Compensation in *Moral Science: Protecting Participants in Human Subjects Research*

Contents

I. Introduction

In *Moral Science: Protecting Participants in Human Subjects Research* (*Moral Science*), the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) assessed contemporary standards for protecting individuals participating in research.[1] In this report, the Bioethics Commission examined many aspects of human research protections—including treatment and compensation for research-related injury—and made recommendations for improving the current system.[2]

[1] Presidential Commission for the Study of Bioethical Issues (PCSBI). (2011, December). *Moral Science: Protecting Participants in Human Subjects Research*. Washington, DC: PCSBI.

[2] Throughout this module, the terms "treatment" and "compensation" are used in ways that reflect Bioethics Commission usage or the language of particular institutional policies. Treatment refers generally to medical treatment provided in response to a research-related injury, whereas compensation refers to financial payments made following a research-related injury.

II. Learning Objectives

Students should be able to:

1. Discuss the ethical principles that give rise to an obligation to provide treatment or compensation for research-related injuries.

2. Discuss the benefits and challenges associated with providing treatment or compensation for research-related injuries.

3. Describe international requirements and guidance concerning treatment or compensation for research-related injury.

4. Describe different models for compensating participants for research-related injuries and some of the strengths and weaknesses of each.

5. Describe the differences between compensation for research-related injury and reparations for past unethical research.

III. Background

In *Moral Science*, the Bioethics Commission considered compensation for research-related injury. Compensation is an established practice in most developed countries, excluding the United States, in which sponsors, investigators, or others engaged in research provide treatment or compensation when research-related injuries arise.[3] Providing treatment or compensation for research-related injuries helps ensure that certain research participants are not disproportionately burdened by their participation in research.[4]

A. Guiding Principles

In *Moral Science*, the Bioethics Commission concluded that those "harmed in the course of human research should not individually bear the costs of care required to treat harms resulting directly from that research."[5] This conclusion was grounded in a number of principles—including distributive justice, corrective justice, beneficence, and

[3] PCSBI, (2011, December), op cit.
[4] For more information about compensation for research-related injury, please see the *Compensation for Research-related Injury Background*.
[5] PCSBI, (2011, December), op cit, p. 69.

professional ethical obligations[6]—and in practical considerations of utility and harmonization.

A number of ethical principles support providing compensation for research-related injury. Distributive justice, for example, requires equitable distribution of the benefits and burdens of research.[7] Compensating injured research participants helps remedy the fact that the benefits of research redound to the common good, while the risks are borne disproportionately by injured research participants.[8] Corrective justice requires repairing the harms that one's conduct creates; providing compensation helps limit or reverse the harm that subjects may experience as a result of their participation in research.[9] Moreover, providing compensation is an act of beneficence, which calls on professionals to ensure the wellbeing of others.[10] Providing treatment or compensation for the cost of medical care demonstrates benevolent regard for individuals' willingness to participate in activities like research.[11] The Bioethics Commission also noted that providing compensation to injured research participants is justified by professional ethical obligations.[12] Researchers must act in accordance with discipline-specific professional codes of ethics, which often entail acting in accordance with the principles of beneficence.[13]

Practically speaking, compensation is supported by principles of general utility. Research participants might be more likely to enroll in research if they know that they will be protected if a research-related injury does result.[14] In addition, ensuring that participants injured in federally sponsored research receive compensation for research-related injuries could help harmonize research protections across countries, many of which require compensation for research-related injuries.[15]

B. Legal Background

Federal regulations governing federally supported U.S. research have been codified by the U.S. Department of Health and Human Services in the Code of Federal Regulations at

[6] PCSBI, (2011, December), op cit.
[7] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The National Commission). (1977). *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.
[8] PCSBI, (2011, December), op cit, p. 56.
[9] Ibid.
[10] The National Commission, op cit.
[11] PCSBI, (2011, December), op cit, p. 58.
[12] Ibid, p. 61.
[13] Ibid.
[14] Ibid.
[15] Ibid, p. 62.

45 C.F.R. Part 46 (Subpart A of which is often referred to as the Common Rule). The Common Rule establishes general requirements for informed consent including, but not limited to, explanation of the research study, description of expected benefits and potential risks, explanation of confidentiality, and a statement of voluntariness specifying that participants can withdraw from the study at any time with no penalty.[16] The Common Rule does not require that compensation or any medical treatments actually be provided in the event of a research-related injury, however it requires that for research involving more than minimal risk, an explanation be provided about "whether any compensation [or] any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained."[17]

C. Deliberative Process

As part of its analysis and deliberative process, the Bioethics Commission convened a subcommittee of international experts in bioethics and biomedical research. This subcommittee, the International Research Panel, published its proceedings in 2011, *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues* (*Research Across Borders*), in which it advised the Bioethics Commission on the "effectiveness of current U.S. rules and international standards for the protection of human subjects in scientific studies supported by the U.S. Government."[18] Although the International Research Panel's findings and recommendations are not the Bioethics Commission's recommendations, their work informed the Bioethics Commission's final recommendations to the President in *Moral Science*.

The International Research Panel's fourth recommendation to the Bioethics Commission states:

> **The United States should implement a system to compensate research subjects for research-related injuries. One promising model might be based on the U.S. National Vaccine Injury Compensation Program, a no-fault alternative to the traditional tort system that provides compensation to people found to be injured by certain vaccines.**[19]

[16] *Protection of Human Subjects, HHS*. 45 C.F.R. § 46.116.
[17] *Protection of Human Subjects, HHS*. 45 C.F.R. § 46.116(a)(6).
[18] International Research Panel of the Presidential Commission for the Study of Bioethical Issues. (2011, September). *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues*. Washington, DC: PCSBI, p. ii.
[19] Ibid, p. 11.

The Bioethics Commission carefully considered the International Research Panel's recommendation in its deliberations.

D. Bioethics Commission Recommendations

The Bioethics Commission recognized that a number of principles give rise to an ethical obligation to compensate injured research participants. The arguments in favor of treatment or compensation for research-related injury are primarily based on the principle of justice and fairness, which supports the equitable distribution of the risks and benefits of research. Because research participants take on unavoidable risks, and because society benefits from research participants' acceptance of these risks, it is fair that they are protected from some of the ameliorable harms that they might sustain as a result of their participation.

In *Moral Science*, the Bioethics Commission likened the responsibility to protect research participants in the event of an injury to that of a lifeguard who has both a primary duty to prevent swimmers from drowning and a secondary duty to rescue swimmers who begin to drown. Like a lifeguard, researchers should both protect participants from exposure to undue risks (the primary duty) and limit or reverse the harm that participants experience as a result of participating in research (the secondary duty). The Bioethics Commission recommended further study of the issue before altering the current U.S. approach. Two of the Bioethics Commission's 14 recommendations in *Moral Science* addressed treatment or compensation for research-related injury.

> **Recommendation 3: Treating and Compensating for Research-Related Injury**
>
> **Because subjects harmed in the course of human research should not individually bear the costs of care required to treat harms resulting directly from that research, the federal government, through the Office of Science and Technology Policy or the Department of Health and Human Services, should move expeditiously to study the issue of research-related injuries to determine if there is a need for a national system of compensation or treatment for research-related injuries. If so, the Department of Health and Human Services, as the primary funder of biomedical research, should conduct a pilot study to evaluate possible program mechanisms.**[20]

[20] PCSBI, (2011, December), op cit, p. 69.

Recommendation 4: Treating and Compensating for Research-Related Injury Follow Up

The Commission recognizes that previous presidentially appointed bioethics commissions and other duly appointed advisory bodies have made similar recommendations regarding compensation or treatment for research-related injuries; yet no clear response by the federal government has been issued. Therefore, the federal government, through the Office of Science and Technology Policy or the Department of Health and Human Services, should publicly release reasons for changing or maintaining the status quo.[21]

IV. Reading

For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission's website at www.bioethics.gov under "Projects"; educational materials are available for download on the Bioethics Commission's website at www.bioethics.gov under "Education"):

Moral Science: Protecting Participants in Human Subjects Research, pp. 56-70 ("Treating and Compensating for Research-Related Injury").

Moral Science, pp. 184-185 (Appendix III: U.S. Treatment/Compensation for Treatment Methods).

Moral Science, pp. 186-190 (Appendix IV: International and Transnational Requirements for Treatment and Compensation for Research Injuries).

Compensation for Research-related Injury Background, pp. 2-17 ("Introduction" and "Background").

Also on the *Moral Science* page of the Bioethics Commission's website:

Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues, p. 11 (Recommendation 4).

Research Across Borders, p. 58 ("Compensation for Research-Related Injury").

[21] PCSBI, (2011, December), op cit, p. 70.

V. Discussion Questions

The following questions are based on the information provided above and through the indicated reading and are intended to reinforce important aspects of compensation for research-related injury that are highlighted in *Moral Science*. Important points are noted with each question to help the instructor guide a group discussion. The "Additional Resources" section is a helpful source in answering these questions.

1. **What ethical principles and other factors support providing treatment or compensation for research-related injury?**

   Starting points for discussion:

   a. Society benefits from research participants' acceptance of research risks—risks of bodily injury that participants sometimes take on with no prospect of direct benefit. Justice and fairness suggests that they be protected from some of the ameliorable harms they might sustain as a result of their participation.

   b. The principles of beneficence and non-maleficence support taking steps to maximize possible benefits and minimize potential harms to research participants. Ensuring treatment or compensation for research-related injuries is a way of minimizing the physical and financial harms that could result from research participation.

   c. Researchers—including physicians, nurses, and clinical psychologists, among others—have professional ethical obligations that encourage systems that minimize the harms that could befall research participants (e.g., compensation for research-related injury).

   d. General utility suggests that potential research participants might be more likely to participate if they know they will be taken care of in the event that they are injured as a direct result of their participation.

2. **How is treatment or compensation for research-related injury different from reparation for past unethical research?**

   Starting points for discussion:

   a. Treatment or compensation for research-related injuries is justified by distributive or corrective justice—the duty to distribute the benefits and burdens of research equitably and the duty to make whole one you have injured, respectively—and by duties of beneficence, or the ethical obligation

to maximize possible benefits and minimize potential harms. Providing treatment or compensation for research-related injury does not imply wrongdoing.

b. Reparation describes the expression of regret for wrongs done to victims of unethical human subjects research and calls for acknowledgment of wrongdoing and contrition, along with actual or symbolic repayments for wrongdoing. Treatment or compensation for research-related injury might be part of reparation, but reparation might also include acknowledgement of wrongdoing, an apology, or a symbolic gesture of contrition.

3. What did the Bioethics Commission recommend with respect to compensating injured research participants?

Starting points for discussion:

a. The Bioethics Commission recognized that participants harmed in the course of human research should not individually bear the costs of care required to treat harms resulting directly from that research.

b. The Bioethics Commission recommended that the federal government move expeditiously to study the issue of research-related injuries to determine if there is a need for a national system of compensation or treatment for research-related injuries.

c. If the results of the initial study show that there is a need for a national system of compensation or treatment for research-related injuries, the Department of Health and Human Services should conduct a pilot study to evaluate possible program mechanisms.

4. What questions might be addressed in determining how best to implement a system of treatment or compensation for research-related injury?

Starting points for discussion:

a. Some questions to be addressed include:
    i. To what extent do established (and emerging) public and private health insurance programs contribute to compensating individuals for research-related injuries?
    ii. What types of injuries are or should be compensated?

iii. How might causal links between research protocols and medical problems be established?
iv. How might research participants in foreign countries be compensated?
v. Should there be limits placed on the time, amounts, and categories of compensation?
vi. Who should bear the costs of providing compensation for research-related injury?
vii. Should a compensation system preempt state tort remedies?

5. What U.S. agencies or institutions have implemented systems of care or compensation for research-related injuries?

Starting points for discussion:

a. The Department of Defense provides health care services from military treatment facilities for participants injured in the course of research, but no compensation (i.e., payment) for injuries.

b. The National Human Environmental Effects Research Laboratory (funded by the Environmental Protection Agency) provides up to $5,000 to cover costs for treatment of research-related injuries. Costs for insurance are paid by the government as part of research awards.

c. The University of Washington health care system administers a university-wide system of treatment and compensation for treatment of research-related injuries. This system, self-funded through the institution's operating budget, provides up to $10,000 for out-of-pocket expenses and for treatment at University of Washington.

d. Private clinical trial insurance providers, for example, RJ Ahmann Company, cover a number of different types of liability, including general liability, latent liability, latent injury liability, and incidental medical malpractice liability.

6. What different systems could be used to provide treatment or compensation to injured research participants? What are the characteristics of each?

Starting points for discussion:

a. Tort liability: This system is available to all and does not require modification of existing U.S systems. The legal system provides limited protection if the

researcher is not at fault. In tort, the burden of proof of negligence is on the injured party and this is hard for all injured research participants.

b. Research institution self-insurance: This system could be an effective means of cost-spreading and ensuring that any burden of research-related injury does not fall disproportionately on any individual research participant. This approach requires institutions to act and purchase insurance.

c. Individual health insurance: This approach does not require additional infrastructure or modification of existing U.S. systems. Health insurance payouts are generally limited to the costs of medical care (compensation for other harms, such as lost wages, likely would not be possible).

d. Model based on the National Childhood Vaccine Injury Act: This system is less time-consuming and burdensome than bringing a tort lawsuit but, unlike with the tort system, it allows for no-fault liability. Implementing this system could be difficult for research-related injuries: The National Childhood Vaccine Injury Act covers a small number of specified adverse events that are likely caused by the vaccine. The side effects that arise from clinical research trials may not be as limited or as predictable.

VI. Problem-Based Learning

Scenario A. *You are a university administrator evaluating potential claims for compensation that could be made by a research participant. The clinical trial at issue is conducted at your university, but is sponsored by a pharmaceutical company. Through no fault of the researcher, the novel intervention being tested causes unforeseen injury to a research participant. Your university has the following compensation policy:*

> *"In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the RESEARCHER will help you get medical care. The UNIVERSITY has not set aside funds to pay you for any such injuries or related medical care. The PHARMACEUTICAL COMPANY has agreed to pay all reasonable medical expenses for the treatment of injuries related to the intervention being studied, or as a direct result of properly performed study procedures. The PHARMACEUTICAL COMPANY will not pay for the treatment of any underlying disease or condition that you have. Any costs for medical expenses not paid by the sponsor will be billed to you or your*

INSURANCE COMPANY. By signing this form, you do not give up any of your legal rights."

The following additional reading might be useful in considering this scenario:

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

1. Does this statement satisfy the ethical obligations that the researchers and the sponsor have to the participants?

Starting points for discussion:

a. Sponsors of human subjects research have an ethical obligation to protect people who volunteer as research participants. This obligation is both primary—to protect participants from exposure to undue risk—and secondary, to limit or reverse the harm participants experience. The statement asserts that the researcher will help the participant get medical care and the pharmaceutical company will pay for reasonable medical expenses for the treatment of research-related injuries, both forms of secondary protection.

b. The argument to provide treatment and compensation for research-related injuries is based in the principle of justice and fairness. Because society benefits from research participants' acceptance of risks of bodily injury, research participants should be protected from some of the ameliorable harms that they sustain as a result of their participation. Further, general utility supports a compensation system as potential research participants might be more likely to participate in research if they know they will be cared for if harmed by research. The pharmaceutical company's agreement to bear the costs of injury related to the intervention helps satisfy this ethical obligation.

c. Whether harm results from a foreseen risk about which a participant is informed, or from an unforeseen risk, the participant should not individually bear the costs of medical care for those harms. The policy states that the pharmaceutical company will pay all reasonable medical expenses for the treatment of research-related injuries, thereby providing injured research participants some protection.

2. **Where could the injured party turn to pursue a claim for compensation for their injury?**

   Starting points for discussion:

   a. *Researcher*: Per the language in this policy, the researcher will help the participant get medical care, but is not responsible for providing medical care or compensation.

   b. *University*: The university has not set aside funds to pay for medical care or compensation. Participants do not waive their legal rights, so could potentially bring a lawsuit against the university.

   c. *Pharmaceutical company*: The company agrees to pay all "reasonable" medical expenses for the treatment of injury related to the intervention or related study procedures, but does not define the limits of reasonability.

   d. *Insurance Company*: The participant's personal health insurance company might pay the costs of receiving necessary medical care, but is unlikely to pay for other harms that arise from the research injury (including the costs of any lost wages).

   e. *Lawsuit*: Any lawsuit is unlikely to succeed because the researcher in this case was not at fault.

3. **Is this statement clear enough for a research participant to understand? What might you change to make it clearer?**

   Starting points for discussion:

   a. The institutional review board might suggest that the researchers include what amount of money the sponsor considers to be reasonable medical expenses.

   b. The researchers might include information on what steps they will take to help a research participant get medical care in the event of an injury.

Scenario B. *You are a principal investigator of a multinational clinical trial. The trial is set to proceed in Belgium, Denmark, Uganda, and the United States.*

1. **What does each of these countries require with respect to compensating injured research participants?**

The following readings from *Moral Science* might be useful in considering this scenario:

> *Moral Science: Protecting Participants in Human Subjects Research*, p. 57, ("Table 3.1: International Requirements for Treatment of Research-Related Injury").
>
> *Moral Science*, pp. 186-190 (Appendix IV: International and Transnational Requirements for Treatment and Compensation for Research Injuries).

Starting points for discussion:

a. As of 2011, Belgium requires that participants receive treatment for injury and compensation for death; the sponsor is required to enter into an insurance contract which covers this liability.

b. As of 2011, Denmark requires the establishment of a fund ensuring treatment for injury and additional compensation for pain and suffering, loss of earnings, loss of earning capacity, for children, and injury to a person's feelings or reputation.

c. As of 2011, Uganda requires that participants receive treatment for injury and compensation for any resultant impairment, disability, or handicap.

d. The United States requires that the researcher should disclose to research participants during the informed consent process whether compensation will be provided. If the researcher's institution has an injury compensation system, participants would be covered; if not, participants would have to rely on the tort system.

2. What ethical challenges might arise when conducting multi-country trials where the countries have different policies for the compensation of injured research participants?

The following additional reading might be useful in considering this scenario:

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

Starting points for discussion:

a. It can be a challenge complying with different countries' requirements. Different requirements mean that participants in different countries are treated differently in the event of research-related injury, which itself gives rise to potential unfairness or injustice.

Scenario C. *As a federal policymaker in the United States, you are asked to design a system that will address some of the problems with the current system of providing treatment and compensation for research-related injury.*

1. **What ethical considerations might you take into account when designing this new system?**

   Starting points for discussion:

   a. In order to address the practical questions associated with treatment and compensation, the scope and nature of compensation for research-related injuries across the United States must be determined. This could be assessed through a federally funded study to determine the nature and extent of injury, the type of research in which the injury is occurring, and the costs of the injury to participants, investigators, and society.

   b. Studies could take into account considerations such as deterrence, loss spreading, and internalization of risk.

   c. The compensation system must define standards for when an injury should be considered eligible for treatment or compensation for research-related injury.

2. **What reasons might there be against researchers taking on some or all of the costs associated with a compensation system? What other options are there for funding compensation programs?**

   Starting points for discussion:

   a. Researchers play an essential role in advancing biomedical research and discovery, and the compensation system should not unnecessarily burden the researchers or impede their ability to undertake novel research programs that advance scientific progress and discovery.

b. Research sponsors and institutions can provide case-by-case compensation through insurance or self-insurance. A centralized governmental system can provide compensation for research participants. An entirely new institution or system-wide regulation can be established to provide guidelines for compensation.

Scenario D. *During the Bioethics Commission's seventh public meeting in November 2011, Dr. Kenneth R. Feinberg, Administrator of the Gulf Coast Claims Facility and Special Master of the September 11 Victim Compensation Fund, discussed the necessity of compensation if a "victim is harmed through no fault of his or her [own] and through no fault of the researcher."*[22] *Transcripts and archived webcast video of Mr. Feinberg's presentation can be found on the Bioethics Commission's website (Meeting 7, Session 7). Watch Mr. Feinberg's presentation and discuss the following:*

1. **Mr. Feinberg contrasts the tort system with a compensation program. What differences are there between these two systems? What are their advantages and disadvantages?**

   Starting points for discussion:

   a. The tort system works well for many types of intentional and accidentally caused injuries. A research participant injured as a direct result of the research can sue for damages through the tort system. Claims can be brought on a range of intentional, negligence, strict liability, and products-liability theories. However, this system is not very efficient.

   b. In the context of research-related injuries, using the tort system to sue for damages might be overly burdensome for the research participant. The participant might not have access to funds for medical care when injury occurs. If the tort system is used, the participant might not receive those funds until well after the medical care is necessary.

2. **What questions does Mr. Feinberg suggest should be considered when designing a compensation system? Why are these important?**

   Starting points for discussion:

   a. What form of compensation should be given to participants injured during research? What is the source of the funding for this compensation? How much funding will be given, and how much funding will be set aside?

[22] PCSBI, (2011, December), op cit, p. 58

b. Will the compensation that is provided be the same or different than the compensation that can be received through a tort lawsuit?

c. What criteria will be used to trigger the compensation? What criteria will be imposed in deciding how much compensation is appropriate?

VII. Exercises

Exercise A. *Read and discuss the University of Washington's policy on human subjects assistance. The following resources provide useful information:*

Moe, K.E., Director and Assistant Vice Provost For Research, University of Washington. (2011). University of Washington Human Subjects Assistance Program. Presentation to the Presidential Commission for the Study of Bioethical Issues, November 17. Retrieved August 15, 2014, from http://bioethics.gov/sites/default/files/Moe.pdf.

University of Washington. (2013). UW Policy Directory. Policy on Assistance for Human Subjects. Retrieved August 15, 2014, from http://www.washington.edu/admin/rules/policies/BRG/SOCh6.html.

University of Washington. (2013). Standing Committees. Retrieved August 15, 2014, from http://www.washington.edu/regents/meetings/2013/june/docs/a-1.

1. **What is the University's human subjects assistance policy?**
2. **What are some of the strengths and weaknesses of this policy?**
3. **What modifications, if any, might you make to the policy to improve clarity and protections for human subjects?**

Exercise B. *Different countries have implemented different approaches to compensating injured research participants. Conduct additional research on compensation systems in one of the following countries or regions and answer the questions below. The following resources provide useful information:*

European Union:

The European Parliament and the Council of the European Union. (2001). Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2011. Retrieved August 15, 2013, from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF.

The European Parliament and the Council of the European Union. (2014). Regulation (EU) of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Chapter XII, Article 76. Retrieved August 15, 2014, from http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+AMD+A7-2013-0208+291-291+DOC+PDF+V0//EN.

Australia

National Health and Medical Research Council. (2014). National Statement on Ethical Conduct in Human Research. Retrieved August 15, 2014, from http://www.nhmrc.gov.au/guidelines/publications/e72.

Brazil

National Health Council. (1987). Resolution 196/96 On Research Involving Human Subjects. Retrieved August 15, 2014, from http://www.prefeitura.sp.gov.br/cidade/secretarias/upload/saude/arquivos/comiteetica/Reso196_English.pdf.

Israel

Ministry of Health. (2006). Israel – Guidelines for Clinical Trials. Retrieved August 15, 2014, from https://firstclinical.com/regdocs/doc/?db=INT_Israel_Clinical_Trials.

Uganda

Uganda National Council for Science and Technology. (2007) National Guidelines for Research Involving Humans as Research Participants. Retrieved August 15, 2014, from http://www.uncst.go.ug/dmdocuments/Guideline,%20Human%20Subjects%20Guidelines%20Marc.pdf.

Japan

English Regulatory Information Task Force, Japan Pharmaceutical Manufacturers Association. (2012). Pharmaceutical Administration and Regulations in Japan. Retrieved August 15, 2014, from http://www.jpma.or.jp/english/parj/pdf/2012.pdf.

1. **Does the country mandate treatment or compensation for research-related injury?**

2. **What kind of system does the country use?**

3. **How well does this system work?**

4. **Compare and contrast this country's approach with that of the United States.**

VIII. Glossary of Terms

Autonomy: The capacity to direct the course of one's own life or to live according to one's own values and beliefs.

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

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.

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

Protocol: A plan for the conduct of a research project, including all aspects of the project from recruitment to obtaining informed consent to dissemination of results.

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.

IX. Additional Resources

Feinberg, K.R., Administrator of the Gulf Coast Claims Facility and Special Master of the September 11 Victim Compensation Fund. (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/.

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.

Moe, K.E., Director and Assistant Vice Provost For Research, University of Washington. (2011). University of Washington Human Subjects Assistance Program. Presentation to the Presidential Commission for the Study of Bioethical Issues, November 17. Retrieved August 15, 2014, from http://bioethics.gov/sites/default/files/Moe.pdf.

Pike, E. (2012). Recovering from research: A no-fault proposal to compensate injured research participants. *American Journal of Law & Medicine*, 38(1), 7-62.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982, June). *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects, Volume One: Report*. Washington, DC: U.S. Government Printing Office.

Resnik, D.B., et al. (2014). Research-related injury compensation policies of U.S. research institutions. *IRB: Ethics and Human Research*, 36(1), 12-19.

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 the Presidential Commission for the Study of Bioethical Issues, November 17. Retrieved August 15, 2014, from http://bioethics.gov/node/391.