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## Biomedical and Behavioral Research on Juvenile Inmates: Uninformed Choices and Coerced Participation

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BIOMEDICAL AND BEHAVIORAL RESEARCH ON JUVENILE  
INMATES: UNINFORMED CHOICES AND COERCED  
PARTICIPATION

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I. INTRODUCTION

In 1997, Stanford University and the California Youth Authority [hereinafter “CYA”] conducted a biomedical research experiment on sixty-one male inmates from ages fourteen to eighteen.<sup>1</sup> All of the subjects were given a drug named Depakote, used primarily for treating seizures and mania.<sup>2</sup> The drug was tested to see if it would reduce the amount of aggressiveness in juvenile inmates.<sup>3</sup> The possible side effects to such a drug include “drowsiness, nausea, indigestion and vomiting . . . hair loss, anxiety, depression, and a decrease in white blood cells.”<sup>4</sup> These particular juveniles were selected as a target population because they had been convicted of violent crimes.<sup>5</sup> While Stanford attempted to obtain consent from parents of the juvenile inmates, not all parents responded.<sup>6</sup> Where parents did not respond or could not be found, the CYA consented for the juveniles.<sup>7</sup> This experiment presents various issues in biomedical and behavioral research on human subjects in vulnerable populations. The Stanford study led to such serious concerns, that the Governor of California asked the attorney general and inspector general to investigate the study’s “legal implications.”<sup>8</sup>

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<sup>1</sup>Tracy Weber, *1997 Drug Test on Teenage Inmates Probed*, L.A. TIMES, Aug. 16, 1999, at A1.

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

<sup>3</sup>Neela Dasgupta, *Stanford Study on Prisoners Investigated*, STAN. DAILY, Aug. 19, 1999, available at <<http://daily.stanford.org/daily98%2D99/8%2D19Y.2D1999/news/newpsych19.html>>.

<sup>4</sup>Weber, *supra* note 1.

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

<sup>6</sup>Dasgupta, *supra* note 3.

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

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

The most important issue presented by the Stanford study is whether children who are incarcerated can give voluntary, informed consent to such experiments.<sup>9</sup> Federal regulations govern biomedical and behavioral research on human subjects.<sup>10</sup> These regulations give separate additional protections to both children and prisoners.<sup>11</sup> However, there are no regulations specifically covering the area of biomedical and behavioral research on juvenile prisoners or inmates. This is an especially vulnerable class of individuals to target for conducting biomedical and behavioral research. Voluntary informed consent is an essential element to any type of research, and when dealing with juvenile inmates as subjects, that consent is more difficult to obtain. Yet biomedical and behavioral research is still conducted on this population, as evidenced by the 1997 Stanford University study.<sup>12</sup>

The question that will be addressed here is whether juvenile inmates can voluntarily give informed consent to participate in biomedical and behavioral research. Further, can juvenile inmates act voluntarily in the midst of coercion used by researchers to persuade the subjects to participate, and coercion that is inherent in the nature of being a juvenile inmate? Can consent be informed when a juvenile inmate's comprehension and understanding of what biomedical and behavioral research entails is limited by age and maturity level? Finally, even if juvenile inmates are deemed capable to give voluntary informed consent to biomedical and behavioral research, is simply participating in such research violative of their constitutional rights?

This note begins briefly by defining biomedical and behavioral research according to the federal regulations. Then, the development and history behind the federal regulations is highlighted to show the origin of the current form of the regulations. This development includes an examination of the current form of the regulations, which illustrates the general provisions and their application to biomedical and behavioral research on human subjects. This section on the general provisions covers what is termed an Institutional Review Board [hereinafter "IRB"], informed consent standards, and possible sanctions for noncompliance.

Following the section on general provisions is an analysis of two specific provisions that add protections for vulnerable classes of persons as research subjects. These two additional protections are for children and prisoners. Before there can be an investigation into research on juvenile inmates, there must first be a description of the additional protections provided for children and prisoners. The provision that relates to children is examined first, and covers definitions, minimal risk standards, and parental consent attached to informed consent standards. Following the section on children is the section on adult prisoners, which covers definitions, additional provisions for IRBs, and avoidance of coercion.

Finally, there will be an analysis of biomedical and behavioral research on juvenile inmates and the specific problems that are entailed. This section covers reasons why this is a particularly vulnerable population to research, with problems of informed consent and coerced choices. There is also an examination of the juvenile

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<sup>9</sup>Weber, *supra* note 1.

<sup>10</sup>*See generally* 45 C.F.R. § 46.101 (1999).

<sup>11</sup>*See generally* §§ 46.301, 46.401.

<sup>12</sup>Weber, *supra* note 1.

inmates' constitutional rights when participating in research. Then the two additional provisions on children and prisoners are combined to see how they may apply to juvenile inmates. This section will conclude with the various troubles created by the regulations when applied to juvenile inmates.

## II. WHAT IS BIOMEDICAL AND BEHAVIORAL RESEARCH?

Biomedical and behavioral research involves many types of research. Research, for purposes of the federal regulations, is broadly defined by 45 C.F.R. § 46.102 as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."<sup>13</sup> Research may also be classified as a clinical investigation.<sup>14</sup> A clinical investigation is defined by 21 C.F.R. § 50.3 as "any experiment that involves a test article and one or more human subjects and . . . is subject to . . . the Food and Drug Administration."<sup>15</sup> The definitions of research and clinical investigation, when combined, subject almost every type of research to the authority of the federal regulations.<sup>16</sup>

Biomedical and behavioral research is conducted for many purposes. An argument could be made that such research is too necessary for any sort of regulation. Human experimentation has had many successes that are widely recognized.<sup>17</sup> It has enabled scientists to further "medical understanding" and "unlock knowledge that may profoundly change the nature of our existence."<sup>18</sup>

Despite these accomplishments, various arguments have been made against the use of human subjects for biomedical and behavioral research. These arguments directly conflict with the goals and objectives of the researchers conducting the experiments. Researchers argue that research or human experimentation is useful, or for the "common good."<sup>19</sup> There is a difference between the interests promoted by research (the researcher's motivations) and interests that are at stake due to the research (the interests of the human subject). The researcher is interested in discovery, accomplishment and recognition. By contrast, the human subject is interested in rewards for participating, taking part in improving medicine, and

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<sup>13</sup>45 C.F.R. § 46.102(d) (1999) ("Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.").

<sup>14</sup>21 C.F.R. § 50.3(c) (1999).

<sup>15</sup>*Id.*

<sup>16</sup>Dale L. Moore, *Recurrent Issues in the Review of Medical Research on Human Subjects*, 1 ALB. L.J. SCI. & TECH. 1, at 4 (1991) ("Indeed, even a relatively mundane endeavor, such as a study of nurses' attitudes toward hospital patients who happen to be physicians, is research if it is designed to collect data that will contribute to generalizable knowledge.").

<sup>17</sup>Kevin M. King, *A Proposal For The Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L L. 163, 166 (1998).

<sup>18</sup>*Id.* (stating that biomedical and behavioral research has also awarded us with the "eradication of smallpox and polio").

<sup>19</sup>Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 467 (1996). See generally DONALD EVANS & MARTYN EVANS, *A DECENT PROPOSAL, ETHICAL REVIEW OF CLINICAL RESEARCH* (1996); *ETHICAL ISSUES IN RESEARCH* (Darwin Cheney, ed., 1993).

avoiding physical harm or pain and suffering. Whose interests are being looked out for in research where human subjects undergo pain and suffering in exchange for biomedical advances in medicine?

### III. DEVELOPMENT OF THE FEDERAL REGULATIONS

There is a long history of biomedical and behavioral research conducted on human subjects worldwide. However, only in the twentieth century has concern developed over the abuse of research on human subjects.<sup>20</sup> In 1932, Japan began to experiment on thousands of people in China, including American prisoners of war, to test germ warfare.<sup>21</sup> Also, in 1946, several Nazi German officials were tried in Nuremberg, Germany for conducting “medical experiments on men, women, and children in concentration camps.”<sup>22</sup> From 1932 to 1972, over 400 black men were exposed to syphilis in an experiment, referred to as the Tuskegee Syphilis Experiment, sponsored by the U.S. Public Health Service.<sup>23</sup> Following these twentieth century abuses of experimentation, there arose a demand for regulation of experimentation involving human subjects. The federal regulations were created in 1974 and have been amended several times since.<sup>24</sup>

The federal regulations that have been adopted come from the Food and Drug Administration [hereinafter “FDA”] and the Department of Health and Human Services [hereinafter “DHHS”], titles 21 and 45 of the Code of Federal Regulations, respectively.<sup>25</sup> Many other departments and agencies that experiment or conduct research on human subjects have adopted these regulations as the “Common Rule.”<sup>26</sup> Some state laws have even begun to model the federal regulations. From 1975 to 1990, the New York State Department of Mental Hygiene has issued regulations that match those of the federal regulations.<sup>27</sup> These federal regulations are, themselves, a model of a body of law, the Nuremberg Code.

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<sup>20</sup>Garnett, *supra* note 19, at 465.

<sup>21</sup>Jonathan D. Moreno, *Lessons Learned: A Half-Century of Experimenting on Humans*, 59 HUMANIST 9 (1999) available at 1999 WL 3645408 (pagination unavailable). See also Garnett, *supra* note 19, at 464.

<sup>22</sup>Moreno, *supra* note 21.

<sup>23</sup>*Id.* See generally JAMES H. JONES, BAD BLOOD, THE TUSKEGEE SYPHILIS EXPERIMENT (1981).

<sup>24</sup>Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 71 (1986).

<sup>25</sup>*Id.*

<sup>26</sup>Tom Puglisi, Congressional Testimony on Suspension of Medical Research, Federal Document Clearing House, Inc. (April 21, 1999), available at 1999 WL 16946495.

<sup>27</sup>John M. Oldham, et al., *Symposium: “Conducting Medical Research on the Decisionally Impaired” Regulating Research With Vulnerable Populations: Litigation Gone Awry*, 1 J. HEALTH CARE L. & POL’Y 154, 156-60 (1998).

The FDA and the DHHS have borrowed some of the main principles of the Nuremberg Code, and have included them in the federal regulations.<sup>28</sup> The Nuremberg Code is the “first known attempt to establish international legal guidelines for regulating research on humans.”<sup>29</sup> The general principle emphasized by the Code was that the importance of research and the gathering of scientific knowledge could not outweigh the individual rights of subjects.<sup>30</sup> The most important idea borrowed from the Nuremberg Code is that “voluntary consent of the human subject is absolutely essential.”<sup>31</sup> In addition to the FDA and the DHHS regulations, the Nuremberg Code is binding upon researchers in the United States.<sup>32</sup>

The federal regulations have the force of law and are binding on all researchers.<sup>33</sup> Title 21, part 50 only applies to clinical investigations regulated by the FDA, as defined above.<sup>34</sup> Title 45, part 46 covers “all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency....”<sup>35</sup> This coverage, however, is limited only to federally funded or supported research.<sup>36</sup> There are also certain situations in which the regulations will not apply at all.<sup>37</sup> The majority of these exempted types of research deal with research held in educational settings or involving cognitive tests.<sup>38</sup> Furthermore, “department or agency heads may waive the applicability of some or all of the provisions” set forth in these regulations for research activities, as they deem necessary.<sup>39</sup> Thus, it is questionable as to how much coverage the regulations actually have over biomedical and behavioral research.

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<sup>28</sup>Samuel Jan Brakel, *Considering Behavioral and Biomedical Research on Detainees in the Mental Health Unit of an Urban Mega-Jail*, 22 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 1, 6 (1996).

<sup>29</sup>King, *supra* note 17, at 168.

<sup>30</sup>Moreno, *supra* note 21.

<sup>31</sup>The Nuremberg Code, *reprinted in* THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS: FACING THE 21ST CENTURY 431-32 (Harold Y. Vanderpool, ed., 1996).

<sup>32</sup>*In re Cincinnati Radiation Litigation*, 874 F. Supp. 796, 821 (S.D. Ohio 1995).

<sup>33</sup>*See generally* 42 U.S.C. § 289(a) (1999) (“[t]he secretary shall by regulation require” an Institutional Review Board “to review biomedical and behavioral research involving human subjects”).

<sup>34</sup>21 C.F.R. § 50.1(a) (1999).

<sup>35</sup>45 C.F.R. § 46.101(a) (1999).

<sup>36</sup>Robert J. Katerberg, Note, *Institutional Review Boards, Research on Children, and Informed Consent of Parents: Walking the Tightrope Between Encouraging Vital Experimentation and Protecting Subjects' Rights*, 24 J.C. & U.L. 545, 549 (1998).

<sup>37</sup>45 C.F.R. § 46.101(b) (1999).

<sup>38</sup>*Id.* (exempting these types of research: (i) research conducted in commonly accepted educational settings, (ii) research involving the use of educational tests, (iii) research involving publicly available documents and records of existing data, (iv) research which is meant to examine public benefit or service programs, and (v) research involving taste and food quality evaluation).

<sup>39</sup>45 C.F.R. § 46.101(i) (1999).

Title 42, section 289 of the United States Code requires that there be a regulation in force which in turn will require an IRB for the purpose of reviewing “biomedical and behavioral research involving human subjects.”<sup>40</sup> The IRB has the “authority to approve, require modifications in, or disapprove all research activities” covered by the regulations.<sup>41</sup> The IRB fulfills its duties by: (i) ensuring that risks to subjects are minimal, (ii) reviewing informed consent documents and the procedures used to obtain consent, (iii) reviewing the selection of subjects, (iv) balancing the risks with the benefits derived from the research, and (v) providing that the subjects’ privacy is protected.<sup>42</sup> If all of these criteria are satisfied then the research is approved by the IRB. The IRB must also meet member requirements, according to 45 C.F.R. § 46. Every IRB must have five members who are diversified by gender and race.<sup>43</sup> One member must be a person with scientific concerns, another must have concerns in a nonscientific area, and there must be at least one member who is not affiliated with the institution conducting the research.<sup>44</sup>

There are three main interests that an IRB must consider when deciding whether to approve a specific research experiment.<sup>45</sup> They are the interests of: (1) the researchers or investigators, (2) the institution supporting the research, and (3) the research subjects.<sup>46</sup> As to the latter, “the subject’s own health and well-being, which are directly and foreseeably affected by the research, make the subject the most vulnerable of the three parties.”<sup>47</sup> In all, the IRB has the challenge of taking all three interests into consideration and balancing them so that the private rights involved are never underestimated.

As stated, the FDA and DHHS have borrowed from the Nuremberg Code the idea that voluntary informed consent is necessary for research.<sup>48</sup> Informed consent must be “documented by the use of a written consent form approved by the IRB and signed by the subject.”<sup>49</sup> 45 C.F.R. § 46.116(a) provides researchers with eight general requirements to satisfy voluntary informed consent.<sup>50</sup> Those requirements are as follows:

- (1) A statement of what the research involves, and information on its duration, procedures, and purposes;

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<sup>40</sup>42 U.S.C. § 289(a) (1999) (stating that statute is also for the purpose of protecting the rights of human subjects).

<sup>41</sup>45 C.F.R. § 46.109(a) (1999).

<sup>42</sup>§ 46.111. *See also* Moore, *supra* note 16, at 8-9.

<sup>43</sup>45 C.F.R. § 46.107(a)-(f).

<sup>44</sup>*Id.* (requiring that no member may serve on the IRB if he/she has a conflict of interest).

<sup>45</sup>Moore, *supra* note 16, at 12-13.

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

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

<sup>48</sup>*See* 21 C.F.R. § 50.20 (1999); 45 C.F.R. § 46.116 (1999).

<sup>49</sup>45 C.F.R. § 46.117(a) (1999).

<sup>50</sup>§ 46.116. *See also* Puglisi, *supra* note 26; Delgado, *supra* note 24.

- (2) A statement of “any reasonably foreseeable risks” to the subject;
- (3) A statement of “any benefits to the subject or to others”;
- (4) A disclosure of alternative procedures if available;
- (5) A statement explaining “confidentiality of records”;
- (6) When “more than a minimal risk” is involved, a statement explaining any compensation or medical treatment that would be available if injury were to occur;
- (7) A statement of whom to contact for any questions the research subject might have;
- (8) A statement informing subjects “that participation is voluntary” and “they may discontinue participation at any time without penalty or loss of benefits.”<sup>51</sup>

Both the FDA and the DHHS prohibit the use of exculpatory clauses in obtaining informed consent.<sup>52</sup> These provisions specifically prohibit “any language through which the subject . . . is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”<sup>53</sup>

The federal regulations reach some but not all biomedical and behavioral research, and provide for sanctions when they are not followed. There are only two sections within the regulations that provide for remedies or penalties for violations of the regulations. 45 C.F.R. § 46.113 provides that an IRB may suspend or terminate research that is not “conducted in accordance with the IRB’s requirements.”<sup>54</sup> The other, 45 C.F.R. § 46.123, provides that a “department or agency head” may terminate any funding or support provided by that specific agency or department for failure to comply with the regulations.<sup>55</sup>

There are a number of deficiencies in these regulations and the requirements for informed consent.<sup>56</sup> The DHHS provides the IRB with great discretion for granting

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<sup>51</sup>*Id.*; see also § 46.116(b) (delineating other elements of information that may be required to be included with informed consent: (i) a statement that the treatment will invoke risks which are currently unforeseeable, (ii) anticipated circumstances by which the experiment may be terminated, (iii) additional costs to the subject, (iv) consequences of a subject’s decision to withdraw from the procedures, (v) statement of any additional findings during the research experiment, and (vi) the number of other subjects involved in the research project).

<sup>52</sup>See 21 C.F.R. § 50.20 (1999); 45 C.F.R. § 46.116 (1999).

<sup>53</sup>21 C.F.R. § 50.20 (1999); 45 C.F.R. § 46.116 (1999).

<sup>54</sup>45 C.F.R. § 46.113 (1999).

<sup>55</sup>§ 46.123.

<sup>56</sup>Delgado, *supra* note 24, at 75-76.



broad waivers to the requirement of informed consent.<sup>57</sup> The requirement to obtain informed consent may be waived when the “research could not practicably be carried out without the waiver or alteration.”<sup>58</sup> The IRB may also waive the requirements for informed consent when “the research involves no more than minimal risk to the subjects,” “the waiver . . . will not adversely affect the rights and welfare of the subjects,” and “when the subjects will be provided with additional pertinent information after participation.”<sup>59</sup> This leaves the IRB with many ways to approve the research without requiring informed consent.

In addition to the above general regulations, the DHHS has recognized the need to provide additional protections for human subjects belonging to a vulnerable class of people.<sup>60</sup> Vulnerable classes of subjects can include children, prisoners, pregnant women, and handicapped or mentally disabled persons.<sup>61</sup> The classes of children and prisoners are the focus here.

#### IV. BIOMEDICAL AND BEHAVIORAL RESEARCH ON CHILDREN

The regulations define “children” as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”<sup>62</sup> This definition leaves to the states the discretion to apply their own “legal age for consent” according to state laws. The result is that the additional protections for children contained in the federal regulations do not apply to certain children due to the state laws that set the age of legal consent at a young age.<sup>63</sup>

From a researcher’s perspective, a test population of children is an ideal group to target for research. Some argue that research or experimentation on children is necessary, because the problems and illnesses studied in children are specific to children.<sup>64</sup> Examples of problems studied in children that are age specific are childhood autism and suicidal adolescent depression.<sup>65</sup> Genetic research on children is also a benefit since it allows researchers to identify genetic diseases and early development in humans.<sup>66</sup> Inherent in genetic research is the process of determining the genetic traits children develop as they mature.<sup>67</sup>

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<sup>57</sup>45 C.F.R. § 46.116(c)-(d) (1999).

<sup>58</sup>§ 46.116(c)(2); 46.116(d)(3).

<sup>59</sup>§ 46.116(d)(1); 46.116(d)(2); 46.116(d)(4).

<sup>60</sup>§ 46.107(a).

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

<sup>62</sup>§ 46.402(a).

<sup>63</sup>Katerberg, *supra* note 36, at 558.

<sup>64</sup>Garnett, *supra* note 19, at 484.

<sup>65</sup>Oldham, *supra* note 27, at 171.

<sup>66</sup>Allen J. Wilcox, et al., *Genetic Determinism and the Overprotection of Human Subjects*, 21 NATURE GENETICS 362 (1999).

<sup>67</sup>*Id.*

Subpart D of title 45, part 46 of the Code of Federal Regulations provides the protections for children, as subjects of research, that are in addition to the general regulations on all research involving human subjects.<sup>68</sup> The regulations specific to children are based on the concept of “minimal risk.”<sup>69</sup> “Minimal risk” is defined by 45 C.F.R. § 46.102(i) as when “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>70</sup> The major problem with the standard is that it likens ordinary, daily activities in a child’s life with the activities that are conducted under research.<sup>71</sup> One example of the defect of this standard applies where children who are chronically ill receive ongoing treatments for their medical condition. These children are probed and exposed to different types of medicine with side effects, on a “daily” and “routine” basis, to treat their medical condition.<sup>72</sup> Under this minimal risk standard, researchers will be able to probe or expose these children to experimental drugs with the same or similar side effects as those which are used in the children’s medical treatment. The reason for this is that the research will not pose a higher risk than what these children are already experiencing.<sup>73</sup> The standard of minimal risk, which is the basis of the additional protections for children, is unworkable with such defects.

The DHHS divides the research to be approved by IRBs into three main categories:

- (1) Where no greater than minimal risk to children is presented;
- (2) Where greater than minimal risk to children is presented, as long as a direct benefit to the individual subjects is also presented;
- (3) Where greater than minimal risk to children is presented with no direct benefit, as long as the research is likely to yield generalizable knowledge about the subjects’ disorder or condition.<sup>74</sup>

As to the first category, when research involves no greater than a minimal risk, then the research will be permitted.<sup>75</sup> In the second category, as long as there is an anticipated benefit to the subjects, the research will be permitted regardless of the

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<sup>68</sup>45 C.F.R. § 46.401(a) (1999).

<sup>69</sup>Katerberg, *supra* note 36, at 555.

<sup>70</sup>45 C.F.R. § 46.102(i) (1999).

<sup>71</sup>Lainie Friedman Ross, Feature, *Children as Research Subjects: A Proposal to Revise the Current Federal Regulations Using a Moral Framework*, 8 STAN. L. & POL’Y REV. 159, 162 (1997) (“[c]hildren commonly encounter experiences at school that threaten their self-image, but this does not justify similar threats in the research setting.”).

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

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

<sup>74</sup>*See generally* 45 C.F.R. §§ 46.404-06 (1999).

<sup>75</sup>§ 46.404.

magnitude of the risk involved.<sup>76</sup> The third category extends the researchers' ability to research on children by permitting research that will yield at least generalizable knowledge, even if it does not present an outright benefit to the subjects.<sup>77</sup> This last category is a prime example of how researchers' interests may be given more weight than those of the individual subjects.

In addition to these three categories of research involving different levels of risk, 45 C.F.R. § 46.407 goes even further to approve research on children that is not otherwise approved by the three categories specified.<sup>78</sup> Even if the research does not yield generalizable knowledge specific to the individual subject, as long as the research "presents responsible opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of [all] children," then the research will be permitted (no risk level is specified).<sup>79</sup> Since most research conducted on children points to this purpose as the end to be achieved, it could be approved by IRBs on all occasions.<sup>80</sup>

Another major problem with researching on children that the regulations attempt to address is whether children can give informed consent.<sup>81</sup> 45 C.F.R. § 46.408(a) provides that a child research subject must "assent" to participation in the experiment whenever the IRB decides on account of age, maturity, and psychological state that the child subject may give such assent.<sup>82</sup> However, assent may be waived as not necessary by the IRB in two circumstances: (1) where "the capability of some or all of the children is so limited that they cannot reasonably be consulted," or (2) where "the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of research."<sup>83</sup>

In addition to requiring assent from the child subject where appropriate, 45 C.F.R. § 46.408(b) requires that "adequate provisions are made for soliciting the permission of each child's parents or guardian."<sup>84</sup> "Parent" is defined by the regulations as "a child's biological or adoptive parent."<sup>85</sup> "Guardian" is defined as "an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care."<sup>86</sup> Since states and localities may determine

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<sup>76</sup>§ 46.405.

<sup>77</sup>§ 46.406.

<sup>78</sup>§ 46.407.

<sup>79</sup>§ 46.407(a).

<sup>80</sup>See Garnett, *supra* note 19, at 484; Oldham, *supra* note 27, at 171.

<sup>81</sup>Delgado, *supra* note 24, at 94.

<sup>82</sup>45 C.F.R. § 46.408(a) (1999). See also § 46.402(b) ("Assent" means a child's affirmative agreement to participate in research.).

<sup>83</sup>§ 46.408(a). See also Ross, *supra* note 71, at 164 (noting that age seven had been designated by the National Commission as the age at which a child's assent is required because most children over the age of seven have some understanding of the research).

<sup>84</sup>45 C.F.R. § 46.408(b) (1999).

<sup>85</sup>§ 46.402(d).

<sup>86</sup>§ 46.402(e).

who qualifies as a guardian, the number and type of people who may give permission for the child to participate is overly broad. State or local laws may permit next of kin, friends, or even neighbors who know the child well to give consent.

These provisions allow the parent or guardian's permission to override the child's refusal or objection to assent to the research.<sup>87</sup> When the child is not required to give assent according to 45 C.F.R. § 46.408(a) because it is deemed unnecessary, the parent may still give permission to proceed with the research.<sup>88</sup> This seems detrimental to a child's personal autonomy.<sup>89</sup> Informed consent is the standard used to justify experimentation on human subjects, because giving consent protects autonomy.<sup>90</sup> It is thus often argued that "proxy consent" is an oxymoron because it bypasses the principle behind informed consent, which is to recognize self-determination and autonomy.<sup>91</sup> It could also be argued that a parent's responsibility to his or her child is a fiduciary one and, in certain cases, permission to let the child participate in biomedical and behavioral research may be a breach of that duty.<sup>92</sup>

The DHHS also provides that the requirement for the parent or guardian's permission may be waived in certain circumstances.<sup>93</sup> The requirement for parental permission is waived when the IRB determines that parental or guardian permission is an unreasonable requirement for the protection of the individual child subject.<sup>94</sup> The regulations provide examples where these types of waivers will occur, such as when the parents are neglectful or abusive to the children.<sup>95</sup> Also, whenever the general waivers to the requirement of informed consent occur due to the exemption provisions in 45 C.F.R. § 46.101(b), *viz.*, cognitive tests in educational settings, public benefit and service programs, etc., there is no need to acquire either the parent's or guardian's permission or the child's assent to research.<sup>96</sup>

Furthermore, informed consent may be given without parental permission if the minor is emancipated.<sup>97</sup> Emancipated minors are those "adolescents who are entitled to give legal consent because of their status," which includes being a "mature minor" according to state law, married or parenting adolescents, and college students living away from home.<sup>98</sup> A "mature minor" is a person of juvenile age, but who exhibits

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<sup>87</sup>Ross, *supra* note 71, at 167.

<sup>88</sup>45 C.F.R. § 46.408(a) (1999).

<sup>89</sup>Garnett, *supra* note 19, at 486.

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

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

<sup>92</sup>Ross, *supra* note 71, at 159.

<sup>93</sup>45 C.F.R. § 46.408(c) (1999).

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

<sup>95</sup>*Id.*

<sup>96</sup>§ 46.101(b).

<sup>97</sup>Katerberg, *supra* note 36, at 565.

<sup>98</sup>Gideon Koren, et al., *Maturity of Children to Consent to Medical Research: The Babysitter Test*, 19 J. MED. ETHICS 142, 144 (1993).

an understanding of the research and its procedures.<sup>99</sup> Some states specify that a child is a mature minor by age; others take into account the child's level of comprehension of the risks and benefits as a deciding factor.<sup>100</sup> Also, there is an argument known as the "babysitter test," which incorporates the idea that a babysitter (a child who is mature enough to supervise younger children) should also be held as mature enough to give informed legal consent to participation in research.<sup>101</sup>

#### V. BIOMEDICAL AND BEHAVIORAL RESEARCH ON ADULT PRISONERS

The DHHS defines "prisoner" as "any individual involuntarily confined or detained in a penal institution."<sup>102</sup> This broad definition covers individuals sentenced under both criminal and civil statutes.<sup>103</sup> Prisoners have been targeted as research populations in the United States extensively since the end of World War II.<sup>104</sup> The United States was actually the only Western nation continuing to conduct biomedical and behavioral research on prisoners after the Nuremberg Trials.<sup>105</sup> Prisoner research has decreased substantially over the years, but it still remains in certain locations across the United States.<sup>106</sup>

Researchers continue to target prisoners as a research population due to the various benefits that result to the researchers and institutions that conduct the experiments. It has been argued by many that prisons are an almost ideal location for conducting research because they consist of routine life subject to few variations.<sup>107</sup> That is, prison life is already controlled for the researcher. Prisoners eat the same food, sleep at the same times, and partake in the same types of activities. Researchers also argue that it is less burdensome on prisoners to be subject to any sort of research compared to those who are not incarcerated.<sup>108</sup> Another reason why conducting research on prisoners is so desirable is that researchers can pay less money to carry out experiments since prisoners can be paid substantially less than other subjects who are not incarcerated.<sup>109</sup>

Additional protections are placed on research on prisoners by Subpart C of title 45, part 46 of the Code of Federal Regulations.<sup>110</sup> The purpose of these protections is "to provide additional safeguards for the protection of prisoners involved in"

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

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

<sup>101</sup>*Id.* at 146.

<sup>102</sup>45 C.F.R. § 46.303(c) (1999).

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

<sup>104</sup>Kathleen Schroeder, Note, *A Recommendation to the FDA Concerning Drug Research on Prisoners*, 56 S. CAL. L. REV. 969, 971 (1983).

<sup>105</sup>Moreno, *supra* note 21.

<sup>106</sup>Schroeder, *supra* note 104, at 971.

<sup>107</sup>Garnett, *supra* note 19, at 478.

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

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

<sup>110</sup>45 C.F.R. § 46.302 (1999).

biomedical and behavioral research.<sup>111</sup> One important aspect of these additional protections is that they give prisoners the chance to have representation on the IRB.<sup>112</sup> The regulations specific to prisoner subjects require that at least one member of the Board is a prisoner or a prisoner representative with the background and experience needed to adequately represent such prisoners.<sup>113</sup> This representation is meant to give prisoners a voice for expressing their rights when decisions are made by the IRB.

The IRB is also charged with other duties and determinations specific to research on prisoners.<sup>114</sup> The IRB must determine that the following conditions are met before approving any research sought to target prisoners as subjects:

The research is permissible under the regulations specifically relating to prisoners under 45 C.F.R. § 46.306(a)(2);

The advantages of participation in the research are not of such a magnitude that a prisoner's ability to weigh the risks of the research against the value of such advantages is impaired;

The risks involved are equal to the risks that would be involved for persons not incarcerated;<sup>115</sup>

All prisoner subjects are chosen equally and randomly;

The information presented to the prisoners is clear and understandable;

Prisoners are informed that their participation in the research will not have an effect on their parole;

There is a follow-up examination when necessary for the care of participants after the research experiment has ended.<sup>116</sup>

These seven considerations, that are to be determined by the IRB, are important for deciding whether the research is equitable and whether the prisoners are acting voluntarily in participating.<sup>117</sup> The type of research conducted must fall within one of the four types of research permitted under § 46.306(a)(2).<sup>118</sup> The IRB then approves the research by finding that it qualifies for each of the seven considerations listed

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

<sup>112</sup>§ 46.304(b).

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

<sup>114</sup>§ 46.305.

<sup>115</sup>See discussion of minimal risk standards, *supra* notes 68-81 and accompanying text.

<sup>116</sup>45 C.F.R. § 46.305(a) (1999).

<sup>117</sup>Schroeder, *supra* note 104, at 991-97.

<sup>118</sup>45 C.F.R. § 46.306(a) (1999).

above.<sup>119</sup> Under section 46.306(a)(2), the first two types of research permitted use the same “minimal risk” standard used in the additional protections for children.<sup>120</sup> First, the regulations provide that if the research involves a “study of the possible causes, effects, and processes of incarceration, and of criminal behavior” and there is “no more than a minimal risk,” then it will be permitted.<sup>121</sup> The second type permits any research on prisoners that studies “prisons as institutional structures or of prisoners as incarcerated persons” and that involves “no more than a minimal risk.”<sup>122</sup>

The last two of the four types of research permitted on prisoners are very broad and do not involve the concept of “minimal risk.”<sup>123</sup> The third type allows the conducting of research on conditions affecting prisoners as a class of persons, including research on social and psychological problems among inmates without any consideration given to “minimal risk” (like category two but without a minimal risk standard).<sup>124</sup> The fourth type permits any “research on practices . . . which have the intent and reasonable probability of improving the health or well-being of the subject.”<sup>125</sup> It has been argued that these last two types of permitted research allow a large spectrum of research, especially since the “minimal risk” standard is disregarded.<sup>126</sup>

The regulations fail to address adequately the ability of prisoners to give voluntary informed consent to participation in research. There are two extremes to the argument of voluntary informed consent by prisoners.<sup>127</sup> On the one side, it is argued that “wholly uncoerced consent is impossible to obtain in the prison setting.”<sup>128</sup> An alternative view is that “there is no such thing as an uncoerced decision by anyone, in prison or in the free world.”<sup>129</sup> This would be like making an unmotivated decision, which is a human impossibility.<sup>130</sup> To analyze these problems when it comes to prisoners making decisions on whether to participate in research, it is necessary to look at informed consent, separated from voluntary consent. Even though the terms “informed consent” and “voluntary consent” are similar, the

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<sup>119</sup>§ 46.306(a)(1).

<sup>120</sup>§ 46.306(a)(2).

<sup>121</sup>§ 46.306(a)(2)(i).

<sup>122</sup>§ 46.306(a)(2)(ii).

<sup>123</sup>§§ 46.306(a)(2)(iii)-(iv).

<sup>124</sup>*Id.*

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

<sup>126</sup>*See generally* Bailey v. Lally, 481 F. Supp. 203 (D. Md. 1979).

<sup>127</sup>Brakel, *supra* note 28, at 14.

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

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

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

concepts must be looked at separately.<sup>131</sup> There can be no informed consent if the consent given is not also voluntary.<sup>132</sup>

Turning first to obtaining informed consent of prisoners, recall that the fifth consideration for the IRB under section 46.305(a) is that information provided to the prisoners be understandable.<sup>133</sup> Consent must be clear and reasonably understood by the prisoner without any exculpatory clauses added to the consent form.<sup>134</sup> Consent forms are often difficult to read, not just by prisoners but by anyone; forms that are not understandable by prisoners fail to comply with the regulations.<sup>135</sup> It has also been noted that when high-risk experiments are involved, additional disclosure should be made beyond that required by the general informed consent requirements in Subpart A of title 45 of the Code of Federal Regulations.<sup>136</sup> However, as previously noted, the only requirement added by the provision is that the prisoners “understand” the information provided to them about the research and procedures.<sup>137</sup> This simple requirement leaves room for error, especially where informed consent is otherwise waived according to section 46.116 of Subpart A, title 45.<sup>138</sup>

The voluntary consent problem presents even more complications in the realm of prisoner research. When it comes to research on prisoner subjects, the driving force that affects their ability to act voluntarily is coercion. Coercion is often defined as a constraint or induced influence on the chooser.<sup>139</sup> Here, the prisoner choosing to participate in research. Coercion is a serious deprivation of a person’s rights, with arguments often directed towards violations of constitutional rights.<sup>140</sup> These types of arguments revolve around the Fifth, Eighth, and Fourteenth Amendments to the United States Constitution.<sup>141</sup> The Eighth Amendment argument stems from the cruel and unusual punishment prohibition; it is often used to show that where a prisoner did not act voluntarily, the prisoner, instead, has undergone cruel and unusual punishment due to the harmful effects of the experiment.<sup>142</sup> The Fifth and Fourteenth Amendments are used to argue that prisoners’ equal protection and due process rights have been violated. Where prisoners are disadvantaged due to being incarcerated and any other coercion used by researchers, they have acted involuntarily and therefore should have been entitled to due process before

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<sup>131</sup>Schroeder, *supra* note 104, at 973.

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

<sup>133</sup>45 C.F.R. § 46.305(a)(5) (1999).

<sup>134</sup>*See* Valenti v. Prudden, 397 N.Y.S.2d 181 (1977).

<sup>135</sup>Schroeder, *supra* note 104, at 977.

<sup>136</sup>*Id.*

<sup>137</sup>45 C.F.R. § 46.305(a)(5) (1999).

<sup>138</sup>§ 46.116 (1999).

<sup>139</sup>M. Gregg Bloche, *Beyond Autonomy: Coercion and Morality in Clinical Relationships*, 6 HEALTH MATRIX 229, 271 (1996).

<sup>140</sup>Brakel, *supra* note 28, at 23-24.

<sup>141</sup>*Id.*

<sup>142</sup>*Id.*



undergoing any such research.<sup>143</sup> Due process entitles a prisoner the reasonable opportunity to make a voluntary, uncoerced decision. Prisoners, however, are deprived of this right from the moment they begin their sentence. Prisoners are persons who are inherently coerced due to the prison environment and conditions. The equal protection principle is used to show that when a prisoner participates in research, that prisoner's right to be treated equally with respect to "autonomy accorded other citizens" is violated because the prisoner was coerced.<sup>144</sup>

There have been very few cases decided that relate to biomedical and behavioral research on prisoners. Of those, the leading prison research case is *Bailey v. Lally* in which a group of former state prisoners who had participated in research medical tests brought a class action suit in federal court.<sup>145</sup> They claimed that conditions of coercion and inducement had caused them to participate in the research involuntarily, which violated their constitutional rights to due process and against cruel and unusual punishment.<sup>146</sup> During the time of the experiments, the prison where these former prisoners were serving their sentences had very poor conditions; there was no hot water, no heat in the winter, overcrowding (two men to a cell), excessive noise and sanitation problems.<sup>147</sup> For the purpose of the research experiments a Medical Research Unit [hereinafter "MRU"] was established outside of the prison.<sup>148</sup> The prisoners were offered money as payment for participating in the research project at a rate higher than they would have been able to get through the available prison jobs.<sup>149</sup>

Prisoners were given the chance, if they participated, to leave the conditions of the prison to go to the MRU. The MRU was adequately heated, quiet, and had hot water, color television, and three separate bathroom facilities.<sup>150</sup> The researchers "considered a written consent form insufficient and relied on the repetitive oral explanations to inform the prisoners," but would at some point later require the prisoners to read and sign written consent forms.<sup>151</sup> The MRU researchers conducted experiments involving common infectious diseases such as the flu or common cold.<sup>152</sup> None were harmed by or infected with a disease that could not be cured quickly; the harm that these former prisoners claimed was that they were deprived of their right to voluntarily choose to participate due to the inherent and extrinsic coercion placed on them.<sup>153</sup>

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

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

<sup>145</sup>*See* 481 F. Supp. 203; Schroeder, *supra* note 104, at 978.

<sup>146</sup>*Bailey*, 481 F. Supp. at 203.

<sup>147</sup>*Id.* at 205.

<sup>148</sup>*Id.* at 206.

<sup>149</sup>*Id.*

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

<sup>151</sup>*Bailey*, 481 F. Supp. at 210.

<sup>152</sup>*Id.* at 203.

<sup>153</sup>*Id.* at 205.

Neither of the constitutional claims was successful; the court stated that because the research was not incompatible with “the evolving standards of decency that mark the progress of a maturing society” and because it did not involve “the unnecessary and wanton infliction of pain,” the claim of violation of the Eighth Amendment must fail.<sup>154</sup> Because the prisoners were informed that they could withdraw from the experiment at any point, the court stated that the prisoners could not have been subject to cruel and unusual punishment.<sup>155</sup> As to the Fourteenth Amendment, the court reasoned that because the acts of the defendants did not “shock the conscience” of mankind, the plaintiffs were not entitled to due process.<sup>156</sup> Since the researchers continuously informed the prisoners about the experiment and many prisoners were not attracted to undergo the experiment despite its benefits, the court found that the prisoners acted both voluntarily and informed.<sup>157</sup>

There are several causes of coercion in the prison setting, some that qualify as inherent situational coercion and others that qualify as inducement from the researcher or institution supporting the research. Monetary compensation paid to prisoners is one of the most common coercive tools used by researchers.<sup>158</sup> Paying prisoners more money than what they could get otherwise may make participation seem overwhelmingly attractive and may motivate prisoners to take risks that they would not normally agree to take.<sup>159</sup> However, it is also argued that if pay is so minimal as to be equal to or less than normal prisoner pay, then prisons will become the most attractive research setting because of such a low price to pay for conducting the research.<sup>160</sup> Other coercive tools that are often used are:

Separating the prisoners for the experiment, which can provide prisoners with better housing conditions (i.e. receiving a single cell or being able to participate in research outside of the institution at a medical hospital as opposed to living in overcrowded conditions);

The chance to avoid less attractive prison related jobs involving hard labor and less attractive conditions of the prison setting, such as sanitation, heating, and water (this is often referred to as “situational coercion”); and,

The idea that participation will make the prisoner appear to be a better and improved person when his/her parole is up for review (Even though the prisoner might think this, recall that one of the IRB’s determinations to be

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<sup>154</sup>*Id.* at 219.

<sup>155</sup>*Id.*

<sup>156</sup>*Bailey*, 481 F. Supp. at 219

<sup>157</sup>*Id.* at 220.

<sup>158</sup>*See id.* at 203; *Mastrian v. Schoen*, 725 F.2d 1164 (8th Cir. 1984); *Bibeau v. Pacific Northwest Research Found. Inc.*, 188 F.3d 1105 (9<sup>th</sup> Cir. 1999).

<sup>159</sup>*Brakel*, *supra* note 28, at 19.

<sup>160</sup>*Id.*

made is that there will be no consideration given to the participation in the research by the prisoner's parole board).<sup>161</sup>

All of these, separately or combined, can have the effect of coercing an individual prisoner to participate in research that he or she would not ordinarily participate.

The DHHS's additional protections for prisoner subjects do not place much weight on preventing coercion and use vague rules to try to prevent such coercion.<sup>162</sup> However, it is clear that the DHHS had coercion in mind when creating the additional protections for prisoners; the statement of purpose in 45 C.F.R. § 46.302 recognizes that prisoners are under constraints due to their incarceration that may affect their ability to voluntarily consent to participation in research.<sup>163</sup> Also, recall that the second determination the IRB must make is that the advantages of participation in the research are not of such a magnitude that a prisoner's ability to weigh the value of each is impaired.<sup>164</sup> This consideration is meant to prevent coercion in the prison setting.

The FDA also does a poor job of addressing coercion used to achieve research regulated by that agency.<sup>165</sup> 21 C.F.R. § 50.20 requires only that the "investigator shall seek [to] . . . minimize the possibility of coercion or undue influence."<sup>166</sup> This allows a researcher to show that coercion has been minimized where it might have been great before by only decreasing it by a small increment. This small decrease in coercive forces would not make a difference in prison settings where coercion is an inherent force.

#### VI. BIOMEDICAL AND BEHAVIORAL RESEARCH ON JUVENILE INMATES

There are many reasons why juvenile inmates are an especially beneficial population of research subjects to target for conducting biomedical and behavioral research. The most prominent of those reasons is that the benefits of researching on children and prisoners are combined. Juvenile inmates for the most part consist of poor urban males.<sup>167</sup> Many of the juveniles who are detained are uneducated and have a great number of medical problems upon admission to the detention facility, ranging from sexually transmitted diseases to mental illnesses.<sup>168</sup> These diseases give

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<sup>161</sup>*Bailey*, 481 F. Supp. at 203. See also *Brakel*, *supra* note 28, at 20; *Bloche*, *supra* note 139, at 285.

<sup>162</sup>45 C.F.R. § 46.305(a)(2).

<sup>163</sup>§ 46.302.

<sup>164</sup>§ 46.305(a)(2) (1999). ("Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.").

<sup>165</sup>21 C.F.R. § 50.20 (1999).

<sup>166</sup>*Id.*

<sup>167</sup>Ronald A. Feinstein, et al., *Medical Status of Adolescents at Time of Admission to a Juvenile Detention Center*, 22 J. ADOLESC. HEALTH 190, 194 (1998).

<sup>168</sup>*Id.*

researchers an opportunity to research and test possible cures and treatments. Something else that works to the benefit of researchers is the fact that, when admitted to the detention facility, most juvenile inmates need medical treatment and cannot afford to obtain such treatment.<sup>169</sup> Juvenile inmates in such a situation will likely be willing to undergo experimental treatment if they are led to believe it will help them. Researchers can test their promising drugs and cures on these children without having to spend money coercing them, and without obtaining “assent” (consent) to the research since it directly benefits the welfare of the child.<sup>170</sup>

There are also a number of behavioral problems among juvenile inmates that might lead researchers to conduct experiments on this group. Behavioral problems, depression and even learning disabilities are higher in juvenile inmates than other children.<sup>171</sup> Antisocial personality disorder, borderline personality disorder, paranoid disorder, and passive-aggressive disorder are the most common personality disorders found among juvenile inmates.<sup>172</sup> These are heavily researched areas of psychology, and therefore, juvenile inmates are one of the best sources for that research.

There are many problems that arise with juvenile inmates who participate in biomedical and behavioral research that are not addressed by the federal regulations. One important issue that relates to juvenile inmates seeking remedies for any injury caused by research is the statute of limitations.<sup>173</sup> This issue arises when side effects due to the research show up years after the actual experiment.<sup>174</sup> These side effects are the injury resulting from the participation in the research while in prison.<sup>175</sup> By the time the side effects are known by the former juvenile inmate, possibly now an adult, the statute of limitations may have run, which bars any claims the injured might otherwise be able to bring.<sup>176</sup> What is referred to as the discovery rule is often the determining factor in these cases.<sup>177</sup> Under the discovery rule, once the injured person discovers the injury the statute of limitations starts to run, but diligence must be used in discovering the critical facts of the injury.<sup>178</sup>

One prime example of this scenario is *Bibeau v. Pacific Northwest Research Foundation, Inc.*<sup>179</sup> In this case a former inmate, while incarcerated, participated in a research experiment that tested the effects of radiation on human testicular

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<sup>169</sup>*Id.*

<sup>170</sup>*Id.* See also 45 C.F.R. §§ 46.408(a), 46.405 (1999).

<sup>171</sup>Feinstein, *supra* note 167, at 191.

<sup>172</sup>Thomas D. Eppright, et al., *Comorbidity of Conduct Disorder and Personality Disorders in an Incarcerated Juvenile Population*, 150 AM. J. PSYCHIATRY 1233, 1235 (1993).

<sup>173</sup>See generally *Bibeau*, 188 F.3d 1105.

<sup>174</sup>*Id.* at 1106.

<sup>175</sup>*Id.*

<sup>176</sup>*Id.*

<sup>177</sup>*Id.* at 1107.

<sup>178</sup>*Bibeau*, 188 F.3d at 1108.

<sup>179</sup>*Id.*

function.<sup>180</sup> Side effects from the experiment had developed some twenty years later causing pain to the former inmate.<sup>181</sup> However, all of the former prisoner's claims were barred by the statute of limitations.<sup>182</sup> The plaintiff in this case had experienced various symptoms and ailments through his life such as severe testicular pain and periodic groin rash, which he had considered "common male complaints."<sup>183</sup> The plaintiff never consulted a doctor, nor did he ever think that the various symptoms were directly related to the experiment that had taken place years ago.<sup>184</sup> The court held, according to these facts, that the plaintiff had not acted diligently in discovering the injury.<sup>185</sup> This type of problem is more likely to occur with juveniles since they might not become aware of any injury until years later, when it might become comprehensible to them.

Another problem for juvenile inmates is that there are inadequate protections available for them as a group under the federal regulations. Remember that there are two separate additional sets of regulations for both prisoners and children created by the DHHS.<sup>186</sup> In order for both of these regulatory provisions to apply to juvenile inmates, this class of persons must meet both the definitions given for "children" and "prisoner."<sup>187</sup> A combining of the definitions allows only individuals "involuntarily confined or detained in a penal institution"<sup>188</sup> and "who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction"<sup>189</sup> where conducted to be covered by both regulations.

There are many discrepancies that arise when the two sets of additional protection regulations are applied to juvenile inmates. Recall that one protection for prisoners is that a prisoner is required to be a member of the IRB to give adequate representation of prisoners' interests.<sup>190</sup> If this requirement is fulfilled in the juvenile prisoner setting, then the prisoners' interests could not possibly be adequately represented. A child, who cannot even give "legal consent" by definition, cannot give reasonable input on the decisions made by the IRB on approving or disapproving of the research protocol.<sup>191</sup>

Both additional protection regulations apply a "minimal risk" standard, which compares that risk to the "physical or psychological harm that is normally

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<sup>180</sup> *Id.*

<sup>181</sup> *Id.* at 1109.

<sup>182</sup> *Id.*

<sup>183</sup> *Bibeau*, 188 F.3d at 1109.

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *See generally* 45 C.F.R. §§ 46.300, 46.400 (1999).

<sup>187</sup> §§ 46.301, 46.401.

<sup>188</sup> § 46.303(c).

<sup>189</sup> § 46.402(a).

<sup>190</sup> § 46.304(b).

<sup>191</sup> *Id.* *See also* § 46.402(a).

encountered in the daily lives.”<sup>192</sup> Again, this is an ambiguous standard, which does nothing but harm the rights of juvenile inmates. It is ambiguous as to whether “minimal risk” is to be measured by the risks encountered in the daily life of an average, everyday person, or whether it is to be measured by the risks encountered by the actual subjects who are participating in the research, here being juvenile prisoners.<sup>193</sup> The fact that juvenile prisoners engage in more dangerous activities and live in harsh social conditions, creating higher risk situations in their daily lives, could broaden the definition of “minimal risk.”<sup>194</sup> If this definition becomes too broad, then many types of research that might have been rejected by a strict standard, as was intended by the regulations, would be permitted.

The two sets of regulations also conflict in other ways. There is a special provision in Subpart D of title 45, part 46, which provides the additional protections for research on children, that covers children who are wards of the state.<sup>195</sup> Research can only be conducted upon wards of the state when related to their status as wards and when the majority of other children involved in the same research experiment are not wards.<sup>196</sup> The second of these two requirements conflicts directly with the additional protections placed on prisoners. Under 45 C.F.R. § 46.305(a) the fourth consideration to be made by the IRB in deciding whether to approve the research protocol is that the prisoner subjects be selected equally and randomly.<sup>197</sup> Since there may be participants who are wards, a strong possibility in juvenile institutions, researchers cannot select possible participants randomly, when at the same time they are required to give careful consideration in making sure that there is a majority of prisoners who are not wards of the state. Juvenile prisoners cannot be selected randomly if care must be taken to make sure that there is a majority of prisoners who are not wards of the state and actually have parents or guardians to consent for them. It may also be very difficult to choose subjects among juvenile prisoners equally when certain children must assent to the research, while others are not required to give such assent.<sup>198</sup>

Another conflict between the two sets of regulatory protections revolves around the issue of informed consent. The additional protections for prisoners require, in the fifth consideration made by the IRB, that information be provided to the subject population in a way that is understandable to the subjects.<sup>199</sup> This poses a problem when dealing with juvenile inmates who, due to their maturity level, may have a hard time understanding and comprehending certain information. While strictly adhering to this requirement could prevent all research on juvenile inmates, several states that

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<sup>192</sup> § 46.303(d).

<sup>193</sup> Katerberg, *supra* note 36, at 556.

<sup>194</sup> *Id.*

<sup>195</sup> 45 C.F.R. § 46.409 (1999).

<sup>196</sup> §§ 46.409(a)(1)-(2).

<sup>197</sup> § 46.305(a)(4).

<sup>198</sup> § 46.408.

<sup>199</sup> § 46.305(a)(5).

carry "mature minor" laws may still permit research on these juveniles.<sup>200</sup> These laws allow children to give informed consent to medical treatment when they have attained such early ages as fourteen or fifteen.<sup>201</sup> Sometimes these "mature minor" laws permit a child, who can exhibit a competency to understand the research and its procedures, to be the deciding factor of legal age to give informed consent, rather than allowing consent dependent on the age of the minor.<sup>202</sup> In a study conducted on researchers, three-fourths of all of the researchers "said they would use their clinical judgment to evaluate whether the child had sufficient maturity to assent."<sup>203</sup> Given a researcher's self-interest, this is too much discretion in his/her hands.

One argument against the researcher having so much discretion is that researchers have a fiduciary duty to their subjects.<sup>204</sup> The law of fiduciary duty is meant to protect individuals with less expertise, here the subjects, from the abuse of power given or delegated to the fiduciary, here the researcher or investigator.<sup>205</sup> Although this is a concept borrowed from the field of medical treatment, it may also be applied to biomedical and behavioral research, since subjects often depend on the researcher's knowledge and expertise as patients depend on their physicians to assist them in making medical decisions.<sup>206</sup> Researchers are associated with a class of individuals with superior knowledge similar to other professionals who have fiduciary duties.<sup>207</sup> One important fiduciary duty is to prevent any unnecessary inducement or coercion to persuade the subject to participate in the research.

Coercion is a much more difficult problem among juvenile inmates than any other class or group of individuals who participate in biomedical and behavioral research. The same modes of coercion or influence that may be tolerated in research on adult prisoners would be very problematic in the experimentation on juvenile prisoners.<sup>208</sup> The inducement needed to obtain consent in a vulnerable class of individuals is easier than that required for obtaining consent from average individuals.<sup>209</sup> The more disadvantaged a class of individuals is, the less inducement or coercive external force is needed.<sup>210</sup> The combination of prison life and maturity level of children, often with behavioral problems, makes for a very disadvantaged population.

The same coercive tools can be used on juvenile inmates to induce them to participate in research, as on adult prisoners. However, coercive tools can have a

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<sup>200</sup>Koren, *supra* note 98, at 144.

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

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

<sup>203</sup>*Id.*

<sup>204</sup>Delgado, *supra* note 24, at 106-10.

<sup>205</sup>*Id.*

<sup>206</sup>*Id.*

<sup>207</sup>*Id.*

<sup>208</sup>Bloche, *supra* note 139, at 293.

<sup>209</sup>King, *supra* note 17, at 194-95.

<sup>210</sup>*Id.*

more extreme effect on juveniles who are incarcerated. Again, money paid to the prisoners is the most common inducement.<sup>211</sup> One argument used often to address this problem is to offer the prisoners the same rate of pay as would be received for any other prisoner job or work activity.<sup>212</sup> There are two deficiencies that make this suggestion flawed in its application. The first, is that the more the pay rate is lowered, the more attractive the group becomes for experimentation to researchers because the research then becomes much cheaper to conduct.<sup>213</sup> This in turn would increase the amount of research ultimately conducted on juvenile inmates. The second flaw to this suggestion, is that even though juvenile prisoners will be paid the same rate that they would have received through other prison jobs, they are being paid for easier work. Prison jobs often are accompanied by hard labor; therefore, juvenile inmates might want to give up their jobs for easier activities by participating in a research experiment. However, one federal district court has held that where an adult prisoner is presented with other opportunities to make money besides participation in a research experiment, there is no coercion on the part of the researcher.<sup>214</sup>

Situational coercion also plays a large role in the problems facing biomedical and behavioral research on juvenile inmates. According to psychology principals, “myriad life situations” cause coercion in and of themselves without any external force.<sup>215</sup> Based on this principle, all aspects that make up a juvenile prisoner’s daily life already have a coercive nature to them, before any inducement comes from researchers. One example of situational coercion in a juvenile prisoner’s life might be that the prisoner currently shares a cell with a violent cellmate; that individual is already coerced into doing anything that may give him a single cell or the chance to move to another location.<sup>216</sup> Other situational coercion might include unsanitary living conditions, inadequate heat or hot water, overcrowding and excess noise within the prison, which may cause anxiety or fear.<sup>217</sup> All of these types of conditions are examples of situational coercion affecting the juvenile prisoner’s right to choose to participate in research voluntarily. Even the court in *Bailey*, which found no coercion in that case, acknowledged that “where there are no opportunities for productive activity, research projects might offer relief from boredom.”<sup>218</sup>

Coercion is at the core of the constitutional arguments that would be made by juvenile prisoners. Unfortunately, these arguments have not been successful in the courts. It has been held that constitutional remedies will not be granted if the subjects are granted the ability to withdraw from the experiment at any time during

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<sup>211</sup>Brakel, *supra* note 28, at 8.

<sup>212</sup>Schroeder, *supra* note 104, at 990-91.

<sup>213</sup>*Id.*

<sup>214</sup>Roach v. Kligman, 412 F. Supp. 521, 527 (E.D. Pa. 1976).

<sup>215</sup>Schroeder, *supra* note 104, at 990-91.

<sup>216</sup>Bloche, *supra* note 139, at 285.

<sup>217</sup>Schroeder, *supra* note 104, at 977.

<sup>218</sup>*See Bailey*, 481 F. Supp. at 215.



such experiment.<sup>219</sup> This is a major problem when the informed consent provisions of 45 C.F.R. § 46.116(a) require that every consent form contain a statement informing subjects that they may discontinue participation at any time without penalty or loss of benefits.<sup>220</sup> Even where there is coercion from the outset, if there is “proper” informed consent, containing a provision that allows for withdrawal from the experiment at any time, then all constitutional claims will be barred. There appears to be an inherent penalty that subjects must face. As long as that statement is required to be a part of informed consent by 45 C.F.R. § 46.116(a), the subjects are barred from bringing any constitutional claims for any violations of rights based on coercion as the courts suggest.<sup>221</sup> If this dilemma can be overcome, then the best argument for juvenile prisoners to make is a violation of the Eighth Amendment’s cruel and unusual punishment clause.

Even if the Eighth Amendment argument is reached, it is also very hard to win, especially for a juvenile prisoner who is a subject in a research experiment. Few cases have heard Eighth Amendment claims brought by prisoners who have participated in research experiments, but the ones that have have dismissed the claims.<sup>222</sup> The courts have held that in order to show cruel and unusual punishment, the thing or injury that had occurred must be “shocking to the conscience” of mankind.<sup>223</sup> The “cumulative impact of several prison conditions” can amount to cruel and unusual punishment, but even then, the combination of those conditions must still be shocking to the conscience of mankind.<sup>224</sup> There have been other standards applied in Eighth Amendment cases involving prisoners who are not research participants. One, which may be borrowed for purposes of research cases, is that prison officials have a duty to provide humane conditions and to take reasonable measures to guarantee the prisoners’ safety.<sup>225</sup> It has also been held that, according to the Eighth Amendment, there must not be any “serious deprivation of basic human needs.”<sup>226</sup> Another common standard is that treatment that is “incompatible with ‘evolving standards of decency that mark the progress of a maturing society’” violates the Eighth Amendment.<sup>227</sup> However, no case has actually been heard where juvenile prisoners brought an action for violation of the Eighth Amendment. There is one case, from the Ninth Circuit Court of Appeals, that held

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<sup>219</sup>*Id.* See also *Tripp v. Carter*, No. 99-3304, 1999 WL 966099 (N.D. Ill. Oct. 12, 1999) (holding in a research experiment testing saccharin by placing it in the prisoners’ punch, the prisoners were to have a free choice whether they wished to continue drinking the punch).

<sup>220</sup>45 C.F.R. § 46.116(a)(8) (1999).

<sup>221</sup>See generally *Bailey*, 481 F. Supp. 203.

<sup>222</sup>*Id.*; *Roach*, 412 F. Supp. 521.

<sup>223</sup>See *Bailey*, 481 F. Supp. at 219. See also *Roach*, 412 F. Supp. at 525.

<sup>224</sup>*Roach*, 412 F. Supp. at 527.

<sup>225</sup>*Hudgins v. DeBruyn*, 922 F. Supp. 144, 149 (S.D. Ind. 1996).

<sup>226</sup>*Moore v. Scully*, No. 87-4773, 1990 WL 66494, at \*2 (S.D.N.Y. May 15, 1990).

<sup>227</sup>*Oliver v. Deen*, 77 F.3d 156, 159 (7th Cir. 1996).

that “tinkering with [one’s] mental processes” as some research does might raise serious constitutional questions as to cruel and unusual punishment.<sup>228</sup>

Another major problem with bringing claims of injury resulting from participation in research experiments is that even if the claims are successful, the named defendants in the cases are often excused by what is termed “qualified immunity.”<sup>229</sup> Qualified immunity applies to most researchers who either are public officials or who contract with the government to carry out the research.<sup>230</sup> The defense was created to balance public policy concerns between protecting individuals’ constitutional rights and defending public officials from suits brought against them for every error, thereby diverting them from their public duties.<sup>231</sup> If a defendant did not know or should not have reasonably known that his/her action would violate the constitutional rights of the plaintiff, or did not take action with “malicious intention to cause deprivation of constitutional rights or other injury to plaintiff,” then the qualified immunity defense will be granted to the defendant.<sup>232</sup> Qualified immunity has been used, in many cases, to excuse defendants for their violations of the subjects’ individual rights.<sup>233</sup> No case has yet been brought in the federal courts involving juvenile inmates, but the same defense of qualified immunity could apply. *Bailey* held that the preference of society not to research on the socially or economically underprivileged (e.g. prisoners) “does not add up to a presently established constitutional absolute.”<sup>234</sup>

Juvenile prisoners who have been injured may also bring suit under the Federal Tort Claims Act (hereinafter “FTCA”).<sup>235</sup> Unfortunately, prisoners who have brought claims of injury under this tort theory have had their claims dismissed.<sup>236</sup> The FTCA requires that plaintiffs exhaust their administrative remedies before bringing an action in the courts.<sup>237</sup> However, in two of these cases the plaintiff prisoners attempted to bring an action in the administrative agency before commencing suit in court, and were rejected by the administrative agency which the plaintiffs contacted.<sup>238</sup> The court in both cases still held that the plaintiffs had failed to exhaust

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<sup>228</sup>*Mackey v. Procunier*, 477 F.2d 877, 878 (9th Cir. 1973).

<sup>229</sup>*See generally Bibeau*, 188 F.3d 1105; *Roach*, 412 F. Supp. 521, *Lee v. Armontrout*, 991 F.2d 487 (8<sup>th</sup> Cir. 1993); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796.

<sup>230</sup>*In re Cincinnati Radiation Litig.* at 807.

<sup>231</sup>*Id.*

<sup>232</sup>*Roach*, 412 F. Supp. at 528. *See also O’Conner v. Donaldson*, 422 U.S. 563, 577 (1975).

<sup>233</sup>*See generally Mackey*, 477 F.2d 877.

<sup>234</sup>*Bailey*, 481 F. Supp. at 225.

<sup>235</sup>28 U.S.C. §§ 1346(b), 2671 (1999).

<sup>236</sup>*See McNeil v. United States Public Health Service*, No. 89-1822, 1991 WL 9994 (N.D. Ill. Jan. 24, 1991); *Wilson v. United States Public Health Service*, No. 89-2163, 1989 WL 39778 (N.D. Ill. Apr. 14, 1989).

<sup>237</sup>28 U.S.C. § 2675(a) (1999).

<sup>238</sup>*See Wilson*, 1989 WL 39778, at \*1; *McNeil*, 1991 WL 9994, at \*1.

their administrative remedies.<sup>239</sup> In one of the cases, the plaintiff merely wrote a letter to the FDA asking for damages for the injury caused by the experiment, which the court held was not sufficient for exhausting his administrative remedies.<sup>240</sup> In the other case, the plaintiff did file an administrative claim with the DHHS, but the claim was denied in a letter to the plaintiff, notifying him that he had six months to file an FTCA suit in court.<sup>241</sup> The plaintiff did not meet that demand, and therefore, the court barred his claim for failing to meet the requirements of the administrative procedure.<sup>242</sup> With these strict guidelines, juvenile inmates, who may not be able to afford or obtain legal assistance, will be unable to succeed on FTCA claims.

This leads to another major problem with juvenile inmates, which is that they usually have no legal representation and often fail to recognize when legal representation is needed.<sup>243</sup> Juvenile prisoners can hardly seek to recover under any of the possible claims when they cannot receive legal advice. One suggestion is that the researchers and institutions that seek to conduct experiments on this particularly vulnerable population provide legal representation for the individual subjects.<sup>244</sup> However, this presents a conflict of interest where the attorney would be hired by the researcher, yet at the same time represent the inmate. Again, there is a risk that the juveniles will not be able to comprehend what it is that the attorney is advising.

Finally, 45 C.F.R. § 46.124 permits implementing additional protections for juvenile inmates.<sup>245</sup> That section provides that “with respect to any research project...the department or agency head may impose additional conditions prior to or at the time of approval when...necessary for the protection of human subjects.”<sup>246</sup> This provision should be used frequently when considering research subjects who are juvenile inmates.

## VII. CONCLUSION

The current regulations are not enough to protect juvenile inmates from coercive “choices,” caused by the nature of prison and incentives used by researchers. However, as stated by J. Thomas Puglisi, Director of the Division of Human Subject Protections under the DHHS, during congressional testimony, “We are always interested in improving the system to make research as safe as it can possibly be.”<sup>247</sup> The system needs improvement in various ways to remedy the flaws that have been discussed. One of two things must occur to remedy these flaws.

Either there must be additional protections passed by the DHHS addressing the specific issues of juvenile inmates, or there should be a total prohibition against

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<sup>239</sup>See *Wilson*, 1989 WL 39778, at \*1.

<sup>240</sup>*Wilson*, 1989 WL 39778, at \*1.

<sup>241</sup>See *McNeil*, 1991 WL 9994, at \*1

<sup>242</sup>*Id.*

<sup>243</sup>King, *supra* note 17, at 200.

<sup>244</sup>*Id.*

<sup>245</sup>45 C.F.R. § 46.124 (1999).

<sup>246</sup>*Id.*

<sup>247</sup>Puglisi, *supra* note 26.

research on juvenile prisoners. If additional protections are created, they should set a cutoff age by which only the oldest juvenile inmates may participate in research experiments. Such age provisions might limit participation at age fourteen or fifteen, and any person below those ages would be prohibited from research experiments. For those individuals who are ages fourteen or fifteen and above, participation in any research experiment should depend on their ability to pass an informed consent test, which would assess the individual's ability to understand the ramifications of any such experiment. This informed consent test should be reviewed by the IRB before being administered to the individual. In order for the total prohibition to be implemented, the subject would have to meet both the definitions of a child and a prisoner according to the federal regulations. Research is still being conducted on juvenile inmates, as evidenced by the 1997 Stanford University study on sixty-one juvenile inmates, and will continue to be conducted in the future so long as it is possible for researchers to do so.<sup>248</sup> Therefore, the need for these proposed changes is immediate.

Researchers may be faced with the loss of a very beneficial research group if research experimentation is prohibited, but there are alternative groups that are just as beneficial.<sup>249</sup> One example is the use of military programs such as Medical Research Volunteer Subjects programs.<sup>250</sup> These types of programs involve healthy soldiers who are willing to participate in biomedical and behavioral research.<sup>251</sup> These types of programs can supply researchers with a group of healthy, well-informed, and uncoerced subjects who require little money to participate.<sup>252</sup> There are also other ways to conduct research on children who are not incarcerated to experiment on the same types of behavioral problems.

The Nuremberg Code provides that subjects of research "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."<sup>253</sup> A population of juvenile prisoners is not so situated.

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<sup>248</sup>Weber, *supra* note 1.

<sup>249</sup>Moreno, *supra* note 21.

<sup>250</sup>*Id.*

<sup>251</sup>*Id.*

<sup>252</sup>*Id.*

<sup>253</sup>King, *supra* note 17, at 195. *See also* The Nuremberg Code, *supra* note 31.

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