Institutional Review Boards and the Statutory Compliance "Defense" to Intentional Tort Liability

Kevin M. Samuels
INSTITUTIONAL REVIEW BOARDS AND THE STATUTORY COMPLIANCE "DEFENSE" TO INTENTIONAL TORT LIABILITY

I. INTRODUCTION

A restaurateur is busy sifting through his mail, typically consisting of bills and invoices, when he notices a letter sent from an individual. The restaurateur’s curiosity abounds as he opens the letter and reads its contents. The sender claims to have been a patron of the restaurant who had chosen that restaurant over all the other local restaurants to celebrate a very special occasion, his first anniversary with his wife. He alleges that after eating at the restaurant he became violently ill from food poisoning. The sender implies that if you do not respond accordingly, he will report you to the Better Business Bureau or the Department of Health.1 The restaurateur scrambles to uncover the possible cause of the food poisoning by questioning the cooks, the servers, the restaurant’s vendors, and anyone else who may have caused such discomfort to one of his patrons. He cannot sleep during the following weeks, knowing that the possibility existed that his restaurant, his dream, may shut down as a result of this alleged incident.

A month later, after the restaurateur has tirelessly searched to uncover the cause of his patron’s illness and suffered extreme stress, he receives another letter from the same individual. This time, however, the sender claims that he never ate at the restaurant, much less ever became ill. Instead, the sender identifies himself as a researcher with a major university who sent the letter describing the false incident of illness to study the restaurateur’s reaction. The researcher explains that he sent the letter because he was conducting a study on how restaurateurs react to such incidents. Although profusely apologetic, the researcher claims that he was compelled to make false claims to obtain the best data for his study; only by making a false claim could he

control any bias from restaurateurs, who might otherwise be inclined to exaggerate their response to a food poisoning incident if they knew they were responding to a hypothetical situation. After reading the second letter, the restaurateur is furious. He spent countless hours worrying and making excessive demands on his staff to uncover the possible source of the incident that, in reality, was the product of a researcher “conducting a study.” He, like many of the restaurateurs who were part of the study, asks himself, “How can someone get away with this?” “Where does this researcher get the audacity to put me through this, all for the so-called pursuit of science?”

These are facts analogous to a New York civil case, 164 Mulberry Street Corp. v. Columbia University, in which a professor from Columbia Business School was accused of numerous tort claims, including intentional infliction of emotional distress (IIED), for his recent research study of vendor reactions. 164 Mulberry Street presented a novel issue; it was the first case in which a plaintiff claims IIED against a social science researcher. The issues raised in this case impact the bounds of social research, especially research projects in which the informed consent requirement is either waived or altered.

In addition, such a lawsuit could determine if Institutional Review Boards (IRB) adequately protect human subjects from extreme and outrageous behavior. The case also addresses the larger issue of whether compliance with federal regulations can create a presumption of the exercise of due care; and if so, what impact this presumption should have on an intentional tort claim, including IIED. If a statutory compliance defense can succeed to dismiss an IIED claim, then it is imperative that compliance with the IRB protocol adequately protect human subjects from extreme and outrageous conduct.

Researchers may believe that following federal protocol and procedures required to gain IRB approval would render them immune from tort liability. This thought, however, has no merit, as statutory compliance alone has never conclusively shielded a defendant from liability. Federal regulations merely outline the requirements for IRBs and contain a savings clause specifically stating that the policy does not affect applicable state laws “which provide additional protections to human subjects.” Accordingly, compliance is not a complete defense. However, this Note will argue that statutory compliance creates

---

2 Id.
3 Id. at 18.
4 One must assume that in the research project conducted by Professor Flynn, the informed consent requirement was not required under IRB protocol and, therefore, waived.
5 See infra Part III.A-B.
a rebuttable presumption of an exercise of due care; therefore, statutory compliance may be a "defense" to tort liability, including IIED.

This Note will first describe the facts of the 164 Mulberry Street case and the issues raised by the plaintiffs in that case. It will then describe the IRB, which federal legislation created to protect the interests of human subjects during research projects; the statutory compliance defense; and the cause of action for IIED. While both the IRB and the judicial system are necessary to protect and provide safety for the subjects of human research, this Note will argue that the two systems must work together. Absent care, judges performing a hindsight analysis must not completely undermine the IRB process and hold that a researcher who complied with the IRB regulations acted in a manner that is intolerable to a civilized society. To prevent this conflict, the legal system must increase judicial deference to regulatory standards, barring special circumstances, upon the finding of compliance with the requisite regulations in an IIED case. Finally, this Note will outline the analysis that courts should follow when facing an IIED claim against a researcher who is required to comply with IRB protocol. Previously, no social researcher had been accused of IIED; therefore, such issues are unsettled.

This Note examines how a court should analyze the statutory compliance defense when a researcher complied with the IRB regulations. Under this circumstance, a finding of compliance creates a rebuttable presumption of due care. Therefore, compliance is admissible as evidence of the exercise of due care, absent circumstances that would cause a reasonable person to take additional precautions.7 The next step is for the court to determine if any circumstances existed that would rebut the presumption of due care created by statutory compliance. If the court determines that the researcher complied with the IRB regulations and no such circumstances existed, the presumption of care is not rebutted. And, because the presumption of an exercise of due care is inconsistent with an IIED claim, an IIED claim cannot prevail.

However, if the court determines that a researcher did comply with the IRB regulations, but circumstances requiring additional care did exist, the presumption of due care is rebutted. In this situation, the court must consider a second prong before determining a researcher’s IIED liability. The court should ascertain if the accused researcher acted as a reasonable researcher would in a similar situation. This additional determination is an added judicial deference to the research community and follows the precedent created by the Supreme Court,

7 See, e.g., RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965).
which has determined that additional precautions to statutory requirements are only necessary when the situation calls for the reasonable man to take such precautions. Therefore, this Note concludes that only if the court determines that the researcher failed to follow the IRB regulations or circumstances requiring additional care existed and the researcher failed to act as a reasonable researcher, may the court determine a claim for IIED under the traditional four-element analysis. This analysis allows both the judicial system and the IRB to protect human subjects, but also, eliminates the possible conflict between a court finding that a social research's conduct was extreme and outrageous, yet fulfilled the requirements of the IRB, which is intended to protect human subjects, that will arise if a court fails to follow the prescribed analysis.

II. 164 Mulberry Street v. Columbia University

Francis Flynn, a Columbia Business School professor, sent false complaint letters to various locally-owned Manhattan restaurants as part of a social science research project designed to determine how restaurateurs respond to customer complaints. In each letter, Flynn claimed to have chosen the particular restaurant to celebrate his first anniversary with his wife and that after dining at the restaurant, he became violently ill. As an example, in one letter, Flynn claimed,

> the symptoms began to appear about four hours after eating. Extended nausea, vomiting, diarrhea, and abdominal cramps all pointed to one thing: food poisoning. It makes me furious just thinking that our special romantic evening became reduced to my wife watching me curl up in a fetal position on the tiled floor of our bathroom in between rounds of throwing up.

Although the body of each letter slightly differed, each closed with: "Although it is not my intention to file any reports with the Better Business Bureau or the Department of Health, I want you, Mr. [restaurant owner], to understand what I went through in anticipation that you will respond accordingly." Flynn’s research focused on how the various restaurateurs would "respond accordingly." Flynn stated in

---

8 See Grand Trunk Ry. Co. v. Ives, 144 U.S. 408, 430-31 (1891) (discussing contributory negligence of person killed by defendant railway company’s train in negligence action).
10 Id. (emphasis added).
his testimony that "he did not intend to contact [the] regulatory authorities," despite the implicit threat to do so.\textsuperscript{11}

About one month later, Professor Flynn sent a letter of apology to each restaurateur and admitted the falsehood of the previous letter. He explained in his second letter that "the [first] letter was fabricated to help collect data for a research study that I designed concerning vendor response to consumer complaints."\textsuperscript{12}

The plaintiffs, various restaurateurs, filed a complaint against the defendants, Columbia University and Professor Flynn, for various torts including negligence, libel, libel per se, and IIED.\textsuperscript{13} The case settled out of court, but prior to the settlement, the court ruled on the defendant's motion to dismiss the IIED claims and held that there was a "sufficient basis to allow a jury to decide whether the conceded conduct . . . was outrageous."\textsuperscript{14}

III. THE INSTITUTIONAL REVIEW BOARD

A. History, Background, and Purpose of the IRB

Modern fundamental ethical standards were created in regards to the conduct of research involving human subjects following the Nuremberg Trials.\textsuperscript{15} Judges, not legislatures, created these ethical standards during the criminal trials against the Nazi physicians who conducted research on prisoners of war. The Nuremberg Code stood as the research guidelines in the United States until 1974 when Congress established the first federal guidelines, which since have been amended several times.\textsuperscript{16}

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{12} Id. at 19. In addition to receiving the subsequent letter from Professor Flynn, the owners also received a letter from the Dean of the Columbia Business School apologizing for the actions of Professor Flynn and promising "to put into place procedures and guidelines for empirical research projects so that this will never happen again." Id. According to several members of the University's IRB, Columbia University's IRB records are not available to the public, but similar to most institutions, IRB approval is required for any research conducted by a university employee. Telephone Interview with Shannon Serich, IRB Assistance, Columbia Univ. (Feb. 15, 2005).
\item \textsuperscript{13} 164 Mulberry St., 771 N.Y.S.2d at 20.
\item \textsuperscript{14} Id. at 23.
\item \textsuperscript{15} Originally, there were two cases, 164 Mulberry St. and Josephine v. Columbia University, 2003 N.Y. App. Div. LEXIS 3056 (N.Y. App. Div. 1st Dep't Mar. 14, 2003), which were consolidated into one case, 164 Mulberry St. After speaking with two attorneys who represented Columbia University, George Davidson and Arthur Toback, I learned that the case had been settled.
\item \textsuperscript{16} Richard Delgado & Helen Leskovac, Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice, 34 UCLA L. REV. 67, 71
\end{enumerate}
\end{footnotesize}
The purpose of the federal regulations is to protect the rights and welfare of human research subjects by requiring (1) IRB approval of qualifying research projects involving human subjects, (2) informed consent of the subject,17 (3) verification that the design of the research project is such that it could provide useful results for the good of society, and (4) continual oversight and review by the IRB to ensure that the study follows the guidelines.18 The Code of Federal Regulations lists the regulations for the protection of human research subjects and stipulates that the Secretary of the Department of Health and Human Services (DHHS) shall by regulation require that . . . any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for [a] grant, contract or cooperative agreement assurances satisfactory to the Secretary that it has established . . . a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subject of such research.19

In Chapter 21, section 56.102 of the Code of Federal Regulations, an IRB is defined as "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of rights and welfare of the human subjects."20 Because 42 U.S.C. § 289(a) requires an entity to establish an IRB when seeking government research funds, most academic institutions have created an IRB and established research protocols that require all research projects, regardless of whether they receive federal funding, to go through the IRB process if they involve human subjects.21

17 See 45 C.F.R. § 46.116(c) (2005) (outlining factors that the IRB must find before approving a consent procedure in which the informed consent requirement is either waived or altered).
18 See id. § 46.111 (2005) (outlining criteria that must be satisfied for IRB approval of research).
B. Outline of the Statutory Provisions

In addition to the establishment of IRBs, the Code of Federal Regulations outlines who is required to gain IRB approval and in what situations. The DHHS policy for protection of human subjects "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research," subject to listed exceptions that include research involving surveys, observations, and interviews. The Code further allows for state or local laws to provide heightened protections for human subjects and requires compliance with other federal laws or regulations that may provide additional protection for human subjects.

The DHHS policy applies to most human research, including almost all human research at a university. The Code defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes." Again, any qualifying program or project engaged in human research must provide assurance to an IRB that the researcher will protect the rights of the human subjects before it commences the project.

Although the creation of an IRB is flexible, the Code outlines general requirements and restrictions. An IRB must have "at least five members, with varying backgrounds." The board "shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members . . . to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." Furthermore, to create a diverse board based on background and expertise, the Code states that the IRB shall include "at least one member whose primary concern is in scientific areas and at least one member whose primary concern is in the non-scientific areas." In

22 45 C.F.R. § 46.101(a).
23 Id. § 46.101(b).
24 Id. § 46.101(f).
25 Id. § 46.101(e).
26 Id. § 46.102(d).
27 Id. § 46.101.
28 Id. § 46.107(a).
29 Id.
30 Id. § 46.107(c).
addition to the expertise and diversity requirements, the Code requires that "the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice." The regulations place a practical requirement on the members to not only understand the standards of ethical research and potential legal violations but also the ability to apply them to the research projects seeking approval before the board. To minimize any possible conflict of interest, "[e]ach IRB shall include at least one member who is not otherwise affiliated with the [research] institution and who is not part of the immediate family of a person who is affiliated with the institution." All other members of the IRB "may be staff members and individuals who are, themselves, conducting clinical trials at the research facility." The IRB is able to enforce its decision because the Code stipulates that the IRB has actual authority when reviewing proposals to approve, modify, or disapprove research projects.

C. Informed Consent

Additionally, the IRB functions to assure that the researcher did or will gain informed consent from all human subjects. The Department of Health, Education and Welfare defined informed consent in 1974 as "the knowing consent of an individual . . . to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion." Rather than adopting this or a different definition, the regulations list eight basic elements of informed consent and six additional optional elements that the IRB may consider when determining if the researcher has met the informed consent requirement. Therefore, under the current regulations, there is no specific or canonical definition for informed consent. The federal regulations require that a human subject be informed of the following: (1) "the purposes of the research and the expected duration of the subject's participation . . . [and] the procedures to be followed" and whether the procedures are experimental; (2) the "foreseeable risks or discomforts to the subject";

31 Id. § 46.107(a).
32 Id. § 46.107(d).
34 45 C.F.R. § 46.109(a).
35 See Delgado & Leskovac, supra note 16, at 73 (describing this function as one of the IRB's "principal tasks").
37 Delgado & Leskovac, supra note 16, at 73; see also 45 C.F.R. § 46.116(a)(1)-(8).
(3) the benefits of the research to the subject or others; (4) the "appropriate alternative procedures or courses of treatment" that may be advantageous to the subject, if applicable; (5) the extent to which records identifying the subject will remain confidential; (6) the compensation offered or treatment available if injury occurs in "research involving more than minimal risk"; (7) the name of a person whom the subject may contact regarding the research, their rights as a research subject, and what to do "in the event of a research-related injury"; and (8) the voluntary nature of the program and the subject's right to refuse to participate at any time during the research without "loss of benefits to which the subject is otherwise entitled." In special situations, the IRB must also consider some additional elements beyond those listed above to determine if the subject has been adequately informed and consents.

The main objectives of the informed consent doctrine are "(1) [t]o promote individual autonomy; (2) to protect the patient subject's status as a human being worthy of respect; (3) to avoid fraud and duress; (4) to encourage self-scrutiny by the physician—researcher; (5) to promote rational decision making; and (6) to involve the public in important questions about health care policy and research." Nevertheless, there are certain situations in which the consent requirement may be altered or waived by the IRB. An IRB has the power to approve an informed consent procedure that modifies or waives the above listed elements of informed consent in limited research situations. The regulations permit informed consent to be altered or waived if (1) "[t]he research involves no more than minimal risk to the subjects," (2) the subject's "rights and welfare" are not adversely affected by the waiver or alteration, (3) "[t]he research could not practicably be carried out without the waiver or alteration," and, if appropriate, (4) information will be provided to the subject. In addition, a researcher may be relieved from obtaining informed consent

38 45 C.F.R. § 46.116(a)(1)-(8).
39 Id. § 46.116(b)(1)-(6).
41 45 C.F.R. § 46.116(c); see also Delgado & Leskovic, supra note 16, at 74.
42 Id. § 46.116(c)-(d).
43 Id. § 46.116(d)(1); see also id. § 46.102(i) (defining "minimal risk" as a level of risk where "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").
44 Id. § 46.116(d)(2)-(4).
from the subject if the research involves surveys, interviews, or ob-
servations of public behavior, unless the information "is recorded in
such a manner that human subjects can be identified, directly or
through identifiers linked to the subjects." Deceptive research, a
style of research project in which the informed consent requirement is
waived, entails research that presents minimal risk and could not be
practically carried out without the waiver. This type of research, or
any other that involves the alteration or waiver of the informed con-
sent requirement, is not without opposition, as many commentators
believe that such waivers of informed consent endanger the values
which the requirements intend to protect.

D. Interests Protected by the IRB

The IRB process is a preventative system that analyzes each pro-
ject on a case-by-case basis and was created to protect human subjects
from harms caused by research. The process protects subjects by re-
quiring informed consent in most situations, and stipulating a rigorous
approval process to ensure respect for human subjects' rights, to pro-
tect their welfare, and to minimize harm. The regulations are capa-
bile of modifying research in an immediate manner since the IRB has
the authority to approve, disapprove, or modify any project before it
begins. When reviewing the proposal, the IRB attempts to balance the
benefit of a research project against the possible risks of harm to any
of the subjects and to confirm that all projects meet "applicable law
and standards of professional conduct and practice." The IRB ass-
ures that the subject's interests are adequately protected although
some minimal risks of harm may exist. Therefore, the federal regu-
lations, although flexible, provide significant protection to human
subjects through the rigorous framework and requirements a re-
searcher seeking to conduct research involving human subjects must
follow.

45 Id. § 45.101(b)(2).
46 See Rebecca S. Dresser, Deception Research and the HHS Final Regulations, IRB: Eth-
ics and Human Research, Apr. 1981, at 3, 3-4 (stating that some deception research will be
exempt from informed consent under 45 C.F.R. § 46.101(b), although §46.116(d) will recapture
the requirement in many situations).
47 See Delgado & Leskovac, supra note 16 at 77-78 (discussing the troublesome nature of
"deception research").
48 45 C.F.R. § 46.107(a).
49 Id.
50 See id. § 46.117(c)(2) (stating that the "IRB may waive the requirement for the investiga-
tor to obtain a signed consent form for some or all subjects if it finds . . . [t]hat the research
presents no more than minimal risk of harm to subjects and involves no procedures for which
written consent is normally required outside of the research context").
IV. THE STATUTORY COMPLIANCE DEFENSE

A. The "Defense" as a Presumption Created by Compliance

At common law, an individual's compliance with applicable statutory requirements did not act as a defense to nonstatutory tort liability.\(^{51}\) The rationale against the statutory compliance defense was partially based on the notion that regulations only established a minimum floor of acceptable conduct, which is not sufficient to immunize a defendant from liability.\(^{52}\) The Restatement (Second) of Torts (the "Restatement") had a slightly different view than the common law when it stated that "[w]here there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by . . . the courts as a matter of law, as sufficient for the occasion."\(^{53}\)

Numerous courts have subsequently adopted the view articulated in the Restatement by holding that compliance with a government statute or regulation is admissible as evidence of the defendant's exercise of due care, rather than conclusive proof of nonnegligence.\(^{54}\) In *Grand Trunk Railway Co. v. Ives*,\(^{55}\) the Supreme Court held that a defendant must exercise more than the care required by the statute where circumstances are present that would cause the reasonable man to take additional precautions.\(^{56}\) Therefore, courts have interpreted statutory compliance not as a true affirmative defense but rather as a factor to consider when determining tort liability because it creates a rebuttable presumption of an exercise of due care.\(^{57}\) This presumption cannot be a complete defense, because similar to common law, the minimal exercise of care created by compliance is not a sufficient defense to all tort claims, as some situations may require a defendant to exceed the minimal standard of care presumption created by statutory compliance.\(^{58}\) Furthermore, even if a court determines that a de-

---


\(^{53}\) RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965).


\(^{55}\) 144 U.S. 408 (1892).

\(^{56}\) Id. at 427.

\(^{57}\) See Dueffert, supra note 51, at 175.

fendant raising the statutory compliance "defense" did comply with the regulations, this rebuttable presumption can be extinguished if the court finds that circumstances exist in which a reasonable person would have taken additional precautions.\(^{59}\)

Since the statutory compliance defense requires a defendant to comply with the applicable regulations, the court must first determine if the defendant actually complied with the regulations and thus created the rebuttable presumption of an exercise of due care. If the defendant did comply, the nonmoving party must then demonstrate that circumstances existed in which a reasonable person would have taken additional precautions and therefore demand that the defendant act with a higher standard of due care than the presumed level of care created by compliance with the regulation.\(^{60}\) In a situation where such circumstances exist, the exercise of due care can only be found where a reasonable man would not have taken additional precautions.\(^{61}\)

When such circumstances do not exist and a court holds that a defendant did comply with the applicable regulations, the presumption of a minimal care is created and not rebutted, thus constituting evidence of the defendant's exercise of due care. The Restatement and the courts have not only articulated this argument, but some state legislatures have recommended that the courts establish a presumption that regulatory compliance suffices to illustrate a defendant's exercise of due care.\(^{62}\)

**B. Statutory Compliance Defensive Evidence Regarding Intentional Torts**

Typically, the statutory compliance defense is raised in negligence or strict liability cases, with the most common instance being personal injury lawsuits.\(^{63}\) In *Smith v. Atlantic Richfield Co.*,\(^ {64}\) a rock falling from the roof of a mine injured a coal miner. The Tenth Circuit Court of Appeals held that because the federal Mine Safety and Health Administration had approved the specific mine, it was proper to introduce evidence of the agency's approval because it was relevant in

---

\(^{59}\) *Ives*, 144 U.S. at 430.

\(^{60}\) See id. (requiring additional precautions only when unusual circumstances are present and call for the reasonable man to take such precautions); *Restatement (Second) of Torts* § 288C cmt. a (1965).

\(^{61}\) *Ives*, 144 U.S. at 430.


\(^{63}\) See Dueffert, *supra* note 51, at 188.

\(^{64}\) 814 F.2d 1481 (10th Cir. 1987).
determining whether the mining company met at least a minimum standard of care due. 65

The presumption of an exercise of due care based on statutory compliance extends beyond personal injury lawsuits to product liability suits. Most modern examples of the statutory compliance defense involve cases in which plaintiffs allege defective design or defective labeling against manufacturers. 66 Regardless of the claims, most courts allow the defendant to introduce compliance as evidence of an exercise of due care, though regulatory compliance does not completely shield the defendant from tort liability. 67

Although the statutory defense is not typically invoked as a defense to intentional tort cases, the presumption of statutory compliance as evidence of an exercise of due care is nonetheless the same with an intentional tort as with negligence or strict liability claims. Similar to negligence or strict liability lawsuits, if the court determines that a defendant complied with the relevant federal regulations, the rebuttable presumption of due care will be created, regardless of the fact that it is an intentional tort suit. 68

V. INTENTIONAL INFILCTION OF EMOTIONAL DISTRESS

A. Elements of Intentional Infliction of Emotional Distress

The Second Restatement of Torts established the common standard for IIED when it articulated that "[o]ne who by extreme and outrageous conduct intentionally or recklessly causes severe emotional distress to another is subject to liability for such emotional distress." 69 Almost every jurisdiction, including New York, has adopted this standard for IIED. 70 The New York Court of Appeals has held that the following are the required elements of IIED: (1) the defendant

---

65 Id. at 1487.
67 See Dueffert, supra note 51, at 214.
68 In an IIED claim, if a court finds that a researcher exercised due care, his conduct could not be extreme and outrageous. Although the researcher is aware that he may cause emotional distress, IRB compliance indicates that the IRB did not conclude that the conduct was so egregious.
69 RESTATEMENT (SECOND) OF TORTS § 46(1) (1965).
must act intentionally or recklessly,\(^7\) (2) the conduct must be extreme and outrageous, (3) the conduct must be the cause of the emotional distress, and (4) there must be emotional distress.\(^7\) Commentators have generally agreed that the key to an IIED claim is meeting the extreme and outrageous requirement.\(^7\) Some have gone as far as stating that if a plaintiff meets this single element, a finding of extreme and outrageous conduct imputes the other elements.\(^7\) Therefore, if a defendant’s conduct is extreme and outrageous, a court is likely to imply the causation and distress elements as a result of the outrageous nature of the conduct.\(^7\) Additionally, based on the circumstances of the conduct, a court may also imply that the conduct was intentional by the same rationale, since the conduct goes beyond “all possible bounds of decency.”\(^7\) Accordingly, as a plaintiff may prevail on an IIED claim by simply proving that the defendant’s conduct was extreme and outrageous, understanding how courts define extreme and outrageous behavior is essential to defending an IIED claim.

B. Defining “Extreme and Outrageous” Behavior

The American Law Institute in the Second Restatement articulated a proscribed standard that defined extreme and outrageous conduct in the following manner:

 Liability has been found only where the conduct has been so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community. Generally, the case is one in which the recitation of the facts

---

\(^7\) See Garland v. Herrin, 724 F.2d 16, 19 (2d Cir. 1983) (interpreting the holding of Fischer by stating that although the New York Court of Appeals adopted the Restatement’s formulation of the intentional infliction of emotional distress, there is no authority indicating that New York law is “imposing on a defendant liability for inflicting emotional distress ‘recklessly,’ though not ‘intentionally’”).


\(^7\) Duffy, supra note 73.

\(^7\) RESTATEMENT (SECOND) OF TORTS § 46 cmt. j (1965) (contributing that “[s]evere distress must be proved; but in many cases the extreme and outrageous character of the defendant’s conduct is in itself important evidence that the distress has existed”).

to an average member of the community would arouse his resentment against the actor, and lead him to exclaim, "Outrageous!"77

Countless courts articulate this definition of extreme and outrageous behavior when holding a defendant liable for IIED.78 Besides restating this definition, however, few courts have proffered a clearer definition of extreme and outrageous conduct or any insight as to the factors considered in making its determination.

In a law review article dissecting IIED, Daniel Givelber stated that the tort fails to define the proscribed conduct beyond suggesting that it is very bad. "The term [extreme and outrageous] . . . does not objectively describe an act or series of acts; rather, it represents an evaluation of behavior."79 Prosser stated that such a broad definition will open the floodgates to litigation and therefore reasons that the purpose of the extreme and outrageous requirement is to prevent "petty insult, indignity, annoyance or threat" and to provide "the necessary assurance that the asserted mental distress is genuine."80 Not surprisingly, because the definition of extreme and outrageous does not outline specific behaviors, courts have been scattered and inconsistent in their findings of conduct that reaches the level of extreme and outrageous.81

C. Statutory Compliance as Defensive Evidence in an IIED Case

Statutory compliance is not typically a defense in IIED cases, but there are similar "defenses" that entail the presumption of meeting a standard of care created by compliance with a federal regulation. In Melorich Builders v. San Bernardino County,82 a California Court of Appeals stated that a contractor who acted in reliance on the judgment

---

77 Restatement (Second) of Torts § 46 cmt. d. (1965) (emphasis added); see also Freihafer, 480 N.E.2d 349; Murphy, 448 N.E.2d 86; Fisher, 373 N.E.2d at 1217.
of a professional could "hardly be said to be extreme or outrageous even though the . . . advice later proved to be . . . unsound." The court made numerous rationales for dismissing the IIED claim as a matter of law against the contractor including the technical nature of the stop notice, the strict statutory compliance requirements to utilize such a lien, and the policy reason for not discouraging a businessman to follow the advice of his attorney. The court narrowed the holding by stating that a defendant can raise a defense against an IIED claim of extreme and outrageous conduct if the evidence shows "(1) the defendant acted on the opinion and advice of counsel; (2) counsel's advice was based on full disclosure of all the facts by the defendant . . . ; and (3) the defendant's reliance on the advice of counsel was in good faith." The court set a precedent of allowing people the ability to rely in good faith on the advice and judgment of professionals and not fear IIED liability. In those situations, the court ruled that the conduct could not rise to the level of extreme and outrageous.

Although Melorich Builders specifically entails reliance on the advice of legal counsel, the same analysis can be used in a situation where a researcher relies on the approval of the IRB and complied with the federal regulations. His reliance on IRB approval creates an analogous scenario to that of the contractor in Melorich Builders. Because compliance is determined after the fact, there will be a determination of whether the researcher made full disclosure of all the facts during the IRB approval process and whether the researcher relied in good faith on the advice of the IRB. Therefore, the court should follow the same standard to allow researchers the presumption that it acted with the appropriate care since the researcher relied on the approval of the IRB. In both situations, the court is conducting an ex post analysis to determine whether the defendant followed the mandate of the IRB and complied with federal regulations in order to determine if the defendant's conduct could rise to the level of utterly intolerable in society.

The presumption of due care created by statutory compliance, or reliance on a professional as in Melorich Builders, indicates that unless the presumption of due care is rebutted, a court cannot hold that the conduct rose to the level of extreme and outrageous. Although the presumption is only that the defendant exercised the minimal standard of care, this level is inconsistent with that required

83 Id. at 50 (noting that in relying on the advice of his attorney, a contractor filed a stop notice against his client, and the client subsequently sued him for numerous causes of action, including IIED).
84 Id.
85 Id.
by an IIED claim of extreme and outrageous conduct. Therefore, the statutory compliance defense will protect a defendant from IIED liability by the showing that the defendant's conduct was at least a minimal exercise of due care.

VI. IS IRB COMPLIANCE A "DEFENSE" TO IIED?

The case involving Professor Flynn was a case of first impression, in which the subjects of a human research project brought claims of IIED against a social researcher. Although the court did not find the researcher liable, before the case settled, the court did hold that there was sufficient support of extreme and outrageous behavior by the researcher to allow a jury to determine if the defendant was liable for IIED.86

Based on federal regulations, approval by the IRB is required before a researcher can commence any qualifying project involving human subjects. It is under this backdrop that the New York Supreme Court in *164 Mulberry Street v. Columbia University* could have had the opportunity to set the standard for how to analyze a situation in which a researcher, who must comply with IRB regulations, is alleged to have caused IIED. Although the defense has not been raised yet, this Note will consider the possible statutory compliance "defense" by a researcher to an IIED claim.

If a similar case should ever reach the court, such court must understand that it needs to increase judicial deference to IRB regulations in order to minimize any possible conflict between the federal regulations and the judicial system. Otherwise, a court may determine that a defendant complied with the IRB regulations, yet acted in such a manner as to be utterly intolerable to society and therefore liable for IIED. With such a ruling, the court will indirectly hold that the IRB cannot adequately protect human subjects from even extreme and outrageous conduct.

A. Approval Versus Compliance: The Judicial Determination

The IRB approval process plays a major role in protecting the safety and liberties of human subjects, but courts can provide additional protection and therefore, must be used to increase protection of human subjects. Conflict between the two systems would arise if a court were to undermine the IRB regulatory process by holding that a

---

86 *164 Mulberry St. Corp. v. Columbia Univ.*, 771 N.Y.S.2d 16, 23 (App. Div. 2004). Knowing that all human subject research studies at Columbia require IRB approval, this Note assumes Professor Flynn must have received IRB approval.
project both complied with the federal IRB regulations yet was utterly intolerable in a civilized community.

At this point, it is imperative to understand the difference between approval and compliance with IRB regulations. When a researcher applies to his institution's IRB and that IRB grants the researcher the authority to commence the project, the researcher has gained approval. An IRB grants approval based on the requirements outlined in the federal regulations. Compliance is different because it is an ex post analysis to determine if the researcher actually complied with the federal regulations by evaluating a researcher's IRB submission and how he conducted his research. A researcher's approval by an IRB is a factor in determining compliance, but is not per se compliance. When a researcher raises the statutory compliance defense, the court must evaluate the researcher's submission and his conduct during the study before holding that he either complied or failed to comply with IRB regulations.

B. IRB Compliance Is a Presumption of an Exercise of Due Care

The statutory compliance defense stems back to 1892, when the Supreme Court ruled in Grand Trunk Railway Co. v. Ives that a defendant may be liable for negligence though he fully complied with the applicable regulations. The Court added a caveat when it implied that regulatory compliance is evidence of due care and may be sufficient for the circumstances unless extraordinary circumstances are present in the case and the reasonable person would have taken additional precautions. The Restatement adopted precisely this position: absent special circumstances, the court as a matter of law may accept the minimum standard prescribed by the legislation as sufficient for the occasion. Therefore, under Ives and the Restatement, IRB compliance by a researcher implies an exercise of due care, absent circumstances in which a reasonable person would take additional precautions.

---

88 By determining compliance through an ex post analysis, the court will likely uncover any information that the researcher withheld during the IRB approval process and determine if the researcher conducted the study in accordance with any IRB requirements and the IRB regulations.
89 See 42 U.S.C. § 289(a) (2000) (stating that any qualifying research project must have IRB approval before commencing and therefore a researcher that fails to gain IRB approval will not comply with the federal IRB regulations).
90 144 U.S. 408, 420-21 (1892).
91 Id.
92 RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965).
Since compliance with IRB regulations is at least evidence of satisfying a minimal standard of care where circumstances requiring additional care do not exist, compliance is only evidence in certain situations. In other words, IRB compliance creates a rebuttable presumption of an exercise of due care, which can be rebutted by the showing of the existence of circumstances in which a reasonable person would take additional precautions. Thus, IRB compliance triggers a presumption that a researcher exercised due care towards his subjects, but the showing of such circumstances requiring additional care will extinguish the presumption.

Such a circumstance arises, for example, when an IRB approves a research project in which the informed consent requirement is either altered or waived and therefore the safety of the subject lies solely in the hands of the IRB and the researcher because the subject may not be capable of protecting himself. In this situation, the study creates a significantly higher potential harm to the subject because of his lost autonomy than compared to a study where a subject grants an informed consent. Since there could be significant harm to the subject, the court should apply a per se rule that a circumstance in which a reasonable researcher would take additional precautions exists in all situations where the informed consent requirement is either altered or waived by the IRB. This analysis will allow the court to make additional determinations before holding that a researcher exercised due care. Although the waiver or alteration complies with the regulations, the subject may not have been capable of protecting or dismissing himself from the study and, therefore, the court should not bar recovery without evaluating the researcher’s conduct against that of a reasonable researcher in a similar situation. Therefore, any alteration or waiver of informed consent indicates the existence of a circumstance requiring the court to take an additional step to determine the researcher’s level of care towards the human subject.

C. Exercise of Due Care by a Researcher and an IIED Claim

To prevail on an IIED claim, the court must find that the defendant’s conduct was “extreme and outrageous.” The conduct protected by IIED includes acts that go beyond “all possible bounds of decency, and [are] to be regarded as atrocious, and utterly intolerable in a civilized community.”

---

93 Fisher v. Maloney, 373 N.E.2d 1215, 1217 (N.Y. 1978) (discussing conduct that is “extreme and outrageous” (quoting RESTATEMENT (SECOND) OF TORTS § 46 (1965))).
Can conduct that is utterly intolerable in a civilized community comply with federal regulations created to ensure safety for human research subjects? Can a researcher who complies with IRB regulations act in such an atrocious manner? When a defendant exercises due care, an IIED claim cannot survive because such care is inconsistent with the extreme and outrageous conduct required by an IIED claim. Thus, if a researcher provides evidence of compliance with the IRB regulations, there is a rebuttable presumption of an exercise of due care. This presumption may be a defense to an IIED claim, unless it is rebutted as a result of the existence of circumstances in which a reasonable researcher would have exercised additional care because due care cannot be extreme and outrageous. Although society may want a defendant to act in a manner above the standard of care created by compliance, the exercise of due care cannot be extreme and outrageous.

Many courts, especially those in New York, have a strict application of the outrageous element. Therefore, absent rebuttal of the presumption of due care by a defendant, statutory compliance would clearly be a defense to an IIED claim because acting with due care makes the alleged conduct not sufficiently outrageous. Furthermore, the Second Circuit has held that outrageous conduct lacking "any reasonable justification" fails to meet the extreme and outrageous element. When he gains IRB approval, a researcher is clearly justified to act in reliance on that approval unless he acts in bad faith (for example, by lying about his project to the IRB). Therefore such conduct cannot meet the extreme and outrageous element under the Second Circuit standard either. If a researcher can prove that he exercised due care towards his subject, an IIED suit cannot survive.

---

95 RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965) (stating that "where there are no special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by . . . the court as a matter of law, as sufficient for the occasion").


97 See Gay v. Carlson, 60 F.3d 83, 89 (2d Cir. 1995) (noting "that New York courts have been 'very strict' in applying [IIED] elements" (citing Martin v. Citibank, N.A., 762 F.2d 212, 220 (2d Cir. 1985))); see also Howell v. N.Y. Post Co., 81 N.Y.2d 115, 121-22 (1993) (stating that the extreme and outrageous "requirements . . . are rigorous, and difficult to satisfy" (citing PROSSER AND KEETON ON TORTS § 12, at 60-61 (5th ed. 1984))).

98 Martin, 762 F.2d at 220.

99 See, e.g., Melorich Builders, 207 Cal. Rptr. at 49-50 (asserting that it is a complete defense of extreme and outrageous conduct when the defendant relied, after full disclosure, on counsel's advice in good faith).
D. The Judicial Analysis to Determine a Researcher's Liability in an IIED Claim

If a researcher raises the statutory compliance defense, he will have the burden of proving compliance with the federal regulations, as do almost all defendants when raising a defense or rebuttable presumption. If the court concludes that the researcher complied with the regulations, it creates the rebuttable presumption that he exercised due care. If the court concludes that the researcher complied and fails to find any circumstances that would cause a reasonable researcher to provide additional care, it must dismiss the suit because an IIED suit cannot prevail. In this scenario, where no circumstances requiring additional care are present, the presumption, if created by statutory compliance, cannot be rebutted because the researcher’s compliance is evidence that he exercised due care and an IIED claim cannot prevail where a researcher exercised due care. Again, the presumption of due care is rebuttable by showing the existence of circumstances in which a reasonable researcher would have taken additional precautions. If a reasonable person would have taken additional precautions, the presumption has been rebutted as compliance is not necessarily evidence of due care.

In a situation where informed consent was waived, there is a per se presence of such circumstances where a reasonable researcher should take additional precautions. Therefore, if the IRB either altered or waived informed consent, the social researcher’s compliance with the federal regulations is not evidence of due care because the presence of circumstances requiring additional precautions rebuts the presumption. In this situation, the court must make a determination in addition to compliance, by evaluating whether the researcher’s conduct to protect the subject equates to the reasonable researcher. A researcher has a duty to act in a manner to minimize the harm toward the subject and to provide additional protection to ensure that harm is minimized. Therefore, comparing the conduct of the accused researcher to that of a reasonable researcher in a similar circumstance, the court will conclude whether the researcher acted in such a manner as to protect the subjects from such circumstances or whether a reasonable researcher would have taken additional precautions to protect the subject.

When circumstances exist that would cause a reasonable researcher to take additional precaution, the analysis to determine if the researcher exercised due care requires the court to determine (1) whether the researcher complied with the federal regulations, and if

100 See supra Part III.A-B.
so, (2) whether the reasonable researcher in his position would have acted in a similar manner. If the court determines that the researcher both complied with the federal IRB regulations and acted in a similar manner as a reasonable researcher in his position, the court must hold that the conduct was not extreme and outrageous. Thus, the court will bar recovery for an IIED claim since the researcher exercised due care towards the subject although such circumstances were present. If the researcher complied with federal regulations and acted as a reasonable researcher in his position, the conduct cannot be considered extreme and outrageous.

On the contrary, if the court determines that the researcher failed to comply with the IRB regulations or, where circumstances exist requiring the researcher to take additional care, and the researcher failed to act as a reasonable researcher, the court must hold that the statutory compliance defense fails, as the researcher has not proffered evidence of due care. The court must then apply the traditional IIED analysis to determine the researcher’s liability. Failure to comply with the regulations or act as a reasonable researcher does not demonstrate all of the elements of an IIED claim and therefore cannot be a per se finding of IIED liability. IIED requires that a plaintiff suffer emotional distress and that the conduct of the defendant caused his emotional distress. A researcher who failed to comply with IRB regulations or act as a reasonable researcher does not, without more evidence, demonstrate that the plaintiff suffered emotional distress or that the acts of the researcher were the cause of the plaintiff’s distress. Therefore, in an IIED case where the court rejects a defendant’s statutory compliance defense because the researcher failed to comply with the IRB regulations or failed to act as a reasonable researcher, the court must still determine if the researcher’s conduct was extreme and outrageous and goes beyond all possible bounds of decency.

Only under this analysis, can the courts and the federal regulations work in harmony to protect the rights of human subjects. If a court holds a researcher liable for IIED, though he complied with the federal regulations, Congress must amend the IRB regulations so that conduct that a society finds utterly intolerable does not comply with a regulation intended to protect human subjects. The same result and

101 Fisher v. Maloney, 373 N.E.2d 1215, 1217 (N.Y. 1978) (outlining the four elements of intentional infliction of emotional distress as the defendant must act intentionally or recklessly, the conduct must be extreme and outrageous, the conduct must be the cause of the emotional distress, and there must be emotional distress).

102 In making an amendment to the IRB regulations, Congress can either (a) change the IRB standards to prevent this type of conduct from being approved or (b) direct the courts that a researcher who complies with IRB standards is not liable for IIED. This Note does not address this determination.
immediate action by Congress must occur if a court holds that a researcher who altered or waived the informed consent but complied with the federal regulations and acted as a reasonable researcher is liable for IIED. The IRB protocol was implemented to protect human subjects and any system that approves extreme and outrageous behavior cannot adequately protect human subjects. Furthermore, if a reasonable researcher would have acted in such an intolerable manner, the regulations on the research community must be increased to create a higher level of care by the research community towards human subjects.

E. Application of the Required Analysis for an IIED Claim in 164 Mulberry Street v. Columbia University

In the case against Francis Flynn and Columbia University, the researcher was conducting a project to study various restaurateurs' responses to consumer complaints by submitting fictitious letters. After going through varying hardships, the vendors filed numerous lawsuits, including IIED. Because federal IRB regulations govern Flynn, he was able to raise the statutory compliance defense as evidence of his exercise of due care and thus eliminate a claim for IIED against him.\footnote{There is no evidence to indicate that Professor Flynn or Columbia University ever raised such a defense to the IIED claims.}

If Flynn had raised the statutory compliance defense, the court should have followed the aforementioned analysis or have been prepared to articulate a ruling that the current federal IRB regulations are not sufficient safeguards to protect human subjects from extreme and outrageous behavior. The court had already denied the defendants' motion to dismiss the subjects' IIED claims by stating that there was a sufficient basis to conclude that the conduct was outrageous, though the court did state a "willingness to revisit" the issue at a later stage of the trial.\footnote{164 Mulberry St. Corp. v. Columbia University, 771 N.Y.S.2d 16, 22 (App. Div. 2004).}

Compliance with the IRB regulations raises a rebuttable presumption that a researcher exercised due care. If Flynn raised the statutory compliance defense, he would have had the burden of proving he complied with the IRB regulations. In addition, because his project entailed deceitful research, which includes a waiver of the informed consent requirement, there was a per se existence of a circumstance requiring additional precautions. Such a circumstance rebuts the presumption of due care, though Flynn could have proffered evidence...
that his conduct complied with that of a reasonable researcher in his situation, as such evidence shows an exercise of due care.

In a situation where a circumstance exists requiring additional care, such as this, the court must conduct a two-prong analysis before making a determination of liability for an IIED claim. The court first would have had to determine: (1) if Flynn complied with the federal IRB regulations, and if so, (2) whether he acted as a reasonable researcher would have in his situation. Only if the court determined that Flynn either failed to comply with the federal regulations or did not act as a reasonable researcher would the court have been able to determine whether his conduct reached the level of extreme and outrageous.

VII. CONCLUSION

If an analogous case of 164 Mulberry Street goes to trial, the court will have an opportunity to set the proper analysis on how courts must determine IIED liability when a party raises a statutory compliance defense. Although the statutory compliance defense does not provide complete immunity for a researcher who complied with IRB regulations, the defense may create a rebuttable presumption of an exercise of due care. Generally, the statutory compliance defense is only raised in negligence or strict liability cases, but the defense can protect a researcher from IIED liability by indicating an exercise of due care. With the showing that a defendant exercised due care, a court cannot hold that his conduct reached the level of extreme and outrageous behavior; such conduct goes beyond all bounds of decency within society and clearly due care is inconsistent with this standard.

If a defendant raises the statutory compliance defense, the court must first determine if the defendant complied with the applicable regulations. A finding of compliance with the regulations creates a rebuttable presumption of due care. Therefore, after determining compliance, the court must evaluate the circumstances surrounding the research project to determine if circumstances exist that would have caused a reasonable researcher to provide additional care. If such circumstances exist, the court must make a second evaluation of the researcher's conduct to ensure that additional precautions were taken to protect the human subject from such circumstances. This step requires the court to compare the conduct of the accused researcher to

---

105 Because federal IRB compliance is an extremely facts specific determination, this Note cannot pinpoint the specific factors the court will utilize in making their determination in this case because the specific facts of Professor Flynn's IRB approval and information about his conduct during the study are not public record; see supra note 12.
that of a reasonable researcher and determine if the accused provided the necessary safeguards against the additional precautions.

In the situation where no such circumstance existed, a court that finds that a defendant complied with IRB regulations, must also find the defendant not liable for IIED. Compliance with federal regulations creates a rebuttable presumption of due care and because no circumstances requiring additional care existed, the presumption cannot be rebutted. Therefore, compliance is evidence of due care, which is inconsistent with the standard of conduct held liable under IIED.

Where circumstances requiring additional care did exist during the research study, a court must make an additional determination beyond compliance. The finding of such a circumstance rebuts the presumption of due care, but as the Supreme Court in Ives held, a researcher is only required to take additional precautions where such circumstances exist and a reasonable person would have taken the additional precautions. Therefore, the court must conduct a second analysis to determine if the researcher acted as a reasonable researcher would in the given situation. If the court holds that the accused researcher acted as a reasonable researcher, the court has indirectly found that the researcher took the required additional precautions to protect human subjects and therefore exercised due care. Again, since the court found due care, it must dismiss any claim for IIED. To hold otherwise will indirectly unravel the current IRB standards.

If the courts follow the outlined analysis, the IRB regulations and the judicial system can work together to provide adequate protection for human subjects. On the contrary, if the courts fail to follow this analysis, the courts will undermine the IRB regulatory process by determining that the IRB cannot sufficiently protect human subjects from extreme and outrageous conduct. Undermining the IRB in this way is "Outrageous!"106

KEVIN M. SAMUELS†

† J.D. candidate 2006, Case Western Reserve University School of Law, B.S. 2000, Wake Forest University. I would like to thank Professor Peter Gerhart, Professor Sharona Hoffman, and Andrew Thompson, my mentor, for their helpful comments and candid advice in preparing this Note. I would also like to thank Kari Carter for her love and support during law school and my family, to whom I am forever indebted.