An Ethically Informed Consideration of the Use of a Waiver of Informed Consent in Emergency Medicine Research

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ABSTRACT

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The concept of informed consent arose in the mid-20th century as a mechanism for protecting patients and research subjects from abuses. But recent technological advances in the field of emergency medicine research have created new challenges for informed consent procedures. As a result, in 1996 the FDA passed a “Final Rule,” which provides for a waiver of informed consent in a narrow class of studies.

In this paper I will first conduct a historical survey of the development of informed consent regulations. Then, I will lay out several of the main arguments for the use of the waiver in emergency medicine research. I will conclude that these arguments are unsatisfactory, and that conducting research on human subjects without their consent is ethically dubious, at best. Lastly, I will consider alternative ways in which this socially valuable research might still be carried out, albeit without the use of the waiver of informed consent.
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I. INTRODUCTION

Informed consent, both in clinical practice and in research\(^1\), is firmly ensconced as a central topic in the bioethics literature. Philosophers and physicians alike have debated what it is, when it should be used, and how it should be used. However, its ubiquity belies its relatively recent origins. It arose in the mid-20\(^{th}\) century as a legal notion, but was quickly adopted, in theory and in practice, by the medical profession, where it developed concomitantly with a shift from a medical ethos based on paternalism to one more focused on the rights and values of the patient.

In the research setting, the doctrine of informed consent gained prominence as a reaction to the abuses of the Nazi doctors during World War II. The Nuremberg Code, which was drafted in conjunction with the trial of those doctors, states that the voluntary consent of the individual is necessary for ethical research. But the Nuremberg Code was by no means the last word on this matter. Since its publication in 1948, some of the landmark documents concerning informed consent in human research include the World Medical Association’s Declaration of Helsinki (1964), the Belmont Report (1978), and multiple instantiations of FDA (Food and Drug Administration) and DHHS (Department of Health and Human Services) regulations in the United States. Most of these documents cite informed consent as a necessary condition for ethical research on human subjects, but vary in how much guidance they give for what constitutes valid consent.

Recent technological and pharmaceutical developments in the field of emergency medicine have fueled an interest in conducting research on new interventions for severe

\(^1\) In this paper I will utilize a distinction between clinical practice, where the patient is treated outside the confines of any sort of organized research study, and research.
brain injuries and cardiopulmonary resuscitation. But research on treatments for these conditions presents a particularly challenging situation, because in such cases the patient-subject is either partially or fully incapacitated, and the therapeutic window is often much smaller than in ordinary clinical care. This means that the treatment must be administered more quickly, and consequently there is less time to obtain consent from the patient-subject or a representative of the patient-subject.

Thus, research in emergency medicine leads to questions in addition to what informed consent should look like: we must now also consider whether it is even possible in such settings, and if it is not, whether research can be done ethically without it. In 1996 the FDA published a “Final Rule” on the issue of informed consent in emergency medicine research. This rule allows a waiver of informed consent requirements for a narrow class of studies of emergency medicine therapies. The waiver is permitted in instances where “the human subjects are in a life threatening situation, available treatments are un-proven or unsatisfactory, and the collection of valid scientific evidence … is necessary to determine the safety and effectiveness of particular interventions.”

It will be useful, as we consider arguments for and against the waiver of informed consent later in the paper, to have a concrete example at hand of a study conducted under the FDA’s Final Rule. One such study being conducted currently is the “Amiodarone,

\[^2\] In this paper, when I am discussing research, I will use the term ‘patient-subject’ rather than alternating between the terms ‘patient’ and ‘subject.’ I do this for two reasons: first, I want to emphasize that in the cases I will be discussing, the line between patient and subject is rather blurry. Second, I hope to avoid any influence the positive or negative connotations associated with either term might have on the arguments presented. However, when I am presenting others’ arguments, and those individuals present the argument in terms of either patient or subject, I will follow suit.

\[^3\] 21 C.F.R. 50.24(a).
Lidocaine, or Neither (Placebo) for Out-Of-Hospital Cardiac Arrest Due to Ventricular Fibrillation or Tachycardia” study. The goal of this study is to determine whether amiodarone or lidocaine, if either, improves the rate of patient survival-to-hospital-discharge for individuals with shock-resistant ventricular fibrillation. This is a condition in which the heart beats rapidly but does not pump a sufficient volume of blood. Patients enrolled in this study will receive amiodarone, lidocaine, or a placebo (a salt-water solution). Both drugs are already being used as treatments for ventricular fibrillation, but there is little data to support their efficacy. This trial is being conducted in nine communities across Canada and the United States, and will eventually enroll up to 3,000 individuals.

Despite its name, however, the Final Rule is anything but final. The literature still abounds with arguments concerning the necessity of informed consent in emergency research situations, and the U.S. finds itself with Australia and Canada as the only three countries that have legislation specifically allowing research to be done without informed consent.

Legal considerations aside, is it ethically permissible to conduct research on human beings in situations of medical emergency without their consent? In this paper I will first conduct a historical survey of the development of informed consent regulations in medical research on human subjects, and explore how and why the current FDA waiver of informed consent arose. Then, I will turn to the ethical side of the matter, and

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4 I will refer to this study later in the paper as the ALP study.
5 National Institutes of Health News Release.
6 Largent et al 669.
lay out several of the main arguments for the use of the waiver of informed consent in emergency medicine research. I will conclude that these arguments fall short, and that conducting research on human subjects without their consent is ethically dubious, at best. Lastly, I will consider alternative ways in which this socially valuable research might still be carried out, albeit without the use of the waiver of informed consent.
II. A HISTORY OF THE ROLE OF INFORMED CONSENT IN RESEARCH ON HUMAN SUBJECTS

The Beginnings of Informed Consent Legislation: The International Stage

The modern emphasis placed on informed consent in research studies involving human subjects arose out of the atrocities committed by Nazi physicians during World War II. The Nuremberg Code (1948), which was written as part of the judgment against those doctors, was the first code of medical ethics prescribed by a court system. It is comprised of 10 principles which, when satisfied, supposedly ensure that research on human subjects is ethically justified. The first principle is the most relevant for our current line of inquiry. It states, “The voluntary consent of the human subject is absolutely essential.” The principle goes on to specify that the subject must be legally competent to consent, must understand the nature of the study being performed, and must consent voluntarily (without the influence of coercive forces).

However explicit it is on the issue of consent, contemporaries of the Nuremberg Code found it problematic in several ways. First, it does not allow for research on subjects who lack the legal capacity to consent, including adults with cognitive impairments and children. Berg et al. believe that this was a result of the origin of the code: most of the concentration camp prisoners were competent adults, and consequently the tribunal was mainly concerned with ensuring that consent for research was voluntary. Second, the language of the code is quite vague, and it provides little practical guidance to researchers. Finally, it is unenforceable: a researcher who violated

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7 Faden and Beauchamp 153.
8 Berg et al. 251.
one of the principles could not be held liable in any way. As a result of these shortcomings, there were calls from within the medical field for a new code of research ethics that reflected the values held by most researchers at that time. Specifically, there were calls for guidelines that were more specific and that allowed for instances of proxy consent and even a complete waiver of informed consent in cases where it was in the patient-subject’s best interests.9

This dissatisfaction with the Nuremberg Code led to the drafting of the World Health Organization’s Declaration of Helsinki in 1961, and its adoption in 1964. While the Declaration of Helsinki also affirmed the importance of informed consent for ethical research, it allowed for exceptions to that rule. Those exceptions were tied to a distinction made between two types of research. The first type, therapeutic research, is conducted as a part of a patient-subject’s care, and holds out some potential benefit for the patient-subject. The second type, non-therapeutic research, is conducted solely for its potential contribution to scientific knowledge; it has no potential therapeutic value for the patient-subject.10 The Declaration requires consent in all cases of non-therapeutic research, unless the patient-subject is incompetent, in which case the researcher must obtain the consent of a guardian. However, in instances of therapeutic research, informed consent requirements may be waived if the physician deems it “essential”; in these cases the physician must state the reason why and have it approved by the independent review committee. This vague loophole, clearly a departure from the absolutism of the

9 Berg et al. 252.
10 The Declaration has been amended 8 times since the original 1964 version. In the sixth instantiation, adopted in 2000, the distinction between therapeutic and non-therapeutic research was abandoned.
Nuremberg Code, provides no other guidance or criteria for such instances, and places a significant amount of authority with the reviewing committee for deciding when research may be conducted without consent.\textsuperscript{11}

The purpose of an independent review committee, or independent review board (IRB), is to oversee research being conducted on human beings. These boards are supposed to provide additional protections for research subjects from overzealous researchers, by acting as a disinterested third party. They have the power to approve, disapprove, or require modifications to proposed research protocols. As we will see later, however, the ability of IRBs to provide such protections has been called into question on more than one occasion by physicians and bioethicists alike.

The Evolution of U.S. Legislation Regarding Informed Consent in Research

Revelations of multiple unethical research studies in the mid-1900s increased pressure to augment existing regulations. One such study was conducted at the Jewish Chronic Disease Hospital in 1963. Twenty-two chronically ill and debilitated subjects were injected with live cancer cells without their consent. The doctors reasoned that their actions were justified because the research stood to provide useful scientific knowledge. The Board of Regents at the State University of New York censured the doctors, and “recognized that informed consent is necessary to protect subjects’ rights of self-determination, even if the level of risk is low and the potential benefit high.”\textsuperscript{12}

\textsuperscript{11} Fost 165.
\textsuperscript{12} Faden and Beauchamp 162.
Another instance occurred at Willowbrook State School, an institution for mentally disabled children in New York. A lack of proper sanitation meant that nearly all children became infected with a mild strain of hepatitis within their first six to twelve months at the institution. Saul Krugman began an experiment in 1964 in which he deliberately infected 750-800 newly admitted children with hepatitis. His stated goals were to immunize them against more virulent strains of hepatitis by inducing an infection of a more mild variety, and to obtain more knowledge about the course of the disease. When the study came to light and Krugman was forced to defend his actions, he argued that he had obtained consent from the parents of the children enrolled in the study, that the research was valuable for advancing knowledge of hepatitis, was potentially valuable to children at the institution, did not expose the children in the study to extraordinary risks, and was executed by competent researchers. However, critics responded that the explanation of the study given to parents who consented did not accurately represent the nature of the experiment, and that some parents were coerced into enrolling their children as a condition of placement at Willowbrook. Eventually, Krugman’s research facility at the institution was closed.13

But the most infamous of these abuses, and arguably the one that led to the most significant policy change concerning subjects’ rights in the U.S., is the Tuskegee Syphilis Study. The study, which began in 1932, involved tracking the course of syphilis in approximately 400 African-American men who were systematically blocked from receiving treatment for their disease. An additional 200 comprised a control group. The

13 Faden and Beauchamp 163-4.
subjects were not told the name or nature of the disease they had; they were merely informed that they were receiving treatment for “bad blood.” But in 1972 an article on the study was published in The New York Times. This prompted the Department of Health, Education and Welfare to create an ad hoc panel to review the study and the Department’s policies for the protection of human research subjects. Ultimately, the panel concluded that it should not be left to the scientific community to decide how to balance patient-subjects’ rights with possible scientific progress. It suggested that a national body be created to oversee research on human subjects.\textsuperscript{14}

In response to this suggestion, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed in 1974. In 1978 it published a document called the Belmont Report. This report dictated three principles that should govern research conducted on human subjects: respect for persons, beneficence, and justice. In addressing informed consent, the report states, “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.” The report goes on to say that there are three elements to consent: information, comprehension and voluntariness. The report notes the possibility of research involving “subjects that one might consider as incompetent,” but merely says that each class of such subjects should be considered individually.

\textsuperscript{14} Faden and Beauchamp 165-7.
Prior to the publication of the Final Rule in 1996, physician-researchers in the United States found themselves caught between the conflicting policies of two federal agencies when it came to conducting research on human subjects using a waiver of informed consent. On one hand, the Department of Health and Human Services (DHHS) allowed research to be conducted with a waiver of informed consent if the following four conditions were met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and,
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.  \(^{15}\)

The FDA, on the other hand, allowed a waiver of consent for the use of a single test article\(^{16}\) if the following conditions were met:

1. The human subject is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
3. Time is not sufficient to obtain consent from the subject's legal representative.

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\(^{15}\) 45 C.F.R. § 46.116(d).
\(^{16}\) The FDA regulations, prior to the publication of the Final Rule in 1996, did not allow for studies of new treatments to be conducted with a waiver of informed consent, though they did allow for the use of a waiver on a case-by-case basis.
(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.¹⁷

These policies, however, lacked the specificity needed to ensure uniformity in the types of studies allowed to proceed with a waiver of consent. In the DHHS guidelines, for example, there was a great deal of controversy over how to interpret the “minimal risk” condition.¹⁸ In addition, because of the vagueness of the guidelines, IRBs were not consistent in the types of studies that they permitted or rejected, and consequently there was concern that some studies were being conducted on shaky ethical grounds. Conversely, some arguably acceptable studies were not approved.¹⁹

The fates of two studies in the early 1990s can illustrate the type of trouble the extant guidelines fostered. In April of 1993, the FDA halted a study of the use of active compression-decompression CPR in instances of out-of-hospital cardiac arrest because of concerns over the study’s design and its use of deferred consent.²⁰ A second study caught in the crosshairs was a clinical trial of Polyethylene Glycol Superoxide Dismutase (PEG-SOD) in treating severe head trauma.²¹ In April 1993 the institutional review board at the University of Nebraska approved the use of deferred consent in this trial, since prospective informed consent would be impossible to obtain from patient-subjects with severe head injuries, and they felt the therapeutic window was too small to obtain proxy consent from relatives of the patient-subjects. The IRB felt that their decision was in

¹⁷ 21 C.F.R. § 50.23(a)(1)-(4).
¹⁸ Fost 166.
¹⁹ Fost 169.
²⁰ Lurie et al.
²¹ Muizelar et al.
accordance with both the DHHS and FDA regulations, although they also felt that those regulations, written in 1981 and revised in 1991, were too restrictive given the state of emergency medicine research in the 1990s. In July of that year, the FDA notified the review board that deferred consent was not an ethically acceptable practice, and decreed that it must obtain prospective consent from patient-subjects or surrogates.\textsuperscript{22}

All of this confusion came to a head in August of 1993 when the director of the Office of Protection from Research Risks (OPRR)\textsuperscript{23} disseminated a letter informing Institutional Officials and Institutional Review Board Chairs that the use of deferred or waived consent was not consistent with the DHHS guidelines concerning research performed on human subjects. Consent, Director Gary Ellis wrote, must be “prospectively obtained.”\textsuperscript{24} The increased fear of sanctions that followed this letter, along with the existing confusion over the appropriate use of a waiver of consent in emergency medicine research and concerns about the inhibiting effect on such research motivated Representative Ron Wyden (D-Oregon), who at that time was the chairman of the House Subcommittee on Regulation, Business Opportunities, and Technology, to hold a series of hearings on the subject.

Then, in January 1995, the FDA and the NIH, an agency of the DHHS, put together the Public Forum on Informed Consent in Clinical Research Conducted in Emergency Circumstances. It was here that the newly formed Coalition of Acute

\textsuperscript{22} Prentice et al.
\textsuperscript{23} The OPRR is now called the Office for Human Research Protection (OHRP). The OHRP helps oversee research conducted by the DHHS, working to protect the welfare of subjects involved in that research.
\textsuperscript{24} Ellis.
Resuscitation and Critical Care Researchers presented a series of recommendations meant to provide guidance for further considerations of the issue by regulators.\textsuperscript{25} Out of this forum, in July 1995, the FDA created a Proposed Rule, which was first sent to the Office of Management and Budget for two months of consideration, and then made available to the public for a 45-day comment period. Out of the 90 comments received, 16 were directly opposed to waiving the informed consent requirement. The rest were in support of the rule, but asked for amendments or clarification of procedures. After nine months of revisions, the FDA’s Final Rule for Exception from Informed Consent was published in October 1996. Both the Final Rule and the DHHS’s regulations for Waiver of Informed Consent in Emergency Research, developed along with the Final Rule, went into effect in November 1996.

The Final Rule provides for a “narrow exception” to the informed consent requirement imposed on research involving human subjects. This exception applies when the patient-subjects are in need of emergency medical treatment but cannot give consent because of their life-threatening condition (i.e. a heart attack or a traumatic brain injury), and do not have a legally authorized representative available to provide proxy consent. The Final Rule is a “response to growing concerns that current rules are making high quality acute care research activities difficult or impossible to carry out at a time when the need for such research is increasingly recognized.”\textsuperscript{26} The Final Rule, which is currently the legal standard in the United States, permits a waiver of informed consent to be used when the following conditions are met:

\textsuperscript{25} Biros 554.
\textsuperscript{26} FDA “Protection of Human Subjects” Summary.
(1) The subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the study is necessary to determine the safety and efficacy of the intervention under study.

(2) Obtaining informed consent from the subject is not feasible because the subjects are unable to consent given their condition, the therapeutic window is too small to obtain proxy consent, and there is no practical way to prospectively identify and obtain consent from potential subjects.

(3) Participation in the study holds out the possibility of benefitting the subject.

(4) There is no other way to practicably conduct the study.

(5) The study specifies a therapeutic window and investigators attempt to contact and obtain consent from a legally authorized representative of the subject.

(6) The investigator has provided, and the IRB approved, informed consent procedures and documents to be used whenever possible.

(7) Additional patient safeguards are observed, including consultation with the community in which the study is being conducted, public disclosure to the affected community of the nature of the study and its risks and benefits before its commencement, public disclosure of the results of the study after its completion, the use of an independent data monitoring committee to oversee the study, and approval of the study by the FDA. ²⁷

²⁷ 21 C.F.R. 50.24(a)(1)-(7).
III. ETHICAL CONCERNS OF CONDUCTING RESEARCH WITH A WAIVER OF INFORMED CONSENT

As the previous section indicates, informed consent, though a young concept legally and ethically, has a rich history in international and U.S. codes and legislation. But the variation in the strictness with which these codes and laws interpret and seek to implement informed consent requirements indicates that the concept is still evolving. This evolution is reflected in the bioethical literature, as well. While the FDA’s Final Rule was the last major policy shift in the United States, philosophers and physicians alike have continued to publish on the topic.

When the Final Rule was first proposed, there was some backlash from the bioethics community. George Annas, for example, worried that the new requirements were an indication that the research community was “trying to make research more efficient at the expense of human rights.”28 Similarly, Jay Katz was concerned that the new regulations would send the message to the research community that it is more important for research to proceed than it is for patients to have the opportunity to consent to be research subjects.29

However, a large portion of the extant literature is supportive of the use of the waiver of informed consent. Even Katz, with time, came to believe that a waiver of informed consent is justified in the situations provided for in the FDA regulations. While he continued to worry about possible problems resulting from the vagueness of the wording of the Final Rule, in a Hastings Center Report published in 1997 he concluded,

28 Kolata.
29 Kolata.
“principles must have exceptions as long as they are rigorously justified and most narrowly drawn.”

That is, he came to believe that even though informed consent is a central element in the protection of research subjects, the FDA’s Final Rule provides for an acceptable exception to that principle. But the fact that articles about the Final Rule and waivers of informed consent continue to be published, even if the vast majority of them support the use of the waiver, indicates that the matter is far from settled.

Proponents of the Final Rule, and thus of allowing emergency research to be conducted with a waiver of informed consent, argue that this allows socially valuable research to be conducted. Many of the extant interventions for severe brain injuries and resuscitation efforts are seen as inadequate, and proponents of the waiver argue that as new interventions are developed we should test their efficacy with clinical trials. They go on to argue that studies conducted with a waiver of informed consent are the best means of conducting this research. They also contend that any concerns about patient-subject welfare that arise in the process of waiving consent are allayed by the extra protections required by the Final Rule.

The arguments for (and against) the use of the waiver of informed consent in emergency research situations fall roughly into three categories:

(1) concerns about protecting the patient-subject from harm,

(2) scientific, or methodological, concerns, and

(3) concerns about preserving the patient-subject’s autonomy.

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Additionally, there are three moral principles that will be relevant to the arguments concerning the waiver of informed consent. These principles, which also factor in discussions in bioethics more broadly, are respect for autonomy, beneficence and justice. But problems arise in treatments of these principles in the abstract, as well as in their application to specific cases. Namely, how do we balance the claims they make on us and adjudicate between them when conflicts arise? Additionally, sometimes it seems as if we cannot consider one principle entirely independently from one or both of the others. The need to respect autonomy, for example, is sometimes justified by its instrumental value in protecting the patient-subject from harm that might befall him as a result of researchers more interested in generating scientific knowledge than in administering the best possible medical care for that individual. That is, we might justify informed consent requirements by appealing to autonomy (i.e. an individual’s capacity for self-determination). But when we ask what it is about autonomy that motivates these requirements, we might say that a person, generally speaking, has a better idea of what course of action is best for him than a physician or researcher, and thus that he should be the one to have final say regarding treatment decisions and research participation.

In discussions of informed consent, autonomy is frequently cited as the central principle, followed by beneficence. Justice, while important to other discussions in bioethics, such as the allocation of scarce medical resources, does not play as prominent a role in the informed consent debate.\textsuperscript{31} However, many prominent bioethicists have argued for the futility of creating an exception-free hierarchy of the three principles.

\textsuperscript{31} Faden and Beauchamp 7, 16.
independent of their application to specific cases. Even W.D. Ross argued that the nature of moral life precludes a hierarchy of moral principles.\textsuperscript{32} Given the relatively narrow scope of this project, I will follow suit in that assumption that no one principle will always override the others. I am inclined to think, as do Faden and Beauchamp, that autonomy takes center stage in discussions of informed consent, and that “the burden of moral justification rests on those who would restrict or prevent a person’s exercise of autonomy.”\textsuperscript{33} However, as we will see below, considerations of beneficence play an important role in my argument when I look at the increased risk of harm the patient-subject is subjected to when she is enrolled in a clinical trial, as opposed to when she is treated outside the confines of such a trial.

Thus, while the continued analysis of these three moral principles, as well as their relationship to one another, is a worthwhile endeavor, the nature of this project does not necessitate a hierarchy. Furthermore, while establishing a rigid hierarchy might be a tempting proposition, any such hierarchy would be controversial. Thus, a more flexible approach to the relationship between these three principles, one that is sensitive to the particularities of different cases, as well as widely shared moral intuitions, is the best way of proceeding. In the sections that follow I will give arguments against the use of a waiver of informed consent in emergency situations drawing on considerations of all three principles. Given that I find the arguments against the use of the waiver compelling on all three accounts, I don’t see a need to argue that one supervenes on the others.

\textsuperscript{32} Ross 23-4.
\textsuperscript{33} Faden and Beauchamp 8.
In the remainder of this section I will outline the main arguments in each of the three categories for the use of the waiver in emergency research, and then argue that none is satisfactory. I will argue, contrary to what pro-waiver authors contend, (i) that the patient-subject is at a greater risk of harm in a study conducted without informed consent, (ii) that while this type of research is, in fact, socially valuable, there are others ways it can be done, and (iii) that conducting research on a person without their consent unjustly violates their autonomy.

Protection from Harm

One line of argumentation that pro-waiver authors take is that patient-subjects are not subjected to a greater risk of harm when informed consent requirements are waived than when they are not. Some authors, as we will see below, go even farther and contend that requiring informed consent in some cases actually puts patient-subjects and their families at an increased risk of harm. In this section I will outline four arguments, each of which contends that waiving informed consent does not put the patient-subject at an increased risk of harm. I will then argue, in response to each argument, that the patient-subject is, in fact, at an increased risk of harm when he is enrolled in a clinical trial without his consent.

The first argument in this class, formulated broadly, is that research participation is in the patient-subject’s best interests. One version of this argument is that, given the choice between the standard treatment with a less-than-good outcome, and an experimental
treatment with an unknown outcome, it is better for the patient-subject to have the opportunity to receive the experimental treatment.\(^{34}\)

However, it does not take much digging into the nature of medical research to see that this is not necessarily the case. The current gold standard of research is the randomized placebo-controlled trial (RCT). In this type of trial the patient-subject is randomly allocated to receive either the treatment (or one of the treatments) being studied, or a placebo. In fact, the ALP study mentioned in the introduction is an RCT. Patients enrolled in that study receive one of two active interventions (amiodarone or lidocaine) or a salt-water placebo. There are three elements of RCTs that are relevant to our current line of inquiry: randomization, double-blind set-up, and placebo control. Considering each of these three elements individually will be instructive.

First, randomization limits the ability of the physician to make decisions about the patient-subject’s treatment. That is, the physician has no control over which treatment the patient-subject receives. While it is supposed to be the case that clinical equipoise exists between the interventions being studied (that is, it is unknown which treatment is more effective and has the fewest and least harmful side effects), it might be the case that a physician has good reason, based on her experience with the available treatment options, to think that one treatment would be better for that patient-subject at that time than another. If this were the case in ordinary clinical care, the physician would be able to tailor her treatment to the patient-subject, and choose the intervention she felt would be most efficacious in that situation. But this ability is taken away if the patient is enrolled

\(^{34}\) CEJA Report. Also, see Fost.
in a clinical trial. Additionally, in an RCT the physician does not have the ability to alter the dosage of the drug given, which could also be detrimental to her ability to treat the patient-subject.

Second, RCTs are generally double blind. That is, neither the patient-subject nor the physician has knowledge of which treatment the patient received. This aspect of RCTs has a similar consequence to randomization: generally speaking, the more knowledge a physician has at hand about the patient-subject, the better she will be able to tailor treatment to that specific individual and situation. But the fact that she does not know which treatment the patient-subject received in the course of the trial (or even, for that matter, whether he received treatment at all, or merely a placebo), might negatively influence her ability to treat him appropriately.

The third element of RCTs that should be considered is the use of a placebo control. Some argue that while a placebo constitutes non-treatment, non-treatment is not necessarily equivalent to non-helpful. If a study is properly designed, researchers will not be able to say beforehand whether the active treatment or placebo will be more helpful or harmful.35 But Katz implores us to look through the “rhetoric” of the FDA regulations. If we do, he says, we will see that, in studies that utilize a placebo control, “some human beings may be sacrificed for the advancement of science so that not present but future patients (as well as medical device companies, pharmaceutical industries, and investigators) will benefit from the research.”36 What it boils down to is that by the time a drug has gotten to a Phase III trial, which is generally where the RCT format is utilized

35 Fost 179.
we often do have reason to believe that the treatment under study is effective. The ALP study, for example, is a Phase III trial. Both drugs in that study, amiodarone and lidocaine, are considered standards of care. That is, if you present to any given emergency department with ventricular fibrillation, you are likely to receive one or the other of those drugs. In fact, this supposition is built into the Code of Federal Regulations, which stipulates that “Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects.”

We also know that the standard treatment is not as effective as we would like it to be. And the use of a placebo control denies certain patient-subjects a drug that we have reason to believe is effective. Patient-subjects receiving the placebo “are denied one of the key elements of personal care: a treatment that their physician believes will be helpful to them.”

The second of the four arguments falling under the category of protecting the patient-subject from harm is that the waiver allows desperately ill patients access to new

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37 There are four phases of clinical trials. In a Phase I study a drug or treatment is tested on a small group of people to evaluate its safety, determine a safe dosage range, and identify side effects. In a Phase II study the drug or treatment is tested on a larger group of people to further evaluate its safety and determine its efficacy. By the time a drug or treatment has gotten to a Phase III trial the goal is to confirm its efficacy, as well as to further monitor side effects, compare it to the standard treatment(s) for the condition, and collect any information that will facilitate the safe use of the treatment or drug. Phase IV trials are conducted after the drug or treatment has been marketed. The goals of these trials are to obtain information on the drug’s effect in various populations and to monitor long-term side effects.

38 C.F.R. 50.24(a)(ii).

39 Berg et al. 282.
therapies.\textsuperscript{40} This argument is even given in the Final Rule itself. The Final Rule, it is argued, “seeks to maximize an individual’s access to potentially beneficial drugs and devices at a time when, due to an emergency which causes incompetency, informed consent cannot be obtained.”\textsuperscript{41}

But there is no reason why promising new treatments could not be administered to patients outside the confines of a clinical trial, on a case-by-case basis as the physician deems it appropriate; there is no necessary connection between the waiver and the use of new therapies. In fact, before the 1996 revisions, the FDA’s regulations allowed only for the use of a single test article of a new drug or therapy. In such a case, the patient would still have access to new, promising drugs or treatments, but the problems with RCTs mentioned earlier (i.e. limiting the physician’s knowledge and decision-making ability) could be avoided. Another problem with arguing that the waiver allows patient-subjects access to potentially beneficial new therapies arises when the use of a placebo-control is taken into account. A more accurate version of this argument is that the waiver allows some desperately ill patient-subjects access to new therapies, because in an RCT some patient-subjects will receive the placebo, rather than the new drug. If such drugs were administered only on a case-by-case basis, then the use of placebos would not be a problem.

The third argument of the four in this category is that requiring consent in emergency situations can cause emotional harm to the patient-subject and his family. Susan Fish goes so far as to say that requiring consent in some cases would violate the principle of

\textsuperscript{40} Truog et al. 806.
\textsuperscript{41} FDA “Protection of Human Subjects” Supplementary Information 51505.
Respect for persons, along with beneficence and justice, is an ethical principle enumerated in the Belmont Report. These three principles are meant to inform the conduct of research on human beings. The principle of respect for persons, which is a version of the principle of autonomy mentioned in the introduction, states that persons should be treated as autonomous agents, but when their autonomy is diminished they should be protected. Fish argues that in a traumatic medical situation a relative of the potential subject (or the potential subject himself, if he is coherent) would not want to be confronted with information about a research study and then be asked to make a decision to participate or not. She argues that in such cases it would be better to waive consent, since it would spare the patient-subject or his family additional emotional harm.

Fish’s argument is problematic on multiple accounts. First, the principle of respect for persons, as formulated in the Belmont Report, says “persons with diminished autonomy are entitled to protection.” Presumably, what they need protection from is harm that might befall them as a result of their diminished autonomy. There are two relevant types of harm: physical and psychological. Fish, however, considers only the latter. I will first respond to her consideration of the relevance of that kind of potential harm before looking at the implications of considering the former.

It seems strange to argue against informed consent requirements, as Fish does, by citing the additional emotional stress they put on patient-subjects and their family. To illustrate her point, Fish has us consider a hypothetical situation: you are the parent of a child. You receive a phone call that your child has been hit by a car while riding her

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42 Fish 451.
bike, and has been rushed to the emergency room. You rush to the hospital, and are confronted by a researcher who asks for 10 minutes of your time. This researcher wants to tell you about a research study, along with its risks and benefits, and ask for your permission to enroll your child in the study. Fish asks us to imagine trying in that moment to comprehend the concepts of randomization and clinical equipoise. She laments the fact that in this hypothetical case (which is based on a real study of a drug called phenytoin) the waiver of informed consent could not be used because there is more than minimal risk involved in the study; that is, this study does not qualify for the use of the waiver of informed consent under the Final Rule. Fish thinks it would be better, in this situation, to waive informed consent requirements purely for the sake of saving you (the parent) the emotional strain of trying to decide whether or not to allow your child to be enrolled in the trial.

But now consider a different hypothetical: you are that same parent, and you arrive at the hospital and are told your child was treated as part of a clinical trial. Would the emotional stress involved be any less than in Fish’s hypothetical? I am inclined to think not. In fact, it might be even greater, if you (the parent) understand that as a part of that study your child may very well have received a placebo, rather than the active intervention. Even if a parent might be inclined to leave the treatment decision entirely in the hands of the doctor, that should be their decision to make in that moment; we are not doing them any kindness by taking away that choice before they find themselves in such a situation. Thus, removing informed consent requirements does not seem like an effective way of mitigating the emotional stress of an emergency medical situation.
But what about protecting those with diminished autonomy from physical harm? As we saw above, the format of RCT trials, including randomization, double-blinding and the placebo-control make this a real worry, especially when compared to the treatment the patient would receive outside the confines of the trial. In the latter instance, the patient receives the treatment the doctor believes will lead to the best possible outcome; in the former instance, this is not the case. Given this, waiving informed consent requirements does not seem like the right way to go about protecting those with diminished autonomy from physical harm.

So, contrary to Fish’s argument, requiring informed consent does not violate the Belmont Report’s principle of respect for persons, which says that individuals should be afforded the respect due to autonomous agents, but if their autonomy is compromised then they should be protected. First, requiring consent in certain emergency situations does not, as Fish argues, cause additional emotional harm to individuals with diminished autonomy, namely the patient-subject or his family. Secondly, enrolling an incapacitated individual in a clinical trial without his consent puts him at a greater risk of harm.

The final of the four arguments of this type is that the extra safeguards required by the Final Rule will serve to protect patient-subjects from any harm that might befall them as a result of waiving informed consent requirements. These requirements include consultation with the community in which the study is being conducted, public disclosure to the affected community of the nature of the study and its risks and benefits before its commencement, public disclosure of the results of the study after its completion, the use
of an independent data monitoring committee to oversee the study, and approval of the study by the FDA.

Several problems with these purported safeguards should be noted here. First, while the researchers are required to consult with the community before the study commences, the community has no power to stop or modify the study being conducted. Second, the effectiveness of this consultation and dissemination of information about the study is not guaranteed. In fact, in one study of 530 emergency department patients, only 5% were aware that a trial using the waiver of informed consent was being conducted in their community.\footnote{McClure et al.} Third, IRBs are frequently cited as safety nets in the clinical trial process. However, several authors have argued that time limitations, composition, and pressure from the pharmaceutical industry, medical device manufacturers and fellow investigators make them unable to properly make judgments about the ethical use of human beings as research subjects.\footnote{See Katz.} This inadequacy is exacerbated by the rise of for-profit IRBs, which have prospered with support from the FDA.\footnote{Katz (1997) 11.} The deficiency of these extra protections, which are supposed to prevent any harm that might befall patient-subjects from whom consent is not required, is reason for concern, to say the least.

Thus, all four arguments for the waiver of informed consent from considerations of protecting the patient-subject from harm fall short of being satisfactory. As a result, we can see that the patient-subject is, in fact, at an increased risk of harm when he is enrolled in a study conducted with a waiver of informed consent.
Scientific and Methodological Considerations

The second category into which arguments for and against a waiver of informed consent fall has to do with the scientific and methodological aspects of the studies being conducted using the waiver. Proponents of the waiver argue that we ought to allow a waiver of informed consent in certain instances for the sake of the scientific knowledge we will gain, and that allowing a waiver is the only way we will acquire such information.

The first of four arguments for the waiver in this category is that if we don’t study these new drugs and treatments they will be adopted “uncritically” into practice. What “uncritically” amounts to in the context of this argument, however, is hard to say. As John Worrall points out, some of the standard treatments for common maladies, such as aspirin for headaches, penicillin for pneumonia, and appendectomies for appendicitis, have not been subjected to RCTs, and yet no one doubts their efficacy, or relative safety, for that matter. So if “uncritically” is to be interpreted as “not evaluated with an RCT,” then this argument is not a terribly strong one, especially when we discover that RCTs may not be the gold standard of scientific knowledge that they are generally considered to be. I will return to this issue below.

It is also interesting to note that this argument, namely, that if new drugs and therapies are not studied then they will be adopted uncritically into practice, contradicts a pro-waiver argument discussed earlier, in the section concerning protecting the patient-

47 Worrall S319-20.
subject from harm. That argument contended that the waiver of informed consent allows desperately ill patients access to new therapies. Thus, in the former case we have the argument that if the drugs are not subjected to clinical trials then they will be adopted into practice anyway, albeit “uncritically.” In the latter case, we have the implied argument that if we don’t study them then patients won’t have access to them. But it can’t be the case that if we don’t study these new drugs then they will both be adopted uncritically into practice and not available to patients at the same time. Thus, the proponent of the waiver of informed consent can have one argument or the other, but not both.

The second argument for the waiver in this category is one from analogy: we use presumed consent in emergency treatment, so we should be able to use it in emergency research. In an ordinary emergency setting (i.e. not a research setting), where an individual’s life or limb is at stake, a doctor is permitted to provide treatment without that patient’s consent. In such a case, consent is said to be implied. The argument behind this reasoning is that a reasonable person would, if he were able, consent to treatment necessary to save his life in such an emergency. Thus, it can be presumed that any given patient would so consent under similar circumstances.

However, there seems to be a very important difference between the two situations. In the ordinary emergency setting, the physician (or other medical professional) provides the treatment she feels is necessary to save the patient’s life or create the best outcome possible. In a research setting, however, that is not necessarily the case. That is, the patient-subject might be randomized into the control group and thus

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48 See Largent et al.
receive a placebo, rather than the new drug or therapy. Thus, while presuming consent in
the former, purely therapeutic, case might be acceptable, that does not provide an
argument for allowing a waiver of consent in the latter. It is one thing to presume
consent to treatment that will save a person’s life, since we can be reasonably sure that
this is in accordance with any given individual’s wishes. However, it is another thing
entirely to presume consent to participation in research, where the treatment administered
will not necessarily be the patient-subject’s best chance at the best possible outcome.

Also undercutting the argument that we should be able to use presumed consent in
cases of emergency research because we use it in emergency treatment is the claim that
standards for consent should be higher in research situations than in standard clinical
situations because of the conflict of interest between the researcher and the patient-
subject. Whereas in a clinical situation the doctor presumably has only the patient’s best
outcome in mind, in the research situation the investigator is also beholden to scientific
interests that at times conflict with the best interests of the patient-subject. The idea is
that stricter informed consent standards protect the patient-subject from possible abuses
by a researcher who is more interested in obtaining knowledge than treating patients.

The third argument for the waiver in this category is that requiring consent in
these cases might (counter-intuitively) make the research ethically problematic.49
Largent et al. argue that exposing patients to research risks without the benefit of
producing valid scientific results is unethical. They worry that enrolling only patient-
subjects who can consent will limit sample size, might introduce selection bias, and could

49 Largent et al. See note 15.
undermine the research’s validity and relevance. They cite a study of the impact of informed consent on stroke research that found that many patients died before they could give consent. As a result, patient-subjects enrolled in the study had a more favorable prognosis than stroke victims in general.

Worrall, however, argues against the claim that RCTs yield the only truly “valid” scientific evidence in clinical trials. Randomized studies, meta-analyses have shown, do not necessarily lead to more trustworthy results. He concludes that carefully conducted (i.e. carefully controlled) non-randomized studies can yield perfectly useful scientific data. Thus, even if we do require informed consent, and that results in a sample that is less like the population at large than if we had waived consent, this does not mean that the scientific data obtained from the study is in any way “invalid.” It may not be up to the same standard as data generated from an RCT, but that does not mean it will not be useful to the scientific community. Given the ethical problems that arise from RCTs, especially when informed consent is waived, it does not seem unreasonable to sacrifice a small amount of scientific rigor to ensure that all individuals receive the best care medicine can provide them. Thus, the argument that it is ethically problematic to require informed consent in such situations is itself problematic.

The last argument in this class is one of the most common arguments (if not the most common argument) for the waiver of informed consent cited in the literature. While it takes many forms, the general point is that there is a need for research in the

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50 Worrall S317.
51 Worrall S329.
52 See Largent et al., Truog et al., Brody, and Faden and Beauchamp.
emergency setting to develop and test better treatments. According to this argument, these studies can be conducted only with a waiver of informed consent. Because this research needs to be done to benefit future patients and society as a whole, and using the waiver is the only reliable way to conduct it, the proponents of this argument conclude that the waiver ought to be allowed.

However, it is simply incorrect to say that emergency medicine research can be conducted only with a waiver of consent. While that might be the most convenient method for the investigators, IRBs, pharmaceutical companies and medical device manufacturers, the truth is that there are other options. As mentioned above, perhaps only individuals who were able to consent, or who had a legal representative who could provide proxy consent, could be enrolled in such trials. Or, a population of individuals predisposed to the condition being studied (for example a heart attack) could be prospectively identified. These individuals could then have the opportunity to indicate whether they would be willing to participate in a study in the event that they did, in fact, suffer a heart attack. While these options might involve significantly more time and cost than waiving informed consent altogether, given the problems with waiving consent we have seen thus far, those inconveniences might need to be tolerated. However, even if it turns out that these alternatives are not plausible, which I highly doubt is the case, the moral transgressions involved in performing research on individuals without their consent should still preclude allowing the use of a waiver of informed consent. The harm to the patient-subject and the violation of autonomy are simply too extensive to write off. I have examined some of these arguments already, and will shortly consider two more that...
turn on the principle of autonomy. I will also say more about these possible alternatives to waiver in the next section.

Thus, we can see that while this type of research is socially valuable, there are other ways it can be conducted that do not require waiving consent. Additionally, as we saw earlier in this section, the other three arguments for the waiver of informed consent from scientific and methodological concerns failed as well.

**Preservation of Autonomy**

The third class into which arguments for and against the waiver of informed consent fall concerns the autonomy of the patient-subject. According to Faden and Beauchamp, the principle of autonomy “is the single most important moral value for informed consent.”\(^{53}\) That is, the importance we place on the process of informed consent is predicated on valuing the autonomy of the patients whose consent we seek; if we did not value their autonomy, we would not worry so much about obtaining their consent before treating them (or conducting research on them). However, Faden and Beauchamp also say that we should be careful to not place too much value in the concept of autonomy; it should not always override other ethical principles.\(^{54}\) This is the framework with which I have approached the arguments given in this paper. Having considered the principle of beneficence in the section concerning protecting the patient-subject from harm, I will now consider some of the arguments for the waiver of informed consent concerning the principle of autonomy, and see that they, too, are unsatisfactory.

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\(^{53}\) Faden and Beauchamp 222.

\(^{54}\) Faden and Beauchamp 222.
In the informed consent process the patient-subject is provided with information about the study being done and is allowed to voluntarily consent or refuse to participate in that study. But how should we deal with research in an emergency situation, where the patient-subject’s ability to comprehend is minimal or nonexistent, or when the therapeutic window is too small to allow that information to be provided to the patient-subject, even if he was capable of understanding?

There are two ways of looking at autonomy in these cases. On one hand we can speak of autonomous agents, and on the other of autonomous actions. If we framed the current issue in terms of autonomous actions, it might be tempting to ignore considerations of autonomy because the patient-subject is unconscious or otherwise incapacitated. But it does not seem correct to dismiss considerations of autonomy simply because a person is temporarily incapable of acting autonomously. Consider an analogy: when a person is asleep, he cannot act autonomously. But we would not want to say that, for that reason, we do not need to respect his autonomy when he is sleeping. While that person cannot act autonomously while asleep, he is still an autonomous agent, and should be treated as such. Similar reasoning should hold when an individual is rendered unconscious or is otherwise incapacitated by brain trauma or a heart attack; just because that person is unable to act autonomously at that moment, it is possible that he will regain those capacities that allow him to do so, and thus we ought to continue to treat him as an autonomous agent. Because we would not consider experimenting on a conscious person without his consent, at least partly (if not mostly) for reasons of respecting his autonomy,
we should not endorse such experiments on unconscious persons. Thus, the relevant consideration here is the appropriate treatment of autonomous agents.

Let’s take a closer look at why waiving informed consent violates the patient-subject’s autonomy. Autonomy, according to Gerald Dworkin, is the power of self-determination, or “the capacity to reflect upon one’s motivational structure and to make changes in that structure.” In so doing we “define our nature, give meaning and coherence to our lives, and take responsibility for the kind of person we are.”\(^{55}\) It is respect for this capacity that underwrites the requirement of informed consent, and more generally, the belief that the final decision-making power about medical treatments rests in the hands of the person being treated.

There are two lines of reasoning open to a researcher looking to justify conducting research on a given patient-subject. On one hand, the researcher could argue from consequentialist grounds that the study will generate socially valuable knowledge. It might help or it might harm this particular patient-subject, but even if it causes harm to this individual the benefit to future generations is the most important factor. The violation of autonomy in this instance is quite apparent: the researcher is subjugating the will of the patient-subject to an ostensible benefit to society in general.

The other line of justification available to the researcher is a paternalistic one, where the researcher argues that it is in the patient-subject’s best interests to be enrolled in the study. But such paternalism, according to Dworkin, necessarily involves a

\(^{55}\) Dworkin 108.
violation of autonomy, because it involves “a usurpation of decision making.”\textsuperscript{56} That is, the researcher substitutes his own judgment of what is in the best interests of the patient-subject in place of the patient-subject’s own judgment.\textsuperscript{57}

Thus, conducting research on a patient-subject without his consent necessarily violates his autonomy, either because the researcher ignores it completely by taking a consequentialist approach to justifying the study, or because he takes a paternalistic approach.

Proponents of the waiver give two arguments that are supposed to justify this violation of the principle of autonomy. The first is an extension of an argument in the section that dealt with considerations of protecting the patient-subject from harm: some argue that the Final Rule’s extra protections serve to preserve the patient-subject’s autonomy just as well as informed consent does. But it is hard to see how this is the case. The crux of autonomy, as we saw above, is the individual’s ability to make informed decisions based on their personal values and ideals; waiving informed consent requirements infringes on this ability. While studies conducted under the waiver are required to have an informed consent protocol for when patient-subjects (or their

\textsuperscript{56} Dworkin 123.
\textsuperscript{57} At this point, one might object that this “usurpation of decision making” occurs in cases of therapeutic emergency interventions, and that if we find it objectionable in the research setting, then we should find it objectionable in the therapeutic setting as well. However, there is a difference between the two cases, and that it turns on the same point as the distinction between the acceptability of the use of presumed consent in therapeutic interventions and the unacceptability of the use of the same type of consent in the research setting. Namely, in a therapeutic setting the physician (or other medical professional) has the patient’s best outcome in mind; while there is a usurpation of decision-making, it is more likely that the decisions being made are in accordance with the wishes of the patient (e.g. having his life saved). In the research setting, on the other hand, the decision being made is less likely to be concomitant with the patient’s wishes.
relatives) are able to give consent, some worry that researchers won’t even try to get consent if it is optional.\textsuperscript{58} Similarly, Katz worries that the Final Rule sends the message to the research community that it is more important for research to proceed than it is for patient-subjects to have the opportunity to agree to be research subjects.\textsuperscript{59}

The second argument for the waiver of informed consent in this section is that, given the choice, most reasonable people would \textit{choose} to take part in a study to have the opportunity to receive the experimental treatment.\textsuperscript{60} Fost cites a survey of the patient-subjects, and the families of those patient-subjects, enrolled in a 1990 placebo-controlled trial that used deferred consent.\textsuperscript{61} This study found that most of them considered that consent process to be adequate.

However, as Fost notes, the conclusion that can be drawn is specific to this one study; it cannot be generalized to the practice of deferred consent in general.\textsuperscript{62} Additionally, another study found that about 50\% of people surveyed do not agree that emergency research done without consent is acceptable.\textsuperscript{63} Thus, the empirical evidence for the claim that people would choose to participate in a study using a waiver of consent, or even deferred consent, is weak, at best. Additionally, even though some people would

\textsuperscript{58} Kolata.
\textsuperscript{59} George Annas expresses this worry. See Kolata.
\textsuperscript{60} Fost 178. Also, see “Waiver of Informed Consent for Emergency Room Research.” American Medical Association \textit{Council on Ethical and Judicial Affairs} Report 1 – A-97: 1997.
\textsuperscript{61} In instances of deferred consent, a patient-subject is enrolled in a study without consent initially, and then consent is obtained either from the patient-subject himself, when he is able, or proxy consent is obtained from a relative, for his continued participation in the study.
\textsuperscript{62} Fost 178.
\textsuperscript{63} Lecouturier. See notes 31 and 34.
be willing to participate in such a study without consent, given the violation of autonomy involved in such a process, as well as the additional harm a patient-subject is exposed to in the research setting, we ought to err on the side of caution when making assumptions about individuals’ wishes. That is, it is better to respect the wishes of those who would not want to be enrolled in such a study without consent.

In summation, the arguments given above show that conducting research on human subjects without their consent constitutes a violation of their autonomy. Given the framework of the ethical principles I started out with, namely, that no one principle always overrides the others, and given that waiving informed consent also violates the principle of beneficence by placing patient-subjects at a greater risk of harm, we ought to conclude that the use of the waiver of informed consent should not be allowed.
IV. ALTERNATIVES FOR EMERGENCY MEDICINE RESEARCH IN THE FUTURE

Conducting research on human subjects without their consent is ethically problematic. I have argued first that the patient-subject is put at an increased risk of harm when he is enrolled in a study without his consent, second, that while this type of research is socially valuable it is not the only option available to us, and third, that conducting research on a person without consent violates his autonomy. Thus, it seems reasonable to conclude that we ought not to allow research to be conducted without consent. But what does this conclusion mean for the future of emergency medicine research?

Some proponents of the waiver of informed consent have argued that if we don’t allow this type of research to occur, then research in emergency medicine will come to a halt, and society will suffer for lack of better treatments. But this is not necessarily the case; there are other ways that we can obtain useful knowledge about various novel emergency medicine interventions without conducting research on human subjects without their consent. Or, in the alternative, we can make the research setting enough like the purely therapeutic setting that we can justify using presumed consent. I will lay out three possible options below.

The first option is to enroll only those individuals who have a family member present to provide proxy consent. In this situation the family member makes a decision for the incapacitated patient-subject regarding medical treatment. There is a hope that this family member will know the incapacitated person well enough to make a decision that is in accordance with the patient-subject’s wishes and values. While proxy consent
is increasingly recognized as a misnomer, in that it is not actually consent at all, and rather bypasses consent, it is commonly used in other medical contexts when the patient-subject is incapable of consenting.

Another option is to obtain advance consent from a large group of people who are at an increased risk of the medical condition under study. For example, researchers studying a new intervention for treating heart attacks might approach a group of elderly people in a community, and ask whether they would be willing to participate in this specific study should they suffer a heart attack. Many commentators have eschewed this option as too time-consuming and expensive. However, given the problems with conducting research with a waiver of informed consent, the additional time and financial cost might have to be tolerated.

A third option, and the last one that I will discuss, is to evaluate the use of new drugs using trials that do not follow the RCT format. We saw Worrall argue above that RCTs are not really the gold standard of scientific knowledge that many consider them to be, and we also saw that their format is responsible for some of the ethical problems that arise from conducting research on persons without their consent. If we allowed physicians to make treatment decisions regarding whether a patient-subject receives the standard treatment, no treatment (i.e. a placebo), or the new intervention, as well as about the dosage given, then we could circumvent many of the problems discussed above. No longer would we be compromising the patient-subject’s care by limiting the physician’s decision-making ability and by denying the patient-subject treatment that the physician believes is in his best interests. Additionally, we would run into fewer problems arising
from compromising the patient-subject’s autonomy; in this case ‘emergency research’
would be much more akin to ‘emergency treatment,’ where presumed consent is
generally considered an acceptable standard.
V. CONCLUSION

The arguments in the preceding sections have shown that conducting research on human beings without their consent is ethically problematic, and consequently that our existing standards for emergency medicine research are problematic. Enrolling individuals in emergency research without their consent places them at an increased risk of harm, and the extra protections required by the Final Rule do not mitigate this increased risk. Further, conducting research with the waiver of informed consent fails to appropriately respect the patient-subject’s autonomy. Given these findings, we ought not allow research to be conducted on people with a waiver of informed consent.

However, this does not mean the end of emergency medicine research, as there are other ways to obtain the socially valuable information that studies currently conducted under the waiver are meant to generate. Responding appropriately to the ethical considerations of performing research on our fellow human beings need not curtail important emergency medicine research.
WORKS CITED


