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# **REFUAH SHE'EINAH BEDUKAH: JEWISH MEDICAL ETHICS AND EXPERIMENTAL TREATMENT**

**Antonio G. Tapia\***

## **ABSTRACT**

Modern medical experimentation and practical doctrines such as informed consent prompt ethical tensions that test adherents and promulgators of religion and law. This article explores difficult questions and positions for followers of Halacha - the legal part of Talmudic literature including Jewish tenets and law - when faced with health care decisions in secular Western cultures. These concerns include the impact of the Halachic approach on the physician-patient relationship, informed consent, and even use of experimental techniques and the resultant data. Jewish medical ethics and Western secular law define different duties influencing the physician-patient relationship. The duty of care owed by secular American medical practice is based on contract, while Halachic tradition obligates the Jewish physician to heal the sick under a different paradigm. Also, while the secular tradition pays deference to patient autonomy, Halachic tradition mandates that the patient give consent for and undergo the best available medical treatment as custodians of G-d's creation. This paper illuminates the need for an integrative

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\* Antonio G. Tapia is a registered patent attorney and chief attorney for AGT Law, P.A. He is also an adjunct professor at the Florida Agricultural & Mechanical University College of Law in Orlando, Florida, where he teaches intellectual property, privacy, and antitrust courses. Bruce Chatman, who is a candidate to receive his J.D. from the Florida Agricultural & Mechanical University College of Law in 2019, contributed to this article.

approach whereby secular law and medicine may advance in a manner that promotes innovation while respecting the dignity and uniqueness of the individual follower of important Halachic traditions.

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*I. Introduction: Jewish Medical Ethics and Experimental Treatment*

Medical experimentation, like other hot topics, sparks much controversy and disharmony between religious and legal perspectives. Between and within each organized mode of thought, the tension arises out of the varied positions for and against the use of human subjects. For some the primary concern is philosophical; for others more empirical concerns prevail.

The Jewish legal tradition, which has been alive for millennia, is often at odds with the modern Western legal tradition. The same can be said for the body of medical ethics for both cultures. Mind you, this does not suggest that these modes of thought are mutually exclusive. Certainly, the Jewish perspective and the secular perspective have had some influence on each other over time. The lines blur as Jewish citizens of the West begin to look to outside sources for guidance in reconciling philosophical and legal tensions. Reconciliation of Jewish and secular law approaches to human experimentation will require an examination into the bodies of medical ethics and the duties that influence the physician-patient relationship.

“Jewish medical ethics can be defined as the resolution of bioethical problems based upon the application of philosophical principles in a manner that is consistent with the adhered tenets and traditions of Judaism.”<sup>1</sup> This Halachic approach, derived from divinely revealed law, informs the inquiry into complex questions in the medical realm. “The role of *Halacha* [(a comprehensive system of laws; literally – the way)] in Jewish tradition has been so central that all of classical Jewish philosophy and theology have been derived through its analysis and interpretation.”<sup>2</sup> This approach is distinct from the Western secular approach in that it “result[s] in interpretations that become normative and binding and ultimately constitute obligatory behavior.”<sup>3</sup> The Western approach takes a more philosophical approach to tough bioethics questions, and when combined with a strong cultural emphasis on individual autonomy, it is often hard to discover or impose a unified cultural consensus.

This article will cast bioethical questions through a Jewish law lens and attempt to examine the influence of the Halachic approach on cases

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<sup>1</sup> LOUIS FLANCAUM, “. . . AND YOU SHALL LIVE BY THEM”: CONTEMPORARY JEWISH APPROACHES TO MEDICAL ETHICS 4-5 (Mirkov Publications, 2001).

<sup>2</sup> *Id.* at 6.

<sup>3</sup> *Id.* at 9.

of human experimentation in the medical arena. The reader will find, after a significant inquiry into the influencing medical ethics and duties, that both Jewish and secular law favor an absolute bar on experimentation on humans that is either non-consensual or not likely to yield more benefit than risk to the individual.

## II. *Duties to Oneself and Others*

### A. *What Are the Duties of Physicians?*

#### 1. *Secular Law: Duty to Treat and the Physician-Patient Relationship*

It is important to understand the basic duties imposed on and held by physicians in the secular American environment. Generally, the physician's duty of care is based on contract.<sup>4</sup> The offer occurs when a patient appears in the doctor's office.<sup>5</sup> This may be a response to the doctor's advertisement of services.<sup>6</sup> The acceptance occurs when an appointment is made and the doctor agrees to see the patient.<sup>7</sup> This is an implied contract.<sup>8</sup> Submitting materials may also create an implied contract.<sup>9</sup> There can also be an express oral or written contract.<sup>10</sup> Because often the terms of the contract are unclear, the specifics of the relationship matter on a case by case basis.<sup>11</sup>

The physician-patient contract is voluntary.<sup>12</sup> Doctors do not have to accept new patients (not even in emergency situations).<sup>13</sup> The doctor's motive of refusal is not relevant.<sup>14</sup>

The contract, and therefore, the duty of the physician to the patient may be terminated.<sup>15</sup> A doctor may terminate the doctor patient relationship if there is a termination by mutual consent, an explicit dismissal

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<sup>4</sup> BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 201 (6th ed., West 2008).

<sup>5</sup> *Id.* at 202.

<sup>6</sup> *Id.* at 201.

<sup>7</sup> *Id.* at 202.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 201.

<sup>11</sup> *Id.* at 202.

<sup>12</sup> *Id.* at 201.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 627.

<sup>15</sup> *Id.* at 201 (citing *Jewson v. Mayo Clinic*, 691 F.2d 405 (8<sup>th</sup> Cir. 1982)).

by the patient, a physician's withdrawal after reasonable notice, a cessation of the necessity that gave rise to the relationship,<sup>16</sup> and a failure of the patient to cooperate with care.<sup>17</sup>

There are statutory exceptions that affect the common law duty. These are embodied in the Emergency Medical Treatment and Active Labor Act (EMTALA),<sup>18</sup> the American's with Disabilities Act (ADA),<sup>19</sup> § 701 of the Federal Rehabilitation Act (FRA),<sup>20</sup> and Title VI of the Civil Rights Act of 1964.<sup>21</sup>

EMTALA prohibits the denial of care to certain classes of patients.<sup>22</sup> It was enacted in response to widespread "patient dumping."<sup>23</sup> It applies only to hospitals that accept payment from Medicare and have an emergency room.<sup>24</sup> This act had to be tied to Medicare to be effective.<sup>25</sup> The statute allows patients to bring civil suits for damages against a participating hospital, but not a treating physician.<sup>26</sup> Simply put, EMTALA places minimum standards for stabilization of a patient even when a voluntary contractual relationship does not exist.<sup>27</sup>

The FRA, ADA, and Title VI of the Civil Rights Act of 1964 mandates and imposes a duty on physicians not to discriminate on the basis of disability<sup>28</sup> or race.<sup>29</sup> The ADA<sup>30</sup> prohibits discrimination against patients with disabilities from facilities that accept federal funds.

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<sup>16</sup> Weiss v. Rojanasathit, 975 S.W.2d 113, 119-120 (Mo. 1998).

<sup>17</sup> Brumbalow v. Fritz, 358 S.E.2d 872, 873 (Ga. Ct. App. 1987).

<sup>18</sup> Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2015).

<sup>19</sup> Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101-12213 (LexisNexis, LEXIS through PL 115-39, approved 6/6/17).

<sup>20</sup> Federal Rehabilitation Act of 1973, 29 U.S.C. § 701 (LexisNexis, LEXIS through PL 115-39, approved 8/17/17).

<sup>21</sup> 42 U.S.C. § 2000d (1964).

<sup>22</sup> See generally Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2015).

<sup>23</sup> Gatewood v. Washington Healthcare Corp., 933 F.2d 1037, 1039 (D.C. Cir. 1991) (affirming district court's dismissal of widow's claims under the EMTALA, but alternatively holding that the widow failed to state a claim cognizable under the Act); see H.R. Rep. No. 241, 99<sup>th</sup> Cong. 1<sup>st</sup> Sess. Pt. 1, at 27 (1985).

<sup>24</sup> FURROW ET AL., *supra* note 4, at 610.

<sup>25</sup> James v. Sunrise Hosp., 86 F.3d 885, 886 (9<sup>th</sup> Cir. 1996) (quoting Eberhardt v. City of Los Angeles, 62 F.3d 1253, 1255 (9<sup>th</sup> Cir. 1995)).

<sup>26</sup> FURROW ET AL., *supra* note 4, at 610.

<sup>27</sup> 42 U.S.C.S. § 1395dd(b)(1)(A) (2015).

<sup>28</sup> 42 U.S.C.S. § 12112; 29 U.S.C.S. § 794.

<sup>29</sup> FURROW ET AL., *supra* note 4, at 634.

<sup>30</sup> Federal Rehabilitation Act of 1973, 29 U.S.C. § 701 (LexisNexis, LEXIS through PL 115-39, approved 8/17/17). Through Congressional measures, the FRA was transformed and incorporated into the ADA.

Title VI “prohibits discrimination on the basis of race, color or national origin by any program receiving federal financial assistance.”<sup>31</sup> Hospitals that receive Medicare or Medicaid funding must not discriminate.<sup>32</sup> In order to bring a private action under Title VI, only intentional discrimination is actionable.<sup>33</sup>

## 2. *Jewish Law: Beneficence, Paternity, and Autonomy*

Jewish law takes a different approach. A cardinal principal of Judaism is that human life is of infinite value.<sup>34</sup> “In order to preserve human life, the Sabbath and even the Day of Atonement may be desecrated, and most other rules and laws are suspended.”<sup>35</sup> In fact, a physician is obligated to use his medical skills to heal the sick and does not consider contractual relationships.<sup>36</sup> The Halacha clearly states in the Shulchan Aruch that “a physician who withholds himself from healing is guilty of shedding blood.”<sup>37</sup>

By studying the Israeli physicians’ strike of 1983, the reader may be able to extract the modern state of duties imposed upon physicians. Because physicians were on strike, a council of Rabbis and Jewish law experts issued a ruling on the matter.<sup>38</sup> At its simplest, the following principles were decreed: 1) physicians may not withhold treatment;<sup>39</sup> and 2) physicians may do no harm.<sup>40</sup>

Lord Immanuel Jakobovits, former Chief Rabbi of Great Britain, delineates further principles governing the physician’s interaction with a patient.<sup>41</sup> These principles attempt to establish a boundary and clarify the interaction between the concepts of autonomy, beneficence, and paternity.<sup>42</sup> Of the six principles, the first, second, and sixth are similar to those already discussed. The first principle states that “[i]t is a religious

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<sup>31</sup> FURROW ET AL., *supra* note 4, at 634.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*; Alexander v. Sandoval, 532 U.S. 275 (2001).

<sup>34</sup> See FRED ROSNER, BIOMEDICAL ETHICS AND JEWISH LAW 47 (KTAV Publishing House, Inc., 2001).

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 44.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 43-44.

<sup>39</sup> See Yoreh Deah 336:1.

<sup>40</sup> ROSNER, *supra* note 34, at 44 (quoting Rambam, Chovel Umazik 8:1 that “it is prohibited for a person to wound either himself or his fellow man”).

<sup>41</sup> FLANCAUM, *supra* note 1, at 84.

<sup>42</sup> *Id.* at 85-86.

obligation to protect human life and health, incumbent upon a doctor as upon any other person in a position to do so.”<sup>43</sup> The second principle states that “[a] doctor is therefore never morally entitled to withhold or withdraw his services, whether or not a contractual relationship exists between him and his patient, unless a more competent doctor is available.”<sup>44</sup> “A refusal to render medical aid where required is deemed as tantamount to shedding blood.”<sup>45</sup> The third principles expounded by Jakobovits will be discussed later regarding the patient’s obligation not to refuse treatment. He states that “[a] patient has no right to refuse medical treatment deemed essential by competent medical opinion for the preservation of his or her life or health, and his or her consent need not be procured for such treatment.”<sup>46</sup>

Lastly, the sixth principle states that “the onus of choosing between various alternative forms of medical treatment, or none at all, rests upon the doctor, and patients should never be expected to render what are purely medical decisions.”<sup>47</sup> These three principles reinforce the ideas regarding a doctor’s duty to treat and the obligation of a patient to act as a custodian.

Lord Jakobovits’ last three principles governing a physician’s duties are of special importance in regard to experimental treatments. The fourth principle states that “in the discharge of the doctor’s obligation to save life and limb, and in the absence of the patient’s consent, the doctor may even be required to expose himself to the risk of legal claims for unauthorized ‘assault and battery.’”<sup>48</sup> This is an especially important mandate in the realm of medical experiments. This creates a clear Halachic prohibition and relationship between harming a patient and consent.

The fifth principal is also significant in the analysis of Jewish law and experimentation. It states that “while the patient should always be informed of treatments and procedures to be applied, prior consent is required, and should be sought, only in cases of a) high risk treatments, b) doubtful or experimental cures, and c) differences of opinion among

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<sup>43</sup> *Id.* at 84.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 84-85.

<sup>46</sup> *Id.* at 85.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

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equally competent medical experts.”<sup>49</sup> This is an express Halachic prohibition of performing experimental treatments without consent.

*B. What Are the Duties of the Patient?*

*1. Secular Law: Autonomy and Informed Consent*

The patient also exhibits a spectrum of duties regarding healthcare. In the Western secular tradition, it is hard to suggest that a patient has any duty at all with regard to their health. This largely stems from the emphasis on autonomy and individualism throughout the West. For the purposes of this article and comparison, I will limit my explanation to the American law principle of informed consent.

“Informed consent has developed out of a strong judicial deference to individual autonomy.”<sup>50</sup> Therefore, the individual has the “right to be free from nonconsensual interference with his or her person” and cannot be forced to “act against his or her own will.”<sup>51</sup> Informed consent has six functions: “1) protect individual autonomy, 2) protect the patient’s status as a human being, 3) avoid fraud or duress, 4) encourage doctors to carefully consider their decisions, 5) foster rational decision-making by the patient and, 6) involve the public generally in medicine.”<sup>52</sup>

There also exists a spectrum of informed consent standards in American law. They are: 1) legal consent, 2) professional disclosure, 3) the reasonable patient standard, and 4) full disclosure.<sup>53</sup> Legal consent is the least protective of all schemes in American law. It refers to the institutional practice of using a consent form or similar device.<sup>54</sup> For legal consent the law requires that institutions document consent in a patient’s record and obtain consent if experimental therapy is used. Under legal consent no experimental treatment is authorized.<sup>55</sup>

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<sup>49</sup> *Id.*

<sup>50</sup> FURROW ET AL., *supra* note 4, at 230; *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (1914)

<sup>51</sup> FURROW ET AL., *supra* note 4, at 230.

<sup>52</sup> *Id.* at 231; Alexander Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U.PENN.L.REV. 340, 365-76 (1974).

<sup>53</sup> BARRY R. FURROW ET AL., *HEALTH LAW: 123-24* (3rd ed., West 2015).

<sup>54</sup> FURROW ET AL., *supra* note 4, at 287.

<sup>55</sup> *Id.*

Professional disclosure was until recently the standard in England.<sup>56</sup> This standard requires more than just a form, but less than assessing all the alternatives. It focuses on what the doctor thinks is professionally required to be disclosed.<sup>57</sup> This standard exhibits high therapeutic privilege (i.e., the doctor has a lot to say about what goes on).<sup>58</sup> This approach is highly paternal and does not allow the patient to make an informed decision.<sup>59</sup>

The reasonable patient standard offers the best middle ground between patient autonomy and medical paternalism. “The test for determining whether a particular peril must be divulged is its materiality to the patient’s decision; all risks potentially affecting the decision must be unmasked.”<sup>60</sup> This could include the patient’s psychological ability to handle a truthful disclosure.<sup>61</sup> This is highly subjective.<sup>62</sup>

Lastly, and the most autonomous, is the full disclosure standard. In this standard, low weight is given to what the physician thinks is relevant and grants high autonomy for the patient.<sup>63</sup> This too fails to mimic the standard imposed by Jewish law.

There are only two exceptions in American law to informed consent.<sup>64</sup> The doctor may act without consent if “the patient is unconscious or otherwise incapable of consenting, and harm from failure to treat is imminent and outweighs any harm threatened by the proposed treatment.”<sup>65</sup> The doctor may also withhold information if “risk-disclosure poses such a threat of detriment to the patient as to become unfeasible or contraindicated from a medical perspective.”<sup>66</sup> Either way, none of these standards integrate fully with the Jewish law perspective.

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<sup>56</sup> Sarah W. Chan, Ed Tulloch, E Sarah Cooper, Andrew Smith, Wojtek Wojcik & Jane Norman, *Montgomery and informed consent: where are we now?*, THE BMJ (May 12, 2017), <http://www.bmj.com/content/357/bmj.j2224>.

<sup>57</sup> See, e.g., *Woolley v. Henderson*, 418 A.2d 1123 (Me. 1980).

<sup>58</sup> FURROW ET AL., *supra* note 4, at 287.

<sup>59</sup> See generally *id.*

<sup>60</sup> *Canterbury v. Spence*, 464 F.2d 772, 786-87 (D.C. Cir), *cert. denied*, 409 U.S. 1064 (1972).

<sup>61</sup> *Id.* at 789.

<sup>62</sup> *Id.* at 791.

<sup>63</sup> FURROW ET AL., *supra* note 4, at 1160.

<sup>64</sup> *Id.* at 283.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

## 2. *Jewish Law: Custodians of G-d's Creation*

Unlike the secular informed consent doctrine, whereby a patient can refuse treatment altogether, Jewish law imposes an obligation on patients to undergo treatment.<sup>67</sup> The obligation is based on the Jewish law view that individuals are responsible for their bodies while on earth.<sup>68</sup> They are, in essence, custodians of G-d's creation.<sup>69</sup> The obvious conclusion becomes then, "if man is charged with being the prudent steward of his body, required to accept medical treatment," then there therefore can be no "meaningful concept of informed consent in Jewish Law."<sup>70</sup>

In contrast, Daniel Eisenberg, M.D., in his article *Medical Informed Consent in Jewish Law – from the Patient's Side*, urges that this is not the case.<sup>71</sup> Eisenberg argues that "Judaism requires a type of informed consent that, while not identical to the secular concept, in some ways is actually more stringent than its secular counterpart."<sup>72</sup> To him, the key distinction between the secular and Jewish approaches centers on the "difference between rights and obligations."<sup>73</sup> The secular approach has a key focus on the autonomy of the patient.<sup>74</sup> The Jewish law approach takes a paternalistic approach whereby the patient has the duty to BOTH become informed AND give consent for the best available treatment.<sup>75</sup> "[A]s the prudent steward of one's body, one MUST acquaint oneself with all reasonable medical options, including inaction, before making a decision. But after evaluating all reasonable options, the Torah requires one to choose the sensible option, the one that the prudent steward would choose."<sup>76</sup> One may only refuse treatment until she is convinced that the proposed course of treatment is prudent.<sup>77</sup>

The Jewish patient's decision on prudence of a procedure is based on two different medical treatments: "those about which the medical ef-

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<sup>67</sup> FLANCAUM, *supra* note 1, at 65.

<sup>68</sup> *Id.*

<sup>69</sup> Daniel Eisenberg, *Medical Informed Consent in Jewish Law – from the Patient's Side*, JEWISH LAW, <http://www.jlaw.com/Articles/MedConsent.html> (last visited Feb. 23, 2018).

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

ficacy is known (refuah bedukah) and those where the efficacy is unproven (refuah she'einah bedukah).<sup>78</sup> In cases involving refuah bedukah, Jewish authorities have held that the patient "is obligated according to Halacha to undergo treatment."<sup>79</sup> In cases of refuah she'einah bedukah, the patient is generally given more autonomy.<sup>80</sup> This distinction will become very important later in this article during the discussion of experimental procedures.

### III. *Human Experimentation*

#### A. *Secular Law: Statutory and Case Law Bars*

Law governing human experimentation is, with the exception of constitutional law, one of the only places in American law that expressly incorporates moral language into the statutory text.<sup>81</sup> The Nuremberg Code is such an attempt to legislate the prevention of human experimentation.<sup>82</sup> This code was borne of the tragedies perpetrated by Nazis on categories of "special" persons.<sup>83</sup> The ten concepts that inform decisions on human experiments under the Nuremberg Code require consent, and they address the balance of risks and benefits.<sup>84</sup>

<sup>78</sup> FLANCAUM, *supra* note 1, at 69.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 70.

<sup>81</sup> FURROW ET AL., *supra* note 4, at 1569.

<sup>82</sup> *See generally id.*

<sup>83</sup> *Id.* at 1569-70.

<sup>84</sup> Nuremberg Code: Permissible Medical Experiments: 1) The voluntary consent of the human subject is absolutely essential. 2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature. 3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment. 4) The experiment should be so conducted as to avoid all unnecessary physical suffering and injury. 5) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur except, perhaps, in those experiments where the experimental physicians also serve as subjects. 6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. 7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death. 8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment by those who conduct or engage in the experiment. 9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible. 10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the

What is stunning for the new examiner of American law is that Americans too have been involved in experimentation on human subjects.<sup>85</sup> While the United States was prosecuting Nazi doctors, the U.S. government was conducting research on human radiation by injecting subjects (claimed to be terminally ill, and not informed as to the nature of their treatment) with plutonium or uranium.<sup>86</sup> Other instances of American violations of the Nuremberg Code include the Tuskegee Syphilis Study.<sup>87</sup> In this study many disenfranchised individuals were infected with syphilis so that the government could track the progress of the disease. Even though penicillin was available and shown to be a proper treatment, scientists prohibited and discouraged the infected subjects from seeking treatment.<sup>88</sup>

Public disclosure of the Tuskegee Syphilis Study in 1974 led Congress to enact the National Research Act (“NRA”).<sup>89</sup> In turn, the NRA established the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research (“National Commission”).<sup>90</sup> The role of the National Commission was to “conduct a comprehensive investigation and study to identify basic ethical principles that should underlie the conduct of human subject research.”<sup>91</sup> This report led to the creation of institutional review boards (“IRB”) in almost every university, medical school, and research hospital.<sup>92</sup> These principles were eventually codified in the Code of Federal Regulations (“CFR”).<sup>93</sup> Within the CFR, issues such as to what the policy applies, IRB creation and regulation, informed consent, and use of federal funds, were addressed.<sup>94</sup> Similar steps have been taken abroad by the promulgation of the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.<sup>95</sup>

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good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject.

<sup>85</sup> *Id.* at 1573.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 1574.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 1575.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *See generally* 45 C.F.R. §§ 46.101-46.124 (2017).

<sup>94</sup> *Id.*

<sup>95</sup> FURROW ET AL., *supra* note 4, at 1571.

Protecting vulnerable subjects is also accomplished through research regulation litigation. *Grimes v. Kennedy Krieger Institute, Inc.*<sup>96</sup> is a perfect case to consider. The Court of Appeals considered two distinct actions involving negligence of a corporation and children that “allegedly developed elevated levels of lead dust in their blood while participating in a research study” with Kennedy Krieger Corporation.<sup>97</sup> Both of the claims asserted that “the children were poisoned, or at least exposed to the risk of being poisoned, due to negligence on the part of the corporation.”<sup>98</sup>

The trial court ruled that a corporation conducting a non-therapeutic scientific study of lead paint abatement did not have a duty to warn minor volunteer participants and/or their legal guardians regarding dangers present when the researcher had knowledge of the potential for harm and the subjects were unaware of the danger.<sup>99</sup> The appeals court disagreed.<sup>100</sup> The appeals court reasoned that research programs at issue in the case normally create special relationships and/or can be of a contractual nature which creates a duty.<sup>101</sup> Breach of such duties could ultimately result in viable negligence actions.<sup>102</sup> At the very least, there were viable and genuine disputes of material fact concerning whether a special relationship or other relationships arising out of agreements giving rise to duties existed between the corporation and both sets of appellants. Based on the record, no degree of parental consent and no degree of furnished information to the parents could have made the experiment at issue ethically or legally permissible.<sup>103</sup> It was wrong in the first instance. The appeals court held the trial court erred in granting summary judgment.<sup>104</sup>

Overall, the combination of statute and litigation has created express and strict requirements in the American legal system against experimentation on vulnerable human subjects.

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<sup>96</sup> *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001).

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 818.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 861.

<sup>101</sup> *Id.* at 819.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

*B. Jewish Law: Refuah She'einah Bedukah*

Risk-benefit analysis is extremely relevant in Jewish law analyses.<sup>105</sup> For any treatment, even those *refuah bedukah* whose risks are well known, a risk-benefit analysis still exists.<sup>106</sup> However, despite the real risk inherent in any medical procedure, *refuah bedukah* tends to favor treatment.<sup>107</sup> In cases of *refuah she'einah bedukah*, the risk-benefit analysis may not clearly favor treatment or non-treatment.<sup>108</sup> In these cases Jewish law grants the patient more autonomy, and in certain cases one can refuse treatment.<sup>109</sup> This still does not mirror the secular document of informed consent.

However, what is to be said for the experimental treatment that may achieve results such as a long term cure for the patient? It is important to stress that this question only concerns itself with curing the individual patient and not future individuals. Dr. Louis Flancbaum, an expert in general surgery, trauma surgery, gastrointestinal surgery, bariatric surgery, surgical critical care, and nutrition support with over 20 years of clinical experience, argues that in cases where risks and outcome of medical treatment are uncertain, the patient, as custodian of his body, still "retains the prerogative to subject himself to an increased short term risk of dying . . . in order to potentially achieve a cure or normal functioning."<sup>110</sup> How does this apply to cases of medical experimentation?

The autonomy of a patient in circumstances of experimental treatment provides two options.<sup>111</sup> First, the patient may retain full autonomy.<sup>112</sup> As such, the patient may refuse experimental treatment.<sup>113</sup> The corollary to refusal of course is the option to agree to undergo the experimental procedure.<sup>114</sup> This too is allowed in these special cases.<sup>115</sup>

How does Jewish law address instances of human experimentation involving participation in a study or clinical trial? This question is altogether different than the one immediately above. In this case, the results

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<sup>105</sup> FLANCAUM, *supra* note 1, at 102.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.* at 102-103.

<sup>111</sup> *Id.* at 103.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

will not necessarily benefit the participant, but may ultimately help others.<sup>116</sup> Since there is a prohibition against placing oneself in danger,<sup>117</sup> the permissibility of participating in human experiments depends upon the risks involved.<sup>118</sup> If the risks to the participants or the side effects of the experiment are minimal, some say that it is permissible.<sup>119</sup> This view is documented in the Tziz Eliezer,<sup>120</sup> the Lev Avraham,<sup>121</sup> the Central Conference of American Rabbis,<sup>122</sup> and the NARR.<sup>123</sup> Prohibition of participation in experiments entailing high risk is reflected and recorded in the very same sources.<sup>124</sup>

Jewish law also recognizes the fact that some individuals might feel that the potential to save other lives by participating in experiments outweighs any risk to themselves.<sup>125</sup> Jewish law responds to that notion of sacrifice and altruism by retorting, “Who knows that your blood is redder? Perhaps his blood is redder.”<sup>126</sup> It is important to remember that the sense of stewardship and custodianship of G-d’s creation supersedes all other factors.<sup>127</sup> Humans do not exert unrestricted proprietorship over their own bodies and may not sacrifice them in order to save others.<sup>128</sup> Arguably, the only permissible voluntary participation with experimental treatment is where there is a possibility for benefit to the patient and there is no other available alternative for treatment.<sup>129</sup> Only in this instance do medical experiments align themselves with the obligation to act as a custodian of G-d’s creation.<sup>130</sup>

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<sup>116</sup> *Id.*

<sup>117</sup> Babylonian Talmud, Shabbat 32a.

<sup>118</sup> FLANCAUM, *supra* note 1, at 104.

<sup>119</sup> *Id.*

<sup>120</sup> Tziz Eliezer (Responsa of R. Eliezer Waldenberg) XII, #101.

<sup>121</sup> See generally Avraham Steinberg, *Medical Halachic Decisions of R. Shlomo Zalman Auerbach*, 3 ASSIA- JEWISH MED. ETHICS 30, 30-43 (Jan. 1997) (medical ethics work) (containing many responses of R. Shlomo Zalman Auerbach that were otherwise not published).

<sup>122</sup> See generally Central Conference of American Rabbis, <http://ccarnet.org/about-us/> (referring to Responsa #17).

<sup>123</sup> See generally WALTER JACOB, CONTEMPORARY AMERICAN REFORM RESPONSA (Central Conference of American Rabbis, 1988). The Tziz Eliezer, the Lev Avraham, the Central Conference of American Rabbis, and the NARR are all significant as powerful and respected voices of Rabbinic thought in the religious life of the American and international Jewish communities.

<sup>124</sup> FLANCAUM, *supra* note 1, at 104.

<sup>125</sup> *Id.* at 103.

<sup>126</sup> Babylonian Talmud, Sanhedrin 74a.

<sup>127</sup> FLANCAUM, *supra* note 1, at 69-70.

<sup>128</sup> *Id.* at 104.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

IV. *Synthesis – Past Results, Present Use, and Future Experimentation*

Since the advent of medical technology, more and more possibilities and attempts to conduct human experiments have surfaced. Because progress will never be stayed, nor should it ever be, the Jewish and secular law communities must now work to create a framework that determines the permissibility of future experimentation. How may existing and improperly collected data be used, if at all? What experiments on humans will be permissible in the future?

A. *Sins of Nazi Doctors: Reliance On or Banishment Of Existing Improperly Collected Data*

To Jewish and secular perspectives on human experimentation, it is clear that the procedures executed by Nazi doctors on unwilling participants violate all sense of morality and dignity. The only real tension present today regarding Nazi procedures is whether modern science can use the improperly collected data, and if so, how?

Some scientists believe that use of the Nazi's data would justify the horrors perpetrated, and dishonor the victims.<sup>131</sup> Others believe that it would be a travesty not to use the Nazi data, considering that the damage is already done and lives can genuinely be saved through its use.<sup>132</sup>

"The data should be taboo," said Dr. Benno Muller-Hill, a molecular biologist and director of the Institute for Genetics at the University of Cologne in West Germany.<sup>133</sup> "We should remember those who died. We should not try to squeeze a profit out of it."<sup>134</sup> Other scientists reject the use of the data on another basis.<sup>135</sup> According to Dr. Roger Berger, a heart surgeon at the Harvard Medical School, the Dachau freezing experiments had "all the ingredients of a scientific fraud."<sup>136</sup> Sigmund Rascher was trying to prove an idea of Himmler's.<sup>137</sup> In doing so he failed to record essential data, as required by scientific methods, and

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<sup>131</sup> Isabel Wilkerson, *Nazi Scientists and Ethics of Today*, N.Y. TIMES, May 21, 1989, § 1 at 34.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* (internal quotations omitted).

<sup>135</sup> *Id.*

<sup>136</sup> Nicholas Wade, *The Errors of Nazi Science: Even in Dachau, an Urge to Falsify*, N.Y. TIMES, May 27, 1990, at E12.

<sup>137</sup> *Id.*

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some of his results were so doubtful as to suggest fabrication.<sup>138</sup>

Scientists supporting the use of Nazi data argue that it would serve no purpose to science to ignore data that could help people.<sup>139</sup> “We are talking of the use of the data, not participation in these heinous studies, not replication of the atrocities,” said Dr. Benjamin Freedman, a bioethicist at McGill University in Montreal.<sup>140</sup> “The wrongs perpetrated were monstrous; those wrongs are over and done. How could the provenance of the data serve to prohibit their use?”<sup>141</sup>

Dr. Robert Pozos, Director of the Hypothermia Laboratory at the University of Minnesota of Medicine at Duluth, and Dr. John Hayward, a Biology Professor at the Victoria University in Vancouver, Canada, who conducts hypothermia research, “see it criminal *not* to use the available data, no matter how tainted it may be.”<sup>142</sup> Dr. Hayward justifies using the Nazi Hypothermia data in the following way:

I don’t want to have to use the Nazi data, but there is no other and will be no other in the ethical world. I’ve rationalized it a bit. But not to use it would be equally bad. I’m trying to make something constructive out of it. I use it with my guard up, but it’s useful.<sup>143</sup>

Ultimately, there is a bright-line consensus among conservative Americans and Jewish law scholars. According to Attorney Baruch Cohen, “the moral climate in the Jewish community is unforgiving to those who find any redeeming merit from Nazi horrors.”<sup>144</sup> Even though there is a split within the secular school of thought, the fact that the data is being discredited and medical journals veto the publication of studies that incorporate Nazi data, implies that it is more likely that Nazi data will be discarded as a scientific tool.

### *B. Future Experimentation*

Secular and Jewish law approaches to experimentation create an absolute bar to any experimentation on an unknowing or non-consenting

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<sup>138</sup> *Id.*

<sup>139</sup> Wilkerson, *supra* note 131.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* (internal quotations omitted).

<sup>142</sup> Baruch C. Cohen, *The Ethics of Using Medical Data From Nazi Experiments*, <http://www.jlaw.com/Articles/NaziMedEx.html> (last visited Feb. 26, 2018).

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

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human, or in any case where the risks outweigh the potential benefit.<sup>145</sup> However, the question has been posed: What is the stance of Jewish law in cases where even though the participant is not aware of all aspects of his treatment, no major harm comes to the patient? An example of this may be an instance where a psychiatrist, Dr. Smith, selects a group of similarly situated patients to conduct an efficacy study without their knowledge. Throughout the course of this “study,” Dr. Smith prescribes a different dosage of medication so that he may monitor over time which yields the best result. One could argue that the psychiatrist is still fulfilling his duties under the physician-patient relationship contract. Each patient is getting the required attention and minimum dosage of medication. No patients are in deteriorating conditions. In essence the doctor is doing no harm, and aiding in treatment, even though still subversively experimenting on his human subjects.

Some optimists may say that this hypothetical is too contrived. This could never happen. However, it happens on a regular basis, as doctors attempt to respond to the constantly changing supply of available and new prescription drugs.

The “no harm, no foul” mentality does not excuse this doctor’s behavior. According to the secular law approach discussed above, this doctor is violating patients’ autonomy and not considering any accepted standard of informed consent. Of the functions of informed consent, the doctor 1) is not protecting individual autonomy, 2) is not protecting the patient’s status as a human being, 3) is committing fraud upon the patient, and 4) is not fostering rational decision-making by the patient.<sup>146</sup> These are clear violations of the policy behind informed consent requirements.

Of the standards of informed consent, only the reasonable patient standard and full disclosure would govern this situation. The reasonable patient standard, even though highly subjective, still suggests that experimentation involving unorthodox use of prescription drugs is material to the patient’s decision on treatment. Full disclosure is clearly violated here by Dr. Smith’s failure to notify the participants.

Dr. Smith also violates statutory and case law mandates. In this hypothetical, the psychiatrist violates Rules 1, 2, 3, 4, 9, and 10 of the Nuremberg Code.<sup>147</sup> Further, the precedent established in litigation also

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<sup>145</sup> See generally FLANCAUM, *supra* note 1.

<sup>146</sup> See FURROW ET AL., *supra* note 4, at 231.

<sup>147</sup> See Nuremberg Code: Permissible Medical Experiments, *supra* note 84.

disfavors the doctor's conduct. In litigation, a court would likely compare the facts and apply the holding in *Hiser*.<sup>148</sup> In essence, the lack of information disclosed to the patient would make this particular experiment unethical.

The Jewish law approach would also bar this type of seemingly benign experimentation, but on different grounds. It is Halachic principle that a physician may do no harm to a patient.<sup>149</sup> None. There is no relativity to this mandate.

Further, Dr. Smith is avoiding Lord Jakobovits' principles in which he must inform the patient in cases of experimental cures, and is in fact committing assault and battery.<sup>150</sup> It is also a great moral wrong that Dr. Smith is interfering with the patients' duty to act as knowing and careful custodians of G-d's creation. Dr. Flancbaum argues that in cases where risks and outcomes of medical treatment are uncertain, the patient as custodian of his body, may retain full autonomy.<sup>151</sup> Therefore, Dr. Smith has violated key tenets in both Jewish law and secular law, and in bioethics.

#### V. *Conclusion*

There is a formal absolute bar on experimentation on non-consenting and vulnerable human subjects. Even with consent of a lucid and informed subject, one is still hard pressed to find a morally unencumbered instance of human subject experimentation. However, it is realistic to expect that human experimentation will continue as medical technology blossoms.

Because the secular law approach heralds individualism and autonomy, it offers more leeway for the individual to consent and be a subject, and therefore fosters a human experiment-safe environment. One should take respite, however, in the fact that the requirements for the administrators of the experiments have been formalized in statute and impose considerable burdens, duties to disclose, and the ability for a subject to terminate at will.

Jewish law, having a more definite tradition in religious bases, takes a much more paternal view and as such sees the human body as G-

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<sup>148</sup> *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 807 (Md. 2001).

<sup>149</sup> FLANCBAUM, *supra* note 1, at 85.

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

d's creation. Humans, therefore, do not have complete proprietorship over it. Humans, therefore, must not participate in experimental treatments, when other modes are available or the risks outweigh the benefits. All in all, as an observer of technology and humanity at large, one can hope that the law will develop alongside medical advances in a manner that aids innovation, and yet respects the dignity and uniqueness of the individual.