

Misconceptions in the Medical Profession Regarding the Doctrine of Informed Consent

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Abstract

This article focuses on misconceptions in healthcare regarding how the doctrine of informed consent is applied by both medical researchers and physicians. The specific misconception addressed relates to the standard of care required by medical professionals when caring for their patients. There has been a long-standing public misconception that medical researchers are held to a lower standard of care in informed consent lawsuits, than medical physicians in similar situated lawsuits. We argue that this misconception is largely attributed to the fact that statutes, ethical regulations, guidelines, and legal precedents within the medical and research profession are governed by two separate bodies of laws and regulatory guidelines. A thorough review of these two separate bodies of law and regulatory guidelines reveals that both medical researchers and physicians are held to a high standard of care in informed consent lawsuits. Our research is grounded in both primary and secondary historical, legal, and medical documentation. We rely mainly on historical, legal, and medical research and analysis to advance our argument that both medical researchers and physicians are held to a high standard of care in informed consent lawsuits.

Keywords

Informed Consent, Medical Setting, Healthcare, Biomedical Research, Research Setting, Human Research

1. Introduction

The doctrine of informed consent is legally and ethically required to perform medical procedures and medical research (Schenker et al., 2011). The doctrine of

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informed consent within the medical field is governed mostly by case law, while informed consent related to medical research is governed by statutory law. From an initial glance, it may appear that informed consent is treated differently for lawsuits filed against medical researchers as opposed to lawsuits filed against physicians. This confusion is partly because statutes, ethical regulations, guidelines, and legal precedents within the medical and research profession are separate bodies of laws and guidelines.

Furthermore, patients and research subjects have something in common, they do not fully understand the medical procedures or research (Graham & Brookey 2008); (Nijhawan *et al.*, 2013). There is inequity in the knowledge and understanding possessed by patients and research subjects and medical practitioners and researchers. As a result, it is up to the physicians and researchers to provide their patients and subjects with enough information to make a reasonable decision about their treatment or participation in research. The end goal of both medical researchers and physicians is to improve the condition of patients and society at large. Sometimes the goals of research and treatment are incompatible with each other, and this can cause legal and ethical problems. Such legal and ethical problems can result in harm to the patient and a breach of the physician's medical duty to not harm. In contrast to treatment, researchers adhere to different protocols to ensure that their research study has validity and reliability (Furrow *et al.*, 2018).

To better protect patients' international bodies and individual countries has enacted regulatory agreements with specific guidelines regarding informed consent. One such international agreement is The Nuremberg Code (1947). Countries such as the United States have followed up with internal laws. For example, the United States addressed the issue of informed consent in the National Research Act (1974), the Belmont Report (1979), and the Common Rule (1981). Even though the United States government operates under a system of federalism, individual states have also enacted a patchwork of state laws to further protect medical research participants and to fill in the gaps when federal law is not applicable (Furrow *et al.*, 2018). Furthermore, case law refined the issue by providing an avenue for patients harmed to seek compensation and other remedies through informed consent lawsuits. Patients harmed during medical research experiments or medical procedures tend to seek compensation via claims of negligence, breach of informed consent, breach of contract, or other state law claims under medical lawsuits. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), developed a standard to assess lack of informed consent that helped to solidify and support the patient's right to be fully informed. There have been other court cases that have done the same and have also helped to develop legal standards for informed consent. However, *Canterbury v. Spence* provides one of the most straight forward tests that courts can look to when deciding informed consent cases.

When Courts examine whether the requirement to obtain informed consent

has been violated, they look to the following factors: 1) the court will look to see if there was a duty by the researcher or physician to warn the participant and or patient; 2) If the court determines that a medical researcher or physician breached their duty to warn; 3) they then look to see if an injury occurred to the patient(s)/participant(s), and; 4) If an injury did occur, the court then determines if the injury was caused by the medical procedure or experiment.

This article argues that elements of breaching informed consent for medical researchers and physicians are essentially the same. It starts by providing a historical overview of the origins of informed consent within both the medical research and physician settings. This paper then explains how the legal history of informed consent has led to misconceptions about informed consent as applied to both medical researchers and medical physicians. Next, this paper will present key standards of informed consent in medical malpractice and research.

2. The Western Development of the Informed Consent

2.1. Greek Physician

The doctrine of informed consent in healthcare has a long history. In Western civilization, it can be traced back to the Greeks. In the United States, it was present during colonial times and is also present today. Free born citizens within ancient Greece had a positive right for medical doctors to provide them with informed consent before they rendered medical care. Medical doctors in ancient Greece became medical doctors via apprenticeship. Some slaves are trained in healing while working alongside a freeborn medical doctor and thus are regarded as medical doctors. Slave medical doctors do not practice informed consent or explain to other slaves the nature of the operation and their medical prognosis. This was primarily males. There were slaves who assisted their owners in medical procedures, but they generally did not do any major operations. These freeborn male medical doctors had to obtain informed consent before they operated on Greek citizens (Kumar, 2013); (Canterbury v. Spence, 1972). The difference between freeborn patients and slave patients is that freeborn patients had a positive right to provide informed consent to Greek freeborn physicians. For a freeborn medical doctor to obtain informed consent, usually a person trained in speaking with the public (e.g., a sophist) or a medical doctor trained to influence patients is called upon to persuade patients to give informed consent (Jones, 2007). Many Greek intellectuals discussed this concept in their works (Jones, 2007); (Kumar, 2013).

In Ancient Greece, as in England, physicians did not have a duty to obtain informed consent from slaves. However, English law did require physicians to provide informed consent to English citizens. This was codified in the Duke of York's Laws (1665).

2.2. Duke of York's Law 1665

The Duke of York's Laws of 1665 required medical doctors to obtain consent

from their patients before conducting medical treatment. However, the law allowed doctors to operate on their patients without their permission if the operation did not pose a danger to their patient ([Historical Society of the New York Courts, n.d.](#)). It was at the physician's discretion if the medical procedure posed a high-risk threat to the patient.

As stated above, the Duke of York's law did not pertain to slaves in England. This was also the case during the American Colonial Period. During this period American physicians were not required to obtain informed consent from Black slaves ([Long, 1991](#)). However, some physicians did claim to have obtained informed consent before operating on Black slaves. One such physician was Dr. Marion Sims.

2.3. Marion Sims Lived 1813-1883

Dr. Marion Sims claimed to obtain informed consent from both the slave owners and the enslaved Black women ([Sartin, 2004](#)). Writers of the mid-twentieth century repudiated him for unethical behaviors. The unethical behavior was that in 1845 he quartered enslaved Black women behind his home, to find the cure for vesicovaginal fistula ([Wall, 2006](#)). In one example, Sims made 30 attempts to cure Anarcha Westcott, an enslaved black woman on the Wescott plantation. Anarcha's case was complicated for Sims because she had holes within her bladder and rectum to be sutured closed.

Under the modern standards of informed consent, the court would likely rule that Dr. Sims did not obtain informed consent from the enslaved Black women. If we apply the Canterbury standards, Dr. Sims breached his duty to provide informed consent resulting in irreversible harm to the enslaved Black women. Irreversible harm is that some of these Black women died at the hand of Dr. Sims. However, because enslaved Black women were not considered people, they would not have any legal standing or any rights to sue Dr. Sims for damages for the irreversible harm caused to them (U.S. Const. Art. I. §2.).

The issue of physicians not obtaining informed consent from patients was prevalent in other countries besides America during the Colonial Period and Industrial Revolution. One such country was Prussia (i.e., modern day Germany). In 1898 Prussia decided to provide regulation regarding non-therapeutic medical research as a response to the Neisser Case (1898).

2.4. Neisser Case 1898

Dr. Neisser wanted to find a vaccine for syphilis. Therefore, he inoculated prostitutes that came to him for medical treatment with cell-free serum from people with syphilis. He rationalized that the serum did not work when the prostitutes' contracted syphilis. He also justified that the reason why the prostitutes' contracted syphilis is that they were sex workers and not because of his serum ([Vollmann & Winau 1996](#)).

When he published his findings, the local newspaper triggered public debate

by attacking Neisser for using prostitutes in his experiment without their consent and that they could have contracted syphilis (Vollmann & Winau 1996). Despite the attack from the local newspaper, some physicians still supported him (Vollmann & Winau 1996). These physicians believed that society should sacrifice the few for the greatest happiness of the majority. Therefore, these physicians believed that Dr. Neisser was justified in not obtaining informed consent from the prostitutes. Other physicians, such as Dr. Albert Moll, were at odds with Dr. Neisser because they believed the greatest happiness principle obstructed the doctor's role as a healer (Maehle, 2012). Utilitarianism would suggest that "experimentation on a dying patient might be justified in the interest of developing treatment for future patients (Maehle, 2012: p. 220)."

Triggered by the Neisser case, the Prussian parliament pressured the Minister to create laws governing experimentation on human subjects. The Minister responded by creating a detailed report on the regulation of using human subjects in medical experiments (Vollmann & Winau, 1996). After the Minister's report, it became clear that research on human subjects without their informed consent was illegal in Germany.

2.5. Pratt v. Davis 1906

In the United States one of the first cases dealing with informed consent was in *Pratt v. Davis*, 224 Ill. 300, 79 N.E. 562, decided by the Supreme Court of Illinois in 1906 (Pratt v. Davis 1906). In *Pratt v. Davis*, Dr. Edwin Pratt had gotten permission to operate on a Mrs. Pratt from her husband. Mrs. Pratt argued that despite having epilepsy she was a competent person and capable of providing informed consent. Dr. Pratt's defense was that the patient implicitly consented to all medical procedures he saw fit to perform simply by virtue of presenting herself for treatment. The Court ruled against Dr. Pratt writing, "Ordinarily, where the patient is in full possession of all his mental faculties and in such physical health as to be able to consult about his condition without the consultation itself being fraught with dangerous consequences to the patient's health, and when no emergency exists making it impracticable to confer with him, it is manifest that his consent should be a prerequisite to a surgical operation (Pratt v. Davis, 1906: p. 300); (12)." After Pratt, another important case dealing with the issue of informed consent was *Schloendorff v. Society of New York Hospital*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1914).

2.6. Schloendorff v. Society of New York Hospital 1914

The doctrine of informed consent was also influenced by *Schloendorff v. Society of New York Hospital*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1914) (Schloendorff, 1914). In *Schloendorff v. Society of New York Hospital*, Mrs. Schloendorff went to the Society of New York Hospital because she was not feeling well. Upon medical examination, a growing mass was detected. To remove the mass, the medical doctor had to perform a hysterectomy. Mrs.

Schloendorff did not want to have the mass removed because she would be infertile. She expressed her desire not to have the mass removed by the medical doctor. Against her will, the medical doctor performed the hysterectomy and removed the mass without her consent. There was also a medical complication when the mass was removed. The medical difficulty is that some of the patient's digits on her left hand became gangrenous. The medical doctor had to operate on her a second time. The second operation involved removing gangrenous digits on her left hand.

The Court ruled in Mrs. Schloendorff's favor stating, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages." Pratt and Schloendorff set the legal precedent in the medical setting that physicians must obtain permission from competent patients before initiating medical care. This legal precedent would in turn lay the framework for informed consent to be applied in the research setting. This application was first prominently done on an international scale in the Nuremberg Trial (1946).

2.7. The Nuremberg Trial 1946

The Nuremberg trial was more than just a murder trial. This trial took the question a step further as to whether it was legal for German physicians to perform research operations on human subjects without their informed consent. The Nuremberg trial was about how competent physicians and medical researchers conduct medical experiments within a democratic and civilized world (Shuster, 2018). Chief Prosecutor General Telford Taylor viewed the action of German doctors and researchers as being inhumane and criminal (Brody *et al.*, 2014). During the Nuremberg Trial, chief prosecutor General Telford Taylor charged 23 medical professionals. Among those charged were medical scientists, medical doctors (physicians), and their assistants who conducted medical experimentation on people during Nazi Germany.

During the trial, Dr. Leopold Alexander wrote a memorandum to General Taylor on April 17, 1947. The memorandum presented six main points that provided research participants with positive rights. These positive rights were that a medical researcher must obtain participants' informed consent before commencing medical research (13). His six principles were later reinterpreted as the ten principles within the Nuremberg Code (Ghooi, 2011: pp. 72-76).

The three key expert witnesses were physicians. They were Dr. Leopold Alexander, Dr. Andrew C. Ivy, and Dr. Werner Leibbrandt. These physicians identified themselves as Hippocratic physicians. Hippocratic physicians are physicians that have taken the Hippocratic Oath not to harm patients. Some of these doctors provided testimony that helped to convict 16 out of the 23 medical professionals during the Nuremberg trials (Shuster, 2018). Dr. Alexander did not provide a testimony. However, his memo helped to convict 16 out of the 23 medical

professionals. Alexander may have also played a crucial role in Dr. Leibbrandt serving as an expert witness.

Dr. Leibbrandt testified as an adverse expert witness against the 23 professionals. He cited Dr. Moll when explaining that German culture and medicine have lost their way to morality and respect for life (Shuster, 2018). Dr. Leibbrandt said that the German culture and medicine lost their sense of compassion for people they view less than them because of a book (Shuster, 2018).

The name of the book is *Die Freigabe der Vernichtung Lebensunwerten Lebens*. The name of the book translates to permission to destroy life unworthy of life. One of the authors of the book stated that it was the physicians' responsibility to euthanize individuals who were mentally ill, deformed, or useless eaters (Shuster, 2018). The German concept of eugenics (aka life unworthy of life) supported Hitler's racial hygiene program. Under Hitler's racial hygiene program, the Nazi regime killed more than a quarter-million people (Shuster, 2018). Dr. Leibbrandt's introduction helps to explain how the concept of permission to destroy life, unworthy of life, was prominent when Hitler came to rise in Germany and why German physicians thought it was permissible to experiment on patients without obtaining their informed consent.

The defense contended during cross-examination of Dr. Leibbrandt that the physician must comply with their superior orders and that the state's interest is more important than the individual's welfare (Shuster, 2018). Dr. Leibbrandt replied that the state could order the physician to conduct unethical experiments on people they view as less than them. However, the physician should still be held accountable for their actions (Shuster, 2018).

During a direct examination by the prosecution, Dr. Ivy had testified that he had created three principles governing researchers using human subjects at the request of the American Medical Association (Shuster, 2018). The first principle is that the researcher must obtain informed consent from the human subject. The researcher must not force the human research subject to participate in the experiment. The second principle requires that the research question cannot be answered by other means, such as animal studies. The third principle is that the researcher must be qualified to do the medical experiment.

During cross-examination, the defense counsel made Dr. Ivy agree that there was no written research principle in the United States or elsewhere before the doctors' trial. The defense counsel then asked him why there is a need to formulate new principles and apply the Hippocratic Oath in a research context. Dr. Ivy answered that the new principle is needed to address current conditions. The new ethical principles did not change the Hippocratic Oath, and that the Hippocratic Oath carried fundamental truths (Shuster, 2018).

The defense counsel then referenced Leibbrandt, that it is unethical to use prisoners in the human experiment because they are in a forced situation while referencing America's malaria prison experiments. Dr. Ivy defended the action of the researchers within the United States, by saying that prisoners participating

in a medical research study do not violate fundamental medical ethics. The reason is that prisoners are competent individuals and that competent individuals can give their informed consent to participate in medical experiments (Shuster, 2018).

The defense undermined Dr. Ivy's position that the Hippocratic Oath can be applied to doctors within the research context by asking Dr. Ivy a specific question (Shuster, 2018). The question was as follows: Does the Hippocratic Oath forbid giving poison to patients, and if the Oath prohibits researchers from giving harmful substances to human research participants (Shuster, 2018)? Dr. Ivy said that treating physicians is forbidden to give their patients poison even if they asked for it and that it does not apply to doctors within the experimental settings.

After both parties presented their arguments in front of the tribunal, the tribunal recommended that 16 out of the 23 defendants were convicted and sentenced to prison, and seven were executed (15). The tribunal ruled that there are laws governing crimes against humanity. These crimes include but are not limited to slavery, killing, and torture. The tribunal also ruled that obeying orders is not a defense for committing crimes against humanity. The tribunal judges expressed ten research principles known today as the Nuremberg Code (Shuster, 2018). The Nuremberg Code includes but is not limited to the Hippocratic Oath that physicians must protect life and the welfare of their patients.

2.8. Salgo v. Leland Stanford Jr. University Board of Trustees 1957

After the Nuremberg trial, various jurisdictions in the United States started to adopt language from the Nuremberg code, such language is informed consent. For example, in 1957, the California Court of Appeals adopted the term informed consent from the Nuremberg trial in the case *Salgo v. Leland Stanford Jr. University Board of Trustees* (Salgo v. Leland Stanford Jr. University Board of Trustees, 1957). The plaintiff in the case, Martin Salgo, had pain in his calf, so he went to Stanford hospital for medical care. The medical doctor told him that he just had to undergo a routine Aortography. However, the medical doctor never advised/informed him that he could become permanently paralyzed by the surgery. Mr. Salgo was permanently paralyzed by the surgery. Salgo sued the hospital because they failed to warn him of the risks involved with the surgery. The Court ruled in Salgo's favor and awarded him \$250,000 because the medical doctor should have warned him of the risk involved in doing the surgery. In support of the Court's decision, they wrote that, "...a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment (Salgo v. Leland Stanford Jr. University Board of Trustees, 1957: p. 181)." Thus, *Salgo v. Leland Stanford Jr. University Board of Trustees*, 17 P.2d 170, 181 (1957), established the legal precedent that a medical doctor must warn patients of risks related to care rendered and must also provide patients with alternative medical care (Bazzano et al., 2021).

3. Infamous Unethical Experiments Leading to Increased Regulations

As explained above, there were a multitude of unethical medical procedures leading to a shift in case law and ethical regulations governing informed consent in the United States and Germany. Today the concept of informed consent is broadly embraced by the United States, Germany, and other countries around the world. It must be noted that this is not merely a Western phenomenon. For example, the West African country of Mali has embraced the concept of informed consent in laparoscopic surgery. Specifically, Article 13 of Mali's 2008 charter for patient's provides that, "information provided to the patient must enable him to obtain a complete overview of all the medical and other aspects, of his condition and to take himself decisions or to participate in the decisions that may affect their well-being." Furthermore, it provides that the burden of establishing that informed consent was provided is on the physician and not the patient. This has been the shift in the United States, however historically in the U.S. the burden was placed more on the patient. This section will briefly discuss some of the prominent unethical research experiments from 1932-2016 influencing legislators to create statutory regulations and guidelines in the United States and international guidelines from 1932-1979 governing informed consent in the research setting. This section will start with a discussion of the inhumane and unethical Tuskegee Syphilis experiment. The focus will be on how this experiment was performed without obtaining informed consent from the African American male patients.

3.1. Tuskegee Syphilis Experiment (1932-1974) & The National Research Act (1974)

The Tuskegee Syphilis experiment occurred in 1932. During this experiment, researchers denied African American men treatment to cure their syphilis due to creating new diagnostic methodologies (Alsan & Wanamaker, 2018). It took the United States nearly 40 years after this atrocious experiment to acknowledge the harm they caused to the participants in the Tuskegee Syphilis experiment. After acknowledging the harm caused to the African American men in this experiment, and the African American community at large, Congress passed the National Research Act in 1974. The National Research Act was the first law to shape policies regarding bioethics in America by creating the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research (Furrow *et al.*, 2018). Four years later, the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research published the Belmont report in 1979 to provide a framework to review and assess research experiments on human subjects (Furrow *et al.*, 2018). A brief description of the Belmont Report is provided below.

3.2. Belmont Report 1979

The Belmont Report centers around three main principles. These principles are:

1) respect for persons, 2) beneficence, and 3) justice 4). The principle of respect for persons consists of two different groups; the first group is legally competent, and the other are lawfully incompetent. The division is because human subjects might have legal or might not have the legal right for self-determination. Self-determination is a competent person's right to choose to participate, no longer participate, or not participate in medical research without a guardian's obstruction. An incompetent person does not have the right to self-determination. They might require a guardian's approval to participate in medical research. The fundamental theme of respect for persons is giving a competent person or guardian of an incompetent person enough information to make a rational decision to not to participate, no longer participate, participate in a research study, and respect their choices (Furrow *et al.*, 2018).

The second principle of the Belmont Report is beneficence. As the name beneficence implies, the second principle of the Belmont Report is to avoid harm or reduce harm to human participants (Brothers *et al.*, 2019). The two general rules of beneficence are: 1) not to harm and increase benefits and 2) simultaneously eliminating as much harm as possible to human subjects. Do no harm is a key component of the Hippocratic Oath. The third principle of the Belmont Report is justice.

According to the principle of justice, medical researchers should not systematically use convenient groups (Quinn, 2015). Convenient groups are typically marginalized groups in society such as Medicaid patients, welfare patients, minorities with low income and education, college students, institutionalized psychiatric patients, and prisoners. Researchers usually prefer human subjects that belong to convenient groups because they are more easily manipulated. If individuals from convenient groups are used in medical experiments, the group must benefit from such an experiment. For example, researchers are not allowed to use African American males in medical research that only white American males will benefit from. After the Belmont Report, Congress passed a series of acts leading towards providing general requirements for research participants to provide informed consent in research experiments. The United States inhumane research experiments were not just confined to the United States. Around the same time as the Tuskegee Syphilis experiment, researchers from the United States would conduct unethical experiments on citizens of Guatemala without obtaining their informed consent.

3.3. Henrietta Lacks & The HeLa and Mo Cells (1950)

A few years after the Guatemalan STD study, an American physician by the name of Howard Jones, would unethically extract cervical cells from a Black woman by the name of Henrietta Lacks at John Hopkins Hospital, without obtaining informed consent. The Guatemalan STD study consisted of over 5000 Guatemalans, with 1300 of them being intentionally infected with an infectious agent (Bagdady & Lombardo, 2018). Dr. Jones would later give He-

nrietta's cells to Dr. George Gey to experiment on. From Dr. Gey's research he discovered that the cells could reproduce indefinitely (Nature.com, 2020, <https://www.nature.com/articles/d41586-020-02494-z>).

Dr. Gey then shared Mrs. Lack's cells with researchers around the globe. Due to the unique properties of the cells, the scientists created two cell lines. The two cell lines are called "HeLa and Mo cells[.]" Historians are divided as to whether Dr. Jones violated informed consent by experimenting on cells extracted from Henrietta before her death of cervical cancer (Nature.com, 2020, <https://www.nature.com/articles/d41586-020-02494-z>). This division is because there were no laws in the United States governing physicians taking cells from their patients and conducting experiments. However, the Nuremberg Code was established before the doctor extracted the cervical cells from Henrietta. The first principle of the Nuremberg Code clearly stated that medical doctors or medical scientists could not conduct experimentation on someone without their informed consent. Unfortunately, researchers in America did not abide by the first principle of the Nuremberg Code for obtaining informed consent from patients and participants. In 1959 an American physician by the name of Dr. Henry K. Beecher would point out this paradox.

3.4. Henry Beecher & His Experimentation in Man (1959)

Dr. Beecher had written and published the most important papers related to using humans as subjects in experiments (Harkness *et al.*, 2001). In 1959, Dr. Beecher published *Experimentation in Man* (Harkness *et al.*, 2001). *Experimentation in Man* is about unethical human experiments. The publication did not have the impact he wanted it to within the medical and research profession, so he decided to go public. He openly talked about unethical human experiments he thought were common occurrences and were omnipresent within the United States at a news conference.

Beecher's war on unethical experiments did not go unnoticed. Beecher was able to influence a new regulation on human experiments. The new regulation on human experiments was the Declaration of Helsinki (1964). Beecher felt that the World Medical Association's (WMA) Declaration of Helsinki provided more protection than the Nuremberg Code. The Declaration of Helsinki has been updated ten times since the time of Beecher's war on unethical experiments, with the most recent update being in 2013. The Declaration of Helsinki has 37 principles.

3.5. Declaration of Helsinki 1964

According to the Declaration of Helsinki, human subjects must volunteer for the experiment and be informed. For research subjects to be informed, the medical doctor must disclose: 1) the research study aim, 2) method, 3) who subsidized the research, 4) any conflict of interest, 5) any benefit to participating in the research study, and 6) all known risks involved in the research study. The medical

doctor must also not force the participant to participate in the research study—medical doctors threatening to take away or not provide any privileges due to the research subjects are prohibited. If the person is incompetent, then the medical doctor must obtain informed consent from their legal guardian. Informed consent from both the competent and guardian of the incompetent is advised to be in writing. Suppose the informed consent is not in writing? In that case, medical doctors must have a witness verifying that the research subject or guardian of the research subject has given their informed consent.

Furthermore, the Declaration of Helsinki requires medical doctors to self-govern by assessing the research for any risk and burden the human subject is likely to endure. In medical experiments, risks and burdens are almost inevitable to human subjects. Also, a medical doctor must only conduct medical experiments when the importance of the medical research exceeds the risks and burdens the human subjects will endure and when they have determined that they can mitigate the risk and burden of the experiment.

Even though the United States played a role in the WMA's Declaration of Helsinki, they have chosen to mainly follow their own federal regulations governing informed consent. The primary federal ethical regulation and guideline governing informed consent is The Common Rule.

3.6. The Common Rule (1991) and the 21st Century Cures Act (2016)

In 1991 during the Clinton presidency, in response to President Reagan's 1981 Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, numerous federal agencies and departments would implement regulations created by the President's commission. These regulations have subsequently been referred to as The Common Rule.

The most updated code of federal regulations is the general requirement for informed consent is The Common Rule (45 CFR §46.116 (2018)). 45 CFR §46.116 (2018) applies to all experiments involving human subjects in the United States and is financially supported by the federal government. A medical researcher's compliance with 45 CFR §46.116 does not preempt state, local, and tribal laws. Medical researchers must comply with both state and federal laws. Furthermore, according to 45 CFR §46.116 (2018), a researcher must obtain human subjects' or their legal guardian's informed consent (Furrow *et al.*, 2018). When the researcher is securing informed consent, researchers must give the prospective human subject the chance to contemplate and speak with the researcher if they should participate or not. Researchers must provide the future human subject or guardian with enough information that a reasonable person would need to make a rational decision to participate or not. Information regarding the risk and discomfort of the experiment should not be presented in technical or language that the average layperson cannot understand. The information regarding risk and discomfort must be to the point and likely to have as-

sisted a reasonable person in making an informed decision. The statute does not clearly define Reasonable Person. What a Reasonable Person would like to know is usually determined by the fact finder. Exculpatory languages are prohibited when obtaining informed consent. The general requirements of informed consent under the Common Rule, 45 CFR §46.116 (1991), were not in line with 21 CFR §50.20 (2014), which applies to the FDA.

The 21 Century Cure Act (2016) requires the FDA's general requirement for informed consent (21 CFR §50.20) to be equivalent to the 45 CFR §46.116 (1992). Therefore, the FDA 2020 revision of 21 CFR §50.20 seems to be comparable to 45 CFR §46.116 (2018). Therefore, it would be duplicative to reiterate the FDA's general requirement for informed consent.

4. Misconceptions of Informed Consent

As a result of prior ethical regulations, guidelines, and courts' decisions concerning informed consent, medical and legal professionals may have misconceptions regarding the doctrine of informed consent. Specifically, they may assume that informed consent operates differently for medical and research professionals. One source of misconception is that ethical regulations, guidelines, and courts' decisions within the medical and research settings, are codified as separate ethical regulations, statutes, and legal precedents. When legislators wrote ethical regulations, guidelines, and statutes governing medical research, they only addressed researchers and vice versa for regulations and laws within the medical setting. As a result, ethical regulations and laws addressing researchers within the research setting make it appear as if the same standards do not apply to a medical physician.

For example, The Common Rule of 2018 (45 CFR §94.4(a)) requires medical researchers to report financial conflict of Interest (FCOI) at <https://era.nih.gov/>. A FCOI is when an investigator has enough financial interest within a research study that could affect the research design. Using the *expressio unius* rule of interpreting 45 CFR §94.4(a) would lead one to believe that the expression of investigator means the inclusion of medical researchers and the exclusion of medical physicians. Despite medical research ethical regulation and medical ethical regulations and laws being bifurcated, medical physicians must also disclose conflict of interest to their patients and the government. In the case of physicians, the American Medical Association's ethical regulation requires physicians to disclose financial conflict of interest in Opinion 8.0321. The law requiring covered entities to reveal anything of value given to covered recipients is the Sunshine Act. A covered recipient usually refers to physicians, and covered entities typically refer to drug and device manufacturers. The Sunshine Act requires that the covered entities disclose to Centers for Medicare & Medicaid Services if they had given anything of value to covered recipients.

In addition to the Sunshine Act, another misconception is the Common Rule. The Common Rule is a set of federal ethical regulations governing biomedical

and behavioral research. 45 CFR §46.116(c)(1) requires medical researchers to disclose all unforeseeable risks and 45 CFR §46.116(b)(2) requires medical researchers to disclose all foreseeable risks. In comparison to Medical malpractice lawsuits such as *Stewart-Graves v Vaughn*, 162 Wash 2d 115, 170 P3d 1151 (2007) and *Dunham v Wright*, 423 F2d 940 (3rd Cir 1970), a physicians can choose to not obtain informed consent under special circumstances. The condition in which physicians can choose not to obtain informed consent is as follows: 1) The patient was incapacitated; 2) during an emergency and the physician did not have the time to obtain informed consent; and 3) The patient had waived their right to be fully informed. However, a physician still needs to be cautious about operating on their patients without obtaining informed consent during life-threatening situations. This was an issue in *Shine v. Vega*, 429 Mass. 456, 709 N.E.2d 58.

In *Shine v. Vega*, 429 Mass. 456, 709 N.E.2d 58, Dr. Vega forcibly incubated Catherine Shine without her informed consent because she was experiencing an asthma attack. Ms. Shine was traumatized from her experience. As a result of this trauma, she would die two years later from an asthma attack because she became fearful of seeking medical treatment. Her father filed a lawsuit on her behalf. The lawsuit alleged that Dr. Vega should have obtained informed consent. The trial court ruled in Dr. Vega's favor. However, Mrs. Shine's father filed an appeal. Eventually, the Supreme Judicial Court of Massachusetts ruled in Shine's father's favor. The court ruled that a medical doctor must obtain informed consent before he renders medical care, even during life-threatening emergencies. In the Court's view a patient has the right to be free from uninvited touching even if it were to save the patient's life because a patient has a right to self-determination.

As explained above, the abundance of ethical regulations governing informed consent in both the medical research setting and the medical physician setting can lead to confusion and misconceptions. Therefore, to better understand that the doctrine of informed consent applies equally in the medical research setting and medical physician setting, we must analyze court cases within both the medical and research settings. The next section will focus on the following five cases: *Canterbury v. Spence*, 464 F.2d. (D.C. Cir., 1972), *Cobbs v. Grant*, 502 P.2d 1 (Cal., 1972), *Wilkinson v. Vesey*, 295 A.2d 676 (R.I., 1972), *Grimes v. Kennedy Krieger Institute*, 366 Md. 29, 782 A.2d 807 (Md., 2001), and *Looney v. Moore*, 886 F.3d 1058 (11th Cir., 2018).

5. Common-Law Standards of Informed Consent

5.1. Canterbury, the Physician's Duty to Warn, the Reasonable Patient, and the Standard of Substantial Harm

The first case discussed is *Canterbury v. Spence*, 464 F.2d. (D.C. Cir., 1972). *Canterbury v. Spence* provided us with a different standard to review lack of informed consent cases. The three elements of this standard are as follows: 1) The

physician must warn the patient, and such a duty was breached by not warning the client of dangers related to the medical procedure; 2) A reasonable person would not have elected to do the medical procedure if the medical physician had fully informed them; and 3) the medical treatment was the substantial causal factor of the patient's injury. Since *Canterbury*, there have been other key informed consent cases that have provided other standards that can be used to assess medical informed consent cases. Two other key informed consent cases also decided during the *Canterbury* case were: *Cobbs v. Grant*, 502 P.2d 1 (Cal., 1972) and *Wilkinson v. Vesey*, 295 A.2d 676 (R.I., 1972).

5.2. Cobbs, Grant, and Grimes Reasonable Physician Standard and Similarities to the Canterbury Test

The legal question in *Cobbs v. Grant*, 502 P.2d 1 (Cal, 1972), was whether a medical doctor should disclose risks that a reasonable medical doctor would reveal to their patient? Cobbs needed medical surgery to heal his stomach ulcer. Cobbs had his spleen and a portion of his stomach removed because of medical complications related to the surgery. Dr. Grant informed Cobbs the reason why he needed the surgery but did not reveal the risks associated with the medical surgery. Cobbs sued Dr. Grant because he did not warn him of the danger related to the medical procedure.

The Supreme Court of California reversed the trial court judgment and ruled in favor of Cobbs. The Supreme Court ruled in favor of Cobbs because it determined that Dr. Grant had a legal duty to inform Cobbs of risks or dangers related to the medical procedure he rendered (*Cobbs v. Grant*, 502 P.2d 1 (Cal, 1972)). Since Cobbs gave consent to undergo the medical procedure, his claim is a negligence claim and not a battery. For this reason, *Cobbs v. Grant* is not a lack of consent case but a lack of informed consent. Another important lack of informed consent case that is further added to the doctrine of informed consent is *Wilkinson v. Vesey*, 295 A.2d 676 (R.I., 1972).

Wilkinson v. Vesey, 295 A.2d 676 (R.I., 1972) was decided during the same year as the Cobbs case. The legal question presented in *Wilkinson* was whether a physician must provide a patient with enough information that a reasonable person would need to make an intelligent decision to participate in medical treatment? Mrs. Wilkinson and her husband brought a claim against Dr. Vesey in the Supreme Court of Rhode Island that Dr. Vesey did not reveal risks related to radiation treatments. As a result of the radiation treatments, Mrs. Wilkinson experienced a severe radiation burn in her chest that required eight surgeries. The main claims raised by Mrs. Wilkinson's in her lawsuit were that 1) the medical doctor incorrectly diagnosed her, 2) the radiation therapy was improperly administered, and 3) Dr. Vesey failed to obtain informed consent. For the sake of brevity, this article only discusses Dr. Vesey's failure to obtain informed consent.

As to the issue of informed consent, the Supreme Court of Rhode Island applied the Natanson Rule as used by the California Supreme Court in the Cobbs

case. However, the Supreme Court of Rhode Island would take it a step further. The Nathanson Rule acknowledges that the medical doctors' and patients' interests are not aligned with informed consent. The Natanson Rule is designed to protect the patients' right to self-determination by requiring that a physician disclose risk unless disclosing such a risk would further agitate a mentally unstable patient and be counterproductive to the medical treatment. The court ruled that a plaintiff does not have to provide expert testimony that the accepted medical standards required the physician to disclose the risks (*Wilkinson v. Vesey*, 295 A.2d 676 (R.I., 1972)). Furthermore, in the *Wilkinson* case, the court asserted that under the Natanson Rule, the patient has a right to be warned of risks related to medical care rendered. The court ruled in *Ms. Wilkinson's* favor. After the *Wilkinson's* there were a multitude of both federal and state lack of informed consent cases related to medical research. Another important case that will be discussed in this article is *Grimes v. Kennedy Krieger Institute*, 366 Md. 29, 782 A.2d 807 (Md., 2001).

The legal questions in *Grimes v. Kennedy Krieger Institute, Inc.* 366 Md. 29, 782 A.2d 807 (Md., 2001) were as follows: Does an informed consent agreement within non therapeutic research constitute a contract? Does such a contract create a duty on the researcher to warn the participants of dangers? Can a researcher be liable for failing to obtain informed consent if they did not warn the participant of hazards related to their research study? The facts of the case are as follows. Kennedy Krieger Institute (KKI) wanted to know if some partial lead reduction was better than others. As a result, they provided landlords with loans and grants for the partial lead abatement and provided parents with food stamps and other interest to stay within the homes for two years. KKI institutional review board (IRB) had known that the parents could not sign a child up for non-therapeutic experiments. Thus, IRB told them how to mask the research to make it look like a therapeutic medical experiment. The parents of the children sued KKI because they owed them a special duty to warn them that their children were being exposed to lead.

Initially, a trial court in Maryland granted the defendant summary judgment. The trial Court ruled that the researchers do not owe participants any special duty to be warned (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001). The parents appealed to the Maryland Court of Appeals. The Maryland Court of Appeals reversed the trial Court's ruling. The Court of Appeals of Maryland ruled that Maryland laws dictate that non-therapeutic research gives rise to a contractual relationship. Such contractual relationships create duties. One of such a duty is to be warned of dangers related to their experiment. The last informed consent case discussed in a research context is *Looney v. Moore*, 886 F.3d 1058 (11th Cir., 2018).

The legal questions in *Looney v. Moore*, 861 F.3d 1303 (11th Cir. 2017) were as follows: Can a participant or patient sue a plaintiff on grounds of lack of informed consent alone? Does the participant need to be injured to file a successful

lawsuit of breach of informed consent? The 11th Circuit applied a standard like that used in *Canterbury v. Spence*, 464 F.2d. (D.C. Cir., 1972). In *Canterbury*, the D.C. Circuit ruled that the patient must be harmed by the medical procedure to file a successful case on the ground of violation of informed consent. A key question raised in *Looney* was whether the *Canterbury* standard still applies when medical treatment and medical research are entangled? In other words, can research participants sue a medical researcher just because they did not obtain informed consent?

Medical treatment and medical research were entangled in *Looney* because parents were receiving medical treatment, and at the same time, the medical doctor was conducting medical research. The medical treatment was giving birth. The medical study assigned parents diagnosed with premature births to a high and low oxygen saturation group to determine a more precise oxygen saturation level that would not lead to poor fetal health. The high and low oxygen saturation levels were both acceptable medical oxygen saturation levels to prevent premature infants from dying, developing retinopathy, and other neurological impairments. The parents of DreShan Collins, Christian Lewis, and Jaylen Malone filed a lawsuit against defendant Moore alleging that the medical experiment injured them.

The parents claimed that Dr. Moore was negligent, negligence per se, breached his fiduciary duty, products liability, and failed to obtain informed consent. The district court granted summary judgment in favor of Dr. Moore. The 11th Circuit also dismissed the parents' appeal on the similar ground that they failed to prove that the medical research was the cause of their premature children's injury. The 11th Circuit concludes that a defendant must prove that the clinician or medical researcher harmed them in a medical malpractice or negligence lawsuit. The 11th Circuit interpreted Alabama law on informed consent that breach of informed consent is a negligence claim (*Looney v. Moore*, 861 F.3d 1303 (11th cir. 2017)); (*Furrow et al.*, 2018). The Supreme Court declined to hear this case on appeal. This article will now briefly compare the informed consent standards from these key cases and how they helped to mold the doctrine of informed consent. This will be done by comparing these cases to the three standards created and applied in the *Canterbury* case.

5.3. Comparison of Common Law Standards of Informed Consent

This section will first address the question as to whether the three standards of *Canterbury* apply to *Wilkinson v. Vesey*? *Wilkinson v. Vesey* is an example of informed consent within the medical setting. Specifically, was there a duty for Dr. Vesey to warn Ms. Wilkinson of the risk involved within their surgery? Yes, Dr. Vesey had an obligation to disclose to Ms. Wilkinson that there was a possible chance that she could experience radiation burn from the treatment. Secondly, did Ms. Wilkinson experience an injury? Ms. Wilkinson's injuries were radiation burn, deterioration of her skin, and that she had her ribs and other

bone in her chest removed. The Wilkinson case was silent on the issue as to whether a reasonable person would have elected not to do the medical procedure. The Court ruled in Ms. Wilkinson's favor that Dr. Vesey should have informed her of the risks related to the medical procedure and that he was negligent for not doing a biopsy to determine if she had cancer before initiating the radiation treatment. The next case to be compared to Canterbury is the Cobbs case.

The legal analysis is if the three Canterbury standards of lack of informed consent apply to Cobbs v. Grant. Cobbs v. Grant is an example of informed consent within the medical setting. Did Dr. Grant have a duty to warn Cobbs? Yes, Dr. Grant had a duty to warn Cobbs about injury related to the medical procedure he provided. Was Cobbs injured by the medical procedure? The medical treatment injured Cobbs that Dr. Grant performed without his informed consent. The nature of his injuries is a severed splenic artery, sutures within his stomach were reabsorbed, he had internal bleeding, and he had to be operated on again. The risks are cutting an artery in his spleen and that his body would absorb the sutures. As in the Canterbury test, it was objectively determined if a reasonable person would have elected to do the medical procedure if the physician fully informed them of the dangers of the medical treatment. A reasonable person would not have elected to do the medical procedure in Cobbs v. Grant. Cobbs was awarded a cumulative total of \$88,800 for his injuries. The next case to be compared to the Canterbury case is the Grimes case.

Grimes v. Kennedy Krieger Institute is an example of a medical court case ruling in the research setting. The legal analysis is if the three Canterbury standards of lack of informed consent apply to Grimes v. Kennedy Krieger Institute. Was there a duty for researchers at Kennedy Krieger Institute to warn the mothers that their child could be exposed to lead? Yes, the researchers at Kennedy Krieger Institute had a duty to warn the participant that their child could be exposed to lead. Was the child injured from being exposed to lead? Yes, the child was injured due to the potential for lead poisoning or lead poisoning. Grimes v. Kennedy Krieger Institute was silent on the issue as to whether a reasonable person would have or would not have elected to participate within Kennedy Krieger Institute's lead abatement study. The last case to be compared to Canterbury is the Looney case.

Looney v. Moore is an example of a medical lawsuit within the research setting. The legal analysis is if the three Canterbury standards of lack of informed consent apply to Looney v. Moore. Did Dr. Moore owe Looney et al. a duty to disclose the risks related to the surfactant study? According to the department of HHS, Dr. Moore owed Looney et al. a duty to warn them of risks and accused Dr. Moore of not obtaining valid informed consents. Was Looney et al. injured from the medical experiment? Looney et al. were unable to prove that the nature of their premature child's injury was due to the experiment and not a consequence of premature birth. The 11th circuit ruled in Dr. Moore's favor because

Looney et al. could not prove that the surfactant medical experiment was the cause of their injury. *Looney v. Moore* set the legal standard within the state of Alabama that research participants must be injured to file a lawsuit on the grounds of breach of informed consent alone. The 11 circuits left the question open about whether research participants can sue medical researchers on the grounds of informed consent alone.

This section has used the Canterbury standard as a comparison to better understand how the doctrine of informed consent has been fashioned and modified by the courts. The legal scholarship and case law on the doctrine of informed consent is extensive. The hope is that this article provides you with a better understanding of how this doctrine works in healthcare law. Furthermore, it helps to make it clear that both medical researchers and medical physicians both must adhere to the doctrine of informed consent.

6. Conclusion

This article has presented historical perspectives of lack of informed consent, legal views, and legal analysis of lack of informed consent to establish that the doctrine of informed consent applies similarly to researchers and medical physicians. This article has explained that the reason why informed consent seems to be applied differently to medical physicians and researchers is that they are separate bodies of statutory laws and federal ethical regulations. Furthermore, informed consent in the medical setting has traditionally been enacted primarily from case law, while informed consent in the research setting has primarily been enacted from statutory law and regulations. The hope is that this article can be used as a guide for medical and legal professionals to better understand how informed consent operates in healthcare law.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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