

## REVIVING INFORMED CONSENT: USING RISK PERCEPTION IN CLINICAL TRIALS

*The current doctrine of informed consent falls far short of its potential to serve as a valuable safeguard for human research subjects. Instead of providing a channel of communication between physician and subject, informed consent is a lifeless entity responsible for a large portion of the misunderstanding existing between these parties. Acknowledging risk perception principles may help transform the informed consent process into an effective communication of health risks.*

### Introduction

Informed consent has become overlooked and underestimated in its role of protecting human research subjects. Some critics have simply given up on informed consent: “informed consent has negligible influence on whether a person enlists in a trial.”<sup>1</sup> Others lament the failure of informed consent by making broad generalizations that offer little constructive criticism, alleging that physicians should do “a better job of warning patients about complications . . . .”<sup>2</sup> “Informed consent must go beyond getting a person’s signature on a form.”<sup>3</sup> But how? There seems to be a unanimous consensus among physicians, the public, and the media that we need to breathe new life into the currently inanimate informed consent document. Principles of risk perception lend constructive advice for transforming the informed consent process.

### The Clinical Trial Process

To market a new drug, the FDA requires the manufacturer to test the new drug in three phases of clinical trials. During the clinical trials, the new drug is tested on human research volunteers to ensure the drug’s safety and efficacy.<sup>4</sup> In phase I, 20-100 healthy volunteers (sometimes patients)<sup>5</sup> receive the new drug to measure drug safety.<sup>6</sup> Phase I tests only safety;

---

<sup>1</sup> Michael Baram, *Making Clinical Trials Safer for Human Subjects*, 27 AM. J. L. AND MED. 253, 282 (2001).

<sup>2</sup> Sara Shipley, *Death Prompts Scrutiny of Research Risks; Girl’s Parents Say Washington U. Didn’t Adequately Warn Them About Side Effects*, ST. LOUIS POST-DISPATCH, Feb. 16, 2003, at C1.

<sup>3</sup> Aoki, *Trials and Errors Stricter Rules for Clinical Studies Sought to Protect Patients*, BOSTON GLOBE, June 12, 2002, at D1.

<sup>4</sup> PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 516 (2d ed. 1991).

<sup>5</sup> Jennifer Washburn, *Informed Consent; Alan Milstein says he wants to rescue us from unscrupulous doctors, undisclosed risks and greedy institutions. But is he a shining knight, or an enemy of medical progress?*, WASH. POST, Dec. 30, 2001, at W16.

<sup>6</sup> HUTT & MERRILL, *supra* note 4, at 516.

researchers at this stage do not gather information about efficacy.<sup>7</sup> Next, during phase II the drug is administered to a group of several hundred patients<sup>8</sup> with the “target” disease.<sup>9</sup> Phase II tests for efficacy as well as safety.<sup>10</sup> Finally, in phase III, the drug is tested on “hundreds and even thousands of patients.”<sup>11</sup> This last phase provides information necessary to confirm the risks and benefits associated with the new drug.<sup>12</sup> After completing phase III trials, the manufacturer may submit the research results to the FDA for approval in the form of a New Drug Application (NDA). About 1 in 10 new drugs successfully pass through the rigorous three-phase process of clinical trials.<sup>13</sup>

In short, drug manufacturers use clinical trials to gather data about whether a drug is safe and effective for human use. Although animal testing and other laboratory studies are useful in ensuring the safety of new drugs, there are some effects that cannot be discovered by any means other than experimental human use. Therefore, clinical trials are necessary to protect the general public. But what safeguards protect the individuals who participate in clinical trials?

### **Legal Protections for Human Research Subjects**

The safety of human research subjects emerged as an issue of international importance after the heinous war crimes of the Nazi doctors came to light. In response to egregious misuse of human experimentation, the Nuremberg court established the Nuremberg Code which set standards for medical experimentation on humans. The first rule of the Nuremberg Code states: “The voluntary consent of the human subject is absolutely essential.”<sup>14</sup> As evidence from its prominent placement, consent is the backbone of ethical medical research. Building upon the Nuremberg Code, the World Medical Association wrote the Declaration of Helsinki, which maintains the voluntary consent requirement, adding further that participation must not only be a voluntary choice, but also an informed one.<sup>15</sup> In the United States, the requirement of informed consent for human research subjects participating in clinical trials is codified at 21 C.F.R. § 50.02 (2003).

---

<sup>7</sup> *Id.*

<sup>8</sup> Washburn, *supra* note 5, at W16.

<sup>9</sup> Baram, *supra* note 1, at 262.

<sup>10</sup> HUTT & MERRILL, *supra* note 4, at 516.

<sup>11</sup> *Id.*

<sup>12</sup> Baram, *supra* note 1, at 262.

<sup>13</sup> HUTT & MERRILL, *supra* note 4, at 516.

<sup>14</sup> Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, 181 Washington, D.C.: U.S. G.P.O., 1949.

<sup>15</sup> World Medical Association, Declaration of Helsinki (1989).

In addition to informed consent, oversight provisions on the state and federal level protect human research subjects.<sup>16</sup> Researchers are also required to report any adverse effects occurring during the course of clinical trials to the FDA and NIH.<sup>17</sup>

### **Reviving Informed Consent**

Patients and physicians alike have lost faith in informed consent. Patients feel that informed consent does not adequately disclose the potential risks. Patients feel uncomfortable deciding whether to participate based on an oversimplified, watered down version of the true risks of the study. However, most patients do not have the medical expertise to understand the risks as described by a physician or by the FDA. Volunteers come from diverse backgrounds, so the same informed consent process may appear too simple to one individual and too complex to another.<sup>18</sup> On the other side, physicians also express frustration with the current informed consent process. Physicians often view informed consent as a legal technicality obstructing progress, and may consequently introduce informed consent by announcing “We have to consent you now.”<sup>19</sup> The message is a command: “We have to get your signature now.” A possible solution is to transform the command into a communication between doctor and patient.

An effective communication must recognize the objectives of both parties. First, the primary goal of the informed consent process is to protect human subjects. Second, the informed consent process must ensure that people will continue to volunteer for the clinical trials so that society can continue to benefit from new drugs.

Constructive criticism of informed consent must also recognize and address the failure of current communication skills in general. The information researchers are trying to convey is mysteriously scrambled somewhere between the speaker’s mouth and the volunteer’s ear, like a very short version of the childhood game of telephone. To close this communication gap, physicians conducting the informed consent process must take responsibility and initiative. Baruch Fischhoff, an expert in risk communication, offers a guiding principle to address this dilemma: “If we have not gotten the message across, then we ought to assume that the fault is not with our receivers.”<sup>20</sup>

---

<sup>16</sup> BARRY R. FURROW et al., *BIOETHICS: HEALTH CARE LAW AND ETHICS* 421 (4th ed. 2001).

<sup>17</sup> Baram, *supra* note 1, at 262, 265.

<sup>18</sup> See Shipley, *supra* note 2, at C1.

<sup>19</sup> Larry R. Churchill et al., *Genetic Research as therapy: implications of “gene therapy” for informed consent*, 26 *J.L. MED. & ETHICS* 38, 42 (Spring 1998).

<sup>20</sup> Baruch Fischhoff, *Helping the Public Make Health Risk Decisions*, in *EFFECTIVE RISK COMMUNICATION: THE ROLE AND RESPONSIBILITY OF GOVERNMENT AND NONGOVERNMENT ORGANIZATIONS* 111, 112 (Covello et al. eds., 1989).

In sum, reviving informed consent requires improving communication skills and addressing the objectives of both patient and physician.

### **Viewing Informed Consent as a Health Risk Communication**

Informed consent is not the only context for practicing risk communication. Principles of risk communication, and health risk communication in particular, have been explored in a variety of contexts. For example, the threat of groundwater pollution requires industry representatives to engage in health risk communication with the local community. The United States government may face the task of using health risk communication to inform the American public about the threat of biological warfare.<sup>21</sup> Likewise, the informed consent process for clinical trials represents a situation that deserves a tailored health risk communication plan.

#### *The Inadequacy of Factual Data*

Despite the extensive laboratory testing of a new drug, the fact remains that a clinical trial is an experiment. The information most useful to a potential volunteer—what will happen?—is unknown. Even the known “facts,” such as toxicology reports and statistics from animal testing, are merely interpretations of data. A statistician can easily manipulate such data to imply the desired results. Those with experience in financial accounting may testify to the manipulability of numerical data. The following example demonstrates how scientific data, while completely true and accurate, can be communicated in a way to mislead the public:

Take the example of a story made famous a couple of years ago, when a junior high school student named Nathan Zohner surveyed a group of classmates for a school science project. Zohner told them about a chemical called dihydrogen monoxide. It is colorless, odorless, tasteless, and causes thousands of deaths every year. Prolonged exposure to its solid form causes severe tissue damage, exposure to its gaseous form causes severe burns, and it has been found in excised tumors of terminal cancer patients. Of 50 people Nathan surveyed, 43 said that dihydrogen monoxide should be banned, 6 weren't sure what to do, and only one person correctly identified dihydrogen monoxide as plain old water, or H<sub>2</sub>O.<sup>22</sup>

Regardless of additional regulations of clinical practice to monitor the accuracy of statistical data, the final numbers do not determine the success or failure of a health risk communication. Furthermore, the potential volunteer, an inexperienced layperson, will probably

---

<sup>21</sup> *See id.* at 111.

<sup>22</sup> Gregory Conko, Behind the Headlines: What Laymen Should Know About Everyday Issues in Science and Health, Presentation to the International Association of Culinary Professionals (April 19, 2002), ¶ 3, available at <http://www.cei.org/gencon/027,02975.cfm>.

not find raw scientific data useful in making a decision about whether to participate in a clinical trial.

### *The Inadequacy of the Printed Word*

When designing informed consent documents, researchers and physicians debate at length the words that will effectively communicate the risks of enrolling in a particular clinical trial. A national committee recommends “documents be written at an eighth-grade or lower reading level.”<sup>23</sup> But others disagree: “If you have to put everything in eighth-grade terminology, that leaves out a lot, and that’s wrong.”<sup>24</sup> In this way, drafters of informed consent documents face a double-edged sword. If the document is simple, it lacks the specificity to adequately describe the particular risks. If the document describes the detailed risk, the document would undoubtedly be too long and too complex to be understood by a layperson. Efficiency demands the standardization of informed consent documents. However, to effectively communicate health risks, we must resist standardization and consider the subjective, individual needs of the volunteer. The informed consent document should serve merely as a starting point for the communication.

### *Risk Perception as a Feasible Framework*

Fishoff suggests that effective health risk communication should begin by identifying “where the public is coming from.”<sup>25</sup> As a first step to health risk communication, defining “where the public is coming from” recognizes that risk, like beauty, is in the eye of the beholder.

Too often, physicians and researchers mistakenly believe that if the data for a particular trial is good (that is, if the benefits outweigh the risks), then the rational reaction is to accept the risk. In other words, the practitioner assumes that the subject perceives risk and reacts to risk in a rational way. However, risk perception is not simply a balance between risks and benefits. Risk reaction is often an emotional process, not a rational one. The irrational process of risk reaction is demonstrated by public reaction to the September 11, 2001 terrorist attacks and the subsequent anthrax threat:

Many of us were afraid, and rightly so. But some people responded by driving to a distant destination rather than flying, even though the facts clearly showed that flying remained the far safer mode of transportation, even after September 11. Some people bought guns, raising their risks from firearms accidents far more than reducing their risk of being

---

<sup>23</sup> Shipley, *supra* note 2, at C1.

<sup>24</sup> *Id.*

<sup>25</sup> Fischhoff, *supra* note 20, at 112.

attacked by a terrorist. Many people took broad-spectrum antibiotics even though they had no evidence that they had been exposed to anthrax—but they didn't get an annual flu shot.”<sup>26</sup>

Whether the decision to rely on emotional factors is conscious or unconscious, the fact remains that most individuals respond to risk in a way that reflects their *feelings* about risk, not their *knowledge* about risk. Risk perception is an emotionally-based, individual response to a situation.

To revive informed consent, we must acknowledge the emotional nature of risk reaction. Potential volunteers are likely to follow the general rule of emotional risk reaction behavior. In contrast, the physician might not view the risk from such a subjective perspective. The physician is acting in a professional capacity, and professionalism often demands objective judgment, free from emotional bias. Similarly, the FDA will not approve a new drug based on *feelings* that the drug is safe and effective. This rational viewpoint conflicts with the emotional viewpoint of the potential volunteer. In order to effectively communicate the risks involved in a given clinical trial, the physician must acknowledge this contrast in perspectives. The physician must ask not “What do I need to know to decide about the safety of this drug?” but rather “What does this potential volunteer need to know?” To better understand the volunteer's perspective, we refer to accepted principles of risk perception and apply them to the informed consent scenario.

### **Using Risk Perception in the Informed Consent Process**

The previous section focused on the subjective nature of risk perception. However, despite a broad spectrum of potential emotional reactions to perceived risk, “humans tend to fear similar things, for similar reasons.”<sup>27</sup> Ropeik and Gray describe a series of guiding principles that predict how people perceive risk. Application of some of these principles to the clinical trial setting may provide a better understanding of how risks should be communicated in the informed consent process. Perhaps surprisingly, these risk perception principles often work in favor of effective risk communication. In other words, according to this guide, the clinical trial setting is actually conducive to effective risk communication. The following discussion describes several risk perception concepts and how they affect the informed consent process in clinical trials. One has already been demonstrated:

---

<sup>26</sup> DAVID ROPEIK & GEORGE GRAY, *RISK: A PRACTICAL GUIDE FOR DECIDING WHAT'S REALLY SAFE AND WHAT'S REALLY DANGEROUS IN THE WORLD AROUND YOU* 15 (2002).

<sup>27</sup> *Id.* at 16.

- “You will generally be more afraid of a risk that could directly affect you than a risk that threatens others.”<sup>28</sup>

This risk perception concept describes why the physician and the volunteer react differently to clinical trial risks. The volunteer perceives a direct risk, while the physician perceives only an indirect risk. Additional elements of perception may lend increased clarity to the informed consent process.

### **Emphasize the Voluntary Choice of Participation**

- “Most people are less afraid of a risk they choose to take than of a risk imposed on them.”<sup>29</sup>

Ropeik and Gray elaborate on this choice concept by providing an illustrative example: “Smokers are less afraid of smoking than they are of asbestos and other indoor air pollution in their workplace, which is something over which they have little choice.”<sup>30</sup> Thus, the health risk, long-term lung disease, is less troubling when the individual voluntarily accepts that risk. The support for this principle may be a bit circular. Is the connection between choice and risk perception one of causation or mere correlation? In other words, does choice affect risk perception before or after the choice has been made? Before picking up a cigarette, a person might ignorantly believe that lung disease is not dangerous. Based on this ignorant belief, the person decides to smoke. Here, the decision to engage in risky behavior is based on incorrect information, not the freedom to choose. In contrast, the lifelong smoker may also believe that lung disease is not dangerous. Many habitual smokers claim to be aware of, but indifferent to evidence that smoking is dangerous. In this case, the voluntary nature of the act causes the perception that smoking is low risk behavior. The issue is whether one chooses to take risks because he or she believes the risk is low or whether he or she believes the risk is low because of a choice to engage in the risk.

Clarifying the relationship between choice and risk perception is necessary in order to apply the principle to the informed consent process. By necessity, the informed consent process must take place before the subject participates in the risky behavior. Thus, the choice concept will have a greater impact on the informed process if the relationship between choice and risk perception is causative rather than correlative. By emphasizing the voluntary nature of clinical trials, participants will feel a greater freedom of choice, and thus will perceive a lower risk. If the

---

<sup>28</sup> *Id.* at 17.

<sup>29</sup> *Id.* at 16.

<sup>30</sup> *Id.*

freedom of choice causes the individual to perceive the risk as low, then emphasizing voluntary participation is even more important.

If voluntary choice is both requisite and beneficial, why do physicians often downplay the voluntary nature of clinical trials? Researchers may fear empowering participants due to their urgent need for volunteer subjects. The enormous industry demand for new drugs translates into an enormous demand for clinical trial participants.<sup>31</sup> Adding to the weight of demand, physicians and researchers also feel pressured by time. Because of the restraints of patent term expiration, the manufacturer must push a new drug through the FDA approval process as quickly as possible.<sup>32</sup> Although the FDA and the Patent and Trademark Office (PTO) have worked together to promulgate regulations that help accommodate the unique requirements of the drug industry,<sup>33</sup> manufacturers must still race to get products to market. In short, researchers urgently need clinical trial volunteers.

In order to recruit clinical trial volunteers, the informed consent process must communicate a tolerable level of risk to the subject. The goal of recruiting volunteers could be achieved by omitting or misrepresenting the risks so that the subject views participation as a negligible risk. This approach blatantly violates the rules governing ethical medical research and is therefore an unacceptable means of conducting the necessary risk communication.<sup>34</sup> As opposed to simply lying, the researcher might be tempted to present the clinical trial as the only viable choice for the subject. The legality of such implied coercion is highly questionable. If alternative treatment is available, the physician must present each option and its probable consequences to the potential volunteer.<sup>35</sup> Disclosing all alternatives should include presenting the option of not pursuing any further medical treatment. In some cases of terminal or incurable illness, the clinical trial might represent the last option for a patient. Many cancer patients who have shown resistance to standard forms of treatment view clinical trials as a means to gain access to experimental drugs that offer a glimmer of hope for recovery.<sup>36</sup> It is tempting to present an experimental protocol as the only remaining viable choice to this vulnerable class of potential subjects. Even when both the patient and the physician view the clinical trial as a last resort, the informed consent process should not present enrollment as the only option.

---

<sup>31</sup> Aoki, *supra* note 3, at D1.

<sup>32</sup> Washburn, *supra* note 5, at W16.

<sup>33</sup> 35 U.S.C. § 156 (2003).

<sup>34</sup> 21 C.F.R. § 50.20 (2003).

<sup>35</sup> § 50.25(a)(4).

<sup>36</sup> See Bernadette Tansey, *Experiments of humans; A split verdict on clinical trials; Studies offer hope – and raise a series of ethical questions*, S.F. CHRON., Aug. 6, 2002, at A1.



Coercion, even well-intentioned coercion, stands contradictory to the risk perception model of voluntarism described above. Because individuals are more likely to engage in risks chosen voluntarily, coercion is more likely to deter than attract participants. A researcher should accentuate that participation is voluntary and present all other available options including the option of discontinuing medical treatment. By using the risk perception concept of voluntary choice, the informed consent process can heighten both safety and participation.

- “Most people are less afraid of a risk they feel they have some control over”<sup>37</sup>

For example, many people would rather drive as opposed to riding as a passenger in a car or airplane.<sup>38</sup> The relationship between control and risk perception is a simple extension of the previous discussion about choice. Exerting control over a risk means maintaining voluntary choice.

The risk perception principle of control can positively affect participation in clinical trials. Physicians must inform subjects that they may quit the clinical trial at any time.<sup>39</sup> Thus, the decision to participate is voluntary not just at enrollment, but throughout the duration of the trial. This risk perception concept highlights the ideal model of an ongoing, communicative relationship between physician and volunteer.

### **Confronting the Therapeutic Misconception**

- “Most people are less afraid of risks if the risk also confers some benefits they want.”<sup>40</sup>

This risk perception principle is most predictive of how a potential volunteer perceives the clinical trial risk. An analysis of the benefits of clinical trials reveals how the risk perception principle of benefit plays out in the clinical trial setting. First, participation may convey a “direct benefit, that is, benefit to subjects from receiving the intervention being studied.”<sup>41</sup> In other words, a direct benefit occurs when the experimental drug itself conveys a benefit to the subject. Second, participation also conveys a “collateral benefit, benefit anticipated for all subjects by virtue of being a subject in a study, rather than by virtue of receiving the intervention being studied (such as the provision of free care of the assertion that patients get better treatment on

---

<sup>37</sup> ROPEIK & GRAY, *supra* note 26, at 17.

<sup>38</sup> *Id.*

<sup>39</sup> 21 C.F.R. § 50.25(a)(8).

<sup>40</sup> ROPEIK & GRAY, *supra* note 26, at 17.

<sup>41</sup> Gail E. Henderson and Nancy M. P. King, *Studying Benefit in Gene Transfer Research*, IRB: ETHICS & HUMAN RESEARCH 23, No. 2, 13, 13 (2001).

study because of increased monitoring, state-of-the-art testing, etc.).”<sup>42</sup> Lastly, participants may associate clinical trials with the altruistic “benefit to society, to scientific knowledge or to future patients, rather than to current subjects.”<sup>43</sup> The risk perception principle indicates that when a volunteer recognizes potential benefits of participation, the volunteer is more likely to enroll in the clinical trial. Thus, the risk perception principle guides the physician to disclose all related benefits associated with the clinical trial. Furthermore, the current legal standard requires the physician to disclose benefits.<sup>44</sup> Thus, risk perception and law seem well aligned in this instance. Trouble arises, however, in early phase clinical trials when direct benefits remain unconfirmed.

Most subjects volunteer for clinical trials in pursuit of direct benefits, although collateral benefits and benefits to society also play a role in encouraging participation.<sup>45</sup> A 1999-2000 survey asked 1,050 volunteers why they participated in clinical trials. Although some were primarily motivated by collateral or societal benefits, the majority of respondents participated to obtain direct benefits:

Percent of respondents stating their top reason . . .

- Find relief: 60%;
- Advance science: 23%;
- Earn extra money: 11%;
- Receive better medical care: 6%<sup>46</sup>

This revelation becomes problematic for the informed consent process when volunteers are motivated by perceived, but unsubstantiated, direct benefits. Direct benefits are not supported by scientific data until the third and final stage of clinical trials. Recall that phase 1 clinical trials only test for toxicity. Phase 2 trials are the first attempt to measure efficacy for human subjects. It is not until phase 3 clinical trial that direct benefits find support in the form of phase 2 efficacy studies.<sup>47</sup> Thus, clinical trial protocols often lack immediate factual support for direct benefits. Nevertheless, most subjects choose to enroll based on the distant hope that the experimental drug will offer relief. Experts in risk communication use the term “therapeutic misconception” to

---

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 13-14.

<sup>44</sup> 21 C.F.R. § 50.25(a)(3).

<sup>45</sup> Tansey, *supra* note 36, at A1.

<sup>46</sup> *Id.*

<sup>47</sup> See HUTT & MERRILL, *supra* note 4, at 516.

describe this “unrealistic expectation of direct benefit to subjects.”<sup>48</sup> Sometimes, the therapeutic misconception is so powerful that it generates its own direct benefits:

Studies show that patients believe they will receive a therapeutic benefit from research – even if they know they may receive only a placebo treatment. And, strangely enough, they often do: one recent study showed that 35 per cent of placebo patients improved, in trials involving seriously ill subjects. Apparently, the sheer hope of recovery is often enough to alleviate symptoms.<sup>49</sup>

Because the therapeutic misconception exists in the minds of so many potential volunteers, understanding this false hope is a crucial part of understanding “where the public is coming from.”<sup>50</sup> The informed consent process should not only provide accurate representations of the risks and benefits, but should also debunk the closely held misperceptions that guide many volunteers.

One of the easiest ways to help eliminate misconception is to start with semantics. For example, informed consent documents refer to gene transfer protocols as “gene therapy.” Using the term “therapy” inappropriately implies that the experimental protocol is designed to treat, to offer direct benefits.<sup>51</sup> By consistently renaming the protocol “gene transfer research”, subjects may begin to more fully understand the intention of the clinical trial. Beyond that, physicians should also candidly confront the therapeutic misconception. Yet false hope may stubbornly survive: “Even when they have been explicitly informed to the contrary, subjects still believe they are getting the treatment that is best for them, not best for science.”<sup>52</sup>

The risk perception principle of benefit suggests that the associated benefits of clinical trials positively affect enrollment. Although collateral and societal benefits motivate some participants, most volunteers enroll to obtain direct benefits. Because most clinical trial protocols cannot offer direct benefits, the physician must not only decline from offering such false promises, she must also strive to undermine the therapeutic misconception that erroneously entices many subjects.

---

<sup>48</sup> Henderson & King, *supra* note 41, at 13.

<sup>49</sup> Patti Waldmeir, *The guinea pigs demand justice: Those who claim to have suffered in medical trials are seeking redress the American way – through the courts*, FIN. TIMES (LONDON), Oct. 18, 2001, at 19.

<sup>50</sup> See Fishcoff, *supra* note 20, at 112.

<sup>51</sup> Churchill, *supra* note 19, at 32.

<sup>52</sup> Waldmeir, *supra* note 49, at 19.

## Financial Conflicts of Interest

- “Most people are less afraid of risks that come from places, people, corporations, or governments they trust, and more afraid if the risk comes from a source they don’t trust.”<sup>53</sup>

The element of trust works both for and against the physician in his effort to effectively communicate during the informed consent process. During the course of clinical trials, the manufacturer will test the experimental new drug on subjects who suffer from the target disease. These subjects often learn that they are candidates for a clinical study from their doctor. After enrollment, the volunteer is both a patient and a subject. Similarly, the doctor becomes both a physician and a researcher. In cases where the subject-researcher relationship grows from a patient-physician relationship, the foundation of trust is already built; the trust between patient and physician grows from a sustained professional relationship. This trust is especially strong when the patient and physician have been working together for years specifically to treat the target disease. When the physician’s role shifts from administering treatment to administering an experiment, trust alleviates the patient’s fears about ethical misconduct. On the other hand, trust deceives the patient into believing that the clinical trial is a form of treatment, thereby exacerbating the therapeutic misconception.<sup>54</sup>

In addition to the conflict caused by the physician acting as both physician and researcher, the more troubling conflict of interest results when the physician-researcher also has a financial interest in the outcome of the clinical trial. Just as the volunteer holds unsubstantiated hopes that the experimental drug will produce the intended results, a physician with a financial interest in the experimental drug holds similar unsubstantiated hopes. And just as a subject’s hope alone may boost health, it appears that the hope of profit is enough to boost data results too: a “report in the *Journal of the American Medical Association* . . . found that nonprofit studies of cancer drugs were eight times more likely to reach unfavorable conclusions than industry-sponsored studies.”<sup>55</sup>

Despite the possible consequences of financial ties between research and medicine, this symbiotic relationship makes sense. The physician invests her professional life in pursuit of wellness - why not her financial interests as well? Physicians, like all other professionals, must draw a line between being bought and being paid. Responsible disclosure and oversight, as

---

<sup>53</sup> ROPEIK & GRAY, *supra* note 26, at 17.

<sup>54</sup> See Tansey, *supra* note 36, at A1.

<sup>55</sup> Washburn, *supra* note 5, at W16.

opposed to absolute restriction and prohibition, should govern the financial interests of physician-researchers.

Financial conflict of interest affects the informed consent process by affecting trust between patient and physician. Trust, in turn, affects risk perception. The medical professional must reach a balance between using trust and abusing trust. An appropriate relationship of trust helps create the ideal model of partnership between physician and subject.

## **Conclusion**

Risk perception creates a framework in which to address the current failure of informed consent. The concepts of choice, control, benefit, and trust shed light on how a volunteer perceives risk. By understanding how the volunteer perceives and reacts to risk, we can revise the existing informed consent process to better achieve its objectives of protecting volunteers as well as encouraging participation.

*By: Dana Ziker*