Compensation Background

Contents

I. Purpose and Design of this Module

The Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) conducts research and develops reports and other materials for public distribution in order to advise the President of the United States on bioethical issues that arise as a

consequence of advances in biomedicine and related areas of science and technology. To support ethics education and facilitate the integration of bioethical analysis into existing curricula across traditional and nontraditional educational and professional settings, we have developed pedagogical materials designed to increase distribution of the Bioethics Commission's work and to facilitate easy access to the material in its reports by professors, instructors, teachers, and professional leaders (collectively "instructors").

This module was prepared for instructors who want to include in their teaching a discussion of compensation for research-related injury. It provides foundational information, ethical reasoning, applications, questions, discussion points, and additional readings that are designed to give the instructor enough information to plan lectures, discussions, or activities. These materials are not intended to be a lecture script or outline, but rather to support the instructor in developing his or her own presentation(s).

In addition to the background information provided here, further modules provide a guide for instructors to facilitate incorporation of the Bioethics Commission's published reports as a resource for teaching and discussions. The featured Bioethics Commission reports illustrate relevant and current applications of ethical concepts related to compensation for research-related injury.

Instructors are invited to use these materials, or any portion of them, to integrate bioethics into coursework and professional development activities in all disciplines. Feedback is welcome, including insight into how the materials have been used and suggestions for how they might be improved for use in the future. (Send feedback to education@bioethics.gov.)

II. Introduction

Compensation for research-related injury ensures that individuals who are injured as a result of participating in research receive financial compensation and/or medical treatment as a way of making the injured research participant whole. Compensation for research-related injury is distinct from other types of compensation that arise in the context of human subjects research (including reimbursement for travel arrangements and time spent participating).

An obligation to compensate injured research participants is grounded in a number of ethical principles. The principle of justice and fairness recognizes that the benefits and burdens of research should be distributed equitably. A system of compensation for research-related injury can help redistribute benefits to those disproportionately burdened as a result of participating in research, that is, those injured as a result of participation.

The principle of beneficence, and its corollary non-maleficence, requires maximizing benefits and minimizing harms to research participants. Providing compensation to injured research participants is one way of minimizing harms that can befall research participants. Compensation is also justified by the professional ethical obligations of those who conduct research, including the principles of beneficence and non-maleficence enshrined in professional codes of ethics.

A number of national bodies in the United States—including several bioethics commissions—have considered the issue of compensation for research-related injury over the past four decades. Each of these bodies recognized an ethical obligation to compensate injured research participants. Despite the consistent recognition of an ethical obligation to compensate injured research participants, the United States still does not have a system to ensure that injured research participants routinely receive compensation. This is true, in part, because unanswered questions remain about compensating injured research participants. For example, should all physical, emotional, and psychological injuries receive compensation? Is medical care all that is required? Should monetary compensation for missed wages or other losses be provided as well? How many research participants are injured as a result of participating in research? And what are the costs of providing medical care or compensation?

These questions are challenging to answer, and there might not be a single solution. Many of the countries most involved in research have implemented systems of compensation for research-related injury. Some federal agencies and other institutions in the United States have implemented systems as well. Considering this pressing ethical issue can help ensure that injured research participants are not forced to bear the physical and financial harms of research-related injuries alone.

III. Learning Objectives

Students should be able to:

1. Define compensation for research-related injury.
2. Distinguish between injuries incurred during research and injuries incurred in non-research contexts.
3. Describe ethical justifications for compensating injured research participants.
4. Identify and consider the challenges encountered in providing compensation for research-related injury.

5. Describe the different systems through which injured research participants can be compensated.

6. Describe current systems of compensation for research-related injury in the United States and compare them with other approaches used around the world.

IV. Background

A. Why Compensate Injured Research Participants?

The goal of compensation for research-related injury is to ensure that individuals who are injured as a result of participating in research are left no worse off as a result of their participation than they would have been had they not participated. People can be injured in various activities—for example, playing sports, driving cars, receiving medical care—and there is typically no guarantee or expectation that they will receive free medical care or compensation for their injuries. Unlike individuals in these other situations, those injured as a result of participating in research might have an ethical claim to compensation for at least two reasons. First, in most cases the benefits of research accrue to society more broadly rather than to individual participants. Many elements of research (e.g., randomizing controls, double blinding, adherence to strict protocols) are designed specifically to collect information that will benefit society as a whole, rather than any individual research participant.[1] And research participants might undergo procedures (e.g., blood draws, biopsies, or radiologic scans), or participate in tests or games (e.g., those that reveal something distasteful to the participant about himself or herself), that incur burdens or risk without providing any prospect of direct benefit to the participant.[2]

By contrast, people who choose to take on additional risks by playing sports or driving cars generally do so in hopes of obtaining benefit for themselves. Even when individuals undergo risky medical procedures, they generally do so for their own benefit. For example, people who are sick might agree to undergo surgery for the prospect of direct individual benefit even though the procedure carries risks. Whereas medical care is dedicated to providing individual patients with the best treatment for their particular condition, a primary goal of medical research is to create generalizable knowledge that can be used to benefit *future* patients.[3]

---

[1] Miller, F.G. (2006). Revisiting the Belmont Report: The ethical significance of the distinction between clinical research and medical care. *APA Newsletter on Philosophy and Medicine*, 5(2), 10-14.
[2] Ibid.
[3] Ibid.

Second, research interventions can have risks that are unforeseeable at the outset. While some potential harms are known before the research is conducted, new and experimental interventions can give rise to unknown or unforeseeable risks. For example, in the 1993 National Institutes of Health (NIH) clinical trial of an experimental drug, fialuridine, for the treatment of hepatitis B, significant unforeseen toxicity of the drug caused five of the 10 research participants to die.[4] The Institute of Medicine concluded, however, that there was "no evidence of negligence or carelessness on the part of the investigators or sponsors."[5] This example is extreme, nevertheless, we as a society need volunteers who are willing to undertake these risks and participate in research so that scientific knowledge can advance for the public good.

B. Ethical Justification

Researchers have a general obligation to protect participants from risks that can be avoided or ameliorated.[6] Accordingly, a number of safeguards have been implemented to protect research participants. These safeguards include prior review of research by an institutional review board (IRB) and the implementation of informed consent processes.[7] These safeguards cannot, however, prevent all harms; some risks are unforeseeable and others are unavoidable. For participants who become injured as a result of participating in research, providing medical care or financial compensation is an additional protection against bearing the burdens of additional physical and financial harm.

A number of ethical principles support compensating injured research participants. For instance, various notions of justice and fairness support the idea that participants who are injured as a result of participating in research should be compensated. One theory of justice, distributive justice, suggests that the benefits and burdens of research be distributed equitably.[8] Accordingly, safeguards should protect research participants from being disproportionately burdened, physically or financially, by research.[9] Without appropriate safeguards, research participants who incur injury are likely to be among

---

[4] Levine, S. (2001, August 13). Clinical trial was near-death experience worth his while. *The Los Angeles Times*. Retrieved August 14, 2014 from http://articles.latimes.com/2001/aug/13/health/he-33634.
[5] Manning, F.J., and M. Swartz (Eds.), Committee to Review the Fialuridine (FIAU/FIAC) Clinical Trials, Institute of Medicine. (1995). *Review of the Fialuridine (FIAU) Clinical Trials.* Washington, DC: The National Academies Press, p. 12.
[6] Presidential Commission for the Study of Bioethical Issues. (2011, December). *Moral Science: Protecting Participants in Human Subjects Research*. Washington, DC: PCSBI, p. 56.
[7] *Protection of Human Subjects, Department of Health and Human Services (HHS)*. 45 C.F.R. § 46.
[8] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The National Commission). (1978). *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research* (DHEW Publication OS 78-0012). Washington, DC: Department of Health, Education, and Welfare.
[9] PCSBI, (2011, December), op cit.

those who are disproportionately burdened. Providing necessary medical care or monetary compensation to injured research participants can redistribute benefits and burdens to help reduce this disproportionate burden.[10]

A second theory of justice, compensatory justice, embodies an ethical obligation to make whole one injured in research.[11] Providing medical care or compensation to injured research participants is one way of attempting to make whole those injured by participating in research.

The principle of beneficence calls on professionals to take actions to ensure the wellbeing of research participants, and its corollary non-maleficence requires not imposing harm.[12] When conducting research with individuals with diminished capacity, respect for persons—which recognizes that individuals are capable of making autonomous decisions—similarly requires not exposing participants to unnecessary risks and providing additional protection from the physical and financial harms that can result from research.[13] Despite the risk inherent to some research, researchers have an ethical obligation to remove harms that can be eliminated while minimizing those that cannot.[14] Minimizing harms requires both minimizing the risks of conducting research—including by using lower risk procedures, whenever possible—and minimizing the physical and financial harms that can result from research-related injuries by providing compensation.[15]

Providing compensation to injured research participants is justified by professional ethical obligations. Many researchers—physicians, nurses, clinical psychologists, and other professionals, including educators—are obligated to act in accordance with professional codes of ethics.[16] These codes call upon professionals to avoid acting in ways that cause harm or to work to remedy any harm that is caused.[17]

---

[10] Resnik, D.B. (2006). Compensation for research-related injuries: Ethical and legal issues. *Journal of Legal Medicine*, 27(3), 263-287.
[11] Office of the Secretary, U.S. Department of Health, Education, and Welfare. (1977). Secretary's Task Force on the Compensation of Injured Research Subjects (DHEW Publication No. OS-77-003). Washington, DC: Department of Health, Education, and Welfare.
[12] The National Commission, op cit.
[13] Presidential Commission for the Study of Bioethical Issues. (2013, March). *Safeguarding Children: Pediatric Medical Countermeasure Research*. Washington, DC: PCSBI, pp. 25-26.
[14] PCSBI, (2011, December), op cit, p. 59.
[15] PCSBI, (2011, December), op cit, p. 94.
[16] Association of American Educators. (n.d.). AAE Code of Ethics for Educators. Retrieved August 14, 2014 from http://www.aaeteachers.org/images/pdfs/aaecodeofethicsforeducators.pdf; National Education

A number of other ethical principles have been cited as giving rise to an ethical obligation to compensate injured research participants. These principles include: utility, the concept that participants might be more likely to enroll in research if they know they will be protected in the event of injury; altruism, the idea that people might choose to participate in research because they wish to contribute to scientific progress in general; and reciprocity, the notion that those who choose to contribute to research should be provided with something in return.[18]

C. Practical Considerations

Although the ethical case for compensating injured research participants is fairly well established, several practical considerations—including informed consent and cost and feasibility—must also be acknowledged.

1. Informed Consent

Federal regulations regarding informed consent require that researchers inform participants about the risks involved in research and obtain their consent to participate.[19] Some have argued that because the risks of research have been explained to participants through the informed consent process, and because participants have nevertheless agreed to participate, injured research participants have no claim to compensation if the accepted risks come to pass.[20]

This argument is founded on the idea of assumption of risk and is not unique to research. For example, a boxer who gets punched during a boxing match generally cannot successfully bring a lawsuit for the injury because the boxer knowingly and voluntarily assumed the risks of taking part in a boxing match. By applying this logic to research-related injury, a participant who knowingly consents to the research risks through the informed consent process could similarly be seen as assuming the risks of research.

Association. (n.d.). Code of Ethics [Webpage]. Retrieved August 14, 2014 from http://www.nea.org/home/30442.htm.

[17] PCSBI, (2011, December), op cit, pp. 32-33.

[18] PCSBI, (2011, December), op cit, p. 61; Litton, P., and F.G. Miller. (2005). A normative justification for distinguishing the ethics of clinical research from the ethics of medical care. *Journal of Law, Medicine & Ethics*, 33(3), 566-574; Jansen, L.A. (2009). The ethics of altruism in clinical research. *Hastings Center Report*, 39(4), 26-36; Pike, E. (2014). In need of remedy: US policy for compensating injured research participants. *Journal of Medical Ethics*, 40(3), 182-185; Mein, G., et al. (2012). Altruism and participation in longitudinal health research? Insights from the Whitehall II Study. *Social Science & Medicine*, 75(12), 2345-2352.

[19] *Protection of Human Subjects, HHS*. 45 C.F.R. § 46.

[20] Mariner, W.K. (1994). Compensation for Research Injuries. In A.C. Mastroianni, et al. (Eds.). *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*, Vol. 2, Workshop and Commissioned Papers (pp. 113-126). Washington, DC: The National Academy Press.

But there are important distinctions between a research participant and a boxer. First, certain research risks are wholly unforeseeable. For example, as described above, the hepatitis B drug trial resulted in the death of five of the 10 research participants due to the unforeseen toxicity of the trial drug, and these deaths did not occur because of any negligence or carelessness by the research investigators or sponsors.[21] Research participants cannot reasonably be thought to have knowingly and voluntarily accepted risks that were unknown or unforeseen at the time they consented to participate. Second, the process of informed consent is intended to protect research participants and ensure that decisions to participate in research are voluntary and uncoerced. Treating informed consent documents as an assumption of foreseen or unforeseen risks obscures the true purpose of the informed consent process. Whether harm results from a foreseen risk, about which they are informed, or from a wholly unforeseen risk, research participants who are harmed as a result of participation in research should not individually bear the costs of medical care for such harms.[22]

2. Cost and Feasibility

A practical consideration associated with compensating injured research participants is the cost of implementing such a system—costs that might come from limited research budgets. However, a number of safeguards that protect research participants—including informed consent and IRB review—are part and parcel of the ethical conduct of research. A compensation system also could be part of the ethical conduct of research.

D. Past U.S. Consideration of Compensating Injured Research Participants

U.S. national advisory bodies have considered the ethical obligation to compensate injured research participants several times over the past four decades. Each advisory body identified an ethical obligation to compensate injured research participants, but disagreed as to how best to implement such a system. The ethical assessments and recommendations of these bodies are summarized in the following table:

Year: Organization, ***Publication Title***	**Excerpt of Ethical Assessment**	**Recommendation**
1973: Department of Health, Education, and Welfare (HEW) Tuskegee	"[N]o matter how careful investigators may be, unavoidable injury to a few is the price society must pay for the	A "'no fault' clinical research insurance plan to assure compensation for subjects harmed as a result of their participation in

[21] Levine, S., op cit; Manning, F.J., and M. Swartz (Eds.), op cit, p. 12.
[22] PCSBI, (2011, December), op cit, p. 58.

Syphilis Study Ad Hoc Advisory Panel, *Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel*	privilege of engaging in research which ultimately benefits the many. Remitting injured subjects to the uncertainties of the law court is not a solution."[23]	research" should be developed, and "institutions which sponsor Federally supported research activities should be required to participate."[24]
1973: HEW Medical Malpractice Commission, *Report of the Secretary's Commission on Medical Malpractice*		"[W]henever a grant or other funding is provided by the Federal government for medical research involving human subjects, the grant should include a sum sufficient to provide either insurance or a self-insurance fund in order to provide compensation to any human subject who may be injured in the course of the research."[25]
1977: HEW Secretary's Task Force on the Compensation of Injured Research Subjects, *Report of the Task Force*	"[T]he Task Force concluded…that because society is both the beneficiary and the sponsor of research, compensatory justice may come into play for the redress of injuries suffered by persons in connection with biomedical or behavioral research conducted, supported, or regulated by the Federal Government."[26]	"Human subjects who suffer physical, psychological, or social injury in the course of research conducted or supported by the PHS [Public Health Service] should be compensated if (1) the injury is proximately caused by such research, and (2) the injury on balance exceeds that reasonably associated with such illness from which the subject may be suffering, as well as with treatment usually associated with such illness at the time the subject began participation in the research….Subjects participating in PHS-sponsored (i.e., extramural not PHS-conducted) research should be supplied assurance of compensation {and should be informed of such inclusion} in the definition of employees within the F.E.C.A. and if injured, should receive

[23] Department of Health, Education, and Welfare (HEW) Public Health Service. (1973). *Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel*. Washington, DC: U.S. Government Printing Office, p. 23. Retrieved May 12, 2014 from http://biotech.law.lsu.edu/cphl/history/reports/tuskegee/tuskegee.htm.
[24] Ibid, p. 24.
[25] Quoted in President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982). *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects.* Washington, D.C.: U.S. Government Printing Office, p. 41.
[26] Department of Health, Education, and Welfare (HEW) Secretary's Task Force on the Compensation of Injured Research Subjects. (1977). *Report of the Task Force*. Bethesda, MD: National Institutes of Health, p. VI-4.

		such compensation as provided by the Act."[27]
1982: President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Compensation for Research Injuries: The Ethical and Legal Implications of Progress to Redress Injured Subjects*	"Experimentation has its victims, people who would not have suffered injury and disability were it not for society's desire for the fruits of research.…In the absence of a program of compensation of subjects, those who are injured bear both the physical burdens and the associated financial costs."[28] "When, however, as is often the case in research with human subjects, those who bear the risks are not the direct beneficiaries of the research, it is felt that the scales of justice are out of balance."[29]	"[T]he Commission recommends that a modest social policy experiment be conducted to determine the need for, and feasibility of, comprehensive or partial programs to compensate injured subjects."[30]
1995: Advisory Committee on Human Radiation Experiments, *Final Report*	"So that years from now others do not have to revisit and struggle with this issue, the federal government must take steps now to address the issue of compensation for injured research subjects."[31]	"[R]ecommends that the Human Radiation Interagency Working Group review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue."[32]
2001: National Bioethics Advisory Commission, *Ethical and Policy Issues in International Research:*		"The U.S. government should not sponsor or conduct clinical trials that do not, at a minimum, provide the following ethical protections:…d) adequate care of and

[27] Ibid, p. II-2.
[28] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982). *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects.* Washington, DC: Department of Commerce, p. 50.
[29] Ibid.
[30] Ibid, p. 105.
[31] Advisory Committee on Human Radiation Experiments. (1995). *Final Report*. Washington, DC: U.S. Government Printing Office, p. 827.
[32] Ibid.

Clinical Trials in Developing Countries		compensation to participants for injuries directly sustained during research."[33]
2001: National Bioethics Advisory Commission, ***Ethical and Policy Issues in Research Involving Human Participants***	"A comprehensive system of oversight of human research should include a mechanism to compensate participants for medical and rehabilitative costs resulting from research-related injuries. The inclusion of this mechanism has long been justified on ethical grounds.…research participants are entitled to be left no worse off than they would have been had they not participated in the research."[34] "[C]urrently, injured research participants alone bear both the cost of lost health and the expense of medical care, unless they are adequately insured or pursue successful legal action to gain compensation from specific individuals or organizations involved in conducting the research."[35]	"The federal government should study the issue of research-related injuries to determine if there is a need for a compensation program. If needed, the federal government should implement the recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982) to conduct a pilot study to evaluate possible program mechanisms."[36]
2011: Presidential Commission for the Study of Bioethical Issues, ***Moral Science: Protecting Participants in Human Subjects Research***	"The Commission concludes that ethics requires that subjects harmed in the course of human subjects research ought not individually bear the costs of care required to treat qualified harms resulting directly from that research."[37]	"The Commission recommends that the federal government undertake a careful assessment to address how best to satisfy the ethical obligation to compensate individuals who suffer research-related injuries as a result of volunteering in a federally funded study."[38]
2013: Presidential Commission for the Study of Bioethical Issues,	"Justice requires that children who participate in pediatric MCM research, which primarily aims to benefit other	"To ensure the thoroughness and ethical rigor of national-level review, reviewers should apply the Bioethics Commission's

[33] National Bioethics Advisory Commission (NBAC). (2001). *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. Bethesda, MD: NBAC, p. 6.
[34] National Bioethics Advisory Commission. (2001). *Ethical and Policy Issues in Research Involving Human Participants*. Bethesda, MD: NBAC, p. 123.
[35] Ibid, p. 125.
[36] Ibid, p. 126.
[37] PCSBI, (2011, December), p. 62.
[38] Ibid, p. 64.

Safeguarding Children: Pediatric Medical Countermeasure Research	children and society more broadly, be treated or compensated for research-related injuries so that they do not bear a disproportionate share of the burdens of research. In addition, the principles of beneficence and respect for persons require that risks to participants be minimized; in this context, such risks include additional medical or financial harm resulting from research-related injuries."[39]	recommended ethical framework for reviewing pre-event pediatric medical countermeasure research that poses greater than minimal risk, but no more than a minor increase over minimal risk, under Department of Health and Human Services regulations at 45 C.F.R. § 46.407 and/or U.S. Food and Drug Administration regulations at 21 C.F.R. § 50.54….The framework specifies a rigorous set of conditions necessary to determine whether the research would be conducted in accordance with the required 'sound ethical principles' that fall into five general categories [including] (3) post-trial requirements to ensure ethical distribution of medical countermeasures in the event of an attack, as well as a plan for treatment or compensation for research-related injury….Finally, the framework reiterates the importance of informed parental permission and meaningful and developmentally appropriate child assent."[40] "Post-event research should be planned in advance and conducted when untested medical countermeasures are administered to children in an emergency or when limited pre-event medical countermeasure studies have already occurred. Institutional review boards must also ensure that the research design is scientifically sound, children enrolled in research have access to the best available care, adequate plans are in place to treat or compensate children injured by research, and provisions are made to engage communities throughout the course of research."[41]

[39] PCSBI, (2013, March), p. 76.
[40] Ibid, p. 87.
[41] Ibid, p. 97.

E. Current U.S. Approach to Compensating Injured Research Participants

Current U.S. law governing all federally supported research does not require that research participants receive free medical care or compensation for research-related injury. U.S. regulations require only that participants enrolled in greater than minimal risk research receive an explanation as to whether, and to what extent, compensation or medical treatment will be available in the event of a research-related injury.[42]

A 2005 study commissioned by the U.S. Department of Health and Human Services found that most research institutions do not have formal injury compensation policies.[43] Of the 129 policies reviewed, 84 percent of policies did not provide free care or treatment to injured research participants.[44] None of these policies offered compensation for lost wages or pain and suffering.[45]

There are some independent academic centers that provide compensation. For example, the University of Washington maintains a fund that distributes compensation for research-related injuries. This system can provide up to $10,000 for out-of-pocket expenses, as well as the cost of treatment at University of Washington facilities.[46] The university usually receives one or two claims for compensation from this fund per year.[47]

Some federal departments and agencies, including the U.S. Department of Defense (DOD) and the U.S. Department of Veterans' Affairs (VA), also provide treatment or compensation for injured research participants. VA regulations require that care be provided for all research-related injuries, including injuries that occur during minimal

---

[42] *General Requirements for Informed Consent, HHS*, 45 C.F.R. § 46.116(a)(6); Office for Human Research Protections, U.S. Department of Health and Human Services. (1996). "Exculpatory Language" in Informed Consent. Retrieved August 14, 2014 from http://www.hhs.gov/ohrp/policy/exculp.html.

[43] The Lewin Group. (2005). Task Order No. 2: Care/compensation for injuries in clinical research. Draft Final Report prepared for the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. Falls Church, VA: The Lewin Group, p. ES-2.

[44] The Lewin Group, (2005), op cit.

[45] The Lewin Group, (2005), op cit, p. B-8; Resnik, D.B., et al. (2014). Research-related injury compensation policies of U.S. research institutions. *IRB: Ethics and Human Research*, 36(1), 12-20.

[46] Moe, K.E., Director and Assistant Vice Provost For Research, University of Washington. (2011). University of Washington Human Subjects Assistance Program. Presentation to PCSBI, November 17. Retrieved May 12, 2014 from http://bioethics.gov/node/391. See also, University of Washington. (n.d.). *Human Subjects Manual, Section VII (G).* Retrieved August 19, 2014 from http://staff.washington.edu/brz/MANUAL/99-VII.htm#VII-g (explaining that the program "is intended primarily to provide necessary medical care to subjects who sustain bodily injury as a direct result of participation in a research project").

[47] Steinbrook, R. (2006). Compensation for injured research subjects. *New England Journal of Medicine*, 354(18), 1871-1873, p. 1872.

risk research.[48] Individuals injured during the course of research conducted by DOD are protected from medical expenses directly resulting from that research, but do not receive other types of compensation.[49] The NIH Clinical Center provides short-term medical care, but not long-term medical care or financial compensation, to those injured as a result of research conducted at its facilities.[50] And in 2000, Medicare began covering the medical costs of research-related injuries incurred by clients who participated in therapeutic trials as healthy volunteers.[51]

Participants injured while participating in research at institutions that do not provide compensation can seek compensation by bringing a lawsuit, but doing so is difficult. To receive compensation under tort law, the body of law that governs when one is entitled to monetary compensation for harms resulting from another's wrongful acts, injured participants generally must prove that the researcher's negligence led to their injury. To prove negligence, injured research participants must demonstrate: first, that the researcher owed a duty to the participant; second, that the researcher breached that duty; third, that the breached duty caused the participant's injury; and fourth, that the researcher did not have legal justification for the failure. Proving these elements is generally difficult for research participants because research-related injuries can occur absent any fault on the part of the researcher.

F. International Approaches to Compensating Injured Research Participants

Over the past decade, most of the countries that are substantially involved in research, including 31 European countries and several non-European countries, have mandated compensation for research-related injury.

In 2001, the European Parliament and the council of the European Union issued the Clinical Trials Directive, which mandated that E.U. member states implement systematic compensation for research-related injuries. Under the directive, a clinical trial may be conducted only if "provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor" as evaluated and verified by a research ethics

[48] *Treatment of Research-Related Injuries to Human Subjects, HHS*. 38 C.F.R. § 17.85.
[49] U.S. Department of Defense. (2011, November 8). Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research, Number 3216.02. Retrieved August 19, 2014 from http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf.
[50] National Human Genome Research Institute (NHGRI). (2010). NHGRI Institutional Review Board: Consent Form Template. Retrieved August 18, 2014 from http://www.genome.gov/27528182.
[51] Scott, L.D. (2003). Research-related injury: Problems and solutions. *Journal of Law, Medicine & Ethics*, 31(3), 419-428.

committee.[52] Because the directive does not specify precise protocols for its application, E.U. countries have each interpreted the mandate differently.[53] For example, Germany requires research sponsors to carry insurance to cover the costs of injuries to research participants.[54] In Spain, injured research participants are entitled to no-fault compensation for both physical and economic losses.[55]

The European Union recently updated its regulation of compensation for research-related injury. A regulation published on April 2, 2014, titled "[O]n clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC," requires that member states ensure that systems of compensation are in place for any damage suffered as a result of participating in clinical trials.[56] For low-intervention clinical trials—trials that do not pose additional risk—compensation need not be provided if any possible damage is covered by a compensation system already in place.[57]

Several countries outside of Europe—including Brazil, China, India, Israel, Japan, South Africa, and Uganda—also have mandated compensation for research-related injuries.[58] In Uganda, injuries are evaluated for how likely they are to have resulted from research; participants whose injuries are "probably" or "definitely" related to research are entitled to free medical treatment and financial assistance.[59] In Brazil, researchers and sponsoring institutions are responsible for providing care and compensation to research participants for a wide range of injuries, including those that are physical, psychological, moral, intellectual, social, cultural and spiritual.[60]

---

[52] Official Journal of the European Communities. (2001). Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001. Retrieved August 14, 2014 from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF.

[53] European Forum for Good Clinical Practice. (2012). The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe and Beyond: Question 31. Retrieved August 14, 2014 from http://www.efgcp.eu/Downloads/EFGCPReportFiles/EFGCP%20ECs%20Report%202012%20-%20Question%2031%20Updated.pdf.

[54] Institute of Medicine (IOM). (2002). *Responsible Research: A Systems Approach to Protecting Research Participants*. p. 189. Washington DC: The National Academies Press.

[55] Gainotti, S., and C. Petrini. (2010). Insurance policies for clinical trials in the United States and in some European countries. *Journal of Clinical Research and Bioethics*, 1(1), 2-3.

[56] Regulation 536/2014 of the European Parliament and of the Council 27 May 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, 2014 O.J. (L158). 1-76.

[57] Ibid.

[58] PCSBI, (2011, December), op cit, pp. 186-190.

[59] Uganda National Council for Science and Technology. (2007). National Guidelines For Research Involving Humans As Research Participants. Kampala, Uganda, p. 28.

[60] National Health Council. (1987). Resolution No. 196/96 on Research Involving Human Subjects. Decree No. 93933 of January 14, 1987. Retrieved August 14, 2014 from

Other countries—including the United Kingdom, South Africa, Australia, New Zealand and Singapore—have adopted the British Pharmaceutical Industry's Guidelines on Compensation for Trial Related Injuries, which requires compensation as a precondition for research approval.[61] According to the guidelines, research sponsors can choose whether to adopt compensation protocols through third party insurance, self-insurance, and/or direct compensation to injured participants. If participants are injured, they must file an adverse event report; participants only qualify for compensation after investigators review the injury and its relationship to the research project. If injured research participants accept payment through the compensation program, they forfeit their right to any further legal actions. If they do not accept payment, they can proceed to bring a lawsuit.

G. Models for Compensating Injured Research Participants

In developing and implementing a compensation system, many practical concerns need to be addressed. Who should receive compensation and for what types of injuries? To what extent must injured participants prove that their injuries were caused by the research? Would the scope of compensation be limited to the provision of medical care, financial recourse for other losses, or both? Should participants also be able to bring lawsuits, or should no-fault compensation be an exclusive remedy?[62]

There are a number of options that the United States might consider if it were to require a system for compensation. Four models are discussed below.

1. Insurance or Self-Insurance

One approach to compensating injured research participants that has been implemented in a number of countries is insurance or self-insurance—a mechanism by which participants receive compensation regardless of fault (i.e., regardless of whether researchers did anything wrong). Under this system, research sponsors are required to buy insurance or must agree to compensate injured participants directly before research may proceed. No-fault insurance generally provides compensation for the medical and financial costs of injury, but not for pain and suffering, punitive damages, or negligence. Compensation is

---

http://www.prefeitura.sp.gov.br/cidade/secretarias/upload/saude/arquivos/comiteetica/Reso196_English.pdf .

[61] The Association of the British Pharmaceutical Industry. (1994). Clinical Trial Compensation Guidelines. Retrieved August 14, 2014 from http://www.abpi.org.uk/our-work/library/guidelines/Pages/ct-compensation.aspx.

[62] Feinberg, K., Administrator of the Gulf Coast Claims Facility and Special Master of the September 11 Victim Compensation Fund (2001-2004). (2011). Presentation to the Presidential Commission for the Study of Bioethical Issues, November 16. Retrieved August 14, 2014 from http://bioethics.gov/node/392.

also generally contingent upon an agreement not to pursue further legal action against the research sponsors.

2. Specialty Court

Another no-fault compensation system is a specialty claims court. One example of this is the U.S. Vaccine Court, which is operated by the National Vaccine Injury Compensation Program and sets forth a pre-determined list of vaccine-related conditions, complications, and adverse events that qualify for compensation.[63] The compensation provided covers medical and legal expenses, loss of future earning capacity, a limited amount for pain and suffering, and a death benefit.[64] This compensation system, funded by a 75-cent surtax on every vaccine dose administered, provides a streamlined and less expensive alternative to the tort system for filing vaccine-related injury claims.[65]

Despite its advantages, creating a specialty court for research-related injury would face several challenges. First, the adverse events that arise from clinical research might not be as predictable as those that arise from vaccination.[66] Second, funding a research injury court might prove difficult as clinical research does not generate a comparably predictable revenue stream. Finally, the political climate that gave rise to the Vaccine Court—including fear that the vaccine manufacturers would go out of business upon facing rising and unsustainable levels of tort liability—is not present with research injuries, creating a challenge to even establishing an institution.[67]

3. Compensation Fund

A third approach to compensating injured research participants is a dedicated compensation fund. Examples of this approach include the U.S. Radiation Exposure Compensation Act (RECA), the September 11th Victim Compensation Fund, and British Petroleum (BP) Oil Spill Compensation Fund.[68] Although these funds were created in

---

[63] Marwick, C. (1998). Compensation for injured research subjects. *Journal of the American Medical Association*, 279(23), 1854.
[64] The Office of Special Masters, United States Court Of Federal Claims. (2004). Guidelines for Practice Under the National Vaccine Injury Compensation Program. Retrieved August 14, 2014 from http://www.uscfc.uscourts.gov/sites/default/files/OSM.Guidelines.pdf.
[65] Health Resources and Services Administration, U.S. Department of Health and Human Services (HHS). (n.d.). National Vaccine Injury Compensation Program. Retrieved September 4, 2014, from http://www.hrsa.gov/vaccinecompensation/index.html.
[66] PCSBI, (2011, December), op cit, p. 69.
[67] Ibid, p. 68.
[68] U.S. Department of Justice. (2011). Radiation Exposure Compensation Act. Retrieved August 15, 2014 from http://www.justice.gov/civil/common/reca.html; *September 11th Victim Compensation Fund of 2001, Department of Justice*. 28 C.F.R. § 104; Gulf of Mexico Restoration. British Petroleum. (n.d.). Compensating the people and communities affected. Retrieved May 13, 2014 from

response to specific events, and are motivated by different justifications than those for compensation for research-related injuries, they nevertheless provide a mechanism through which injured research participants could receive financial compensation as they disburse money from a collective pot. Moreover, this approach has already been implemented to compensate injured research participants in distributing funds through RECA, a system that compensates three distinct groups of injured individuals.[69]

This system of compensation might not be appropriate for compensating injured research participants more generally for several reasons. First, these systems have been created in response to disastrous events that called for a coordinated national response.[70] Second, the funds generally provide a pre-determined amount of compensation, without conducting qualitative or quantitative assessments of variations in injury.[71] Funds for compensating injured research participants generally require more variety in terms of the types and amounts of benefits provided.

4. Personal Insurance

A final approach for compensating injured research participants is a variant of the system that is already in place: compensation through an individual's personal health insurance. Under this approach, injured research participants would file claims with their own insurance providers. The insurance provider would then pay the claim—generally for medical care and perhaps even for financial injuries—on a no-fault basis. The level of compensation would depend on the particular insurance that an injured research participant has.[72]

V. Discussion Questions

The following questions are based on the information provided in the "Background" section above and are intended to reinforce important aspects of the compensation for research-related injury analysis. Important points are noted with each question to help the instructor guide a group discussion. The "Additional Resources" section will be helpful in answering these questions.

---

http://www.bp.com/en/global/corporate/gulf-of-mexico-restoration/deepwater-horizon-accident-and-response/compensating-the-people-and-communities-affected.html.

[69] U.S. Department of Justice. (2011), op cit.

[70] PCSBI, (2011, December), p. 68.

[71] Feinberg, K. (2011), op cit.

[72] Moses and Singer LLP. (2010). Healthcare Reform Law May Impact Clinical Trial Billing and Contract Negotiations. Retrieved August 15, 2014 from http://www.mosessinger.com/site/files/HealthcareReformLawClinicalTrials.pdf.

1. **What ethical principles support compensating injured research participants?**

   Starting points for discussion:

   a. The principle of justice and fairness suggests that researchers seek to distribute equitably the benefits and burdens of the research enterprise. Implementing a research injury compensation system helps ameliorate any disproportionate burden imposed by suffering such an injury.

   b. The principle of compensatory justice gives rise to an ethical obligation to make whole one you have injured.

   c. The principles of beneficence and non-maleficence support taking steps to maximize possible benefits and minimize possible harms to research participants. Ensuring compensation for research-related injuries is a way of minimizing the physical and financial harms that can result.

   d. The professional ethical obligations of researchers—including physicians, nurses, and clinical psychologists—support systems, like compensation, that minimize the harms that could befall research participants.

2. **What features of research make it distinct from other activities in which individuals could get injured (e.g., including playing sports, driving a car, or receiving medical care) that might warrant systematic compensation for injuries?**

   Starting points for discussion:

   a. Research that tests new and experimental interventions can give rise to risks that are both unforeseeable and/or unavoidable.

   b. Participating in research involves undertaking risk for the broader benefit of society, whereas participating in sports, driving a car, or even receiving medical care involve accepting risks in return for benefits that accrue to the individual.

3. **What are some practical considerations that must be assessed in determining whether to implement a system for compensating injured research participants?**

   Starting points for discussion:

a. Some argue that the informed consent process, through which a research participant is apprised of the risks of research and nevertheless agrees to participate, means that injured research participants have *accepted* the risks of research and the consequences that follow.

    i. However, the informed consent process is intended to provide additional protection to research participants, rather than limit remedies available to them in the event of injury.

b. The costs of implementing a system for compensating injured research participants might be seen as a burden to research budgets.

    i. All procedural safeguards—including IRB review and informed consent—have costs; some costs are a necessary part of conducting research ethically.

4. What remedies do injured research participants currently have in the United States? What are some limitations to this approach?

Starting points for discussion:

a. Institutional remedies: Some institutions—including the University of Washington, DOD, and VA—provide access to medical care and, in some cases, compensation for injured research participants.

    i. Other institutions do not offer any compensation, so research participants are left unprotected.

b. Legal remedies: Research participants injured at institutions that do not provide compensation must otherwise bring a lawsuit.

    i. The limitation of this approach is that injured research participants will have difficulty bringing a successful lawsuit, because proving the elements of negligence is a challenge, and participants might be injured through no fault of the researcher—injuries that generally fall outside the tort system.

VI. Exercises

Exercise A. *Conduct additional research on an example of biomedical research that gave rise to injury. The following resources provide useful information:*

Hepatitis B treatment clinical trial:

Levine, S. (2001, August 13). Clinical trial was near-death experience worth his while. *The Los Angeles Times*. Retrieved August 15, 2014 from http://articles.latimes.com/2001/aug/13/health/he-33634.

Chen, E. (1994, May 14). FDA faults drug testers in patient-death probe. *The Los Angeles Times*. Retrieved August 15, 2014 from http://articles.latimes.com/1994-05-14/news/mn-57638_1_drug-companies.

Institute of Medicine. (1995). *Review of Fialuridine (FIAU) Clinical Trials*. Washington, DC: National Academies Press. Retrieved August 15, 2014from http://www.nap.edu/catalog.php?record_id=4887.

Pfizer clinical trials with Trovan in Nigeria:

Stephens, J. (2000, December 17). Where profits and lives hang in balance. *Washington Post*. Retrieved August 15, 2014 from http://www.washingtonpost.com/wp-dyn/content/story/2008/10/01/ST2008100101390.html.

Abdullahi v. Pfizer, Inc., 562 F.3d 163 (2d Cir. 2009). Retrieved August 15, 2014 from http://scholar.google.com/scholar_case?case=10755590652720519638&hl=en&as_sdt=2&as_vis=1&oi=scholarr.

1. **What happened in this case?**
2. **Was compensation justified? Why or why not?**
3. **Was compensation granted? Why or why not?**

Exercise B. *Although a uniform compensation system does not yet exist for research-related injury in the United States, the United States has established compensation systems for other scenarios, such as vaccine-related injury. Conduct additional research on one of the following programs: U.S. Vaccine Injury Claims Court, Workers Compensation Programs, September 11th Victim Compensation Fund, and British Petroleum (BP) Oil Spill Compensation Fund. The following resources provide useful information:*

U.S. Vaccine Injury Claims Court:

U.S. Court of Federal Claims. (n.d.). Vaccine Program/Office of Special Masters. Retrieved August 15, 2014 from http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters.

Health Resources and Services Administration, U.S. Department of Health and Human Services (HHS). (n.d.). National Vaccine Injury Compensation Program. Retrieved August 15, 2014, from http://www.hrsa.gov/vaccinecompensation/index.html.

Workers Compensation Programs:

U.S. Department of Labor. (n.d.). Office of Workers' Compensation Programs (OWCP). Retrieved August 15, 2014, from http://www.dol.gov/owcp/.

September 11th Victim Compensation Fund:

September 11th Victim Compensation Fund. (n.d.). Welcome [Website]. Retrieved August 15, 2014 from http://www.vcf.gov/.

British Petroleum (BP) Oil Spill Compensation Fund:

Gulf of Mexico Restoration. British Petroleum. (n.d.). Compensating the people and communities affected. Retrieved August 15, 2014 from http://www.bp.com/en/global/corporate/gulf-of-mexico-restoration/deepwater-horizon-accident-and-response/compensating-the-people-and-communities-affected.html.

1. **How does this system work?**

2. **What characteristics of the system would be applicable to the development of a system for compensating injured research participants? Which would not?**

Exercise C*. Between 1973 and the present, a number of U.S. advisory bodies other than the Bioethics Commission addressed the issue of compensation for research-related injury. Conduct additional research on one of these advisory bodies. The following resources provide useful information:*

Department of Health, Education, and Welfare Tuskegee Syphilis Study Ad Hoc Advisory Panel:

Department of Health, Education, and Welfare (HEW) Public Health Service. (1973). *Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel*. Washington, DC: U.S. Government Printing Office.

Retrieved August 15, 2014 from http://biotech.law.lsu.edu/cphl/history/reports/tuskegee/tuskegee.htm.

Department of Health, Education, and Welfare Secretary's Task Force on the Compensation of Injured Research Subjects:

Department of Health, Education, and Welfare (HEW) Secretary's Task Force on the Compensation of Injured Research Subjects. (1977). *Report of the Task Force*. Bethesda, MD: National Institutes of Health.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982). *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects*. Washington, DC: Department of Commerce. Retrieved August 15, 2014 from http://www.gwu.edu/~nsarchiv/radiation/dir/mstreet/commeet/meet16/brief16/tab_b/br16b1a.txt.

Advisory Committee on Human Radiation Experiments:

Advisory Commission on Human Radiation Experiments (1995). *Final Report*. Washington, DC: U.S. Government Printing Office. Retrieved August 15, 2014 from https://archive.org/details/advisorycommitte00unit.

National Bioethics Advisory Commission:

National Bioethics Advisory Commission (NBAC). (2001). *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. Bethesda, MD: NBAC. Retrieved August 15, 2014 from https://bioethicsarchive.georgetown.edu/nbac/pubs.html.

National Bioethics Advisory Commission (NBAC). (2001). *Ethical and Policy Issues in Research Involving Human Participants*. Bethesda, MD: NBAC. Retrieved August 15, 2014, from http://bioethics.georgetown.edu/nbac/pubs.html.

1. **What were the advisory bodies' arguments and conclusions? Are they persuasive?**

VII. Glossary of Terms

Beneficence: The ethical principle that calls upon health care providers and researchers to promote the interests and wellbeing of patients and participants.

Compensatory justice: An ethical obligation to make whole one who has been injured.

Distributive justice: The ethical principle that calls for equitable distribution of benefits and burdens across society—for example, the benefits and burdens of biomedical research, or of technological advances.

Informed consent: The process of informing and obtaining permission from an individual before conducting medical or research procedures or tests.
Institutional review board (IRB): A specially constituted review body established or designated by an entity to safeguard the rights and welfare of human research participants. The duties and responsibilities of IRBs are described in U.S. federal regulations.

Non-maleficence: The ethical principle that calls on health professionals and researchers to not cause intentional harm to patients and research participants.

Respect for persons: The ethical principle that calls on health professionals and researchers to treat individuals as independent and self-determining (autonomous) agents and to provide additional protections to persons with diminished autonomy in clinical care and research settings.

Tort law: The body of law that governs when one is entitled to remedies, such as monetary compensation, for harms resulting from another's acts.

VIII. Additional Resources

Advisory Committee on Human Radiation Experiments. (1995). *Final Report*. Washington, DC: U.S. Government Printing Office.

Childress, J.F. (1976). Compensating injured research subjects: I. The moral argument. *Hastings Center Report*, 6(6), 21-27.

Department of Health, Education, and Welfare (HEW) Public Health Service. (1973). *Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel*. Washington, DC: U.S.

Department of Health, Education, and Welfare (HEW) Secretary's Task Force on the Compensation of Injured Research Subjects. (1977). *Report of the Task Force*. Bethesda, MD: National Institutes of Health

Feinberg, K., Administrator of the Gulf Coat Claims Facility and Special Master of the September 11 Victim Compensation Fund (2001-2004). (2011). Presentation to the Presidential Commission for the Study of Bioethical Issues, November 16. Retrieved August 15, 2014 from http://bioethics.gov/node/392 and http://tvworldwide.com/events/bioethics/111116/.

Gainotti, S., and C. Petrini. (2010). Insurance policies for clinical trials in the United States and in some European Countries. *Journal of Clinical Research and Bioethics*, 1(1), 2-3.

Government Printing Office. Retrieved May 12, 2014 from http://biotech.law.lsu.edu/cphl/history/reports/tuskegee/tuskegee.htm.

Henry, L.M.. (2013). Moral gridlock: Conceptual barriers to no-fault compensation for injured research subjects. *Journal of Law, Medicine, & Ethics*, 41(2), 411-423.

Institute of Medicine. (2002). *Responsible Research: A Systems Approach to Protecting Research Participants*. Washington, DC: The National Academies Press. Retrieved August 15, 2014 from http://books.nap.edu/openbook.php?record_id=10508&page=189.

Mamotte, N., Wassenaar, D., and N. Singh. (2013). Compensation for research-related injury in NIH-sponsored HIV/AIDS clinical trials in Africa. *Journal of Empirical Research on Human Research Ethics*, 8(1), 45-54.

Marwick, C. (1998). Compensation for injured research subjects. *Journal of the American Medical Association*, 279(23), 1854.

Miller, F.G. (2006). Revisiting the Belmont Report: The ethical significance of the distinction between clinical research and medical care. *APA Newsletter on Philosophy and Medicine*, 5(2), 10-14.

National Bioethics Advisory Commission. (2001). *Ethical and Policy Issues in Research Involving Human Participants*. Bethesda, MD: NBAC.

Neaton, J.D. (2010). Regulatory impediments jeopardizing the conduct of clinical trials in Europe funded by the National Institutes of Health. *Clinical Trials*, 7(6), 705-718.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982). *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects.* Washington, DC: Department of Commerce.

Protection of Human Subjects, Department of Health and Human Services (HHS). 45 C.F.R. § 46.

Resnik, D.B. (2006). Compensation for research-related injuries. Ethical and legal issues. *Journal of Legal Medicine*, 27(3), 263-287.

Scott, L.D. (2003). Research-related injury: Problems and solutions. *Journal of Law, Medicine & Ethics*, 31(3), 419-428.

Steinbrook, R. (2006). Compensation for injured research subjects. *New England Journal of Medicine*, 354(18), 1871-1873.

Wickler, D., Mary B. Saltonstall Professor of Population Ethics, Professor of Ethics and Population Health, Department of Global Health and Population, Harvard University. (2011). Compensation for Research-Related Injury. Presentation to PCSBI, November 17. Retrieved August 15, 2014 from http://bioethics.gov/node/391.