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Expanding Notions of Self-Determination: International Customs of Informed Consent in Medical Experimentation Pre-1945

Laurel Hattix*

Abstract

In the current era, obtaining informed consent is seen as a touchstone of ethical experimentation. However, the divergent ways in which informed consent is applied in practice have made courts the site of a confrontation between the sometimes contradictory moral, medical, and political dimensions of human experimentation. Arguably, the most notorious example of these competing interests clashing in the legal sphere was The Doctors Trial—the first of the twelve trials that were known collectively as the Nuremberg Trials. During the military tribunal proceeding, twenty-three German physicians and administrators were tried for their participation in war crimes and crimes against humanity—including the employment of a euthanasia program and coordinated experimentation involving non-consenting concentration camp prisoners. On August 19, 1947, the verdict included ten points defining legitimate research, the first of which was: “The voluntary consent of the human subject is absolutely essential.” These ten points comprise The Nuremberg Code, which modern scholars deem to be the first major document to outline the principle of consent. However, just sixteen years prior to the verdict, in 1931, Germany enacted a set of provisions that contained no less adequate provisions guiding human experimentation. This Comment utilizes a legal-historical analysis in order to assess whether the international custom of informed consent in medical experimentation predates the Nuremberg Trials. The assertion that informed consent merely appeared in the twentieth century will be refuted by analysis that reveals concepts of consent have long been essential to the medical tradition. Utilizing relevant records, treaties, cases, and political responses to experimentation, and concluding that the practice of consent was both widespread and legally obligatory, this Comment will provide countervailing evidence of international custom of informed consent as having been established prior to 1945.

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I. INTRODUCTION

In 2010, former United States President Barack Obama issued an apology for unethical experiments conducted by the U.S. government in Guatemala.¹ During the course of an experiment funded by the National Institutes of Health, officials conducted research on over five thousand vulnerable Guatemalan people—without their consent.² At least 1,308 individuals were deliberately infected with sexually transmitted infections (STIs).³ The public had no knowledge of the experiments, which began in 1946, until a historian uncovered the archived papers of the medical officer who conducted them, Charles Cutler, more than half a century later.⁴ On August 20, 1947, the Nuremberg Doctors' Trial found seventeen physicians guilty of crimes based on the non-consensual nature of experiments conducted on individuals imprisoned in concentration camps. Despite the highly-publicized outcome of the trial, the non-consensual experimentation conducted by Charles Cutler did not end until December 1948, and the follow-up work continued through 1953.⁵

While the atrocities exposed at the Nuremberg Trials led to a collective declaration of “never again,”⁶ there had been, and would continue to be, numerous instances of non-consensual human experimentation despite what I will argue is an already-existing requirement of consent.⁷ During the same

¹ Michael A. Rodriguez & Robert Garcia, *First, Do No Harm: The U.S. Sexually Transmitted Disease Experiments in Guatemala*, 103 AM. J. PUB. HEALTH 2122, 2122 (2013).

² *Id.*

³ *Id.*

⁴ Oliver Laughland, *Guatemalans Deliberately Infected with STDs Sue Johns Hopkins University for \$1Bn*, THE GUARDIAN (Nov. 8, 2017), <https://perma.cc/5YJ5-C74S>.

⁵ PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, “ETHICALLY IMPOSSIBLE?: STD RESEARCH IN GUATEMALA FROM 1946 TO 1948,” 6 (2011), <https://perma.cc/DQF2-YD64>.

⁶ John Shattuck, *Legacy and Nuremberg: Confronting Genocide and the Terrorism through the Rule of Law*, 10 GONZ. J. INT'L L. 6, 6 (2007) (“[T]hey looked back at the Holocaust and collectively declared, ‘Never again,’ by drafting an international treaty on the Prevention and Punishment of the Crime of Genocide.”); Daniel Levy & Natan Sznajder, *The Institutionalization of Cosmopolitan Morality: The Holocaust and Human Rights*, 3 J. HUM. RTS. 143, 143 (2004) (“The ongoing association between crimes against humanity and the Holocaust is also apparent in the legal narratives that have invoked the notion of such crimes. Nothing legitimizes human rights work more than the slogan ‘Never Again!’ And behind that imperative is the memory of the Holocaust. It is a mark of just how deeply that memory has saturated our everyday consciousness that the phrase ‘Never Again’ does not require any further specification for us to know what it refers to.”).

⁷ Michael P. Scharf, *The Prosecutor v. Dusko Tadic: An Appraisal of the First International War Crimes Trial Since Nuremberg*, 60 ALB. L. REV. 861, 861–62 (1997). For a historical overview of the international failure to uphold the promise of “never again,” see Gareth Evans, *The Responsibility to Protect: From an Idea to an International Norm*, in RESPONSIBILITY TO PROTECT: THE GLOBAL MORAL COMPACT FOR THE 21ST CENTURY 15, 15 (Richard H. Cooper & Juliette Voïnov Kohler eds., 2009) (“‘Never again’ we said after the Holocaust. And after the Cambodian genocide in the 1970s. And then

period, American physicians exploited black farmers in Tuskegee,⁸ Japanese researchers violated the autonomy of prisoners of war,⁹ and Canadian pediatricians starved aboriginal children as part of nutritional studies.¹⁰ Experiments, both preceding and succeeding the Nuremberg Trials, have illuminated tensions between various competing values—mainly, scientific inquiry, medical advancement, and respect for subjects.¹¹ At the intersection of these values, the law has grappled with its role in human experimentation.

Over time, one of the primary legal doctrines that developed around human experimentation was the principle of informed consent.¹² Despite its prominence in both legal and bioethical studies, the specific contours of informed consent remain contested and the subject of spirited debate.¹³ Notwithstanding this uncertainty, in the case of the 1946 Guatemala STI experiment, a U.S. district court found that “there [was] no doubt” that the government “engaged in nonconsensual human experimentation.”¹⁴ The district court found that nonconsensual medical experimentation violates customary international law.¹⁵ In its order, the district court cited *Abdullabi v. Pfizer, Inc.*,¹⁶ where the Second Circuit determined that the authority for the international custom of informed consent was found in The Nuremberg Code, the World Medical Association’s Declaration of Helsinki, the guidelines of the Council for International Organizations of Medical Sciences, and

again after the Rwandan genocide in 1994. And then, just a year later, after the Srebrenica massacre in Bosnia. And now we’re asking ourselves, yet again, in the face of more mass killing and dying in Darfur, whether we really are ever going to be capable, as an international community, of stopping nation-states from murdering their own people. How many more times will we look back wondering, with varying degrees of incomprehension, horror, anger, and shame, how we could have let it all happen?”).

⁸ Lynn M. Harter et al., *President Clinton’s Apology for the Tuskegee Syphilis Experiment: A Narrative of Remembrance, Redefinition, and Reconciliation*, 11 HOW. J. COMM. 19 (2000).

⁹ Gerhard Baader et al., *Pathways to Human Experimentation, 1933–1945: Germany, Japan and the United States*, 20 OSIRIS 205, 220 (2005).

¹⁰ See Noni E. MacDonald et al., *Canada’s Shameful History of Nutrition Research on Residential School Children: The Need for Strong Medical Ethics in Aboriginal Health Research*, 19 PEDIATRICS & CHILD HEALTH 64 (2014).

¹¹ See generally FRANCES R. FRANKENBURG, *HUMAN MEDICAL EXPERIMENTATION: FROM SMALLPOX VACCINES TO SECRET GOVERNMENT PROGRAMS* (2017).

¹² George H. Martin Jr., *Informed Consent and Medical Experimentation*, 3 IUSTITIA 29, 29 (1975).

¹³ John Fletcher, *Ethics in the Consent Situation*, 32 L. & CONTEMP. PROBS. 620, 627 (1967) (“Within the complex of problems associated with human experimentation, there are several reasons to conclude that the consent situation will be the focal point of the most serious legal difficulties and moral dilemmas.”).

¹⁴ *Estate of Arturo Giron Alvarez v. Johns Hopkins Univ.*, No. MJG-15-950, 2017 U.S. Dist. LEXIS 193053, at 677 (D. Md. Aug. 30, 2017).

¹⁵ *Id.* at 17 (quoting *Abdullabi v. Pfizer, Inc.*, 562 F.3d 163, 187 (2d Cir. 2009)).

¹⁶ *Abdullabi v. Pfizer, Inc.*, 562 F.3d 163, 175 (2d Cir. 2009).

Article 7 of the International Covenant on Civil and Political Rights.¹⁷ Regardless of this relative clarity, the history of nonconsensual experimentation that predates these devices raises a significant question: was the custom of consent established prior to the Nuremberg Trials?

The import of this question is situated in a larger inquiry: why does international law matter at all? For constructivists, “states create and follow international law not because of their instrumental benefits or penalties from complying, but because of their moral and social commitment to ideas embodied in treaties.”¹⁸ Under this framework, the question of consent in the arena of medical experimentation may illuminate norms, preferences, and interactions, which reflect movements aimed at developing formal frameworks for assessing human dignity and autonomy.¹⁹ In this way, the development of customary international law, if it is viewed as legitimate, may speak to “contemporary social aspirations and the larger moral fabric of society.”²⁰ By approaching this question through an assessment of legal history and development of obligation, this Comment seeks to situate “law in its broader social context”—to allow for “cultural explanations of behavior and identity formation.”²¹ In exploring counter-narratives, this analysis contributes to, but also challenges, the majoritarian story about consent in medical experimentation. In adding a multiplicity of stories to this conversation, the goal of the Comment is to disarm presumptions that prior to Nuremberg, conversations, debates and obligations to research subjects did not exist.

Currently, the prevailing view of medical historians is that informed consent had no established place in the medical tradition until the mid-twentieth century.²² This widely endorsed view is put forth by physician and medical ethicist, Jacob “Jay” Katz.²³ While Katz’s assertions primarily deal with consent in the context of treatment, his claims remain relevant to the context of experimentation. Undergirding the concept of consent in both medical treatment and experimentation is the principle of autonomy. In both circumstances, consent is sought to protect the right to be free from an

¹⁷ *Id.*

¹⁸ Shima Baradaran et al., *Does International Law Matter?*, 97 MINN. L. R. 743, 756 (2013).

¹⁹ *Id.* at 757.

²⁰ Martha Finnemore & Stephen J. Toope, *Alternatives to “Legalization”: Richer Views of Laws and Politics*, 55 INT’L ORG. 743, 749 (2001).

²¹ *Id.* at 750.

²² Kathleen E. Powderly, *Patient Consent and Negotiation in the Brooklyn Gynecological Practice of Alexander J.C. Skene: 1863–1900*, 25 J. MED. & PHIL. 12, 12 (2000).

²³ *Id.*

unsolicited invasion of bodily integrity.²⁴ While, in the context of experimentation, the calculus of informed consent may be complicated by the fact that the risks the procedures pose to the subject are less evident, the most basic understandings of informed consent can reasonably be conflated: “The doctrine of informed consent was developed to protect the right of every individual to participate in decision making about his own medical care.”²⁵ In this way, the bedrock principle of informed consent operates in functionally equivalent ways in both the treatment and experimentation contexts. The notion of individual autonomy is particularly appropriate within the scope of this Comment, which seeks to assert that the custom of consent established pre-1945 was merely the deliberate giving of permission.²⁶

Katz’s view centers on the notion that “disclosure and consent . . . have no historical roots in medical practice.”²⁷ Instead, Katz argues that the concept of informed consent entered medical consciousness in the 1957 case of *Salgo v. Leland Stanford, Jr., University Board of Trustees*.²⁸ His assessment posits ancient medical tradition as antithetical to understandings of individual autonomy, because the paternalistic authority of doctors allowed them to direct treatment without any consideration of the patients’ understandings of their treatment options or undesired risks.²⁹ As evidence for his position, Katz cites Hippocrates’ view that physicians should primarily offer reassurance and hope, rather than explain the intrinsic uncertainty of medical practice.³⁰ While Katz acknowledges some exceptions, he generally asserts that, when early doctors did

²⁴ However, this is not to say that there are always compelling justifications for conflating understandings of consent in both the treatment and experimentation context. See AURORA PLOMER, *THE LAW AND ETHICS OF MEDICAL RESEARCH: INTERNATIONAL BIOETHICS AND HUMAN RIGHTS* 49 (2005) (“Notwithstanding judicial trends in the US to conflate liability for innovative or experimental medical treatment with liability for standard medical treatment, there are, as Dieter Giesen argues, compelling reasons to distinguish the two: ‘the individual doctor trying out new techniques is undeniably engaged in medical experimentation. It is unacceptable . . . to place the burden of this experimentation upon the patient by confining his right of recovery in relation to consent to the tort of negligence.’”).

²⁵ Maria Woltjen, *Regulation of Informed Consent in Human Experimentation*, 17 *LOY. U. CHI. L. J.* 507, 512 (1986).

²⁶ This limiting factor is discussed further in Section II, *infra*.

²⁷ Martin S. Pernick, *The Patient’s Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy*, in 3 *MAKING HEALTH CARE DECISIONS* 1, 1 (1982).

²⁸ 317 P.2d 170 (1957).

²⁹ Powderly, *supra* note 22, at 12.

³⁰ *Id.* at 12–13 (“Katz cites Hippocrates who had promoted this tradition when he said: Life is short, the Art long, Opportunity fleeting, Experiment treacherous, Judgment difficult. The physician must be ready, not only to do his duty himself, but also to secure the co-operation of the patient, of the attendants and of externals.”) (internal quotation marks omitted).

educate their patients, the reasons were steeped in paternalism and not the promotion of autonomy.³¹

While Katz may hold the majority view of medical historians,³² others have argued that historical analysis lends itself to the idea that consent and autonomy have long been a part of medical tradition.³³ Historian Martin Pernick is the best known proponent of this viewpoint, which suggests that “truth-telling” and “consent-seeking” have long been part of medicine.³⁴ Underlying these practices were “medical theories that taught that knowledge and autonomy had demonstrably beneficial effects on most patients’ health.”³⁵ Based on case records, Pernick argues that autonomy, though not as fundamentally important as it is understood to be today, played a significant part in medical practice before the twentieth century legal landmarks most frequently referenced today.³⁶ Consent offered individuals the opportunity to make a judgment about whether to accept or reject the treatment proposed by a physician. Autonomy requires that an individual be able to accept or reject medical intervention, and choose between alternative interventions, in both the treatment and experimentation context. In this way, autonomy is realized by principles of informed consent.

Even some who favor Katz’s position dispute his assertion that “the doctrine of informed consent surfaced, seemingly out of nowhere.”³⁷ Reconciling the positions of Katz and Pernick, physician Ruth Faden and scholar Tom Beauchamp provide a historical analysis that demonstrates nineteenth-century consent and disclosure practices in both clinical medicine and research.³⁸ Their position is distinct from Pernick’s in that the underlying ethos of these practices was the benefit of the individual, rather than a process focused on ensuring individual autonomy.³⁹ In their view, rights-oriented social movements of the late twentieth century ushered in new understandings of informed consent—understandings by which consent was seen as deriving from the right of self-determination.⁴⁰

³¹ *Id.* at 13.

³² *Id.* at 12.

³³ Pernick, *supra* note 27, at 2.

³⁴ Lori B. Andrews, *The Right and Rite of Informed Consent*, 21 L. & SOC’Y R. 765, 767 (1988).

³⁵ *Id.*

³⁶ Powderly, *supra* note 22, at 13–14.

³⁷ Andrews, *supra* note 34, at 766.

³⁸ RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 54 (1986).

³⁹ *Id.*

⁴⁰ Andrews, *supra* note 34, at 769.

Following the viewpoint presented by Pernick, and utilizing physician records, legal and political responses to experimentation, and philosophical articulations of self-determination, this Comment argues that the international custom of consent in medical experimentation predates the Nuremberg Trials.⁴¹ Specifically, this legal-historical analysis will assert that prior to 1945 consent, the voluntary giving of permission for experimental intervention,⁴² was widespread, and researchers engaged with consent practices because of a perceived legal obligation. This Comment does not allege that the medical and legal communities reached a consensus on understanding consent, nor does it contend that examples of non-consensual experimentation infrequent; rather, it provides countervailing evidence of clear ethical and legal obligations of informed consent prior to 1945.

While this Comment approaches the question of the prevalence of consent pre-Nuremberg through a historical analysis, the stakes and implications of this Comment extend beyond the merely hypothetical or academic. This determination of custom necessitates accountability for previously inactionable claims, and heightens future accountability for researchers and institutions. While the opportunity for individuals to litigate claims may be procedurally limited, renewed attention to the legal norm surrounding medical experimentation may expose previously harbored atrocities. This is more plausible in light of the fact that the Guatemalan experiments only came into public consciousness in 2010, over sixty years after they had officially ended, and descendants finally had their day in court beginning in 2017.⁴³ Even if unsuccessfully litigated, the expanded opportunity and incentive for these stories to come to the surface could impact future accountability for the institutions that bear responsibility for such exploitation. This is likely to arise in the context of non-litigation-based reparations, such as funds, monuments, rigorous training, or revised standards.⁴⁴

⁴¹ The consent discussed here is not informed consent; rather, it follows the basic definition outlined in Section II.

⁴² This Comment does not contend that the custom of consent pre-Nuremberg fully comports with modern understandings of consent.

⁴³ Colin Campbell, *Judge Allows \$1 Billion 'Guatemalan Experiment' Suit Against Hopkins and Others to Move Forward*, BALT. SUN (Aug. 31, 2017), <http://www.baltimoresun.com/health/bs-md-hopkins-guatemala-suit-20170831-story.html>.

⁴⁴ For example, in the case of the Tuskegee experiments, which was settled out of court, the U.S. government guaranteed lifetime medical benefits and burial services to all living participants through the Tuskegee Health Benefit Program. The program later expanded the benefits to include health, as well as medical, and wives, widows, and children were added to the program. See Claudia R. Baquet et al., *Clinical Trials: The Art of Enrollment*, 24 SEMIN. IN ONCOLOGY NURSING 262, 265 (2008).

Additionally, in setting forth the Nuremberg Trials as the first articulation of the necessity of consent, states, particularly the U.S., engaged in a form of exceptionalism relating to a history of exploiting marginalized peoples in the name of medical progress. This may be connected to the lure for Western physicians to conduct human experimentation outside their home states. Being aware of both the moral boundaries and legal consequences of human experimentation without consent, an unscrupulous physician would have clear incentive to conduct their research in communities where legal intervention was inaccessible and where their subjects would fall beyond the gaze of the world's eye.⁴⁵

Having considered the stakes and opportunities, the Comment advances as follows. Section I describes theoretical understandings of customary international law as well as the current state of informed consent as provided by international treaties, and global regulations and procedures devoted to human experimentation. Section II assesses the relevant treaties, records, and political and legal responses to experimentation prior to 1945 as evidence of state practice and *opinio juris*. Section III considers the legal and historical contours of the Nuremberg Trials themselves as evidence of pre-existing informed consent norms and analyzes post-Nuremberg documents to assess how they reinforce the longstanding customary tradition that the Comment identifies. Section IV directly assesses the ways in which the preceding historical analysis bears on the claim of custom predating Nuremberg and addresses the limitations of the Comment.

II. CONSENT AS ESTABLISHED CUSTOMARY INTERNATIONAL LAW

A. Customary International Law

According to the International Court of Justice (ICJ), customary international law is defined as “evidence of a general practice accepted as law.”⁴⁶ Despite varying scholarly positions, the prevailing view is that customary international law is established by two elements: (1) the repeated and widespread conduct of States, and (2) the belief that this conduct is engaged in on the basis

⁴⁵ Support for this claim can be found in the writing of R.C. Arnold, who supervised Dr. John C. Cutler, the lead physician in the experimentation in Guatemala. See Susan M. Reverby, “Normal Exposure” and Inoculation Syphilis: A PHS “Tuskegee” Doctor in Guatemala, 1946-1948, 23 J. POL’Y HIST. 6, 18 (2011) (“I am a bit, in fact more than a bit, leery of the experiment with the insane people. They can not give consent, do not know what is going on, and if some goody organization got wind of the work, they would raise a lot of smoke.”).

⁴⁶ Tullio Treves, *Customary International Law*, in MAX PLANCK ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW (2006).

of a legal obligation.⁴⁷ The first element, the objective component, evaluates the practice of states—primarily what they say and do. The second element, known as *opinio juris*, is the principal concern of customary international law—“[i]t is what distinguishes a national act done voluntarily . . . from one that a nation follows because it is required to do so by law.”⁴⁸ In this way, custom requires the normative belief that the act or conduct must be followed—this is distinct from conduct formed out of “mere habit or convenience.”⁴⁹ It is the internalization of these norms and the belief that behavior must conform to it that gives customary law its legitimacy.

International law primarily arises out of two sources: treaties and customary international law.⁵⁰ Rather than the formal process utilized in treaty rules, “rules of customary international law arise out of frequently ambiguous combinations of behavioral regularity and expressed or inferred acknowledgements of legality.”⁵¹ Despite the comparative informality in their formation, customary rules play an important role in international law. Where topics have yet to be formally negotiated, where states are not party to formal treaties, or where relevant enforcement mechanisms do not exist, customary international law provides a basis for constraining behavior and providing accountability.⁵² Particularly in the context of human rights and bodily autonomy, the legitimizing impact of customary international law may act as a prominent tool of justice. Where individuals or institutions have disregarded human rights, custom can reinforce principles of justice—even where a state’s own law fails to grant individuals the full protection of those rights. Traditionally, customary international law is viewed as universal in the sense that it applies to “all states regardless of their culture or political system.”⁵³ This consideration is based on the overarching custom of *pacta sunt servanda*,⁵⁴ which assumes that states will perform their binding obligations in good faith.⁵⁵

⁴⁷ *Id.*

⁴⁸ Jack L. Goldsmith & Eric A. Posner, *A Theory of Customary International Law*, 66 U. CHI. L. REV. 1113, 1116 (1999).

⁴⁹ J. Patrick Kelly, *The Twilight of Customary International Law*, 40 VA. J. INT’L L. 449, 462 (2000).

⁵⁰ Goldsmith & Posner, *supra* note 48, at 1113.

⁵¹ MICHAEL BYERS, *CUSTOM, POWER AND THE POWER OF RULES: INTERNATIONAL RELATIONS AND CUSTOMARY INTERNATIONAL LAW* 3 (1999).

⁵² *Id.* at 3–4. *But see* Michael P. Scharf, *Seizing the Grotian Moment: Accelerated Formation of Customary International Law in Times of Fundamental Change*, 43 CORNELL INT’L L.J. 439, 445 (2010) (“Normally, customary international law, which is just as binding on states as treaty law, arises out of the slow accretion of widespread state practice evincing a sense of legal obligation (*opinio juris*).”).

⁵³ Kelly, *supra* note 49, at 451.

⁵⁴ Latin for “agreements must be kept.”

⁵⁵ Kelly, *supra* note 49, at 452.

Despite relatively uniform understandings of these elements, there is widespread disagreement about what constitutes evidence of state practice.⁵⁶ The least controversial sources include domestic legislation, policy statements, and diplomatic correspondence, whereas the most controversial sources include nonbinding statements and resolutions.⁵⁷ Treaties have been utilized as evidence of customary international law, but their use lacks consistency.⁵⁸ Additionally, there are divergences in determining the practical contours of just how “widespread” and “uniform” a state practice must be.⁵⁹ Due to the impracticability of an analysis that includes the practices of all nations, these inquiries typically focus on global powers and concerned states. However, it has become increasingly common to ignore state practice altogether in scholarly analysis of customary international law.⁶⁰ Notwithstanding these fundamental uncertainties and discrepancies, custom remains a central component of international law.

B. Understandings of Consent

It is necessary to discuss the definition of consent in order to explore when the concept arose, because the impartation of modern medical technology and processes of international law have created varied and contested definitions. Additionally, definitions of consent have varied in different contexts—for example, courts of law and medical guidelines understand the term differently.⁶¹ Due to the variety of meanings attached to “consent” and its development over time, it is important to set out the definitions and limitations of consent contemplated in this Comment.⁶² An ideal situation of human experimentation that would require consent would involve a researcher seeking the participation of a subject.⁶³ The individual’s participation would involve “some alteration of

⁵⁶ Goldsmith & Posner, *supra* note 48, at 1117.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* (“For example, they refer to a CIL prohibition on torture at the same time that they acknowledge that many nations of the world torture their citizens. It is thus unclear when, and to what degree, the state practice requirement must be satisfied.”).

⁶¹ FADEN & BEAUCHAMP, *supra* note 38, at 4 (“The law’s approach springs from a pragmatic theory. Although the patient is granted a right to consent or refuse, the focus is on the physician, who holds a duty and who risks liability by failure to fulfill the duty. Moral philosophy’s approach springs from a principle of respect for autonomy that focuses on the patient or subject, who has a right to make an autonomous choice.”).

⁶² Onora O’Neill, *Symposium on Consent and Confidentiality: Some Limits of Informed Consent*, 29 J. MED. ETHICS 4 (2002).

⁶³ Fletcher, *supra* note 13, at 633.

the subject's mental, physical, or social functioning, with the scientist planning to observe and record the results."⁶⁴ Within this process, the subject may experience pain, discomfort, or a temporary loss of rights.⁶⁵

Evolutions in understandings of informed consent, as well as the divergences in its definition, present a complex question—what qualifies as consent? This question expands a tension between choosing criteria lax enough to render the term meaningless and criteria so demanding as to render it impossible to conduct any meaningful historical analysis. Consent, as referenced in this paper, will refer to a singular condition: consent that involves the “intentional giving of *permission* for an intervention.”⁶⁶ This definition does not comport to modern articulations of *informed* consent, which have been elaborated to account for information asymmetries, coercion, and the vulnerability of certain populations.⁶⁷ In fact, this definition alone is not satisfactory to render an experiment “ethical” or establish that it comports with international legal standards.

However, there are several reasons to prefer this definition. First, early records and research accounts do not provide substantial evidence to determine whether consent was informed.⁶⁸ Historical documents often reference “consent” or “voluntariness,” but fail to give any further information, such as what information was given to a subject. Second, even in a post-Nuremberg Code world, key questions about the contours of informed consent remain unanswered. Both the legal and medical fields have struggled to answer the most basic of issues: How much information must be disclosed to a subject before they can make an informed decision?⁶⁹ How does one determine if a subject lacks the mental competence to make an informed choice?⁷⁰ Third, the debate around the trajectory of consent is complicated by changing historical, social, and technological landscapes. “[C]hanges in medical technology, medical theory, professional power, and social structure all have interacted over time to shape the changing role of the patient in medical decision-making.”⁷¹ By narrowing the

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ FADEN & BEAUCHAMP, *supra* note 38, at 54.

⁶⁷ *Id.* at 372.

⁶⁸ *Id.* at 54–55 (“For example, in the diaries of nineteenth-century surgeons, statements may be found that the surgeon *advised* amputation of an infected leg and that the patient *agreed* or *consented*. Without more evidence, we cannot discern whether this reported “consent” was based on accurate and adequate information.”) (emphasis in original).

⁶⁹ Pernick, *supra* note 27, at 1.

⁷⁰ *Id.*

⁷¹ *Id.* at 3.

understanding of consent to mere permission for intervention, this Comment attempts to take into account these changes, while simultaneously presenting an underlying conception of consent that has historical longevity and continuity.⁷²

Lastly, it should be noted that while the Comment's argument deals specifically with consent in the arena of medical experimentation, there are examples, cases, and records utilized in the analysis that refer to consent as it relates to treatment. While these areas of medicine, and the consent requirements surrounding them, are fundamentally distinct, there are points of commonality that provide a richer analysis.

There are several differences between medical treatment and medical experimentation. First, "[i]n the area of human experimentation, the researcher's goal of acquiring new information and the subject's rights may inherently conflict."⁷³ Second, personal ethics may be insufficient to constrain a researcher who faces opportunities for career advancement.⁷⁴ It is for this reason that modern medical institutions have developed robust, but not necessarily sufficient, procedures such as Institutional Review Boards (IRBs).⁷⁵ Third, in a research setting, the care an individual receives is "not chosen exclusively out of a concern for his or her well-being, but with regard to the success of the experiment design."⁷⁶ More obvious, but equally important, is that the risks of experimentation are often not known in advance—hence the need for the research.⁷⁷ It is for this reason that "[t]here is almost universal agreement that the requirement of informed consent should be applied more rigorously in connection with experimental procedures, or 'research,' than with standard medical or psychological treatments."⁷⁸ Scholars have summed up the difference between the two contexts as being twofold:

⁷² There are, of course, many counterpoints to the decision to narrowing the understanding of consent. One may assert that this narrow definition excludes much of what would make this argument meaningful; however, non-informed consent as a baseline ethical principle still serves important theoretical and legal functions. Consent, presented as mere permission for intervention, still serves to address the underlying right at issue—the right of bodily autonomy. Establishing this basic right in the most discernible scenarios establishes a foundation to being able to assert the right in the infinitely more complex modern circumstances, which may introduce questions of technology, globalization, and sociopolitical realities.

⁷³ Woltjen, *supra* note 25, at 513.

⁷⁴ *Id.* at 513–14.

⁷⁵ *Id.*

⁷⁶ CHARLES FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* 75 (1974).

⁷⁷ Richard Delgado & Helen Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 *UCLA L. REV.* 67, 68 n. 1 (1986).

⁷⁸ *Id.* at 67.

The ostensible differences between the therapeutic and experimental contexts may be resolved into two components: in the therapeutic context it is supposed that the physician knows what the sequelae to treatment will be, which information, by definition, is not available in the experimentation situation; and in the therapeutic context the doctor may be said to be seeking his patient's good, in contrast to the experimental context where some other good is being sought.⁷⁹

Nevertheless, there are various similarities between treatment and experimentation that render the utilization of both examples appropriate for the purposes of the Comment. First, the underlying moral necessity for consent in both situations is identical: the right to consent derives from a recognition of the individual capacity to make determinations about invasions of bodily integrity.⁸⁰ Conversely, the consequences of failing to recognize valid consent in both situations can constitute a denial of personhood, but may also have devastating psychological and psychosocial results.⁸¹ In examining consent in the treatment context, the outgrowth of principles will be the focus of the inquiry: these principles also underlay the ethos of consent in the medical experimentation context—mainly, the right against bodily invasion without deliberate approval.

C. The Current State of Informed Consent

While the previous section emphasized the need to move away from informed consent as the basis for the custom that this Comment seeks to discover, it is nevertheless important to understand the current state of the law involving informed consent. There are two reasons for this: (1) to show that the modern doctrine was an outgrowth of the historical principle, and (2) to demonstrate the ways in which, even in the modern era, the specific contours around consent are unsettled.⁸² However, the current state of informed consent is not the standard by which the relevant historical material will be judged.

While ever-evolving, the modern notion of informed consent is based on three basic principles: capacity, disclosure, and voluntariness.⁸³ Despite general

⁷⁹ Benjamin Freedman, *A Moral Theory of Informed Consent*, 5 HASTINGS CTR. REP. 32, 34 (1975).

⁸⁰ *Id.* at 32 (“[O]ur capacities for personhood ought to be recognized by all—these capacities including the capacity for rational decision, and for action consequent upon rational decision.”).

⁸¹ *Id.* at 33.

⁸² Christine Grady, *Enduring and Emerging Challenges of Informed Consent*, 372 NEW ENG. J. MED. 855, 856 (2015) (“Most accept that in practice, particular aspects of informed consent vary by context, and both scholars and practitioners continue to debate these aspects—such as the scope and level of detail provided and the methods of disclosure, whether and how to assess comprehension, what constitutes necessary and sufficient understanding for valid consent, approaches to assessing persons’ capacity to consent and steps taken when they lack that capacity, how to know when choices are sufficiently voluntary, and issues concerning documentation of consent.”).

⁸³ Edward Etchells, *Informed Consent in Surgical Trials*, 23 WORLD J. SURGERY 1215, 1215 (1999).

consensus on these principles, a variety of modern documents elaborate on informed consent and the requirements of medical experimentation.

Nearly all U.S. guidelines for experimentation are guided by the ethical principles articulated in the 1979 Belmont Report.⁸⁴ In 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by federal law.⁸⁵ In its initial charge, the Commission was asked to “identify the basic ethical principles that should underlie the conduct of biomedical and behavior research,” as well as develop guidelines to ensure these principles would be followed.⁸⁶ The outgrowth of these endeavors was The Belmont Report, which states beneficence, justice, and respect for persons as the three principles guiding the protection of human subjects in research.⁸⁷ While the Report has been critiqued for its oversimplification of these ethical considerations, its primary function is an analytical framework by which ethical considerations are viewed.⁸⁸

The 1991 “Common Rule”⁸⁹ was codified by fifteen different federal agencies and established two main protections: (1) informed consent, and (2) IRB requirements.⁹⁰ Under the Common Rule, a subject must give “legally

⁸⁴ DEP’T OF HEALTH, EDUC. & WELFARE, BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, REPORT OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, 44 Fed. Reg. 23, 192 (Apr. 18, 1979) (codified at 45 C.F.R. § 46) [hereinafter the Belmont Report]. See also Jacqueline Fox, *Reinvigorating the Concept of Benefit: The Failure of Drug Company-Sponsored Research on Human Subjects*, 38 SETON HALL L. REV. 605, 615–16 (2008) (“The most basic requirement of research, as demanded by the Belmont Report, is that we must not undertake this research unless the possible benefit to society is substantial enough to justify this use of humans. This requirement alone is certainly not enough to satisfy all ethical requirements for proper use of human research subjects; it is a necessary but not sufficient condition.”).

⁸⁵ K.J. Ryan et al., *The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 81 J. AM. COLL. DENTISTS 4, 5 (2014).

⁸⁶ *Id.*

⁸⁷ Jennifer M. Sims, *A Brief Review of the Belmont Report*, 29 DIMENSIONS CRIT. CARE IN NURSING 173, 173–74 (2010).

⁸⁸ The Report operates from an “ethical paradigm referred to as principlism.” In this framework, “ethical principles are derived from moral theories.” However, studies have shown how the principles exemplified in the Report have cross-cultural limitations. For example, “the Western concept of autonomy focuses on the right of the individual, which contrasts to how certain Asian cultures consider autonomous decision making.” Nancy Shore, *Re-Conceptualizing the Belmont Report*, 14 J. CMTY. PRACTICE 5, 6–7 (2006).

⁸⁹ FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS (“COMMON RULE”), U.S. DEP’T. HEALTH & HUMAN SERV., <https://perma.cc/8EU9-CE9B> (last visited May 20, 2018).

⁹⁰ Victoria Berkowitz, *Common Courtesy: How the New Common Rule Strengthens Human Subject Protection*, 54 HOUS. L. REV. 923, 936 (2017).

effective informed consent.”⁹¹ Specifically, subjects must be given an opportunity to contemplate participation without undue coercion or influence. Additionally, the informed consent document must be given to the participant in a language they understand and it must explain the purpose, provide a contact for questions, and outline the foreseeable risks and benefits of the study. Finally, the document must be signed and informed consent may be withdrawn at any time for any reason without penalty.⁹²

In 2017, a set of revisions were finalized and applied to the “Common Rule.”⁹³ In total, three revisions were adopted: “reduce the types of research covered by the regulations, use a single IRB to review research conducted by multiple institutions, and improve the informed consent process.”⁹⁴

In legal analysis, informed consent, as it relates to medical experimentation, is a norm of customary international law as evidenced by the Geneva Conventions of 1949, The Nuremberg Code, and the International Covenant on Civil and Political Rights.⁹⁵ The Nuremberg Trials proved especially influential. Following the convictions, the court set forth The Nuremberg Code. It outlined ten standards that constitute the basic rules for conducting research on human subjects.⁹⁶ The first principle, establishing that “[t]he voluntary consent of the human subject is absolutely essential,”⁹⁷ is accompanied by two explanatory paragraphs:

This means that the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

⁹¹ *Id.* at 937 (quoting 45 C.F.R. § 46.116).

⁹² *Id.* at 937–38.

⁹³ George J. Annas, *Beyond Nazi War Crimes Experiments: Voluntary Consent Requirements of the Nuremberg Code at 70*, 108 AM. J. PUB. HEALTH 42, 44 (2018).

⁹⁴ *Id.*

⁹⁵ *Id.* at 42–43.

⁹⁶ *Id.* at 43.

⁹⁷ The Nuremberg Code, originally *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law at No. 10*, 181–82 (1946–1949) [hereinafter *Nuremberg Code*].

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.⁹⁸

On the whole, the first principle requires consent to be “voluntary, competent, informed, and understanding.”⁹⁹ Despite the evolving literature, regulations, and international treaties regarding medical ethics, The Nuremberg Code’s emphasis on informed consent is distinct and prominent.

Both the Geneva Convention of 1949 and the International Covenant on Civil and Political Rights (ICCPR) expand upon the Code’s understandings of voluntary and informed consent.¹⁰⁰ The Geneva Convention of 1949 explicitly prohibits the utilization of prisoners of war for medical experimentation.¹⁰¹ While the Convention only applies during war, the ICCPR, which took effect in 1966, applies in both war and peace.¹⁰² Specifically, Article Seven of the ICCPR states: “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”¹⁰³ Seventeen years after the convictions at Nuremberg, the Declaration of Helsinki (DOH) was developed.¹⁰⁴ At the time of its inception, the World Medical Association (WMA) called it “the most widely recognized source of ethical guidelines for biomedical research.”¹⁰⁵ Since it was promulgated in 1964, the DOH has been revised five times: Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996), and Edinburgh (2000).¹⁰⁶ The Declaration states:

⁹⁸ *Id.*

⁹⁹ Annas, *supra* note 93, at 43.

¹⁰⁰ *Id.* (“The Geneva Conventions, for example, assume that prisoners of war simply cannot provide voluntary consent to medical experiments and so prohibit them from being used in non-therapeutic experiments: No prisoner of war may be subjected to physical mutilation or to medical or scientific experiments of any kind which are not justified by the medical, dental, or hospital treatment of the prisoner concerned and carried out in his interested. (Article 13).”) (internal quotation marks omitted).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ International Covenant on Civil and Political Rights, Dec. 19, 1966, 999 U.N.T.S. 171 (entered into force Mar. 23, 1976) [hereinafter ICCPR].

¹⁰⁴ Solomon Ekundayo Salako, *The Declaration of Helsinki 2000: Ethical Principles and the Dignity of Difference*, 25 MED. & L. 341, 342 (2006).

¹⁰⁵ *Id.* (quoting Robert V. Carlson et al., *The Revision of the Declaration of Helsinki: Past, Present and Future*, 57 BRIT. J. CLIN. PHARMACOL. 695 (2004)).

¹⁰⁶ *Id.*

Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured. The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.¹⁰⁷

In 1982, the World Health Organization (WHO) and the Council for International Organisation for Medical Science (CIOMS) developed the International Guidelines for Biomedical Research Involving Human Subjects.¹⁰⁸ Revised in 2002, the Guidelines include specific provisions on vulnerable populations and procedures relating to consent, benefits, and safeguards.¹⁰⁹ Fifteen years after the development of the Guidelines, the European Convention on Human Rights and Biomedicine (ECHR) was ratified.¹¹⁰ While the ECHR reiterated many previously articulated understandings of consent, it also acknowledged developments in medicine such as genetic testing.

III. LEGAL-HISTORICAL ANALYSIS OF CONSENT

This section analyzes research records, legal responses, or lack thereof, and various forms of sociopolitical commentary on experimentation occurring before 1945. These documents and histories serve as evidence of both state practice and existing legal obligation to the principle of consent.¹¹¹ The evidence presented suggests that there were countervailing understandings of the legal necessity of consent before Nuremberg. This evidence does not contend that exploitation was non-existent, or that there was total consensus on the specific contours of consent within legal and medical communities; rather, it invites contemplation of the behaviors and acknowledgments of legal entities, medical communities, and the public, as it pertained to consent. These narratives provide

¹⁰⁷ World Medical Association, *Code of Ethics of the World Medical Association*, 2 BRIT. MED. J. 177, 177 (1946) (accepted at Helsinki in June 1964) [hereinafter Declaration of Helsinki].

¹⁰⁸ Salako, *supra* note 104, at 342.

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 342–43.

¹¹¹ It should be noted that the evidence presented here is largely Eurocentric. This overwhelming emphasis should not be construed as a denial of the history of non-European nations and their contributions to understandings of medical ethics, rights of bodily autonomy, and exercises of accountability for human experimentation; rather, it reflects the view that classical international law is not only borne out of a colonial history, but that imperialism is reproduced in the modern politics of which cultural practices are excluded in considerations of custom and sovereignty. By presenting these examples, this section does not intend to posit this conventional history as superior or facilitate the continued marginalization of non-European peoples; instead, it is meant to reflect the state of classical international law. This leaves the door open for future interrogations of the way customary international law interacts with colonialism to reinforce conventional histories as superior. *See, for example*, ANTONY ANGHIE, IMPERIALISM, SOVEREIGNTY AND THE MAKING OF INTERNATIONAL LAW 1–12 (2004).

support for the conclusion that consent was established as international customary law pre-1945 by providing examples of instances in which the right to bodily autonomy, the ethos of consent, acted as a basis for constraining, altering, or providing accountability for research behavior.

This section is organized in chronological order so as to give a historical understanding of the evolution of consent. While consent in the patient treatment context entered the lexicon in the late eighteenth century, medical experimentation as a practice did not take off until the early-to-mid nineteenth century; therefore, the bulk of this historical analysis focuses on this time period.

A. Early Conceptions of Consent

While pre-eighteenth century physicians focused on autonomy and had early formations of medical ethics, the principles explored in this era offer no substantial evidence of the widespread conduct of consent. There is evidence of the underlying ethos of consent, the principle of autonomy as a right, prior to the Enlightenment.¹¹² This principle of autonomy, “developed in the formulation of medical tradition and human rights,” has its origins in Roman and Stoic thought dating back to 400 B.C.¹¹³ However, the first detailed treatment of medical ethics comes from Hippocrates. Referred to as the “father of scientific medicine,” Hippocrates developed an observational approach that later became the foundation of medical experimentation.¹¹⁴ While little is known about Hippocrates the man, the “oath bearing his name is the oldest and most durable statement of medical ethics.”¹¹⁵ Despite its prominence, the Hippocratic approach did not advocate consent; rather, in many circumstances, it advocated intentionally concealing information so as to maintain hope.¹¹⁶

Despite Hippocrates’ opposition to informed consent, other philosophers of the time gave some credence to the idea of patients participating in the decision-making process. Plato compared “the Greek slave-physicians who gave orders ‘in the brusque fashion of a dictator,’ and the free physician, who takes ‘the patient and his family into confidence . . . [and] does not give prescriptions until he has won the patient support.’”¹¹⁷ Giving even more weight to consent was Henri De Mondeville, a French surgeon and anatomy teacher, who argued

¹¹² Salako, *supra* note 104, at 342.

¹¹³ *Id.*

¹¹⁴ FRANKENBURG, *supra* note 11, at 6.

¹¹⁵ *Id.*

¹¹⁶ Pernick, *supra* note 27, at 4.

¹¹⁷ *Id.* at 5 (quoting Mark Siegler, *Searching for Moral Certainty in Medicine: A Proposal for a New Model of the Doctor-Patient Encounter*, 57 BULL. N.Y. ACAD. MED. 56, 68 (1981)).

that if a patient's consent could not be obtained then a physician should not accept the case.¹¹⁸ De Mondeville's assertion was based on the idea that a defiant patient would have worse clinical outcomes. While not substantial enough to constitute evidence of widespread conduct, the philosophical musings of pre-eighteenth century physicians were nevertheless significant in laying the foundations of rights, autonomy, and joint decision-making.

B. Eighteenth Century

Evidence of consent as a constraining force during the eighteenth century is largely limited to European common law doctrines and the subsequent case history arising from theories of liability. For centuries in English common law, the tort of battery served as the basis of liability against physicians who treated patients without consent.¹¹⁹ This legal doctrine had one major exception—an emergency situation.¹²⁰ The focus of this theory of liability was the individual's bodily integrity, which meant that as a defense a physician could present evidence that the subject had either consented, or that their non-consent could not have been anticipated.¹²¹ Underlying the battery theory of liability was the principle of a right to self-determination, which is “the legal equivalent of the moral principle of respect for autonomy.”¹²² Eventually, the contemporary trend shifted away from battery to negligence as the preferred theory of informed consent liability.¹²³

Decided in 1767 in England, *Slater v. Baker & Stapleton* was the first documented case in which physicians were found liable for performing a procedure without a patient's consent.¹²⁴ After Slater's broken leg failed to

¹¹⁸ Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 YALE J. INT'L L. 401, 409 (1997).

¹¹⁹ Pernick, *supra* note 27, at 4. See also FADEN & BEAUCHAMP, *supra* note 38, at 26–27 (“Under battery theory the defendant is held liable for any intended (i.e., not careless or accidental) action that results in physical contact—contact for which the plaintiff has given no permission, express or implied, and which the defendant therefore knew or should have known was ‘unauthorized.’ . . . The defendant need not have an evil intent, nor must injury result; the unpermitted contact is itself considered offensive.”) (emphasis in original).

¹²⁰ FADEN & BEAUCHAMP, *supra* note 38, at 26–27.

¹²¹ *Id.* at 27–28.

¹²² *Id.* at 28.

¹²³ Courts have given many reasons for the shift towards negligence. Most prominent seems to be the idea that battery, which is seen as more drastic, is only useful in “situations where the procedure has not been disclosed at all.” See *id.* at 29.

¹²⁴ John I. Gallin, *A Historical Perspective on Clinical Research*, in PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH 1 (John I. Gallin & Frederick P. Ognibene eds., 3rd ed., 2012).

properly heal, he sought treatment from a physician named Baker.¹²⁵ Dr. Baker utilized a steel contraption to stretch Slater's leg, which led to further injury.¹²⁶ A jury awarded damages to Slater and the appeals court affirmed the award.¹²⁷ In its decision, the English court determined that without the consent of the patient, the utilization of such a radical instrument constituted malpractice:

[T]his was the first experiment made with this new instrument; and although the defendants in general may be as skillful in their respective professions as any two gentlemen in England, yet the Court cannot help saying that in this particular case they have acted ignorantly and unskillfully, contrary to the known rule and usage of surgeons.¹²⁸

In the absence of consent, the doctors' reckless engagement in experimentation led to legal liability.

Outside of the courtroom, during the late eighteenth century, some prominent European and American physicians developed the early formulations of medical traditions that encouraged the patient's "informed deference to the physician's scientific knowledge," which in turn would be reciprocated by "the physician's respect for the informed patient's autonomy."¹²⁹ While not a complete conception of consent, physicians, including John Gregory, Thomas Young, and Benjamin Rush, propagated these ideals as aligned with and stimulated by, the Age of Enlightenment.¹³⁰ In Rush's view, autonomy was essential because of the way in which it promoted individual and public health.¹³¹ Taking it a step further, Rush also believed that this autonomy must be predicated on accurate information; he encouraged fellow physicians to "strip our profession of everything that looks like mystery and imposture, and clothe medical knowledge in a dress so simple and intelligible, that it may become . . . obvious to the meanest capacities."¹³²

While these early ideas did reflect some reverence for the principles of autonomy and the need for information in order for consent to be valid, this may be attributable to the aims of the Enlightenment period, rather than a concerted attempt to establish ethical medical practice. Additionally, most physicians in this era subscribed to a paternalistic model of authority rather than

¹²⁵ George J. Annas, *Doctors, Patients and Lawyers—Two Centuries of Health Law*, 367 *NEW ENG. J. MED.* 445, 446 (2012).

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.* (quoting *Slater v. Baker and Stapleton*, C.B. Eng. Rep. 860 (Michelman Term, 8 Geo III, 1767)).

¹²⁹ Pernick, *supra* note 27, at 5.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.* at 6.

one based on the informed choice of the individual.¹³³ However, some effort was made to reconcile Rush's view with the paternalism of the day. Thomas Percival, one of the leading medical ethicists of his era, stated that, except in rare emergency situations, doctors should fully disclose all relevant information to patients.¹³⁴ While this articulation did not wholly comport with informed consent, debate about disclosure, particularly when connected with autonomy, can be understood as foundational to later understandings of consent.

C. Nineteenth Century

The nineteenth century, assisted by the invention of surgical anesthesia, new conceptions of cleanliness, and the creation of the microscope, ushered in a new era of medical research.¹³⁵ Researchers began to utilize procedures that allowed them to generate hypotheses and replicate their experimentation. Much of the early human experimentation focused on the development of vaccines. The uptick in experimentation led to an uptick in exploitation. It was normal and accepted for researchers to conduct their experimentation on those who were blind, intellectually disabled, poor, terminally ill, or engaged in sex work.¹³⁶ Researchers justified experimentation on these vulnerable populations by asserting that they were already "damaged."¹³⁷

As the nineteenth century ushered in a new era of medical research, researchers, philosophers, physicians, and scholars naturally began to weigh in on the accompanying medical ethics as they related to experimentation. In 1845, Dr. Maximilian Simon published the *Medical Deontology*, a monograph on medical ethics.¹³⁸ Within the monograph was an entire chapter dedicated to the ethics of experimentation entitled "The Limits with which Experimentation on Human Subjects Should be Maintained."¹³⁹ Simon insisted that a physician should under no circumstances be able to "sacrifice the interests of the individual to those of society": in experimentation, the harm to an individual could not be automatically justified by the benefits the discovery may bring to civilization as a

¹³³ *Id.* at 7.

¹³⁴ *Id.* at 9.

¹³⁵ FRANKENBURG, *supra* note 11, at 25.

¹³⁶ *Id.* at 26.

¹³⁷ *Id.*

¹³⁸ The monograph later appeared in the twenty-first volume of the British and Foreign Medical Review. See Alex Dracoby, *Ethics and Experimentation on Human Subjects in Mid-Nineteenth-Century France: The Story of the 1859 Syphilis Experiments*, 77 BULL. HIST. MED. 332, 352 (2003).

¹³⁹ *Id.*

whole.¹⁴⁰ Despite recognizing the necessity of experimentation for scientific progress, Simon was clear that humanity imposed “strict duties” on the physician—including that he or she exhaust known treatments before employing experimental ones and never subject even the “most useless” to experimentation that might put their lives in danger.¹⁴¹ While monographs of medical ethicists were novel, medical historian Charles Daremberg noted that Simon merely brought together commonly held views on general principles of medical experimentation.¹⁴²

In 1859, two French physicians, Joseph-Alexandre Auzias-Turenne and Camille-Melchior Gibert, relied on the importance of their discovery as justification for their non-consensual experiments. However, not a single medical journal “defended their actions as morally justified.”¹⁴³ At a hospital in Paris, the physicians injected four patients who already had lupus with the contents of syphilitic lesions.¹⁴⁴ The outrage to the experiment was twofold: first, the experiment itself was considered “radical,” and, second, the physicians had not obtained consent to conduct the experimentation.¹⁴⁵ “Although there were no fixed rules on this question, physicians were generally expected to obtain consent prior to risky, painful, or dangerous experimental procedures.”¹⁴⁶ In total, fifteen medical periodicals reported on hearings conducted by the Imperial Academy of Medicine on the ethical questions posed by the physicians’ procedures, and not one defended the experimentation as morally justified.¹⁴⁷ Nearly half unequivocally denounced the experiment’s procedures as unethical.¹⁴⁸

While the consequences for Auzias-Turenne and Gibert were merely professional, there were physicians of the same period who faced legal consequences for failing to obtain consent in their experimental procedures. Gerhard Armauer Hansen, a Norwegian physician, focused on experimentation

¹⁴⁰ *Id.* (quoting MAX SIMON, DÉONTOLOGIE MÉDICALE, OU DES DEVOIRS ET DES DROITS DES MÉDECINS DANS L’ÉTAT ACTUEL DE LA CIVILISATION 334 (1845)).

¹⁴¹ *Id.* at 352–53 (quoting SIMON, *supra* note 140, at 336–37).

¹⁴² *Id.* at 353.

¹⁴³ *Id.* at 355.

¹⁴⁴ FRANKENBURG, *supra* note 11, at 53.

¹⁴⁵ *Id.*

¹⁴⁶ Dracoby, *supra* note 138, at 358 (“Neither Simon nor Bernard discussed consent, but physicians often made clear in their published report that they had obtained consent prior to the experiment, especially if this involved great pain or risk.”).

¹⁴⁷ *Id.* at 355.

¹⁴⁸ *Id.*

to understand how leprosy was transmitted.¹⁴⁹ When he failed to transfer leprosy onto artificial mediums or animals, Hansen turned to self-inoculation, but still failed to develop leprosy.¹⁵⁰ Unable to develop the illness after injecting himself, Hansen then turned to experiments on patients without their consent.¹⁵¹ He utilized “a cataract knife which just previously had been used to cut a nodule from a patient suffering from nodular leprosy, on the eye of another female patient in the hospital.”¹⁵² After the patient experienced immense physical pain and suffering, she turned to the courts for remedy.¹⁵³ Despite the fact that some of Hansen’s colleagues defended him on the grounds that he had “made considerable contribution to the question in mention,” the City of Bergen Law Courts found Hansen “guilty for failure to obtain consent.”¹⁵⁴ As a result of the 1880 court finding, Hansen lost his job as a physician.¹⁵⁵ The legal outcome and subsequent consequences of Hansen’s experimentation represent one of the first times the court emphasized the importance of consent in clinical research, as opposed to just general procedures.¹⁵⁶ The court’s specificity here is critical—while some contend that one cannot conflate the underlying ethos of the consent principle without regard to context, the court provides an explicit reference to the necessity of consent in the experimental arena.¹⁵⁷ Additionally, the public nature of the scrutiny of Hansen’s procedures is evidence of a developing legal obligation. The court’s ability to find an individual who performed an experimental procedure guilty of “failure to obtain consent” would effectively put physicians on notice of the possibility of legal ramifications if they fail to get consent.

¹⁴⁹ Siang Yong Tan & Connor Graham, *Armauer Hansen (1841-1912): Discoverer of the Cause of Leprosy*, 49 SING. MED. J. 520, 520 (2008).

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ See T.M. Vogelsang, *A Serious Sentence Passed Against the Discoverer of the Leprosy Bacillus (Gerhard Armauer Hansen), in 1880*, 7 MED. HIST. 182, 184–85 (1963) (“Although she did not know the reason she had been asked to attend, she stayed anxiously beside the door and started to weep. The doctor asked her to come to the table. She then saw that he had a sharp-cutting instrument in his hand which he brought up to her eye . . . The defendant, however, admitted that he was not justified in carrying out the operation as he had neither obtained her permission in advance, nor told her of his aim in doing it. He had omitted this as he took for granted that the deponent would not regard the experiment from his point of view, and if something happened, he was sure he could get the affection under control.”).

¹⁵⁴ Tan & Graham, *supra* note 149, at 521.

¹⁵⁵ However, Hansen remained a medical officer of health for leprosy. *Id.*

¹⁵⁶ Gallin, *supra* note 124, at 9.

¹⁵⁷ *Id.*

The rise in the globalization of medical experimentation offers further evidence of conduct relating to consent that was not confined to one state's borders nor one group of nationals. While the modern era has seen a sharp increase in globalized medical experimentation,¹⁵⁸ researchers were traveling to other nations to test their medical experiments on other populations as early as the nineteenth century. In the late 1890s, Waldemar Mordecai Wolff Haffkine, a physician from Ukraine, travelled to India, where the population experienced massive cholera outbreaks.¹⁵⁹ Having tested his cholera vaccine on animals, himself, and three Russian friends, Haffkine caught the attention of a former colonial official, Lord Dufferin, who convinced him to travel to India, where thousands died from cholera.

Initially, Haffkine was met with suspicion by the local population.¹⁶⁰ In fact, locals attacked him upon arrival, breaking some of his equipment. In an effort to gain the locals' trust, Haffkine performed a demonstration in which he revaccinated himself. Once the locals saw the vaccine's effectiveness, or possibly the willingness of the researcher to inject himself with it, many in the community agreed to be vaccinated. Within two years, Haffkine and his colleagues vaccinated 42,000 individuals. In Assam, a state in northeast India, the mortality rate from cholera dropped from "between 22–45 percent to 2 percent" as a result of Haffkine's vaccines.¹⁶¹

Following the success of his cholera vaccine, the Indian government asked Haffkine for help in managing a deadly bubonic plague.¹⁶² After testing the vaccine on himself, Haffkine moved his medical experimentation to Byculla jail in Bombay, where the plague was running rampant.¹⁶³ According to recollections of his experiment, Haffkine sought volunteers, and on January 30, 1897, 143 volunteers were injected—including some outside the prison.¹⁶⁴ He remained on the prison premises to monitor the results. He next carried out his controlled experiment at the Byculla House of Correction. According to records of the experiment, 2,200 individuals were inoculated and the 6,000 that refused served as the control group.¹⁶⁵ At his next experimentation site, Aga Khan and 3,184 of

¹⁵⁸ Samantha Evans, *The Globalization of Drug Testing: Enforcing Informed Consent Through the Alien Tort Claims Act*, 19 TEMP. INT'L & COMP. L.J. 477, 477–78 (2005).

¹⁵⁹ FRANKENBURG, *supra* note 11, at 36.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ H.I. Jhala, *W. M. W. Haffkine, Bacteriologist—A Great Saviour of Mankind*, 2 HAFFKINE INST. 105, 112 (1967) ("He appealed for volunteers for his vaccine. The response was good.")

¹⁶⁵ *Id.*

his Khoja sect of followers were inoculated, while 9,516 refused and, again, served as a control group.¹⁶⁶

Beginning in 1897, physicians C.H. Bennett and W.B. Bannerman, utilized Haffkine's vaccine to inoculate a self-contained 26th Regiment of Madras Infantry, which was stationed in the city of Belgaum, located in the Indian state of Karnataka.¹⁶⁷ While Bennet and Bannerman's report does not detail their procedures, it provides evidence of utilizing a procedure of consent before inoculating subjects:

Little difficulty was experienced in persuading the men to consent to be operated on, when it was explained to them that they would be free to return to their lines after inoculation. The example set by General Rolland, the Officer Commanding, and the Medical Officer, who were operated on in front of the men, no doubt also helped to remove prejudice, and 229 sepoy were inoculated during the morning.¹⁶⁸

Additionally, the physicians reported that out of the 1,746 individuals in the population, only 1,665 were operated on.¹⁶⁹ Those not operated on included "infants, women far in advance in pregnancy, and the sick in hospitals chiefly, although one solitary sepoy has, up to the present refused to submit to operation."¹⁷⁰ Following the first inoculation, "[t]he men of the regiment were so satisfied with the effect . . . that they made no objection to being inoculated in August."¹⁷¹

Further evidence of the utilization of some process of consent is found in a letter to the editor published in the *Journal of the American Medical Association* in 1920.¹⁷² The author, Lester H. Beals, was a physician and self-identified "medical missionary."¹⁷³ Having assisted in over 30,000 inoculations, Beals notes, "[w]hen we first came here the people were slow to consent to inoculation, but they have now come to accept it readily in large numbers."¹⁷⁴

¹⁶⁶ *Id.*

¹⁶⁷ C.H. Bennett & W.B. Bannerman, *Inoculation of an Entire Community with Haffkine's Plague Vaccine*, 34 INDIAN MED. GAZETTE 192, 192 (1899).

¹⁶⁸ *Id.* at 193.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² Lester H. Beals, *Immunization against Plague: Experience of a Medical Missionary with Haffkine's Vaccine*, 75 J. AM. MED. ASS'N. 955, 955 (1920).

¹⁷³ *Id.*

¹⁷⁴ *Id.*

While the said consent may not comport to modern standards,¹⁷⁵ Beals presents evidence from the field of some working knowledge about the necessity of consent in some form. More importantly, the trans-national nature of the vaccine experimentation taking place in India demonstrates not only an early procedural commitment to consent, but one that was carried on outside of the physicians' place of origin. The continuity of consent utilized in trans-national experimentation offers evidence that the practice of consent was not compelled through expectations in only one geographic location.

Further evidence that the practice of consent was not merely becoming widespread, but that physicians were seeking consent out of a sense of legal obligation, is the way in which physicians directly responded to and adopted procedures of consent after experiments were publicly criticized. One of the earliest examples of experimentation that caused an international disturbance occurred when Italian physician, Giuseppe Sanarelli, injected five subjects with a solution containing the yellow fever virus without their consent in 1897.¹⁷⁶ Even though the experimentation did not result in any deaths, reports of the experiments caused "an international uproar"—with the ethics of his experimentation becoming the principal discussion at medical conferences.¹⁷⁷ The following year, influential physicians gathered and discussed Sanarelli's work.¹⁷⁸ William Osler, the preeminent clinician of the time, in response to Sanarelli's method, said: "[t]o deliberately inject a poison of known high degree of virulency into a human being, unless you obtain that man's sanction, is not ridiculous, it is criminal."¹⁷⁹

D. Twentieth Century

By the twentieth century, scientific advancement in understandings of medicine, illness, and disease increased the regularity of human experimentation.¹⁸⁰ The increase in research was accompanied by an increase in experimentation being performed on vulnerable populations. Additionally, wars

¹⁷⁵ *Id.* at 956 ("I have had the experience in later years of seeing great crowds gather around an inoculation place, clamoring for admission and actually pulling one another's coats off in the struggle to enter and get their turn to be inoculated, and this where, in former years, it took great persuasion at public meetings, and doles of one or two days wages for the poor, to get even a few to submit to inoculation.").

¹⁷⁶ FRANKENBURG, *supra* note 11, at 49.

¹⁷⁷ Some reports were mistaken, stating that the injections had caused yellow fever resulting in three deaths. *Id.*

¹⁷⁸ GALLIN & OGNIBENE, *supra* note 178, at 10.

¹⁷⁹ FRANKENBURG, *supra* note 11, at 50.

¹⁸⁰ *Id.* at 65.

and colonization drove exploitation, which had a profound impact on the selection of experimentation subjects.¹⁸¹

During the twentieth century, guiding principles and practices related to consent were formalized into documents, such as policy statements and domestic legislation. These early documents usually grew out of a public controversy. One of the best known experiments of the era was conducted by Albert Neisser, a German venereologist.¹⁸² Neisser infected four prostitutes with syphilis while trying to develop a vaccine against gonorrhea—without consent. As a result of his experimentation, Neisser discovered gonococcus, which is the bacteria that causes gonorrhea. Despite the value of his discoveries, the non-consensual nature of the experiments resulted in public outrage.¹⁸³ As a result of the outrage, the Prussian government assembled a panel of leading clinicians and lawyers.¹⁸⁴ After experts reviewed the case, Neisser was issued a fine, and the Prussian government issued a directive in 1900 known as the Berlin Code.¹⁸⁵ The directive forbade experiments on individuals without their express consent.¹⁸⁶ The directive stated that “medical interventions other than for diagnosis and treatment were forbidden under all circumstances if the subject was a minor, not competent, or had not given clear consent after having the procedure, including any adverse consequences, explained to him or her.”¹⁸⁷ Additionally, the Code insisted that the fulfilment of the above requirements had to be documented, and experimentation required authorization by medical directors.¹⁸⁸ While not legally binding, the regulations were among the first governmental interventions of their kind in the field of human experimentation.

In 1931, the German Reich minister of the interior elaborated on the guidelines presented in the directive.¹⁸⁹ Following the death of 72 children who received a contaminated vaccine for tuberculosis, the German government issued a circular entitled “Guidelines for New Therapy and Human Experimentation.”¹⁹⁰ The report reiterated many of the principles outlined in the

¹⁸¹ For example, American colonization in the Philippines allowed researchers to have access to prisons where they conducted yellow fever experiments.

¹⁸² Venereology is the branch of medicine which focuses on the study of sexually transmitted disease. FRANKENBURG, *supra* note 11, at 53.

¹⁸³ *Id.* at 54.

¹⁸⁴ *Id.* at 79.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* at 79–80.

¹⁹⁰ *Id.* at 79.

early directive, but differed in significant ways. First, it forbade experiments on dying persons, but allowed experimentation on children if the risk was low. It also advocated for physicians to be educated on ethical experimentation. Most importantly, these guidelines were not mere regulation—they became binding law.¹⁹¹

Despite utilizing vulnerable populations, several researchers mandated the collection of consent. Beginning in the early 1900s, American physicians Ernest Linwood Walker and Andrew Sellards began investigating dysentery in the Philippines.¹⁹² At the Bilibid Prison, Walker and Sellards began by explaining the project to the incarcerated individuals. Additionally, they obtained written informed consent from each participant prior to beginning the experimentation.¹⁹³ Their contributions to the field were not merely new understandings of amoebic dysentery, but also the utilization of *written* informed consent.¹⁹⁴ Written informed consent left a narrower space for dispute than mere verbal consent.

While many experiments conducted in the early twentieth century do not meet modern understandings of ethical research, they nevertheless utilized a form of consent. Despite the inadequacy of consent and some contemporary criticism, the experiments conducted by Joseph Goldberger at Rankin State Prison starting in 1915 exemplify understanding of the importance of voluntariness, even for incarcerated subjects—who were largely viewed as having diminished rights in the early twentieth century.¹⁹⁵ Goldberg partnered with the governor of Mississippi, Earl Brewer, to conduct experimentations focused on the infectious disease pellagra. Both Goldberg and Brewer met with inmates, offering them full pardons if they would eat a “traditional Southern diet for about six months, and therefore run the risk of developing pellagra.”¹⁹⁶ The promise of pardons does complicate the nature of the consent; nevertheless, the experiment was not a product of physical coercion or secrecy.¹⁹⁷

The public’s scrutiny of human experimentation, as well as the legal consequences for early researchers, helped spur on procedures and policies that safeguarded consent. Subsequent researchers working in the area of yellow fever heeded the lessons learned by Sanarelli. One of these researchers, Walter Reed, a

¹⁹¹ *Id.* at 80.

¹⁹² *Id.* at 69.

¹⁹³ *Id.* at 70.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 81.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 82 (“These so-called parties and the Rankin prison studies would probably have had trouble being approved today because of the risks to the subjects.”).

U.S. Army physician, adopted a policy requiring signed permission from all volunteers in his yellow fever experiments.¹⁹⁸ Reed was appointed to lead the United States Army Yellow Fever Commission of 1900 and 1901. Beginning in 1900, the commission began by experimenting on themselves in Cuba.¹⁹⁹ After receiving approval from military and civilian authorities, Reed established a site of experimentation in the Cuban countryside.²⁰⁰ The experiments began with 33 total subjects—18 American and 15 Spanish subjects.²⁰¹ The Spanish subjects were provided a document that outlined the risks of contracting yellow fever and also noted that there was no known cure for the disease.²⁰² The form emphasized several principles that are consistent with modern understandings of consent: “the respect for autonomy, the emphasis on voluntariness, the outlining of risks and benefits, and compensation.”²⁰³ One example of the form read as follows:

The undersigned, Antonio Benino, (signed) Antoni Benino being more than twenty-five years of age, native of Cerceda, in the province of Corima, the son of Manuel Benino and Josefa Castro here states by these presents, being in the enjoyment and exercise of his own free will, that he consents to submit himself to experiments for the purpose of determining the methods of transmission of yellow fever, made upon his person by the Commission appointed for this purpose by the Secretary of War of the United States, and that he gives his consent to undergo the said experiments for the reasons and under the conditions stated below.

The undersigned understands perfectly well that in case of the development of yellow fever in him, that he endangers his life to a certain extent but it being entirely impossible for him to avoid the infection during his stay in this island, he prefers to take the chance contracting it intentionally in the belief that he will receive from the said Commission the greatest care and the most skillful medical service.

It is understood that at the completion of these experiments, within two months from this date, the undersigned will receive the sum of \$100 in American gold and that in the case of contracting yellow fever at any time during his residence in this camp, he will receive in addition to that sum a further sum of \$100 in American gold, upon his recovery and that in case of his death because of this disease, the Commission will transmit the said sum

¹⁹⁸ GALLIN & OGNIBENE, *supra* note 178, at 11.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 148.

²⁰¹ *Id.*

²⁰² While the American subjects may have also been given consent forms, there is no documentation of these forms. *Id.*

²⁰³ FRANKENBURG, *supra* note 11, at 110.

(two hundred American dollars) to the person whom the undersigned shall designate at his convenience.

The undersigned binds himself not to leave the bounds of this camp during the period of the experiments and will forfeit all right to the benefits named in this contract if he breaks this agreement.

And to bind himself he signs this paper in duplicate, in the Experimental Camp, near Quermados, Cuba, on the 26th day of November nineteen hundred.²⁰⁴

Additionally, Reed included the phrase “with his full consent” in all of his published reports on yellow fever.²⁰⁵ Reed’s utilization of physical documentation, a step further than mere verbal agreement, may represent an increasing need to develop evidence of consent. The formality of the contracts may indicate that physicians were wary of legal accountability for experiments deemed unethical. Not only do Reed’s contracts affirm the practice of obtaining consent, but they also demonstrate a heightened understanding of the obligation. The formality of the procedures offers compelling evidence that Reed, and others who engaged in written contracts of this nature, thought of the attainment of consent as a legal duty to be fulfilled.

Further evidence of an evolving norm of consent, built on ample practice and *opinio juris*, were the ways in which publicly critiqued researchers would adapt their procedures in order to provide more robust autonomy to their subjects. Richard Pearson Strong, an American physician who was part of the first medical class at Johns Hopkins, utilized the backlash to his early work in order to inform more robust procedure for obtaining consent.²⁰⁶ Strong’s research on nutrition involved trials utilizing prisoners in Bilibid Prison in Manila. However, his advanced approach to consent was the result of international backlash to previous, fatal experimentation in the prison. In 1906, while studying the side effects of a cholera vaccine, twenty-four incarcerated individuals were injected with a contaminated vaccine.²⁰⁷ As a result, thirteen of these individuals died after contracting the bubonic plague. In addition to the error, the incarcerated individuals subjected to the research were not given an explanation of the experiment, nor did they give consent.²⁰⁸

²⁰⁴ William B. Bean, *Walter Reed and the Ordeal of Human Experiments*, 51 BULL. HIST. MED. 75, 86–87 (1977).

²⁰⁵ GALLIN & OGNIBENE, *supra* note 178, at 11.

²⁰⁶ FRANKENBURG, *supra* note 11, at 100.

²⁰⁷ *Id.* at 99.

²⁰⁸ *Id.*

While Strong did not face any criminal liability, the backlash and repercussions were undeniable.²⁰⁹ Following the deaths, Strong met with the Governor-General and offered his resignation, which the Governor refused to accept.²¹⁰ After a leak to the press, the Governor drafted a public statement.²¹¹ Subsequently, newspapers and private journals reported on the Bilibid incident, but the incident also piqued the attention of the U.S. government.²¹² Jacob Gallinger, a senator from New Hampshire and a physician, introduced a resolution to the Senate, which received unanimous approval.²¹³ The resolution required the Secretary of War to communicate to the Senate the facts of the experiment—specifically, the Senate sought to know “whether any of the persons so experimented upon were previously informed of the dangerous and possibly fatal character of the experiments.”²¹⁴ Later correspondence requested information about whether the vaccine was compulsory or voluntary. While the result of the investigation was no criminal negligence for Strong, the investigators questioned his use of individuals who were incarcerated, specifically noting “how difficult it would have been for prisoners to refuse to cooperate.”²¹⁵

Despite the lack of official consequences, the ordeal had a direct impact on Strong’s practices.²¹⁶ While he never worked with the vaccine again, in 1912 Strong conducted a nutrition experiment once again utilizing individuals incarcerated in Bilibid.²¹⁷ Strong’s procedures were materially altered from those utilized in his cholera vaccine disaster.²¹⁸ Each prisoner was given documents, written in their own language, explaining the details of the experiment and ensuring his voluntary participation.²¹⁹ As a form of payment, participants were also offered tobacco products in exchange for their participation. Despite the fact that the question of whether incarcerated individuals could give full consent remained unaddressed, Strong’s procedure demonstrated a heightened sensitivity to the value of expressed consent.²²⁰

²⁰⁹ Eli Chernin, *Richard Pearson Strong and the Iatrogenic Plague Disaster in Bilibid Prison, Manila, 1906*, 11 *REV. INFECTIOUS DISEASE* 996, 996 (1989).

²¹⁰ *Id.* at 998.

²¹¹ *Id.* at 999.

²¹² *Id.*

²¹³ *Id.* at 1000.

²¹⁴ *Id.*

²¹⁵ FRANKENBURG, *supra* note 11, at 99.

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.* at 100.

The increased sensitivity towards expressed consent began to find a place in mainstream medical dialogue and curriculum. While not a researcher, William Osler, one of the founding physicians of the Johns Hopkins Hospital, required full consent in human experimentation.²²¹ An admirer of the work of Walter Reed, Osler's contribution to the medical field included his contributions to medical education—most famously, *The Principles and Practice of Medicine*, which became a text famous among medical students and clinicians.²²²

In 1907, the Congress of American Physicians and Surgeons met in Washington D.C. for their seventh triennial session.²²³ Osler contributed “The Evolution of the Idea of Experiment in Medicine.”²²⁴ As a leading clinician and ardent supporter of medical experimentation, Osler traced the roots of experimentation, but also insisted on principles of consent and safety:

For man absolute safety and full consent are the conditions which make such tests allowable. We have no right to use patients entrusted to our care for the purpose of experimentation unless direct benefit to the individual is likely to follow. Once this limit is transgressed, the sacred cord which binds physician and patient snaps instantly. Risk to the individual may be taken with his consent and full knowledge of the circumstances, as has been done in scores of cases, and we cannot honor too highly the bravery of such men as the soldiers who voluntarily submitted to the experiments on yellow fever in Cuba under the direction of Reed and Carroll. The history of our profession is starred with the heroism of its members who have sacrificed health and sometimes life itself in endeavors to benefit their fellow creatures. Enthusiasm for science has, in a few instances, led to regrettable transgressions of the rule I have mentioned, but these are mere specks which in no wise blur the brightness of the picture—one of the brightest in the history of human effort—which portrays the incalculable benefits to man from the introduction of experimentation into the art of medicine.²²⁵

In American law, Justice Benjamin Cardozo is often credited for establishing that informed consent was necessary for self-determination.²²⁶ The landmark case, *Schloendorff v. Society of New York Hospital*,²²⁷ involved a woman with a fibroid tumor. The woman consented to an examination of the fibroid,

²²¹ *Id.* at 110–11.

²²² *Id.* at 111.

²²³ William Osler, *The Historical Development and Relative Value of Laboratory and Clinical Methods in Diagnosis: The Evolution of the Idea of Experiment in Medicine*, TRANSACTIONS CONG. AM. PHYSICIANS & SURGEONS 1, 1 (1907).

²²⁴ *Id.*

²²⁵ *Id.* at 7–8.

²²⁶ Powderly, *supra* note 22, at 25.

²²⁷ *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914).

but clearly did not consent to an operation.²²⁸ However, while the woman was anesthetized, the physician, wishing to avoid the risk associated with a second anesthesia, surgically removed the fibroid.²²⁹ In finding liability for the physician, Cardozo stated: “Every human being of adult years and sound mind has the right to determine what shall be done with his body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.”²³⁰ Despite the historical credence given to the *Schloendorff* case, case notes and records from physicians pre-1914 indicate the utilization of consent in practice.²³¹

The proliferation of human experimentation was not merely limited to the U.S. From 1930 to 1945, human experimentation in Japan burgeoned.²³² Much of this research grew out of efforts to establish Japanese biological warfare (BW) techniques for use against Soviet troops.²³³ Under Lieutenant General Shirô Ishii, biological weapons research flourished as military and medical forces aligned to carry out human experimentation.²³⁴ In 1936, Ishii was appointed as chief of the Kwantung Army’s Water Purification Bureau, which “became a cover for the developing network of BW personnel located in Harbin (Unit 731), Peking (Unit 1855), Nanking (Unit 1644), Canton (Unit 8604), and Singapore (Unit 9420).”²³⁵

In postwar interrogation, Kawashima Kyoshi, chief of the Production Division of Unit 731 from 1941 to 1943, acknowledged occupied territories were used to obtain persons for human experimentation who were not of Japanese nationality.²³⁶ Over a ten-year period, Unit 731 carried out human experimentation that resulted in an estimated 3,000 deaths.²³⁷ Individuals, typically resisters of Japanese rule, were infected with plagues, inoculated with experimental vaccines, forced to drink typhoid-contaminated water, and exposed

²²⁸ *Id.* at 128.

²²⁹ Powderly, *supra* note 22, at 24–25.

²³⁰ *Id.* at 25.

²³¹ *Id.* (“Alexander Skene often expressed beneficence-based, and even paternalistic, beliefs about what should be done for his patients. He did not, however, with the possible exception of his Asylum practice, subject patients to treatment against their will. He sought consent from patients, negotiated with others, and perhaps even coerced some with his explanations and expertise. But in the end, if they did not agree with him, he yielded to them and continued to care for them.”).

²³² Baader et al., *supra* note 9, at 220.

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.*

²³⁶ *Id.* at 221.

²³⁷ *Id.*

to freezing temperatures as a means of studying frostbite.²³⁸ Aerial bombs containing bacteria were dropped as a means of investigating how best to carry out biological warfare.²³⁹

Despite the expansive nature of the medical experimentation, efforts were made to conceal their true brutality.²⁴⁰ Scientific journals and papers documenting the experimentation often obscurely referred to the humans utilized as mere “research material, sometimes disguised as ‘monkeys,’²⁴¹ and often disparagingly called *maruta* (logs).”²⁴² In later testimony, it was revealed that “the designation as ‘logs’ was used for ‘security reasons.’”²⁴³ Additionally, when the Soviet Union advanced in Manchuria in August of 1945, all evidence of the medical atrocities was intentionally destroyed by the Japanese Army.²⁴⁴ The efforts taken to dehumanize and hide the contours of the experimentation offer some evidentiary basis that there was at least a moral, if not legal, understanding of the unjustified brutality of the experimentation.

After the war, U.S. forces did investigate Unit 731, but the Japanese researchers and military personnel escaped punishment for their war crimes.²⁴⁵ From 1945 to 1946, during the Kamakura Conference, American officials and Unit 731 members created an agreement: in return for the immunity of Ishii and his researchers, American authorities received access to the results of their experimentation.²⁴⁶ The U.S. State-War-Navy (Departments) Coordinating Committee outlined in a secret report that “[t]he value to the U.S. of Japanese BW [biological warfare] data is of such importance to national security as to far

²³⁸ *Id.* at 221–22.

²³⁹ *Id.* at 222.

²⁴⁰ *Id.* at 223.

²⁴¹ A paper published in 1944 by Surgeon General Masaji Kitano, Commander of Unit 731, describes an experiment as follows: “We made an emulsion with 203 ground-up North Manchuria mites and salt water, and injected it into the thigh of an ape hypodermically. This first ape became feverish with a temperature of 39.4 degrees Celsius on the 19th day after injection and moderately infected. Then we took blood of this feverish ape and injected it into the second ape, which became feverish and produced protein in its urine.” TAKASHI TSUCHIYA, *THE IMPERIAL JAPANESE EXPERIMENTS IN CHINA, THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS* 31–45 (Ezekiel Emmanuel et al. eds., 2008).

²⁴² Baader et al., *supra* note 9, at 223.

²⁴³ JING BAO NIE ET AL., *JAPAN’S WARTIME MEDICAL ATROCITIES: COMPARATIVE INQUIRIES IN SCIENCE, HISTORY AND ETHICS* 76 (2010).

²⁴⁴ “At Unit 731, all the surviving captives were killed, cremated, and cast into the Songhuajiang River. The main building with its special prisons was totally destroyed by artillery.” TSUCHIYA, *supra* note 241, at 41.

²⁴⁵ Baader et al., *supra* note 9, at 224.

²⁴⁶ *Id.*

outweigh the value accruing from ‘war crimes’ prosecution.”²⁴⁷ Additionally, a 1947 report detailing the alleged human experimentation stated, “[s]uch information could not have been obtained in our own laboratories because of scruples attached to human experimentation.”²⁴⁸

Despite the lack of accountability imposed by the U.S., beginning on December 25, 1949, the Soviet Union tried twelve members of Unit 731 in the Khabarovsk trials.²⁴⁹ However, “the West dismissed the trials as communist propaganda and not much attention was paid to the proceedings.”²⁵⁰ While the trials did not gain much attention, the transcripts present a portrait of medical personnel and military awareness of the legal liability they might face if their experimentation was discovered:

Question: What do you wish to add to your testimony?

Answer: I fully realize that Detachment 731 was a criminal organization which manufactured means for exterminating human beings by barbarous methods prohibited by international rules. . . . Serving in the detachment, I participated in these criminal activities and committed a crime against humanity, for which I must pay the penalty.²⁵¹

The Japanese military personnel were charged under Article 1 of the Decree of the Presidium of the Supreme Soviet of the U.S.S.R.²⁵² While the language of the Article focused on war crimes and did not specifically mention consent, the trial included an expert commission on bacteriological and medical issues.²⁵³ Furthermore, the indictments were divided into four categories, one being “the commission of criminal experiments on living human subjects.”²⁵⁴ The charges for participation in human experimentation were brought against four defendants while three others were “accused of knowingly permitting the experiments to proceed.”²⁵⁵

During arguments, L. Smirnov, State Counsel for the Prosecution, stated:

²⁴⁷ Patrick Fong, *Inter Arma Enim Silent Leges: The Impunity of Japan’s Secret Biological Warfare Unit*, 6 NEW ENG. INT’L & COMP. L. ANN. 79, 86 (2000) (quoting PETER WILLIAMS & DAVID WALLACE, UNIT 731: JAPAN’S SECRET BIOLOGICAL WARFARE IN WORLD WAR II 210 (1989)).

²⁴⁸ BAO NIE ET AL., *supra* note 243, at 61.

²⁴⁹ Fong, *supra* note 247, at 87.

²⁵⁰ *Id.*

²⁵¹ OTOZO YAMADA, MATERIALS ON THE TRIAL OF FORMER SERVICEMEN OF THE JAPANESE ARMING: CHARGED WITH MANUFACTURING AND EMPLOYING BACTERIOLOGICAL WEAPONS 69 (1950).

²⁵² BAO NIE ET AL., *supra* note 243, at 63.

²⁵³ *Id.* at 64.

²⁵⁴ *Id.*

²⁵⁵ *Id.* at 65.

It has been proved that, in Unit 731, inhuman experiments on living human subjects were carried out not only for research into bacteriological warfare. There were also, no less inhuman and painful experiments, which . . . were carried out on a larger scale. These experiments were aimed at determining the limits of a human organism's endurance under specific conditions, and at studying . . . the prevention and treatment of non-infectious disease.²⁵⁶

The reliability of the Khabarovsk Trial remains contested.²⁵⁷ While some individuals have dismissed it as mere propaganda, in recent years authors have argued that portions of the trial present irrefutable data. Among these voices is bioethicist Nie Jing-Bao, who has stated that “the trial established beyond reasonable doubt the facts about Japanese BW war crimes including systematic cruel human experimentation, and its conclusions turn out to be remarkably accurate.”²⁵⁸

While on their own these case studies highlight foundational principles of consent, an analysis of these principles in light of The Nuremberg Trial highlights the true prominence of these norms.

IV. ASSESSING CONSENT IN LIGHT OF NUREMBERG

A. Background Information

The Nuremberg Trials occurred from 1946 to 1947 and featured twenty-three medical scientists and physicians.²⁵⁹ These scientists and physicians were charged with murder and torture-related crimes, which took place in the context of medical experimentation on imprisoned individuals in concentration camps.²⁶⁰ The specific allegations asserted that the experiments “were sadistic and often lethal, and the prisoners did not give their consent.”²⁶¹

Interestingly, the testimony of various individuals, most notably Werner Leibbrandt and Dr. Andrew C. Ivy, vigorously referenced the obligation of every physician to obtain consent.²⁶² While they each had a different theoretical understanding of consent, the crux of their testimony was undeniable: consent was necessary in order to conduct ethical experimentation.²⁶³

²⁵⁶ *Id.* at 67.

²⁵⁷ *Id.* at 70.

²⁵⁸ *Id.* at 71.

²⁵⁹ Evelyn Shuster, *American Doctors at the Nuremberg Medical Trial*, 108 AM. J. OF PUB. HEALTH 47, 47 (2018).

²⁶⁰ *Id.*

²⁶¹ FRANKENBURG, *supra* note 11, at 197.

²⁶² *Id.*

²⁶³ *Id.*

B. The Testimony of Werner Leibbrandt

One of the leading experts the prosecution called to testify was Werner Leibbrandt.²⁶⁴ Leibbrandt, a neuropsychiatrist and a medical historian, was persecuted by the Nazis because of his political views and his marriage to a Jewish woman.²⁶⁵ Leibbrandt's testimony included an analysis of the ways in which Hitler, as well as doctors generally, perverted Hippocratic ethics in their programs of involuntary euthanasia, medical experimentation without consent, and various torturous experiments.²⁶⁶ One of the doctors he cited was Albert Moll, an internationally known and respected physician who "as early as 1920 had denounced doctors who conducted experiments on patients without their consent."²⁶⁷

Additionally, Leibbrandt condemned the medical experimentation on the basis of one of the longest standing moral codes: the Hippocratic Oath.²⁶⁸ Specifically, Leibbrandt testified, "[t]he Hippocratic Oath had been the universal legal and moral code of physicians for 22 centuries and had explicitly forbidden causing harm to patients, injustice, and immorality. Nazi doctors and SS members who had said they relied on the Hippocratic Oath in their practices were simply grotesque."²⁶⁹

However, Leibbrandt's condemnation of the experimentation went further. During cross-examination, the defense lawyers argued that common good was superior to individual welfare.²⁷⁰ Unmoved by anecdotes of experiments conducted in other nations on incarcerated peoples without their consent, Leibbrandt boldly asserted that all experiments on imprisoned individuals were unethical because the coercive nature of their situation precluded voluntary consent.²⁷¹ Underlying Leibbrandt's argument was an emphasis on the humanity of the individuals subjected to experimentation—his argument was consistent with understandings of bodily autonomy.

²⁶⁴ Shuster, *supra* note 259, at 48.

²⁶⁵ *Id.*

²⁶⁶ *Id.* at 48–49.

²⁶⁷ *Id.* at 48.

²⁶⁸ *Id.* at 49.

²⁶⁹ *Id.* (citing *United States v. Karl Brandt*, 1 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10 (1949)).

²⁷⁰ Shuster, *supra* note 259, at 49.

²⁷¹ *Id.* (citing *Karl Brandt*, *supra* note 269, at 1992) ("[A]ny experiment on prisoners is unethical because prisoners are in a forced situation and cannot be volunteers, regardless of what they say or sign.").

The relevance of Leibbrandt's testimony is that it almost exclusively relied on evidence that consent was the normative conduct expected from physicians. Not only was acknowledgment of the necessity of consent widespread, as evidenced by Leibbrandt's citation of Dr. Moll, but also that it had historical roots, as evidenced by his reference to the longstanding Hippocratic Oath. Leibbrandt's testimony thoroughly conflicts with the idea that the consent concept articulated post-1945 was novel—instead, he articulates a pre-existing history of ethics and consent upon which the experiments were legally condemnable.

C. The Testimony of Dr. Andrew C. Ivy

The only physician to testify during the trials was an American doctor, Andrew C. Ivy, the former director of the Naval Medical Research Institute.²⁷² Ivy was nominated by the American Medical Association (AMA) after they were tasked with selecting an individual with expertise on the “rules and practices in prison research.”²⁷³ Lasting three days and comprising 295 pages of the official transcript, Ivy's testimony focused on conditions of research in “civilized” nations, common research principles, and physician obligations.²⁷⁴

Prior to the trial, Ivy had been tasked with examining the conditions of experimentation in various states. The culmination of his findings were three principles that “reflected ‘common agreement and research practices.’”²⁷⁵ The first principle read: “Consent of the human participant must be obtained. All participants have been volunteers in the absence of coercion in any form. Before volunteering, participants have been informed of the hazards, if any.”²⁷⁶

Despite his articulation of consent, Ivy's testimony diverged from Leibbrandt's views on incarcerated individuals participating in medical experimentation. Unlike Leibbrandt, Ivy determined that someone who was incarcerated may be a volunteer when “a competent person says ‘yes’ or ‘no’ without fear of being punished or deprived of privilege due him in the ordinary course of events.”²⁷⁷ However, the significant overlap in Ivy and Leibbrandt's understanding of common practice was that medical experiments required consent.

²⁷² Shuster, *supra* note 259, at 49.

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

While Ivy acknowledged in cross-examination that there were no *written* research principles in the United States before 1946, the principles he developed were not devoid of any history.²⁷⁸ Throughout his testimony, Ivy frequently stated that he relied on Hippocratic ethics; however, he eventually had to admit that there were “differences between a treating physician who acts in his patients’ best interests and a physician-investigator whose goal is to test a scientific hypothesis for the benefit of society rather than the participant.”²⁷⁹

Like Leibbrandt, Ivy’s testimony relied on an analysis of state practice regarding experimentation. In fact, Ivy’s practice of ascertaining what the common research practice was is not dissimilar to the inquiry being undertaken in this historical analysis: to ascertain what widespread beliefs about experimentation would have created the obligation to establish consent from subjects. Again, Ivy’s ability to draw these conclusions undermines Katz’s view of the historical development of consent—Ivy was able to establish consent as a common research principle based on pre-1945 standards.

D. The Impact of the Testimony

The impact of both Ivy and Leibbrandt’s analysis is evident in the Nuremberg judgment. In closing argument, chief prosecutor James McHaney stated, “[i]f the experimental subjects cannot be said to have volunteered, then the inquiry need proceed no further . . . This requirement reflects not just the view of an individual or of an American doctor, but the opinion of all medical men, and decent people of the civilized world.”²⁸⁰ This sentiment was reflected in the court’s ultimate judgment, which articulated the right to “voluntary, competent, informed, and understood consent.”²⁸¹

Disturbingly, at the time of the Nazi experiments, Germany had some of the most advanced regulations on medical ethics in the world.²⁸² In fact, physicians could hardly claim ignorance as, post-1933, two comprehensive governmental guidelines had been implemented.²⁸³ The impact of the first was to unequivocally state that consent was required for research, but regardless, vulnerable subjects were not to be research participants.²⁸⁴ The second, which

²⁷⁸ *Id.*

²⁷⁹ *Id.* at 50.

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² FRANKENBURG, *supra* note 11, at 120.

²⁸³ The two governmental guidelines were the Berlin Code and “Guidelines for New Therapy and Human Experimentation.” *Id.* at 79.

²⁸⁴ *Id.*

was legally binding under State law, reiterated the necessity of consent, but went a step further in banning high-risk experiments on children or terminally ill individuals.²⁸⁵

As part of their defense, the lawyers representing the Nazi physicians argued that the conditions of experimentation were similar to the Stateville prison experiments.²⁸⁶ There, in conjunction with the U.S. Army, the University of Chicago began a series of malaria experiments at Stateville Penitentiary in 1944. While portions of the experiments are now considered unethical, one distinguishing factor from the Nazi experiments was the use of written and signed consent. After researchers explained the study to the incarcerated individuals, each inmate signed consent forms. The Stateville experiments were well publicized and received coverage in *Life* magazine. In all publications, the subjects were referred to as “voluntary subjects,” and most mentioned that they were “proud to be contributing to the war effort.”²⁸⁷

The conclusions here are threefold. First, the standards articulated in Nuremberg did not merely emerge. Instead, they track onto a widespread norm in which physicians conducting research perceived an obligation to receive legal permission. Second, the actual principles articulated by The Nuremberg Code were not radical; rather, previous German regulations held physicians conducting experimentation to a higher standard of consent. Lastly, despite the undoubtedly questionable ethics promulgated in various studies around the globe, the prosecution was required to distinguish cases based on their utilization of some form of consent. In this way, the American doctors as well as much of the world were only able to resist culpability for their experimentation by contending that an obligation of consent existed prior to 1945.

This Comment only provides an overview of legal and social history, but also omits a multitude of cases where physician and research behavior did not conform to the suggested norm. Despite the prevalence of these examples, their existence does not foreclose the claim being made. The character of customary international law is such that “[i]t is inherently not consensual.”²⁸⁸ Unlike other law, customary international law comes from normative, but not uniformly existing beliefs.²⁸⁹ While customary law does require a practice to be widespread, it recognizes the limitations on this requirement by not demanding full agreement.²⁹⁰ Indeed, some scholars have even argued that in certain

²⁸⁵ *Id.*

²⁸⁶ *Id.* at 145.

²⁸⁷ *Id.* at 147.

²⁸⁸ Kelly, *supra* note 49, at 464–65.

²⁸⁹ *Id.* at 465.

²⁹⁰ *Id.*

circumstances considerable countervailing practice may not foreclose a finding of a sufficient customary norm.²⁹¹

While the question of consent was present throughout the early twentieth century, the question was narrow. Contemplations of consent, both in practice and scholarly works, did not usually address whether vulnerable populations, such as individuals who were incarcerated or psychiatric patients, were able to give fully informed consent.²⁹²

V. ESTABLISHING CUSTOMARY INTERNATIONAL LAW BASED ON THE PRECEDING HISTORICAL ANALYSIS

Before the 1850s, the idea of human experimentation in the medical context primarily focused on experiments that were conducted for the benefit of the individual.²⁹³ “[H]uman experimentation—interfering with human bodies to try to understand how they work and help healing—happened only occasionally and usually on a small scale.”²⁹⁴ However, technological advancements of the nineteenth century allowed human experimentation to flourish. Its prominence simultaneously brought life-saving interventions and brutal exploitation.

The first component necessary for establishing customary international law, widespread practice, is evidenced by the multitude of doctors, across different nations and engaging in a variety of experiments, who utilized increasingly formalized methods of consent. The preeminent clinician of the nineteenth century, Osler, responded to non-consensual methods of experimentation with not mere disgust, but assertions that it was criminal.²⁹⁵ Forty-five years prior to the Nuremberg Trials, the state of Prussia issued a directive that explicitly forbade experimentation without consent.²⁹⁶ In 1930, the German Minister of Interior picked up on the directive.²⁹⁷ Even in American prisons, physicians materially altered their methods—particularly after coming

²⁹¹ See Niels Peterson, *The International Court of Justice and the Judicial Politics of Identifying Customary International Law*, 28 EUR. J. INT’L L. 357, 362–63 (2017) (“Furthermore John Tasioulas offers a ‘moral judgment-based account of customary international law.’ Tasioulas argues that ‘customary norms can come into being despite the absence of general state practice, or at the extreme, even in the teeth of considerable countervailing practice.’ He allows for a trading-off of state practice against *opinio juris* if the norm in question is of high moral importance for the legitimacy of international law.”).

²⁹² FRANKENBURG, *supra* note 11, at 66.

²⁹³ Katz, *supra* note 118, at 401.

²⁹⁴ FRANKENBURG, *supra* note 11, at 1.

²⁹⁵ *Id.* at 50.

²⁹⁶ *Id.* at 79.

²⁹⁷ *Id.*

under public scrutiny.²⁹⁸ The historical analysis demonstrates that the custom of evidence was not merely widespread geographically, but widespread in its application to particularized populations.

The second element, *opinio juris* or the belief that this conduct is engaged in on the basis of legal obligation, is evidenced by changing state policies, domestic law, and the responsiveness of physicians to their peers' legal entanglements. In the eighteenth century, the English common law began to define and enforce obligations of the physician to respect a right to bodily integrity through battery theories of liability.²⁹⁹ This evolved through case law, notably *Slater v. Baker & Stapleton*,³⁰⁰ which gave notice to physicians—consent was not a mere moral musing, but a legal obligation. The nineteenth century built on these obligations as physicians faced growing scrutiny, professional disgrace, and even court verdicts of “guilty for failure to obtain consent.”³⁰¹ Reinforcing that this obligation was not merely confined to Western nations, the yellow fever experiments of India and Cuba reveal that the obligation of consent did not end at one's own geographical borders.³⁰² Instead, the formalized documentation of physicians and researchers, such as Reed, reinforce the increased formality with which consent was sought.

VI. CONCLUSION

In an effort to address the exploitative conditions of experimentation in the modern era, the International Criminal Court opened in 2002.³⁰³ As a “permanent Nuremberg,” the court has jurisdiction over biological experiments, torture, and inhuman treatment. Despite this jurisdictional oversight of human experimentation, the U.S. has refused to subject itself to the jurisdiction of the court.³⁰⁴ Most oversight and accountability of human experimentation remains limited to peer ethical review, federal regulation, and domestic law—specifically tort law.³⁰⁵ Despite widespread recognition of the prominence of Nuremberg, federal regulations, at least in the U.S., have departed from Nuremberg in significant ways. Most notably, these regulations “address medical institutions that sponsored research, rather than physicians and scientists who actually

²⁹⁸ *Id.* at 100.

²⁹⁹ Pernick, *supra* note 27, at 4.

³⁰⁰ Gallin, *supra* note 124, at 9.

³⁰¹ Tan & Graham, *supra* note 149, at 521.

³⁰² Bennett & Bannerman, *supra* note 167, at 192; FRANKENBURG, *supra* note 11, at 149.

³⁰³ Annas, *supra* note 93, at 43.

³⁰⁴ *Id.*

³⁰⁵ *Id.*

conducted research; and their protections were primarily procedural (including the review board and forms) rather than substantive.”³⁰⁶

Today, informed consent is distended by complex forms, the primary concern of which is protecting institutions from liability, rather than the bodily autonomy of human subjects.³⁰⁷ Too often, the subjects of this experimentation are vulnerable individuals. From incarcerated men in Philadelphia being exposed to agents of chemical warfare,³⁰⁸ to the injection of viral hepatitis in children with developmental disabilities,³⁰⁹ cases of disregard for ethical standards are not difficult to come by. While not a holistic solution in and of itself, expanding the notion of the custom of informed consent is part of the expanding opportunities for legal liability and requiring higher standards of accountability.

The atrocities of Nuremberg, and the subsequent Codes that resulted, had the effect of characterizing the crimes of the Nazi physicians as exceptional. The sadism of the experimentation led to physicians asserting that the principles articulated by The Nuremberg Code were not applicable to their “less sadistic” experimentation. By demonstrating, through a historical analysis, the obligation that existed to informed consent in medical experimentation pre-1945, physicians are not given the same opportunity to disregard their customary obligation.

³⁰⁶ *Id.* at 44.

³⁰⁷ *Id.*

³⁰⁸ Barron H. Lerner, *Subjects or Objects? Prisoners and Human Experimentation*, 356 *NEW ENG. J. MED.* 356 (2007).

³⁰⁹ Eric G. Yan & Kerim M. Munir, *Regulatory and Ethical Principles in Research Involving Children and Individuals with Developmental Disabilities*, 14 *ETHICS & BEHAVIOR* 31, 32 (2004).