CAT-CR is a semi-structured interview tool. It is designed to evaluate the four subparts of capacity (understanding, appreciation, reasoning and choice). It is mainly used to evaluate dementia, depression, and schizophrenia patient populations. It takes 15-30 min to complete and requires training to administer and interpret results.

According to "Guide to Informed Decision-making in Healthcare" (2012), "There are no cut off scores to differentiate between capacity and incapacity, but the tool provides insight into the various abilities as relevant to decision making capacity."

For Mac CAT-CR, a manual is also provided which explains the scoring guidelines based on which scores are given during the interview, and subsequent follow-up questions are raised based on scores. Hence, a little vigorous training is required to administer this test.

2) Vignette method

Vignettes are the artworks that assist explanation. Different vignettes are proposed as per the situation (what type of trial), and the decision-making capacity is assessed on the featured interview after viewing the vignette. Different questions such as "What might be the problem?" and "What advice would you give to problem described?" are put through to determine the subjects' decision-making capacity. This is used in Alzheimer's Disease (Clare, 2012).

Clare (2012) also stated that vignettes are created with one main character (either male or female). The patients are given opposite gender vignettes to prevent feelings of distress and to make subjects feel it was not related to them.

3) Informed Consent Survey

This is the other acceptable tool to test the decision-making of the mentally impaired subjects. This is a structured interview which involves a series of questions about the information provided in the Informed Consent. Patients are asked different types of questions to determine their understanding levels, and the information is repeated if they fail to answer the questions (Dunn, 2006).

Informed Consent Process in Psychiatric Research

Usher (1998) stated that recommended use of psychiatric medications in psychiatric settings is an excellent example where key elements (e.g., autonomy, specificity and competency) of informed consent process are neglected with regard to treatment. In addition, the regulations for the informed consent process with psychiatric patients are inadequate, and regulations provide exceptionally limited guidance, which is inadequate for all kinds of situations related to consent process for psychiatric patients (Gupta, 2012).

Elements of Informed consent

According to "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (1979), informed consent process is the combination of three elements.

Information: The most valuable part in informed consent, it includes research procedures, research purpose, anticipated benefits and risks, alternative procedures (any therapy involved), subject opportunity to ask questions, statement that states subject can withdraw from study at any time, subject recruitment process, who is responsible for research, and so on.

Comprehension: Presenting the information during the informed consent process in an understandable way to the subjects.

Voluntariness: Informed consent is obtained voluntarily without any coercion and undue influence.

The three elements should be satisfied to obtain informed consent. A special care should be taken for psychiatric patients to satisfy these three elements. According to Appelbaum (1982), information about research is not provided in full length to the subjects, especially about the randomization techniques. As per the observation from two different research projects, approximately 69% of subjects had no idea about the double blind technique used in their project (Appelbaum, 1982). Therefore, Appelbaum (1982) indicated this as therapeutic misconception and deception of subjects in obtaining the consent.

Informed consent can be a benefit to subjects with decisional impairment, if it is explained clearly and adequately to the subjects. Researchers should take necessary steps to make the informed consent process fruitful.

According to Davies (2001), there is a belief that psychiatric research is recommended as part of patient treatment for the benefits of researchers instead of the improvement of treatment options for the patients. For that reason, there is a need to create new conditions for patients urged to participate in psychiatric trials. This will in turn benefit the psychiatric research. An alternative and tailored informed consent process should be developed for psychiatric research.

A patient with psychiatric disorder means that he/she is not completely incompetent. Some can understand, some can appreciate, and some can make a choice whether to participate or not. According to Gupta (2012), many studies indicated that subjects with mental disorders are incompetent in one or two indices of decisional capacity, mostly understanding and reasoning. As a result, tailoring informed consent according to the

subject's cognitive deficits (e.g., memory, language, attention, and awareness) ensures that the subject can provide adequate and reasonable consent.

Appropriate approaches for reasonable consent are as follows (Gupta, 2012):

- Detailed discussion and presentation of study
- Simplified language
- Information disclosure in small consecutive pieces
- Repeated information
- Enough time and opportunity to ask questions

Consequently, one should assess what the impaired capacity indices of the subjects are and customize the informed consent process according to them.

An informed consent process in psychiatric research may be represented at in Figure 3 (Church, 2007).

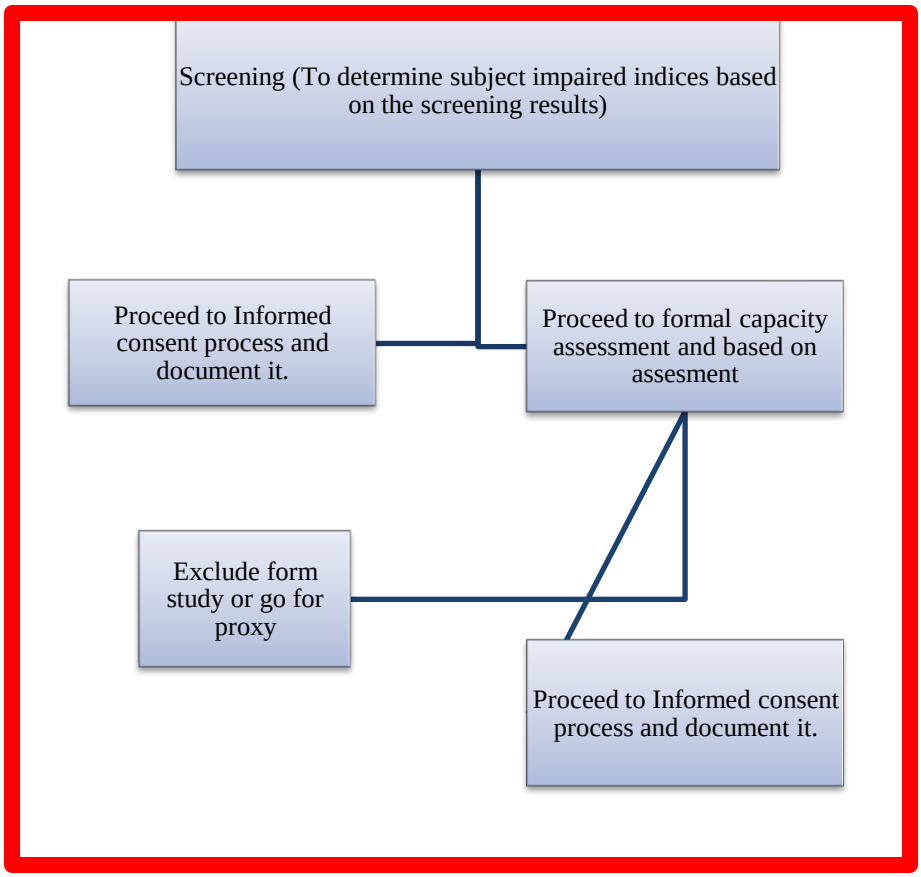

Figure 3. Informed Consent Process in Psychiatric Research (Church, 2007)

The process as described by Church (2007) includes:

Initial Screening

- Initial screening is done before the actual informed consent process.
- This is a general and informal screening to determine subjects' impaired indices (e.g., understanding, reasoning, appreciation and choice). These impairments can affect the subject decision-making capacity. Hence it is advisable to determine these impaired indices before assessing the decision-making capacity.

- In initial screening subjects are explained about the procedures, risks, and benefits of the trial in brief.
- Subject's impaired indices are determined in the initial screening by questioning about risks, anticipated benefits of research, procedures and research purpose, and so on. Based on the screening results we can determine in which particular indices subject is impaired and whether this impaired indices will affect the decision-making capacity of the subject.

After Screening

- After screening, if the subject is determined to have adequate consent capacity, then proceed to the actual consent process by taking all possible steps that support the subject's decision-making capacity; finally, physicians need to document the informed consent process.
- If subject is determined to have a problem in understanding complex information, then physicians should take necessary steps to make the information simple and understandable which can help subjects to make decisions on their own.
- According to Church, there is a need to give very careful attention in writing informed consent for psychiatric patients. Informed Consent should be very simple, uniformly structured, and include shorter sentences and simple words and be in simple format.
- After screening, even after providing the support to understand, if the subject is suspected to be incompetent, the formal capacity assessment is begun. Any

capacity assessment tool (Mac CAT-CR, Vignette etc.) is used to determine decision-making capacity.

- After capacity assessment, if subject is determined to have adequate consent capacity, the formal consent process is conducted and documented.
- If the subject is again determined to be incompetent, the subject should be expelled from the trial, or Legal Authorized Representative (LAR) consent is used to enroll to the clinical trial.

Persons with psychological disorders are not always incompetent. The subject may retain competency during research. Hence, the informed consent should be made as an ongoing process throughout the research (Church, 2007).

Legally Authorized Representative Consent or Proxy or Surrogate Consent

A person who may consent on behalf of another to participate in research is referred as proxy or surrogate (Saks, 2008). Regardless of a code of ethics and statements by professional societies, there are no clear guidelines or conditions for proxy consent. However, current federal regulations allow proxy consent under the permission of Legally Authorized Representative (LAR), "an individual or judicial or other body authorized under applicable law to consent on behalf of the prospective subject to the subject's participation in the procedures involved in the research" [45CFR46.102(c)]. The issue is who can be LAR and whether the laws of the jurisdiction of the state where they are conducting research confirm the LAR. As per the federal regulations, each state has its own laws for research involving mentally-impaired adults.

Saks (2008) stated that courts, guardians, people with durable power of attorney for health care, and family members were accepted as proxies by different states. In general, family members are preferred as proxies as they are more concerned about the subject and know best about the subject. In addition, taking family members as proxy is more time-saving and cost-effective for the researchers.

A person should be legally authorized to give proxy consent. This authorization is attained under applicable state law. Many states have no clear, applicable laws that explain about the proxy consent. In those states, family members or any person who has authority to provide proxy consent for medical treatment or medical procedure itself provides proxy consent to research also if that research involves the same medical procedure as in treatment (Saks, 2008).

Chapter 3: Thesis Statement

1) Are elements of informed consent process neglected in psychiatric research?

Have physicians who have done psychiatric clinical trials neglected any of the elements in the informed consent process? The question will be used to compare the work done in the real world to the physician's perception. If the outcomes obtained are in support of hypotheses, then this study can be used to identify necessary further research on the informed consent process in psychiatric trials and make changes in the consent process.

Based on published literature, the following are some possible findings for the elements that are being neglected in informed consent process in psychiatric research:

- *Information provided in informed consent (especially experimental methods):* The physicians neglect to explain to the subjects in psychiatric research about the experimental procedure (e.g., randomization, blinding, and possible risks) in research as they think that the subject cannot comprehend.
- *Comprehension of informed consent:* In psychiatric research, physicians should focus on the comprehension of the informed consent process as this gives subjects a better understanding about the trial. They need to repeat the information repeatedly until subject understands. The physicians might neglect to do this, as they think the subject is mentally impaired and unable to understand despite recurring explanations.

- *Failure to test the decision-making capacity of the patients:* Physicians assume that patients with psychiatric illness are mentally impaired and neglect to test their decision-making capacity as it is time intensive and involves additional procedures.
- *Investigators delegate informed consent process to lower level assistant:* From the summary of literature review, it was determined that investigators are not involved in the informed consent process of psychiatric research because they delegate that responsibility to their assistants.
- *Failure to explain to subjects the difference between research and treatment:* The subject has a right to know the difference as every research cannot be regarded as treatment. The research procedures are different, and every subject in the research may not receive the drug as the trial may be placebo-controlled. In psychiatric research they may neglect to explain the subject about the research procedure as they think the subject is not competent to understand that information. Hence, the subject should be informed about the research procedures and explained the anticipated risks and benefits.
- *Offer explanations in language difficult to understand by patients:* Every subject in the research may not have English as his or her primary language, and many subjects who even clearly understand and speak the English language may still have difficulty in understanding research language. Offering an explanation of complex experimental procedures to non-English speaking subjects with mental disabilities creates fear of involvement and further misunderstanding.

2) What are the perceptions of physicians (who have participated in psychiatric trials versus the non-participants?) about the informed consent process in psychiatric research?

3) What elements of informed consent are to be tailored or what elements are to be included to enhance the informed consent process in psychiatric research?

Chapter 4: Methodology

Sample Population

This research has been conducted to determine the perceptions of the physicians about the informed consent process in psychiatric research. A well designed electronic survey was developed to determine the perceptions of the study population. The population of interest for this study is physicians. The Michigan Psychiatric Society was selected to forward the electronic survey to all the members of the organization to eliminate bias and to protect population confidentiality.

Selection of Sample Size

Sample size is determined by degree of precision (confidence interval) and accuracy (confidence level) required for the responses to the survey questions. For this study, confidence level is 95% and confidence interval is ±10%. Percentages below and above 50% will have least amount of variance. Therefore, sample for this study is based on 50% point estimated for any question. Sample size needed to obtain the desired precision and accuracy is approximately 100 (MaCorr Research Solutions, n.d.). Anticipating a 10% response rate, survey will be sent to 1000 physicians (Survey sample size, n.d.).

Research Design

The research follows a descriptive method. "Descriptive method attempts to examine situations in order to establish what is the norm, i.e. what can be predicted to happen again under the same circumstances" (Walliman, 2011). It is versatile, fast, and appropriate for this survey, as this technique is used for collecting existing circumstances

in informed consent process in psychiatric research and determines the study population perceptions.

The survey included a total of 19 questions: 7 were demographic questions answered by the physicians (who have done psychiatric trials) work and 12 are related to perceptions about the informed consent process in psychiatric research. In the 19 questions, 9 questions were closed ended questions (multiple choices) and 10 were opinion questions that use a Likert rating scale. The survey may be found in Appendix C.

Human Subjects Protection

Prior to conducting the research or study or survey, an application for Review and Approval to conduct research or survey involving human subjects was submitted to the College of Health and Human Services Human Subjects Review Committee (CHHS-HSRC) at Eastern Michigan University.

The CHHS-HSRC approved the study to conduct the survey on January 15, 2013, along with the research-related documents like research proposal, Informed Consent form and Survey Questionnaire (Appendix A: College of Health and Human Services Human Subjects Review Committee Approval Letter).

All the potential participants were informed clearly about the purpose of the study, procedure for responding to the survey, voluntariness and withdrawal, protecting the rights of the participant by means of an Online Survey Consent Form. (Appendix B: Survey Completion Request or Online Survey Consent Form or Email Survey).

Informed consent form or Online Survey Consent Form was forwarded electronically along with the survey to all the members of Michigan Psychiatric Society. By filling out

the survey, participant has agreed to the conditions of Online Survey Consent Form. If the potential participants decided to participate, they could withdraw at anytime; their participation was purely voluntary. There are no direct benefits or risks associated with their participation, and all the responses to the survey are anonymous and confidential.

Method of Data Collection

The Michigan Psychiatric Society forwarded the survey to all members (potential participants) of their organization in the form of a link entitled "EMU SURVEY" in their newsletter on 02/19/2013 following the approval of CHHS-HSRC. Once the participant clicked the "EMU SURVEY" link, he or she was directed to another link "CLICK HERE to read the informed consent form" along with the background information about the survey. Participants were then directed to the survey link; by clicking on that link they were directed to the survey. The survey instrument included the consent form along with the 7 demographic questions (answered by the physicians, who have done psychiatric trials) and 12 questions related to the perceptions of physicians about the informed consent process in psychiatric research. After completing the required questions (survey), the participant was directed to click the "submit" button, which submitted his or her anonymous answers to the investigator. The data were collected using Google Docs.

Chapter 5: Results

Out of all the participants invited to the survey, only one participant successfully completed the survey. Although the survey was available for more than a month, no additional responses were received.

The single respondent did identify him/herself to the researcher and agreed to be interviewed by telephone. The respondent has participated in 1 to 2 psychiatric clinical trials, in which he/she acted as an investigator or as a sub-investigator. He/she has used informed consent survey method to assess the decision-making capacity of the subjects participated in psychiatric clinical trials. The respondent has taken informed consent from the subjects, instead of delegating to the lower level assistants. Informed consent was retaken from the subjects who have acquired decision-making capacity during the course of a trial, where surrogate consent was used initially. The respondent did not explain the procedure again to the subjects who have short term memory loss; instead he/she showed the informed consent and proceeded when the subject had agreed to a particular procedure. He/she has recruited the subjects who have failed in decision-making capacity.

The respondent believed that it is not important to assess the subject's decision-making capacity before the informed consent process. He/she believed that explaining the experimental methods (randomization, blinding) in detail to the psychiatric subjects may be neglected as they have less capacity to comprehend. He/she also believed that retaking of informed consent from subjects was neglected even though they regain the decision-making capacity during the course of a trial. Psychiatric subjects are simply expelled

from the clinical trials other than psychiatric trials (e.g., diabetes), instead of providing treatment options to them as it is difficult to get informed consent.

The respondent believed that informed consent process in psychiatric trials needs to be changed. He/she strongly agreed that informed consent process can be more useful by having more interactive sessions between the physician and patients before taking the informed consent. The respondent agreed that the use of creative modes of explanation (videos, artworks) can make the informed consent process more successful rather than simply using the paper informed consent form. He/she also agreed that mock informed consent sessions before the actual informed consent process can be useful because subjects will understand what exactly the informed consent process is and this can be more useful to the psychiatric subjects. The respondent also believed that providing informed consent in the language understood by subjects will help.

Chapter 6: Discussion

In the feedback from a single investigator, it seems that the following elements may be neglected in informed consent process of psychiatric research:

- Explaining experimental procedures (randomization, blinding) to subjects during informed consent process
- Retaking of informed consent from subjects after they retain decision-making capacity during course of trial
- Psychiatric subjects are simply expelled from the clinical trials instead of providing treatment options as it is difficult to take surrogate consent

Based on these preliminary data obtained from the survey, it is suggested that the following element needs to be tailored in the informed consent process to make it more successful:

Explain in detail about the trial procedure including experimental procedures

Every subject in the trial has a right to know about the trial procedure in detail. The research coordinators or other staff may neglect the trial procedures as subjects may refuse to participate in the trial if the procedure involves more risks. Even if the subjects are mentally impaired, the researcher must try to provide detailed information as much as he/she can. For example, if the trial is placebo-controlled, they should explain to subjects in detail that they may receive a placebo which may not be helpful for them.

More interactive sessions before actual consent process

Including more interactive sessions with the doctor before the informed consent process makes the consent process easier. These interactive sessions help doctors to determine whether the subject is understanding or not and also help to train the subject about the research. Many new methods of description about the research can be created based on the information explored in interactive sessions. These sessions even allow the subject to get acquainted with the research circumstances.

Creative methods to comprehend information for subjects

Developing new methods for the mode of communicating information to the psychiatric subjects is essential. Psychiatric patients understand well when we do it in action. Describing to subjects about the trials by creating video clips, art works (vignettes), and presentations may help subjects to understand more information.

Use language which is easily understood by the subjects

Explaining to subjects in the language understood by them makes them feel comfortable, especially in case of psychiatric patients. In general, psychiatric patients are incompetent, and describing the experimental procedures in a language other than their native language makes it more complex and subjects feel stressed. Hence, use of a language which is easily understood by the subject is vital.

Mock informed consent process

Conducting a mock informed consent process before the actual consent process may be useful. This gives awareness to the subject about the informed consent

process and allows the physicians to determine the loop holes in the procedure involved and hence make necessary changes to make the informed consent process suitable to the subjects.

Survey research is an important tool in the health care or clinical research field to collect the important information or opinions of the healthcare professionals about a particular issue or subject or matter or topic, which adds knowledge or finds solutions to the existing problems. Without the participation of the healthcare professionals in the survey, we are not able to find the solutions to the existing problems or issues, because their opinion and knowledge matters (Katherine, 2011).

Physicians and health care professionals with their vast knowledge and experience are good sources of information. Their opinions or suggestions are captured through the medical surveys, where the input from the general population is not sufficient. However, researchers have been concerned about the low response rates and the response rates for physician surveys were on average 10% lower than the surveys involving non-physicians (Emily, 2006).

In this research study, only one physician responded to the survey, which is a very low response rate. Unfortunately, this low response has weakened the value of the survey. Conducting surveys on medical professionals is difficult and different from conducting surveys on the general population.

Possible reasons for very low response rate in physicians surveys

- *Questionnaire Fatigue*: This is one of the main reasons for low response rate, as physicians are overwhelmed from receiving tens to hundreds of

questionnaire everyday from wide variety of sources. This glut simply makes them ignore all questionnaires (Clare, 2011).

- *Busy Schedule*: Completion of all the questionnaires received is very time-consuming and difficult to perform during their busy schedules (Carolyn, 2010).
- *Topic of the survey may not be of their interest or uninteresting*: One of the main factors is interest; if the topic of survey is not part of their interest they will not answer and will not even try to answer (Thorpe, 2011).

Well designed, well conducted, very useful surveys are getting lost in the ocean of poorly designed questionnaires (Clare, 2011). How might one increase the response rate in physician surveys?

Suggestions to increase the response rate in physician surveys (Clare, 2011)

- By using a mixed mode of survey administration (combination of email, mail, phone and fax)
- By finding a more interesting questionnaire topic
- By offering monetary incentives along with the survey
- By using shorter questionnaires in the surveys
- By contacting the physicians before sending the questionnaires and doing a follow-up after sending out the questionnaire
- By providing a second copy of the questionnaire to the non-respondents during the follow-up process

Implementation of successful techniques to improve the response is very important because healthcare researchers often depend on the information gathered through the healthcare surveys (Thorpe, 2011). "Cooperation theory would suggest that, if the sampled physicians understood the importance of the survey, they would be more likely to cooperate because there would be a benefit to themselves as well as the survey" (Catherine, n.d.).

Limitations and Recommendations for Future Research

There are limitations to this study; the response rate was very low.

A similar study can be done or replicated with a wide range of healthcare professionals, who have worked or have experience in psychiatric clinical trials. This study tried to capture the perceptions of physicians who have experience in psychiatric clinical trials, which is a select population. A broader population of healthcare professionals would likely increase the response rate as well as wide range of perceptions about the informed consent process in psychiatric research.

Surveys targeting the physicians are encountering low response rate, and researchers are having hard time in obtaining a good response rate. Therefore, following techniques which can increase the response rate in physician surveys can enhance the validity and reliability of the results obtained, which in turn will enhance the usefulness of the survey or the study conducted.

Chapter 7: Conclusion

Through this study the investigator was hoping to find whether the elements of informed consent were neglected in psychiatric research. The survey failed to provide the information due to very low response rate. A single respondent's answers indicate that this may yet be a fruitful area of research if proper incentives could significantly increase the response rate.

References

Ahlers-Schmidt, C. R., Chesser, A., Hart, T., Jones, J., Williams, K. S., & Wittler, R. (2010). Assessing Physician Response Rate Using a Mixed-Mode Survey. *Kansas Journal of Medicine*, 3 (5), 11-24.

Anderson, K. K. and Mukherjee, S. D. (2007). The need for additional safeguards in the informed consent process in schizophrenia research. *J Med Ethics*, 33, 647-650.

Appelbaum, P. S. (1982). The therapeutic misconception: Informed Consent in pychiatric research. *International Journal of Law and psychiatry, 5*, 319-329.

Appelbaum, P. S., and Grisso, T. (2001). *MacArthur competence assessment tool for clinical research (MacCAT-CR).*Sarasota, FL: Professional Resource Press/Professional Resource Exchange.

Arthur, K. A. (1998). Process consent:a model for enhancing informed consent in mental health nursing. *Journal of Advanced Nursing*, 27(4), 692-697.

Bernard, L. (2010). *Ethical Issues in clinical research: A practical guide.* Philadelphia, PA: Wolters Kluwer Health/Lippincott William wilkins.

Bloch, A. R. (1987). Informed consent and the psychiatric patient. *Journal of medical ethics*, 13, 12-16.

Burt, C. D. (2006). Physician Survey Response Methods Research. Retrieved 04 19, 2013, from ASA Section on Survey Research Methods:

http://www.amstat.org/sections/srms/proceedings/y2006/Files/JSM2006-000198.pdf

Cady, R. F. (2010). A Review of Basic Patients Rights in Psychiatric Care. *JONA'S Healthcare Law, Ethics & Regulation, 12* (2).

Clare, L. N. (2012). She might have what I have got: The potential utility of vignettes as an indirect measure of awareness in early-stage dementia. *Aging & Ment Health,* 16 (5), 566-575.

Church, M. and Watts, S. (2007). Assessment of mental capacity: a flow chart guide. *The Psychiatrist,* 31, 304-307.

Davies, T. (2001). Informed Consent in psychiatric research. *British Journal of Psychiatry*, 178, 397-398.

Decision Making Capacity Guidelines. (n.d.). Retrieved 10 14, 2012, from UCSD Human Research Protections: http://irb.ucsd.edu/decisional.shtml

Depression. (n.d.). Retrieved 10 14, 2012, from *Center for Disease Contro*l *and Prevention*: http://www.cdc.gov/mentalhealth/data_stats/depression.htm

Dunn, L. B., Nowrangi, M. A., Palmer, B. W., Jeste, D. V., & Saks, E. R. (2006). Assessing Decisional Capacity for Clinical Research or Treatment: A Review of Instruments. *The American Journal of Psychiatry,* 8 (163), 1323.

Dunn, L. B. and Lindamer, L. A. (2002). Improving Understanding of Research Consent in Middle Aged and Elderly Patients with Psychiatric Disorders. *The American Journal of Psychiatry,* 10, 142-150.

Internation Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). Retrieved 10 14, 2012 from ICH Hormonisation for better health: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf

Gupta, U. C. (2012). Informed Consent in psychiatric clinical research: A conceptual review of issues, challenges and recommendations. *Perspectives in Clinical Research*, 3 (1), 8-15.

Informed Decision-making in Healthcare. (2012). Retrieved 04 20, 2013, from Queensland Health : http://www.health.qld.gov.au/qhpolicy/docs/pol/qh-pol-346.pdf

James, K. M. & Ziegenfuss, J. Y. (2011). Getting Physicians to Respond: The Impact of Incentive Type and Timing on Physician Survey Response Rates. *PMC*, 46, 232-242 .

Jonathan, B. V. & Timothy, P. J. (2007). Methodologies for Improving Response Rates in Surveys of Physicians A Systematic Review. *SAGE Journals*, 30, 303-321 .

Karlawish, J. (2008). Measuring Decision-Making Capacity in Cognitively Impaired Individuals. *Neurosignals*, 16 (1), 91-98.

Kitamura,T. (1999). Image of Psychiatric Patients' Competency to Give Informed Consent to Treatment in Japan. *International Journal of Law and Psychiatry*, 22, 45-54.

MaCorr Research Solutions. (n.d.). Retrieved 10 28, 2012, from http://www.macorr.com/sample-size-methodology.htm

Malhotra, S. (2009). Informed Consent& ethical issues in paediatric psychopharmacology. *Indian Journal of Medical Research*, 129 (1), 19-32.

Mann, T. (1994). Informed Consent for Psychological Research: Do Subjects Comprehended Consent Forms and Understood Their Leal Rights. *Psychological Science, 5* (3), 140-143.

McFarlane, E. (2006). Nonresponse Bias in a Mail Survey of Physicians . Retrieved 04 20, 2013, from AAPOR - ASA Section on Survey Research Methods: http://www.amstat.org/sections/srms/proceedings/y2006/Files/JSM2006-000233.pdf

McLeod, S. (2007). Psychology Research Ethics. Retrieved 10 14, 2012, from Simply Psychology: http://www.simplypsychology.org/Ethics.html

Medco Health Solutions, Inc. (2011). *America's State of Mind: A report by Medco*. Franklin Lakes, New Jersey. Retrieved 04 20, 2013 from http://www.toxicpsychiatry.com/storage/Psych%20Drug%20Us%20Epidemic%20Medco%20rpt%20Nov%202011.pdf

Zalta, E. N. (2011). *Decision-Making Capacity.* Retrieved 04 14, 2013, from The Stanford Encyclopedia of Philosophy: http://plato.stanford.edu/archives/sum2011/entries/decision-capacity/

Non-specific Psychological Distress. (n.d.). Retrieved 10 14, 2012, from *Center for Disease Control and Prevention*: http://www.cdc.gov/mentalhealth/data_stats/nspd.htm

Reilly, J. G. & Ayis, S. A. (2002). Thioridazine and sudden unexplained death in psychiatric in-patients. *The British Journal of Psychiatry*, 180, 515-522.

Research involving individuals with questionable capacity to consent:Points to consider. (2009, November). Retrieved 04 20, 2013 from Office of Extramural Research-National Institute of Health: http://grants.nih.gov/grants/policy/questionablecapacity.htm

Saks, E. R. & Dunn, L. R. (2008). Proxy Consent to Research: The Legal Landscape. *Yale Journal of Health Policy, Law, and Ethics*, 8 (1).

Scott, Y. H. K. (2004). Proxy and Surrogate Consentin Geriatric Neuropsychiatric Research: Update and Recommendations. *American Journal of Psychiatry*, 161, 797-806.

Stanley, M. (1974). *Obedience to Authority:An Experimental View.* New York: Harper & Row.

Survey sample size. (n.d.). Retrieved 10 28, 2012, from Survey Monkey: http://www.surveymonkey.com/mp/sample-size/

Ten Myths About Decision-Making Capacity: A Report by the National Ethics Committee. (2002). Retrieved 10 14, 2012 from National Center for Ethics in Health Care Veterans Health AdministrationDepartment of Veterans Affairs: http://www.ethics.va.gov/docs/necrpts/nec_report_20020201_ten_myths_about_dmc.pdf

The Belmont Report:Ethical Principles and Guidelines for the Protection of Human Subjects of Research. (n.d.). Retrieved 10 14, 2012 from The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: http://www.hhs.gov/ohrp/policy/belmont.html

Thorpe, C. B. (2009). How to obtain excellent response rates when surveying physicians. *Oxford Journals* , 26 (1), 65-68.

Van Staden ,C. W. (2003). Incapacity to give informed consent owing to mental. *J Med Ethics, 29*, 41-43.

Walliman, N. (2011). *Research Methods: The Basics.* Abingdon: Routledge.

Wedderburn, C. (2011). Questionnaires, questionnaires. Retrieved 04 2012, from BMJ Careers: http://careers.bmj.com/careers/advice/view-article.html?id=20003103.

Wirshing, D. A. & Wirshing, M. W. (1998). Informed Consent: Assessment of Comprehension. *American Journal of Psychiatry*, 155, 1508-1511.

Wirshing, D. A., Sergi, M. J. & Mintz, J. (2005). A videotape intervention to enhance the informed consent process for medical and psychiatric treatment research *The American Journal of Psychiatry,* 162 (1), 186.

Appendix A: College of Health and Human Services Human Subjects Review Committee Approval Letter

Dear Sushma and Dr. Martin,

Congratulations! After careful review, your proposal "Physicians Satisfaction with Informed Consent Process in Psychiatric Research" with its suggested revisions has been approved by the College of Health and Human Services Human Subjects committee.

The current version of your paper is available here:

http://commons.emich.edu/cgi/preview.cgi?article=1098&context=chhs_hs

If any revisions become necessary in the future, use the Revise Submission link on the above site and upload to your original file MS #1098.

We stress that you do not stray from your proposed plan. Good luck with your research effort.

Sincerely,

Gretchen Dahl Reeves, PhD

Chair, CHHS-HSRC

Appendix B: Survey Completion Request or Online Survey Consent Form or Email Survey

Survey title:

Physician Satisfaction with Informed Consent Process in Psychiatric Research

Dear Doctor,

As a part of my master's thesis, I am requesting your participation in a survey. You are being invited to complete this survey about "Physician Satisfaction with Informed Consent Process in Psychiatric Research". This research project is done by Sushma Polavarapu from Eastern Michigan University.

The purpose of this research study is to determine the perceptions of physicians on the elements of informed consent that might be neglected in the psychiatric research and on what additional elements might improve the informed consent process in psychiatric trials.

The survey includes 19 multiple choice questions about the informed consent process. The survey should take approximately 15 minutes to complete. Your participation is voluntary and you may choose not to participate. If you decide to participate in this research survey, you may withdraw at anytime. Your participation and responses will be kept anonymous. Your participation in the study will conclude, once you have completed and submitted the survey.

As a researcher I respect your rights to privacy and I will keep the survey results confidential. I am not collecting any kind of personal identifiable information during the course of this survey.

The data will be collected via the online survey (Google Docs) and the results of the survey will be held by me. [Privacy Policy of Google http://www.google.com/intl/en/policies/privacy/]

The results of the survey will be held on a password protected personal laptop: only I have access to it. All raw data will be deleted upon submission of my thesis.

There are no foreseeable risks to you by completing this survey, as all results will be kept completely confidential. There are no direct benefits associated with your participation, but your input is valued. If you decide to participate, you may change your mind at any time and withdraw from the study without any consequences. There is no penalty for discontinuing at any time during the study and all information will remain confidential.

Results will be presented in aggregate form only. No names or individually identifying information will be revealed. Results may be presented at research meetings and conferences, in scientific publications, and as part of a master's thesis being conducted by the principal investigator.

Please click on the following link to access the survey:

https://docs.google.com/spreadsheet/embeddedform?formkey=dHFBWVlPZlk4WC15cHhRNXRjVmxPR2c6MQ

By clicking on the link above, you are indicating that:

- You have read all of the above information about this research study, including the research procedures, possible risks, side effects, and the likelihood of any benefit.
- You understand the content and meaning of this information.
- Your questions, at this time, have been answered.
- You consent and agree to participate voluntarily in the survey.

I hope you will respond. Thank you in advance for your participation.

Sushma Polavarapu, Clinical Research Administration, Eastern Michigan University

If you have any questions concerning your participation in this study now or in the future, you may contact Dr. Irwin Martin, Associate Professor, Health Sciences, Eastern Michigan University, imartin2@emich.edu.

"This research protocol and informed consent document has been reviewed and approved by the Eastern Michigan University College of Health and Human Services Human Subjects Review Committee for use from January 15, 2013 to January 14, 2014. If you have questions about the approval process, please contact Dr. Gretchen Dahl Reeves (Chair, College of Health and Human Services Human Subjects Review Committee, 734-487-3236, greeves@emich.edu)."

Appendix C: Survey

Survey title:

Physician Satisfaction with Informed Consent Process in Psychiatric Research

Survey Questions

1. In how many clinical trials have you participated in which you were an investigator or a sub-investigator?
   - None
   - 1-2
   - 3-5
   - 6-10
   - >10

2. How many psychiatric clinical trials have been or are being conducted under your supervision as an investigator or a sub-investigator?

   - none
   - 1-2
   - 2-5
   - >5

3. If you have conducted any psychiatric research, which of the following tools is used to assess the decision-making capacity of the subjects in psychiatric trials? (Select all that apply)

   - MacArthur Competence Assessment Tool For Clinical Research(Mac CAT-CR)

- Informed consent survey
- Vignette method
- other(Please specify)

4. In psychiatric clinical trials, conducted under your investigation, is informed consent taken by you or delegated to any lower level assistant (usually coordinator)?

- Taken by yourself
- Delegated to Lower level assistant
- Delegated to lower level assistant in your presence
- none

5. In psychiatric clinical trials, conducted under your investigation, is the informed consent is re-taken by the subjects who acquired decision making capacity in the course of the trial, where surrogate consent was initially used?

- Re-taken by the subjects
- Not re-taken
- Just oral consent taken

6. In psychiatric clinical trials, conducted under your investigation, are the trial procedure and informed consent process explained again in detail to the short-term memory loss patient, if he/she refuses to take certain procedures (phlebotomy, MRI scan) or are the procedures just done in coercion with the authorized representative's permission?

- Explained again and again till they understand and agree
- Explained once and proceeded in coercion with permission of representative

- Just showed the informed consent and proceeded when they agreed and failed to explain the procedure again
- Just proceeded even if they are not willing to participate

7. In psychiatric clinical trials, conducted under your investigation, did you recruit subjects who failed in decision making capacity (even though it is not an exclusion criterion), as it might be difficult to get the surrogate's consent due to many rules and regulations?

- Recruited
- Not recruited
- Recruited if the surrogate is ready
- Not recruited even if patient with surrogate is willing to participate, as it is difficult to get surrogate consent.

8. Do you have any concerns regarding the enrollment of mentally-impaired patients in clinical research?

- No, I feel this is appropriate
- Yes, never enroll mentally-impaired patients in research
- Yes, enroll them with certain special precautions
- Yes, enroll them only with legally authorized representative

9. In psychiatric trials, it is important to assess the subject's decision-making capacity before the informed consent process.

- Strongly agree

- Agree
- Neutral
- Disagree
- Strongly disagree

10. Understanding, appreciation, reasoning and choice are the best standards to test the decision-making capacity of the psychiatric patient.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

11. Explaining the experimental methods (randomization, blind) may be neglected in the informed consent process involving psychiatric patients as the patient has less capacity to comprehend.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

12. Repeating the information (in case of short term memory) may be neglected in the informed consent process involving psychiatric patients as it is difficult to explain again and again.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

13. Re-taking informed consent when the subject regains decision making capacity in the course of the trial may be neglected in the informed consent process involving psychiatric patients as they feel it is less important as they have taken it already.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

14. Expelling the subject from the study if he/she is incompetent (even though it is not an exclusion criterion) is appropriate instead of helping them to improve their health condition by using proxies as there are many rules and regulations.

- Strongly agree
- Agree

- Neutral
- Disagree
- Strongly disagree

15. Do you think the informed consent process for psychiatric patients needs to be changed?

- Yes
- No

16. Providing more interactive sessions before the informed consent process (between physician and subject) and information about the trial make the informed consent process more suitable and useful for psychiatric patients.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

17. Use of creative modes for explanation (as psychiatric patients understand better in practical rather than in theory, so videos, artworks etc. can be used) make the informed consent process more suitable and useful for psychiatric patients.

- Strongly agree
- Agree
- Neutral

- Disagree
- Strongly disagree

18. Inclusion of Mock Informed consent process (help to determine the loop holes in present process used and help to make changes as required) before the actual consent process makes the informed consent process more suitable and useful for psychiatric patients.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

19. Providing informed consent in more comprehensible language makes the informed consent process more suitable and useful for psychiatric patients.

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree