Intersections of Science, Ethics and Human Rights: The Question of Human Subjects Protection

Report of the
Science Ethics and Human Rights Working Group[1]
AAAS Science and Human Rights Coalition

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Executive Summary

The AAAS Science and Human Rights Coalition is a network of scientific membership organizations that recognize a role for science and scientists in efforts to realize human rights. The Coalition's Science Ethics and Human Rights Working Group is primarily dedicated to identifying, analyzing and reinforcing the links between international human rights law and the ethical principles guiding the conduct of scientific research, the practice of science and the use of science and technology. We pursue this aim by engaging professional scientific, engineering and health associations in an ongoing dialogue about the relationship of human rights to research ethics.

National and international normative frameworks concerned with responsible scientific practice are informed to varying degrees by both professional codes of ethical conduct and human rights principles, though seldom explicitly so. Using human rights standards to complement and strengthen ethical standards of conduct is consistent with both the increased internationalization of science and efforts to build more bridges across often diverse disciplinary scientific pursuits. Bringing approaches in human rights to bear on the ethical conduct of science broadens the global scientific dialogue about ethics. It also specifically expands our appreciation for how best to define the human subjects of research, respect their rights, and the extent of scientific obligations to them.

The goal of the present report, therefore, is to offer a preliminary framework to address the conduct of scientific research as related to research involving human subjects. Part I briefly sets out the human rights principles relevant to ethical research with human

[1] The Science Ethics and Human Rights working group is co-chaired by Robert Albro and Douglas Richardson. This report benefitted from the contributions of many, in the form of consultations, case write ups, constructive written feedback, reviews, and editing. In particular these include: Steve Behnke, Leonard Rubinstein, Aurora Plomer, David Schrader, and Dawn Wright. Critical background work was contributed by two AAAS interns, Rosh Sethi and Jeremy Weissman. Special thanks are reserved for both Jessica Wyndham and Jen Makrides, who dedicated significant time to help develop the report. We would also like to acknowledge the feedback of Mark Frankel, Director of the AAAS's Scientific Responsibility, Human Rights and Law Program, as well as that of Audrey Chapman, Bernard Gert, Irving A. Lerch, and Joan Sieber, whose internal reviews of an earlier draft of this report greatly improved the final product. Finally, we would also like to acknowledge the editorial improvements of Clinton Anderson.

subjects. Part II describes and assesses the evolution of international standards relevant to human subjects protection. Part III focuses specifically on the development of standards in the U.S. and compares these to international standards. Part IV considers the ethical standards by discipline-specific professional scientific associations, and what their variety might mean for the introduction of human rights into present ethical frameworks. Part V offers some summary conclusions and suggestions for next steps. Finally, the Appendix includes case studies illustrating some of the "ethical frontiers" scientific associations in the U.S. are currently confronting.

As a ground clearing effort, this report reaches several conclusions about the relationship of human rights to the ethical practice of science. As key considerations going forward, these conclusions can be grouped into three sets:

Support and justifications for the further integration of human rights with the existing frameworks for the ethics of scientific research:

1. Although human rights are rarely explicitly noted in international or domestic ethics standards for human subjects protection, both derive historically from the same commitment to the "dignity" of the person.
2. Human rights provide a value-added component to research ethics, as an internationally recognized framework of legal protection for the subjects of scientific research.
3. Integrating the principles of human rights with scientific codes of professional ethics gives increased international legal validity to the standards set out in the ethics codes used by scientists and provides a shared framework for the resolution of disciplinary ethical conflicts.
4. Across international, domestic, and disciplinary ethics we can identify an already existing set of commitments consistent with human rights that can be used to demonstrate their close relationship and to bridge them.

Significant international and domestic challenges to the integration of human rights with research ethics include:

5. Human rights and ethics instruments both employ the language of "rights" but often differently, with reference to different subjects, and human rights *per se* are often viewed as irrelevant to the practice of ethics.
6. The main existing international ethical standards for human subjects protection assume a "bioethics" framework that does not fully encompass the diversity of scientific practice involving people.
7. Since international ethics instruments are principally focused on establishing general principles of conduct while domestic instruments give greater weight to the process of institutional ethics review, each locates ethics differently for the work of science.

The diversity of kinds of scientific practice, and their associated ethics frameworks, offer additional challenges to address:

8. We need to distinguish between the human rights of scientists and the further incorporation of human rights principles into the ethical practice of science.
9. Instead of exhibiting a self-evident unity, the codes of ethics of professional scientific associations in the U.S. tend to exhibit the particularities of method, theory, topic, and practice characteristic of different scientific disciplines.
10. There is a recurrent difference in the treatment of the human being as the subject of human rights, and the "human subject" identified for the purposes of research ethics, where the latter is typically an individual viewed independently from any encompassing social context while the former addresses individuals, but also in ways holistically as members of families, communities, and other demographic groups.

These conclusions and their implications suggest the landscape that should form the basis of any engagement with scientific associations in the U.S., going forward, with respect to the relationship of human rights to the ethical considerations guiding scientific research.

Background and Context

The Science Ethics and Human Rights Working Group[2] is one of five working groups of the AAAS Science and Human Rights Coalition. The Coalition established the working group with the convictions that human rights are integral to the ethical practice of science and the ethics of scientific research will be enhanced by a greater recognition of this fact. Therefore, this group seeks to build upon the shared historical connections between human rights and the ethics of human subjects protections to better harmonize human rights with ethics approaches, disparate national norms and ethics standards, as well as distinct scientific or disciplinary forms of practice. We offer this report as an invitation to further dialogue among professional associations about the relationship of human rights to ethical research practice.

International and domestic ethical standards for human subjects research and international human rights law both spring from the same historical moment of international cooperation in the aftermath of World War II. The Universal Declaration of Human Rights (UDHR) and the Nuremberg Code were both adopted in 1948. Their common historical, moral, and political heritage is most evident in their shared commitment to promote the "dignity" of the person.[3]

The subsequent history of ethics and human rights, however, has largely been that of two distinct, if parallel, frameworks. When attention has been given to human rights in the context of science, particularly throughout the Cold War period, the focus has primarily been on defending the rights of individual scientists against states and other agencies

[2] For further details about ongoing Coalition work with respect to the Science Ethics and Human Rights Area of Activity: http://shr.aaas.org/coalition/AreasofActivity/Science_Ethics_and_Human_Rights.html.
[3] See Roberto Adorno, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics," *Journal of Medicine and Philosophy* 34, (2009): 223-240.

hostile to their work or in cases where conflicts might imperil their work.[4] We believe that there is also a continuing need to address the implications of human rights for the ethical practice of science. Human rights not only support the freedom to conduct scientific research, but also inform the purpose and the practice of science.

Multiple recent developments both in the fields of human rights and of ethics make the present an especially propitious moment to pursue integrating human rights more fully with existing frameworks for science ethics:

(1) Since the late 1990's, increasing international attention has been paid to integrating human rights with the ethics standards of scientific practice, with much of this effort concentrated in the arena of bioethics.[5]

(2) We have also witnessed an increasing frequency of public ethics controversies involving scientists and health professionals. Examples include the alleged involvement of psychologists in the abuse of detainees in the US "war on terror",[6] the complicity of physicians in organ trafficking,[7] and the participation of anthropologists in military field operations[8]. Scientists themselves are increasingly using ethics as the means to debate disciplinary controversies and professional identity and as a basis to scrutinize their own practice.

(3) Human rights discourse in the U.S. has broadened from a historical focus exclusively on civil and political rights to include economic, social and cultural rights. This has been accompanied by a shift from an exclusive focus on human rights violations arising in "other" countries, to an acknowledgement of and greater focus on domestic human rights concerns.[9]

(4) The scientific enterprise has become highly collaborative both within and across countries. To function effectively, the global scientific community must be better integrated, including through the harmonization of standards of conduct. International human rights law provides an existing and recognized framework that could usefully inform the process of developing international norms and standards of conduct in science.[10]

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[4] See Laura Tangley, "Scientists Campaign for Human Rights," Bioscience 34, no. 9 (1984): 544-545; see also the International Council for Science's 1989 "Statement on Freedom in the Conduct of Science."
[5] See, for example, the Universal Declaration on Bioethics and Human Rights, adopted and proclaimed by the United Nations General Conference 33C/Resolution 15, 2005.
[6] See Benedict Carey, "Psychologists Clash on Abiding Interrogations," *New York Times*, August 16 (2008); Physicians for Human Rights, *Experiments in Torture: Evidence of Human Subjects Research and Experimentation in the 'Enhanced' Interrogation Program*, (Washington, D.C., 2010).
[7] UN Global Initiative to Fight Human Trafficking, *The Vienna Forum Report: A Way Forward to Combat Human Trafficking*, (New York: United Nations, New York, 2008), 12.
[8] American Anthropological Association, "American Anthropological Association Executive Board Statement on the Human Terrain System Project," (Arlington, VA, 2007).
[9] Hillary Clinton, "Remarks on the Human Rights Agenda for the 21st Century," (Washington, D.C.: Georgetown University, 2009).
[10] Alan Leshner and Vaughan Turekian, "Harmonizing Global Science," *Science* 326, no. 11 (2009): 1459.

(5) The practice of science, particularly in such fields as genomics, biotechnology, and synthetic biology, continues to raise questions about the very definition of "human",[11] including the "human" of "human rights." At the same time applications of human rights to scientific practice have broadened the understanding of dignity from the "dignity of the person" (as originally specified in the UDHR) to the more encompassing "human dignity."[12] Increasing use of the convention of "human dignity" potentially expands what is entailed in evaluations of "dignity" beyond that of specific persons, discretely considered, to include greater appreciation for "human life" in its full range of expressions. This expanded appreciation can include more attention to the various social contexts within which individual dignity is possible, including membership in distinct demographic groups or categories (e.g. race, class, gender, or religious group) or other collective social arrangements.

(6) Within the scientific community, human rights are now being given significantly more attention not only in the context of the welfare of scientists, but as itself a subject of research in the form of publications and conference presentations, and in a range of collaborations with the human rights community. The steadily growing membership of the AAAS Science and Human Rights Coalition is just one indicator of this, as is the growing collaboration of scientists, engineers and health professionals with human rights organizations to apply scientific methodologies, tools and technologies to human rights work, for example, forensic and budgetary analysis, the use of statistics, and new uses of genomic sequencing.[13]

(7) In early 2010, President Obama convened a new Presidential Commission for the Study of Bioethical Issues. Understood to represent expertise relevant "across the fields of science, policy, ethics, and religion," a major task for this new Commission is a comprehensive review of current federal and international standards to "guard the health and well-being of human subjects in research." The presidential executive order states a need to address the implications of rapid advances in biomedicine and related science and technology and, in doing so, to consider "the intersection of science and human rights."[14]

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[11] See Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (New York: Picador, 2003).

[12] For a discussion of this evolution, see David Feldman, "Human Dignity as a Legal Value" Public Law 44 (1999): 682-702; Harald Schmidt, "Whose Dignity? Resolving ambiguities in the scope of 'human dignity' in the Universal Declaration on Bioethics and Human Rights," *Journal of Medical Ethics* 33 (2007):578-584; Aurora Plomer, 2009, "Human Dignity, Human Rights, and Article 6 (1) of the Biotech Directive" in *Embryonic Stem Cell Patents: European Law and Ethics* eds, Aurora Plomer et al. (New York: Oxford University Press, 2009), 202-226.

[13] Concerning the use of forensic sciences to exonerate innocent people, see Clyde C. Snow, Eric Stover, and Kari Hannibal, 1989, "Scientists as Detectives: Investigating Human Rights," *Technology Review* 92, no. 2 (1989): 42; concerning the use of budgetary analysis to determine spending on programs of human rights relevance, see Fundar and International Human Rights Internship Program, *Dignity Counts: A Guide to Using Budget Analysis to Advance Human Rights* (Washington, D.C.: IIE, 2004); concerning statistical measures of mass human rights violations, see Jana Asher, David Banks and Fritz J. Schueren, eds., 2007, *Statistical Methods for Human Rights* (New York: Springer, 2008); concerning identification of victims of genocide, mass murder, or kidnapping, see Kelly N. Owens, Michelle Harvey-Blankenship, and Mary-Claire King, "Genomic Sequencing in the Service of Human Rights," *International Journal of epidemiology* 31, no. 1 (2002): 53-58.

[14] Executive Order 13521, *Federal Register* 74 No. 228, November 30, 2009.

(8) In recognition of the significantly changed landscape for scientific research over the last few decades, the ethical frameworks for research involving human subjects has been the subject of renewed discussion, primarily among professional associations in the social sciences. At the same time, the overarching U.S. government framework for the ethical treatment of human subjects, the Common Rule (see below), is now undergoing review and change.[15] This change promises to distinguish among kinds of research involving human subjects –for example, clinical trials, non-clinical research, and ethnographic field research—based on different levels of risk or harm to participants.

These developments have focused new attention on research ethics, on the relationship between ethics and human rights, and on a set of new challenges. Scholars have warned that bioethics standards could be problematically subsumed by human rights if current international developments continue.[16] Other commentators have pointed to the ways that bioethics frameworks are not necessarily comprehensive, given differences in method and practice across the sciences. This is particularly the case for different kinds of qualitative field-based methodologies associated with the social sciences.[17]

But these developments also reveal important opportunities. The incorporation of human rights into ethics codes may enhance their credibility, and effectively further the process of internationalizing standards of research ethics, which can bring about a more clearly defined system for legal enforceability.[18] Accordingly, human rights are understood to function as "an internationally accepted ethical discourse"[19] and legal framework to defend the principles of bioethics.[20] While acknowledging the concerns of scholars who have identified the intellectual, practical and societal challenges that may accompany the task,[21] we seek to build on these recent developments for bioethics. And while not ignoring important disciplinary differences with respect to the role of human subjects in research, we seek to extend this process of the incorporation of human rights into bioethics across the spectrum of scientific conduct generally.

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[15] The U.S. Department of Health and Human Service's advanced notice of proposed rule-making, which lays out the proposed changes to the Common Rule (45CFR46), can be found here: http://www.ofr.gov/OFRUpload/OFRData/2011-18792_PI.pdf., accessed June 23, 2011.

[16] Thomas Faunce, "Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration," *Journal of Medical Ethics* 31 (2004): 173.

[17] Dena Plemmons and Robert Albro, 2011, "Practicing Ethics and Ethical Practice: Anthropology, Science, and the Social," (The Social Science Research Council's *Items and Issues,* published July 21) http://itemsandissues.ssrc.org/practicing-ethics-and-ethical-practice-anthropology-science-and-the-social.

[18] See Roberto Adorno, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics"; George J. Annas, "American Bioethics and Human Rights: The End of All Our Exploring," *Journal of Law, Medicine and Ethics* Winter 32, no. 4 (2004): 658-663; Robert Baker, "Bioethics and Human Rights: A Historical Perspective," *Cambridge Quarterly of Healthcare Ethics* 10 (2001): 241-252; Thomas Faunce, "Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration," *Journal of Medical Ethics* 31 (2005): 173-178.

[19] See Baker, "Bioethics and Human Rights."

[20] See Baker, "Bioethics and Human Rights"; Faunce, "Will International Human Rights Subsume Medical Ethics?"

[21] See, Richard E. Ashcroft, "Could Human Rights Supersede Bioethics?" *Human Rights Law Review* 10, no. 4 (2010): 639-660.

The emerging literature on bioethics and human rights acknowledges their shared origins and parallel development, while emphasizing unique applications of each in protecting human subjects. Human rights have been identified by some as determining *what* should be done, and ethics as helping to address *how* such actions should take place.[22] Similarly, human rights are understood to regulate government actors and to establish government responsibilities while bioethics are understood to regulate the activities of researchers and practitioners in the life sciences and medicine. Accordingly appealing to both frameworks offers a complementary – though as of yet unintegrated – mechanism that "maximizes the protection available to the vulnerable,"[23] both individuals and groups.

A first step towards strengthening the relationship between ethics and human rights is to describe the relationship. This includes:

1. identifying human rights principles relevant to human subjects research;
2. broadly characterizing current international and domestic approaches to standards for human subjects protection and their connections to human rights and ethics;
3. identifying convergences, divergences, and gaps in international ethics and human rights instruments;
4. using the analysis of the state of international human rights and research ethics to assess the ethics codes of a representative sample of U.S. scientific associations;
5. identifying the most effective means for the introduction of human rights into existing codes of ethics in dialogue with different professional scientific associations in the U.S.

Part I: Human Rights Standards Relevant to Human Subjects Research

The development of the Universal Declaration of Human Rights (1948) (UDHR)[24] was motivated in large part by the atrocities that occurred during World War II, including the use of science and technology to support genocide. The rights contained in the UDHR also reflect an awareness of the destructive potential of science, while at the same time acknowledging the benefits resulting from scientific advancement. Article 27 of the UDHR states that "Everyone has the right freely … to share in scientific advancement and its benefits." In this report, we focus on those human rights that address issues directly related to the conduct of scientific research that involves human subjects.

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[22] For a fuller discussion of such arguments, see John D. Arras and Elizabeth M. Fenton, "Bioethics and Human Rights: Access to Health-Related Goods," *Hastings Center Report*, 39 no. 5 (2009): 27-38.
[23] See Michael Peel, "Human Rights and Medical Ethics," *Journal of the Royal Society of Medicine* 98 (2005): 171-173.
[24] *Universal Declaration of Human Rights*, adopted and proclaimed by the United Nations General Assembly Resolution 217A (III), 1948.

The Universal Declaration, together with the International Covenants on Civil and Political Rights (1966) (ICCPR)[25] and Economic, Social and Cultural Rights (1966) (ICESCR),[26] comprise the International Bill of Rights. Article 15 of the ICESCR is the right most closely linked to the scientific enterprise, and it requires governments to: (1) recognize the right of everyone "to enjoy the benefits of scientific progress and its applications"; (2) take steps for the "conservation, the development and the diffusion of science"; (3) respect the "freedom indispensible for scientific research"; and (4) encourage and develop "international contacts and cooperation" in science.

The language of Article 15 does not address the ethics or the practice of science in any detail. Nonetheless, the few scholars who have explored the meaning of the right have emphasized that scientific freedom, as explicitly recognized in Article 15(3), is not absolute; it must be balanced by scientific responsibility and accountability to society, including responsibility and accountability with respect to research practices.[27] Furthermore, some of these scholars have argued that Article 15 requires that measures be taken to prevent the use or misuse of science and technology for purposes contrary to the enjoyment of human rights, including rights to life, health, personal freedom and privacy.[28]

The 'precautionary principle' is said to apply to the exercise of the right to benefit from scientific progress, according to which "in the absence of scientific consensus, caution and the avoidance of steps are required in case an action or policy might cause severe or irreversible harm to the public or the environment."[29] And with regard to human subjects research, a statement resulting from a UNESCO process to define Article 15 states that the right requires governments to take steps to "ensure the protection of the human rights of people subject to research activities by entities, whether public or private, in particular the right to information and free and informed consent."[30]

Free and informed consent is also fundamental to the right to freedom from scientific and medical experimentation as recognized in Article 7 of the ICCPR which asserts that "No one is to be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." According to the committee that monitors the ICCPR,

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[25] See *International Covenant on Civil and Political Rights*, (1966) 999 U.N.T.S. G.A. res 2200A (XXI0, 21 U.N. GAOR. Supp. (No. 16) at 52, UN Doc. A/6316. entered into force 23 March 1976.

[26] See *International Covenant on Economic, Social and Cultural Rights*, (1966) 993 U.N.T.S. 3, G.A. Res. 2200 (XXI), 21 U.N. GAOR Supp. (No. 16 at 49, U.N. Doc. A/6316), entered into force January 3, 1976.

[27] See Audrey R. Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications," *Journal of Human Rights* 8 (2009): 1-36; John T. Edsall, *Scientific Freedom and Responsibility* (Washington, D.C.: AAAS, 1975).

[28] William A. Schabas, "Study of the Right to Enjoy the Benefits of Scientific and Technological Progress and Its Applications," in *Human Rights in Education, Science and Culture: Legal Developments and Challenges*, eds. Yvonne Donders et al (New York: UNESCO, 2007), 285.

[29] *Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications*, July 16-17, 2009, s. 12(f); http://unesdoc.unesco.org/images/0018/001855/185558e.pdf, accessed on March 22, 2011.

[30] Venice Statement, s. 15(b).

Article 7 requires safeguards be put in place to protect persons incapable of giving their consent and vulnerable populations, such as prison inmates and children.[31]

Recent concerns regarding the use of "enhanced interrogation" techniques against terrorist suspects in Guantanamo Bay have been raised with specific reference to Article 7. In 2009, Physicians for Human Rights (PHR) concluded that "monitoring…by medical professions to determine the effectiveness [of enhanced interrogation techniques] uses detainees as human subjects without their consent, and thus also approaches unlawful experimentation."[32] PHR recognizes human rights and professional ethics standards not only as protecting human subjects, but also shielding medical professionals by forbidding their compliance with orders that may lead to human rights violations. In 2009, the American Psychological Association (APA) amended its Code of Ethics to clarify that "under no circumstances may this standard (standard 1.02 in the APA Code of Ethics) be used to justify or defend violating human rights."[33]

The APA's recent debate about the potential role for psychologists in enhanced interrogation demonstrates two important points: that scientific associations actively appeal to ethics to resolve disciplinary conflicts about appropriate professional conduct; and that human rights can enhance such efforts, as a limiting condition on such conduct and as a set of additional guidelines for resolving conflicts about the appropriate applications and practice of science. This is particularly the case when specific disciplinary ethics might need to be balanced against national and international laws or the requirements of third parties.

Free and informed consent has direct relevance to all forms of human subjects research, and is therefore a central tenet of several international ethics instruments, particularly the Universal Declaration of Bioethics and Human Rights, the Universal Declaration on the Human Genome and Human Rights, and the United Nations Guide to Ethics and Human Rights in Counter-Trafficking Research. The latter requires free and informed consent in a language and communication method understood by the participants and obtained without influence or coercion, such as excessive financial reimbursement or physical threat.[34]

Free and informed consent has evident applications for medical and human subjects research involving invasive methods or other direct human contact. It also has additional implications for social scientific methods involving different kinds of, often sustained, interactions with people. It is unclear, however, how free and informed consent applies to research with limited or no direct human contact. Satellite image analysis, for example,

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[31] United Nations Committee on Civil and Political Rights (CCPR), *General Comment No. 7: Torture or cruel, in human or degrading treatment or punishment (Art. 7 of the Covenant)*, 10 March 1992.
[32] Physicians for Human Rights, "Aiding Torture: Health Professionals' Ethics and Human Rights Violations Revealed in the May 2004 CIA Inspector General's Report," (2009): 4.
[33] American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct*, amended 2010, available at: http://www.apa.org/ethics/code/index.aspx#, accessed November 15, 2011.
[34] United Nations Inter-Agency Project on Human Trafficking, "Guide to Ethics and Human Rights in Counter-Trafficking: Ethical Standards for Counter-Trafficking Research and Programming," (2008): 14, 20.

can be applied to protect human rights while GPS-enabled cell phones broaden communication capabilities; yet both can be used to violate individuals' privacy and track their movements. Both the Universal Declaration of Human Rights and the ICCPR mandate that "no one shall be subjected to arbitrary interference with his privacy" (Articles 12 and 17, respectively). The committee that monitors the ICCPR has stated that "the gathering and holding of personal information on computers, data banks and other devices, whether by public authorities or private individuals or bodies, must be regulated by law" in order "to ensure that information concerning a person's private life does not reach the hands of persons who are not authorized."[35] These rights are mirrored in healthcare regulations such as the *Health Insurance Portability and Accountability Act (HIPAA) (1996)*, which regulates who may access patient files and for what purposes, as well as in other human subjects research standards.[36]

As reflected in the GPS example above, privacy is not only an issue relevant to the storage and sharing of data, but is also relevant to the production and application of technology that could violate individual privacy through intended or unintended applications. To this end, the Declaration on the Use of Science and Technological Progress in the Interests of Peace and for the Benefit of Mankind (1975) directly requires governments "to ensure [that] the utilization of scientific and technological achievements promotes the fullest realization of human rights and fundamental freedoms without any discrimination whatsoever" and to protect their populations "from possible harmful effects of the misuse of scientific and technological developments, … particularly with regard to respect for privacy."[37]

A fundamental right underlying the principle of free and informed consent is the right to information, which "shall include freedom to seek, receive and impart information and ideas of all kinds" (ICCPR Article 19). The right to information is intrinsic to an individual's ability to form opinions, make informed decisions, and engage in public debate about science and technology research and developments. Similarly, this right is central to scientists' ability to conduct scientific research. In this regard, the Universal Declaration on the Human Genome and Human Rights mandates information sharing, urges international cooperation (Articles 14-18) and encourages the "free exchange of scientific knowledge" (Article 19(a)(iv)). As such, the Universal Declaration echoes the language of Article 15 of the ICESCR which requires the "diffusion" of science and encouragement of "international cooperation" in science.

Finally, overarching principles reflected in all human rights instruments, such as the principles of non-discrimination and equal treatment, which require particular protections

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[35] See United Nations Committee on Civil and Political Rights (CCPR), *General Comment No. 16: The right to respect of privacy, family, home and correspondence, and protection of honour and reputation,* Art. 17, 8 April 1988.

[36] See United Nations Inter-Agency Project on Human Trafficking, *Guide to Ethics and Human Rights in Counter-Trafficking: Ethical Standards for Counter-Trafficking Research and Programming* (Bangkok, 2008).

[37] See Office of the United Nations High Commissioner for Human Rights, *Declaration on the Use of Science and Technological Progress in the Interests of Peace and for the Benefit of Mankind*, United Nations General Assembly Resolution 3384, November 10, 1975.

for vulnerable and marginalized populations,[38] have direct implications for the conduct of research. For example, Article 7 of the Declaration on the Use of Scientific and Technological Progress expressly requires governments "to ensure that the utilization of scientific and technological achievements promotes the fullest realization of human rights and fundamental freedoms without any discrimination whatsoever on ground of race, sex, language or religious beliefs." Article 6 of the Universal Declaration on the Human Genome likewise prohibits discrimination based on genetic traits.

While international human rights instruments make limited references to science, the human rights framework does offer a set of general principles that can usefully inform scientific research and practice. The APA example is one illustration of the added value of addressing human rights in the context of scientific practice in ways that complement discipline-specific ethical standards. In conjunction with this report, we are developing a digital archive of case studies. Each case study addresses the relationship between human rights and ethics for a particular scientific discipline, as an important first step in identifying what this landscape looks like at present for the sciences in the U.S. and as a way to address the potential complementarity of human rights and ethics across distinct disciplines.

Part II: International Context for Science Ethics

The Nuremberg Code (1948) was the first formal international treaty aimed at the protection of human subjects. It was based upon the recognition of the "dignity" of the person, a foundation shared with the Universal Declaration of Human Rights (1948). This concept recurs in the Declaration of Helsinki (1964-2008), and has developed into a recognition of "patient rights" in Helsinki and the US Common Rule (1991). With the adoption of the Universal Declaration on Bioethics and Human Rights in October 2005, the identification of human dignity and patient rights have been brought together under the explicit umbrella of international human rights law.

An examination of these four documents that have promulgated the legal concepts of dignity and patient rights demonstrates the parallels, if also some differences, between the ethical standards of human subjects protection and human rights. These parallels exist, for example, between the principles of voluntary and informed consent and the rights to information, to not be subject to medical experimentation, to liberty and security of person, and freedom from bodily harm. Parallels similarly exist between the principle that the benefits be proportional to the risks, and the right to benefit from the advancements of science. The following discussion chronicles the development of the international arena of protections for human subjects and elucidates the corollaries of these protections in international human rights law. It concludes with consideration of the integrated ethics-human rights framework of the Universal Declaration on Bioethics and Human Rights.

[38] Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications," 15.

Nuremberg Code

Growing out of the same events that lead to the development of the Universal Declaration of Human Rights (1948), the Nuremberg Code originated as a means to protect human research subjects.[39] Consisting of ten principles, the Code makes no specific reference to human rights. Yet, its protection of research subjects, through the requirement or expectation of informed consent and voluntary participation, is consistent with human rights principles, including the rights to information, to liberty, and to security of person, as expressly recognized in the UDHR. The Code places on the physician-researcher the ethical obligation of evaluating the risk and explaining it to the research participant, and establishes an expectation, if not a requirement, of reasonable participant safety and full disclosure of risk. The Nuremberg Code further establishes that the benefits of participation in research should be proportional to the risks.[40]

Declaration of Helsinki (1964 – 2008)

The Declaration of Helsinki, first adopted by the World Medical Association in 1964, built directly upon two precedents: the World Medical Association's (WMA) Declaration of Geneva (1948) and the International Code of Medical Ethics (1949). Like the Nuremberg Code, these precedents coincide with the UDHR and share its spirit.

The Declaration has been revised six times (most recently in 2008). Consistent with the Nuremberg Code and subsequent statements like the International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982), the Declaration of Helsinki as revised articulates a variety of widely accepted standards for scientific practice with respect to human subjects. These standards include an emphasis upon the well-being of the human subject as more important than the research results (Article 6); the security of the person and a mandate to minimize risks to the research subject (Articles 11, 20); the established standard of "freely-given informed consent" (Article 24); the right of access of the subject to the results of research (Article 33); and public dissemination of research results (Article 30).

Although the Declaration is mostly concerned with potential negative implications of experimentation on human subjects, as with human rights, it is built upon the foundation of human dignity. As elaborated in Article 11, medical researchers and physicians must first and foremost aspire to the protection of "the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects." As such, the Declaration presents a more explicitly elaborated rights-based approach to ethics than the Nuremberg Code, insisting that researchers and physicians "promote respect for all human beings and respect their health and rights" (Article 8).

While the Declaration does take steps to stipulate particular protections for research on vulnerable populations (Articles 9 and 17) and to expand reference to "individuals and

[39] Baker, "Bioethics and Human Rights."
[40] See also the *Singapore Statement on Research Integrity*, 2nd World Conference on Research Integrity, 21-24 July 2010; http://www.singaporestatement.org/, accessed September 22, 2011.

communities" (Articles 17-19), it generally assumes individual "human subjects" rather than "populations" or "communities." Even with regard to the right of "access" to the beneficial results of research, the assumption is one of access by particular individual subjects. As such, the "human subject" at the heart of the Declaration of Helsinki differs in important ways from the "human being" referenced in the UDHR and subsequent human rights instruments, in particular, with the assumption that the only human subject of scientific research is an individual one, largely considered outside of any particular context of the research, whether collective, social, political, religious, or economic. The implications of this distinction for the meaning of "human dignity" and its extension as a bridge across the domains of human rights and scientific ethics, requires further consideration, including the challenges involved in bringing human rights and ethical standards for research more closely together.

The Declaration also takes for granted a particular understanding of the process of scientific inquiry that is far from comprehensive in its application to the full diversity of disciplinary scientific practice. This understanding assumes: "participants in medical research" (Article 2); research intended to "understand the causes, development, and effects of diseases" (Article 7); and use of laboratories and of animal experimentation, clinical trials, and blind or double-blind experiments involving the use of placebos (Article 32). This adds up to an approach to scientific practice that is most congruent with classic experimental design and consistent with biomedical research. It is, however, less adequate to the task of human subjects protection in the context of qualitative research methodologies, such as ethnography, surveys, focus groups, or the use of interviewing techniques, which are typically used "in the field," rather than in a laboratory. Because of this focus on clinical research, the ethics of the Declaration for research on human subjects is not comprehensive.

Through successive revisions of the WM, references to human rights in the document have increased. For example, reference to "self-determination" was a later addition to the document that echoes Article 1 of the International Covenant on Civil and Political Rights as well as of the International Covenant on Economic, Social and Cultural Rights. At the same time, revisions have weakened international consensus, with different countries and regions now recognizing different versions of the document. What this suggests is that tensions exist between universally agreed-upon international ethics standards as informed by human rights, on the one hand, and distinct regional or national standards for human subjects protection, on the other. This conflict is also recognized in the U.S. "Common Rule" (see below for further discussion).[41]

[41] 45 CFR 46.101 (6)(f).

Universal Declaration on Bioethics and Human Rights (2005)

Developed by UNESCO and adopted in 2005, the Universal Declaration on Bioethics and Human Rights primarily addresses issues raised by the practice of medicine and research in the life sciences, and the use of associated technologies. It does not directly address comparable questions raised, for example, by other physical sciences and/or by the social sciences.

As its title suggests, the Declaration explicitly uses human rights language in the context of bioethics, including references to "human dignity," "human rights," and "fundamental freedoms." In so doing, the Declaration moves beyond previous international bioethics precedents and makes it clear that, in the context of bioethics, international standards of human subjects protection and human rights standards are mutually supportive.

As an ethics statement, the Declaration is precedent-setting in making explicit reference to human rights principles: it asserts the right to share in the benefits derived from advances in science and technology (Article 15), and the importance of equitable access to health care and essential medicines (Article 14). The Declaration further addresses: balancing scientific benefits with harm (Article 4); the duty to acquire free and informed consent of the research subject (Article 6); and the application of the right to privacy (Article 9). In Article 27, the Declaration acknowledges that the principles set out in the Declaration are not absolute and may be limited when necessary for the protection of human rights.

The Universal Declaration on Bioethics and Human Rights reflects international bioethics precedents from Nuremberg and Helsinki, and is generally consistent with codes of ethics of US scientific associations on the matter of human subjects protection. The Declaration is distinguished from other ethics codes by its explicit references to human rights. The Declaration is also noteworthy for its intention to guide not only government actions but also "individuals, groups, communities, institutions, and corporations, public and private" (Article 2b).

In addition to the Universal Declaration on Bioethics and Human Rights, UNESCO has developed several additional instruments addressing bioethics and human rights. These include the Universal Declaration on the Human Genome and Human Rights (1997) and the International Declaration on Human Genetic Data (2003).

Part III: Domestic U.S. Context for Human Subjects Protection

The domestic U.S. context for human subjects protection is also one built on preceding international ethics instruments, particularly the Nuremberg Code. However, where the international trend has been to begin to integrate explicit references to human rights in ethical standards, in the domestic U.S. context human rights remain entirely absent from government standards, and are so far included only occasionally in the codes of ethics of discipline-specific professional societies. Yet, a shift may be occurring, as demonstrated by the recent attention to "the intersection of science and human rights" as part of the

mandate of the Presidential Commission for the Study of Bioethical Issues. In what follows, we hope to advance dialogue about what this intersection should look like for research with human subjects.

The Belmont Report (1979)

Drafted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and drawing on the history of bioethics begun with the Nuremberg Code, the Belmont Report (1979) laid the groundwork for the U.S. approach to bioethics. The Belmont Report offers a more detailed analysis of how ethical issues may come into conflict than preceding international standards, and lays out a prescription to protect human research subjects.

The right to information emerges repeatedly in the Report, with calls for researchers to provide adequate information about procedures and risks and to communicate this information in such a way as to be fully understood.[42] Achieving this requirement involves assessing the capacity of patients to understand materials, providing adequate time to process materials, and offering a period for questions.[43] The Report also addresses situations in which the circulation of information may hamper study results. In such cases, it nevertheless concludes that risks must be communicated and that "convenience" to the researcher is not by itself sufficient cause to conceal necessary information from the patient.[44]

The right to security of the person is similarly a central tenet of the Report, which holds physicians accountable to develop studies that involve minimal risk to participants and to apply all available technology to minimize harm to the individuals participating in human studies.[45] It also establishes that study subjects should, whenever possible, be drawn from the same social groups that are likely to benefit from the study.[46] Recognizing the potential for studies to be biased by prejudicial social norms, the Report encourages researchers proactively to seek to minimize sampling bias, and to avoid involving certain groups "solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition."[47] An ethical dilemma for which the Report does not provide a solution is how to conduct a risk-benefit analysis when risks are incurred by one person with little chance of benefit, and the benefits are conferred on another. The language of "risk" is not altogether commensurate with the human rights concepts of "dignity."

The Belmont Report exhibits standards for human subjects research that are consistent not only with the right to liberty, security of person and information, but also the equality

[42] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research* (Washington, D.C.: Department of Health, Education, and Welfare, 1979): C.1.
[43] *Belmont Report*, C.1.
[44] *Belmont Report*, C.1.
[45] *Belmont Report*, C.2.
[46] *Belmont Report*, C.3.
[47] *Belmont Report*, C.3.

of individuals. While the Nuremberg Code alludes to the same rights, the more detailed treatment in the Belmont Report offers multiple points of potential intersection with human rights. Yet human rights are not explicitly mentioned.

The Common Rule (1991)[48]

Prepared by the U.S. Department of Health and Human Services and put into place in 1991 to address "protection of human subjects," 45CFR46, typically referred to as the "Common Rule," draws inspiration from the Belmont report and functions as a de facto federal ethics code for scientific research involving human subjects. The Common Rule represents a U.S. response to such controversial ethics cases as the Tuskegee syphilis study (1932-1972) and the Stanford prison experiment (1971). Different federal agencies have gone on to elaborate additional ethics statements. The Department of Defense, for example, established its own ethics policy, 32CFR219. However, it corresponds in almost every particular to the Common Rule.[49]

The Common Rule has a notably different set of priorities compared to the international ethics instruments surveyed above. While the latter seek to articulate an overarching framework of ethical principles, the Common Rule is concerned with more specific considerations of the process of the institutional review of research proposals to ensure their consistency with ethics. The Common Rule elaborates guidelines for the operation of the institutional review boards (IRBs) that compose part of the federal oversight and regulation of scientific activities. The greater emphasis on institutional review reveals the growing significance of ethics in the design and conduct of scientific research.

As distinct from the general trend of international standards, the Common Rule moves beyond the strict bioethics framework of human subjects-based research by referring more expansively to research as "systematic investigation" of any sort that leads to "generalizable knowledge" (46.102 d). This allows for the articulation of standards of human subjects protection applicable to a greater range and diversity of scientific disciplines and practices that engage in human subjects research, going beyond biomedical research.

As with other ethics instruments, the Common Rule specifies the principle of "informed consent" (46.111 a1-2 and 46.116), protection of the "privacy of subjects" (46. 111 a7), access to the "benefits" from research conducted (46. 1116 a3), and protection of the "private information" of "living individuals" (46.102.f). As with the Helsinki Declaration, the Common Rule assumes that human subjects of research are individuals and not collective subjects or categories of persons. This approach is in keeping with the emphasis on individual civil rights found throughout U.S. law.

[48] At present, the Common Rule is under review by the federal Office of Human Research Protections, and will likely be revised.

[49] One goal of the Obama Administration's review of the Common Rule is to unify the process of ethical review for federally-funded research under the same IRB process rather than to allow competing standards.

On the one hand, the Common Rule also goes well beyond international instruments in specifying vulnerable categories of human subjects, a list including infants and children, pregnant women, and people with physical and mental disabilities. At the same time, it offers a series of exceptions for circumstances in which research involving human subjects can be exempt from any requirement of a formal institutional ethics review process, including educational achievement tests, the restudy of existing data, research dedicated to public benefits or to service programs, and consumer acceptance studies (46.101b).

The Common Rule makes repeated reference to the "rights" of the subjects of research. For example, the stated goal of the Common Rule is "protecting the rights and welfare of human subjects of research" (46. 103 b1 and 46. 109b). However, in this case the "legal rights" of subjects are derived not from international human rights standards but from "federal, state or local law" (46. 116). At the same time, while the principle of "human dignity" underlies the development of international ethics standards, the Common Rule does not refer to this principle. Instead, it follows the language of the Belmont Report by replacing dignity with "minimizing risk" to the subject, where "risk" refers to weighing the possibility of "physical and psychological harm" (46. 303d). Therefore, even as the Common Rule is in many ways more specific than international ethics standards, it also draws less direct inspiration from human rights.

In comparison with international standards, the Common Rule is at once more specific and more uneven in the handling of human subjects. With regard to informed consent, for example, the Common Rule tends to assume that the bioethics approach, as derived from the medical sciences, is equally applicable to the uses of qualitative methods frequently used by the social sciences, such as participant-observation ethnography, oral history, action research, or community-based participatory research. However, such qualitative methods are sufficiently distinct from the medical model of research that the question of informed consent is not sufficiently addressed by one-time discrete engagements with individuals. In such cases, the "dignity" in question may be less that of the individual "person" and more a question of peoples' relationship to broader social arrangements. In this sense, "dignity" may be collective in important ways not currently recognized under the Common Rule.[50]

The Common Rule's relative lack of recognition of the diversity of relationships between investigators and the participants in their investigations regularly creates challenges for researchers, especially for social scientists using qualitative or community-based research techniques.[51] The IRB process obliges these researchers to negotiate a model for research derived from the kinds of clinical trials associated with the medical field, which leaves

[50] For further discussion see, Benjamin Mason Meier and Larisa M. Mori, "The Highest Attainable Standard: Advancing a Collective Right to Public Health," *Columbia Human Rights Law Review* 37 (2005): 101-147.

[51] For further details about the several dimensions of these challenges, see: Lainie Friedman Ross et al., "Human Subjects Protections in Community-Engaged Research: A Research Ethics Framework," *Journal of Empirical Research on Human Research Ethics* 5, no 1 (2010): 5-17; Martin Tolich and Maureen Fitzgerald, "If Ethics Committees Were Designed for Ethnography," *Journal of Empirical Research on Human Research Ethics* 1 , no. 2 (2006): 71-78.

little room for the sorts of relationships these researchers maintain with collaborators, research subjects, and other community counterparts. In addition, this model does not accommodate the changing conditions of such research, where social scientists are today less engaged in research *on* individuals or communities as they collaborate *with* them as active participants.[52] Such a poor fit can have a stifling effect on research. The proposed revision of the Common Rule seeks both to specify further exemptions for the kinds of human subjects research associated with such qualitative methods as interviewing while also creating a unified institutional review board process.[53] We suggest that the addition of a human rights approach to research ethics helps to create needed space and language in ethics discussions for such considerations by expanding reference to the collective rights of subjects.

Part IV: Human Rights and the Diversity of Science

Another challenge in the effort to integrate human rights with ethics is the wide diversity of scientific practice across the life, physical, social, behavioral and engineering sciences. Across these disciplinary boundaries, the relationship of scientific practice to human subjects cannot be addressed adequately through reference to a single or unitary understanding of the "experimental method." The differences in practices that are evident across the disciplines include differences in method, theory, professional disciplinary training, conceptions of knowledge production, uses of technology, and settings (i.e., laboratory versus field based research), among others. This diversity poses challenges to efforts to introduce universal human rights language into discipline-specific codes of ethics. Further, it underscores the importance of the need to engage with diverse scientific disciplines to encourage discussion about the potential relationship of human rights to ethics.

Scientific practice is rapidly-evolving. Scientific work is now frequently transnational and often carried out by geographically dispersed and interdisciplinary teams of researchers who straddle multiple geopolitical boundaries. The increasingly transnational work of science underscores a need for harmonizing standards of conduct as common points of departure in conjunction with such national ethical guidelines as the U.S. Common Rule. Likewise, innovations in scientific method create new frontiers for the ethics of human subjects protection, such as the growing uses of geospatial technologies[54] and applications of computational modeling and simulation across disciplines. Likewise, there are new legal and regulatory environments, such as: the changing landscape for intellectual property rights[55] governing the proprietary relationships in the biological sciences; different national government policies regarding genetically modified

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[52] See Joan Sieber, "New Research Domains Create New Ethical Challenges," *Journal of Empirical Research on Human Research Ethics* 5, no. 1 (2010): 1-2.
[53] See David Brown, "U.S. Proposes Rule Changes for Human-Subject Research," *The Washington Post.* July 23, 2011.
[54] See Lars Bromley, "Eye in the Sky: Monitoring Human Rights Abuses Using Geospatial Technology," *Georgetown Journal of International Affairs* 10, no. 1 (2009): 160.
[55] See: Peter K. Yu, "Reconceptualizing Intellectual Property Interests in a Human Rights Framework," *University of California Davis Law Review* 40 (2007): 1039-1149.

organisms or climate change research; and the management of dual-loyalties for scientists working outside the academy, which can lead to conflicts between competing ethics and rights standards.[56]

In June 2008, the AAAS Science and Human Rights Program undertook a survey of the 262 scientific organizations affiliated with AAAS, concluding that eleven of these organizations make direct reference to human rights as a part of their respective codes of ethics.[57] This represents a very small minority of total organizations. An accompanying snowball sample of professional ethics codes in the U.S., however, also revealed a wider compatibility with the objective and purpose of human rights, even in the absence of explicit reference to any human rights instrument or principle. This suggests the evident relevance of basic principles, including Article 15 of the ICESCR,[58] even when explicit mention of human rights is not made.[59]

When explicitly noted, human rights are incorporated in different ways into ethics codes. The American Psychological Association recently modified its ethics code in 2009 in a way privileging human rights as the highest standard, noting: "Under no circumstances may this standard [standard 1.02 of the APA code of ethics] be used to justify or defend violating human rights." Updated in 2008, the ethics code of the American Political Science Association (APSA) refers to human rights in the context of the protection of "academic freedom" and the persecution of scientists. In this case, a concern for human rights is articulated as a concern for the rights of individual political scientists.

Other associations reference human rights differently. The American Anthropological Association does not refer to human rights in the body of its ethics code, but includes the UDHR as among "other relevant codes of ethics" that it lists. However, in addition to a Committee on Ethics, the AAA does maintain a standing Committee for Human Rights, which authored a 1999 "Declaration on Anthropology and Human Rights," and which is formally sanctioned by the Association. Still other associations selectively note human rights specifically relevant to their own work, such as the American Public Health Association, which refers to Article 25 of the UDHR regarding the "right to a standard of living adequate for the health and well-being of himself and his family" in its 2005 ethics code.

There are multiple ways that ethics codes address concerns closely aligned with human rights. We note here three important ways this is the case. As evident with the APSA example (above), many ethics codes stress the importance of "academic freedom" in the pursuit of scientific inquiry in ways broadly consistent with the right to freedom of scientific inquiry set out in Article 15(3) of the ICESCR and other civil and political

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[56] See Physicians for Human Rights' Dual Loyalty Working Group, *Dual Loyalty & Human Rights in Health Professional Practice: Proposed Guidelines and Institutional Mechanisms* (Boston, 2002).
[57] This survey, best understood as a sample of scientific codes of ethics rather than as a comprehensive survey, was carried out by AAAS intern Rosh Sethi (June 2008), and completed by intern Jeremy Weissman (spring 2010).
[58] See: Chapman, "Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications."
[59] This snowball sample was carried out by Jeremy Weissman (April 2010).

freedoms, as contained in the UDHR and subsequent human rights documents. Several ethics codes also include non-discrimination clauses in ways closely approximating the same in Article 2 of the Universal Declaration. Finally, many codes of ethics specifically address questions of, and procedures for, dissemination of scientific results and access to results for relevant stakeholders, in ways commensurate with Article 15 of the ICESCR.

Most generally, ethics codes often refer to the concept of "dignity," albeit in different contexts. To take one example, the Association of American Geographers refers to human rights alongside "social justice" or "ethics of care," all as mutually compatible ways to pursue the goal of "well-being," as this underlies its ethics code. Similarly, the Association for Computing Machinery has as its goal "human well-being." The American Society for Biochemistry and Molecular Biology gives priority to "enhance the public interest or well-being" in the pursuit of "human welfare," while a variety of other associations refer to "human dignity" as a basic ethical goal.[60] Yet other formulations, such as those of the APA and the AAA, underscore their attention to the "rights and dignity" of human subjects and to the "safety, dignity, or privacy" of the people with whom they work. The American Sociological Association, in turn, emphasizes the "rights, dignity, and worth of all people" as one of its general ethical principles. As such, codes of ethics regularly connect a concern with dignity to the question of rights in ways entirely consistent with a human rights-based approach to human dignity.

These findings revealed that human rights language is largely absent from the domestic U.S. framework for the ethics governing human subjects. Notwithstanding this finding, we nevertheless are optimistic that the introduction of human rights language into domestic codes of ethics is consistent with ethics and will not involve the introduction of a totally new or foreign set of concepts. On the contrary, as our review of ethics codes suggests, we believe the concept of human rights complements and supports existing ethical standards. Further, with the increase in international scientific collaboration, human rights offer a framework for further establishing common international ethical standards of scientific conduct.

At present, the codes of ethics of U.S.-based scientific associations exhibit significant disciplinary specificity. The implications of this specificity for interdisciplinary collaborations need to be taken into account in the work of identifying the relationships of human rights standards to codes of ethics. However, at least initially our approach is to provide case studies of the relationship between science ethics and human rights pitched at the level of distinct disciplines and particular scientific associations in the U.S. We believe these cases will enable a better overall appreciation of the continuities and variations within and across the topography of ethics frameworks informing diverse disciplinary commitments, and help to identify the opportunities for the introduction of human rights standards to scientific ethics.

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[60] American College of Dentists, *Core Values and Aspirational Code of Ethics*, (Gaithersburg, MD, 1996); American Medical Association, *Code of Medical Ethics*, (Chicago, IL, 2001); Association for Applied Psychophysiology and Biofeedback, *Ethical Principles*, (Wheat Ridge, CO, 2003); International Association for Impact Assessment, *Mission, Vision, Values*, (Fargo, ND, 2009).

Part V: Conclusions and Next Steps

In this report, we broadly surveyed the topic of international and domestic ethical standards of human subjects protection and explored areas of connection and disjunction between these standards and human rights. We anticipate that the report will serve as a basic framework for further work by the Science Ethics and Human Rights Working Group as well as for colleagues interested in promoting the integration of science ethics and human rights. In addition, this report will be accompanied by a digital archive of case studies that explore the various ways distinct scientific disciplines draw connections between ethical conflict, practice and human rights (or not, as the case may be), and elucidate similarities and differences among scientific disciplines regarding research ethics and human subjects. We hope the archive will encourage dialogue about how human rights might intersect with the practice of science in its many forms. A sample of such cases is included in the Appendix of this document. This archive will be hosted online by the AAAS Science and Human Rights Coalition.

We offer the following conclusions as considerations for future dialogue about the relationship between human rights and the ethics of human subjects protection:

1. Historically, while attention has been given to the human rights of individual scientists, very little effort has been made to incorporate principles of human rights into the ethical practice of science.

2. Domestic codes of ethics of U. S. scientific, engineering and health associations rarely refer to human rights, exhibiting instead ethical language framed by the particularities of their disciplinary practice.

3. Ethics standards relevant to human subjects protection rarely take explicit note of human rights. Yet, they derive their inspiration from the same fundamental principle of "human dignity." Hence, going forward, it makes sense to emphasize these shared beginnings as a bridge between them.

4. There are also some potential challenges in reconciling the subjects of human rights with the human subjects of research, in particular, the focus in both international and domestic ethics statements on the individual human subject with limited recognition of collective or community-based subjects. This focus at once ignores a more expansive appreciation of human dignity and fails adequately to encompass the diversity of forms of scientific disciplinary practice and associated different relationships to human subjects.

5. If ethics instruments employ "rights talk" as applied to the human subjects of research, ethics in the U.S. are framed in terms of civil and legal rights rather than "human" rights. The challenge is to extend discussion of such rights to also encompass social, economic and cultural human rights, as these are implicated in the practice of science.

6. There are also significant differences between international and national U.S. ethical frameworks, such as the U.S. emphasis upon the process of ethics review as compared to the international focus on principle setting alone. This suggests different starting points for the introduction of human rights. These several challenges should be acknowledged and further explored.

7. Across the development both of international and domestic ethics instruments, we can point to a collection of specific injunctions, in particular with respect to human subjects, including:

- respect for human dignity
- security of the person
- a subject's right to privacy and confidentiality
- the right to self-determination
- free and informed voluntary consent
- the right to benefit from science
- public dissemination of results

Found in some form in most ethics instruments, these commitments are also consistent with human rights principles. As such these are key "bridging" concepts between ethics and human rights that may be used to facilitate the introduction of human rights into ethical standards of human subjects protection.

Appendix: Case Studies of the Frontier between Ethics and Human Rights Across U.S. Scientific, Engineering and Health Associations

This section is composed of what we anticipate will be a growing case archive, across diverse disciplines. These cases are meant to provide a bottom-up appreciation of the present landscape of ethics and human rights, to be compared and contrasted with the more top-down discussions of international and national instruments and frameworks for the ethical conduct of science. The report provides a framework for the accumulated cases. We recognize that the ethical state-of-affairs can look different from within particular disciplinary spaces, and so this fact has evident implications for how best to approach the work of introducing a human rights-based ethics into diverse scientific contexts, including helping to identify likely doorways.

It is evident that codes of ethics of different professional associations tend to reflect appreciation and concern for the ethical implications of signature methods, historically established topical foci, and, where relevant, particular relationships to human subjects. As such, when approaching a given professional association, awareness of what these factors are, and of the emerging "ethical frontiers" associated with each, needs to be a part of the process. We expect to develop an approach that brings international and domestic standards together with specific disciplinary codes of ethics, as the best way to identify the value-added relevance of human rights for each case.

Each case study presents a particular "ethical frontier" for a given association, often taking the form of a recent or ongoing ethics controversy or concern. At the same time, it addresses the current status of the relationship between ethics and human rights, identifying lacunae and possibilities, in a given discipline. The cases are intended to be comparative: at once exploring the particular ways ethics and human rights inform the characteristics of a given disciplinary practice, while also highlighting common concerns and approaches, as these emerge across the cases. We anticipate that the archive will be hosted on the AAAS Science and Human Rights Coalition website as a cumulative digital archive, to be steadily added to over time by the Working Group. We also anticipate each case can be used to customize the "starter kit" already elaborated by the Service to the Scientific Community Working Group and now available on the Coalition website, to be used when engaging with different scientific, engineering and health associations about the introduction of human rights into their current ethics codes.

Case 1: Military Work and the American Anthropological Association (AAA)[61]

The AAA's Code of Ethics was created in 1971 amidst the ethical controversies generated by the supposed uses of anthropology in the Vietnam conflict, most obviously Project Camelot and the Phoenix Program. It was revised in 1998, and again in 2009, in response to contemporary concerns about the application of anthropology in the current Global War on Terror (GWOT), in particular, the possibilities of "clandestine research" as an intelligence asset. As a result of recent controversies, the AAA's code of ethics is

[61] This case was provided by Robert Albro, School of International Service at American University.

currently under a three-year review process, after which it will in all likelihood undergo further significant revisions.

Current ethics controversies in the AAA are primarily a response to outreach by military, security, and intelligence agencies, both to add anthropological assets in the context of counterinsurgency in Iraq and Afghanistan and to directly recruit anthropologists to work as social science "embeds" with forward-operating battalion-level units in the theater of conflict to collect sensitive socio-cultural data in this high-risk environment. The embed program is particularly controversial, since it can place research populations in harm's way, data generated are not publicly available, and the research is not subject to external review. Further, the program currently lacks an ethics framework, operating in a state of exception, which undermines individuals' efforts to meet disciplinary and federal ethics standards. Also of note is that this ethics crisis has focused on anthropology's signature method (ethnography) and signature disciplinary concept (culture). But so far the debate has not been conducted in human rights terms.

As with many other ethics statements, the AAA's code of ethics emphasizes that responsibility to the people with whom anthropologists work must supersede all other priorities. And this responsibility is primarily itemized in terms of the proscription to do no harm, to obtain free and informed consent of research subjects, to maintain complete transparency in the communication of research goals and results, and to make research results available to research subjects (primarily found in Articles IIIa, c, VI).

Article IIIb2 includes the following statement: "Anthropological researchers are subject to the general rules of scientific and scholarly conduct." This suggests that anthropology and the activities of anthropologists should be understood in terms of the broader ethical mandate of "Science" as a generic category. But whether existing instruments achieve this is questionable.

It is apparent, for example, that the broad trend with international ethics instruments is to assume a human subject that corresponds primarily to the circumstances of biomedical research and/or to the beneficiary of the applications developed from said research. This person, in the singular, is the "research subject" in a classical sense. But this corresponds awkwardly to the generic subject of anthropological research, most often referred to in its code of ethics as "the people with whom they work" (Article IIIa), in the plural. This difference is not casual. These subjects are typically encountered in very different social arrangements "in the field" as opposed to in the clinical laboratory, pointing to the ethical differences associated with different kinds of scientific practice (e.g., clinical testing vs. ethnographic participant-observation fieldwork).

At the same time the AAA's code of ethics makes mention several times of the importance of the need to consider "other codes, laws, and ethics" applying to the communities, countries, and contexts of research, which leaves the possibility of multiple and competing ethical standards. And yet at the same time it makes note of "other relevant codes of ethics" in section IX, including human rights precedents such as the UDHR and CEDAW. Finally, as distinct from its code of ethics, the AAA has also

ratified a Declaration on Anthropology and Human Rights (1999). This statement enhanced human dignity in a disciplinary-specific manner by equating humanity with the "capacity for culture." As such the Declaration reflects a "commitment to human rights consistent with international principles but not limited by them," in fact it actively builds on them by introducing the principle of human difference as one further criterion of dignity.

Case 2: The Ethics of Interdisciplinarity and the New Biotechnologies[62]

Synthetic biology, like nanotechnology, stem cell research and novel advanced therapies involving the manipulation of DNA in living organisms and genetic engineering hold the promise of securing spectacular advances in the treatment and cure of crippling diseases and solutions to global environmental problems. Yet, there are concerns, both ethical and scientific, about the risks attending the use of novel technologies. In the case of synthetic biology, these include the fact that synthetic biology involves the production of synthetic cells or new living organisms which will be self-replicating and therefore potentially uncontrollable, and security risks posed by ease of access to DNA sequenced data and biomaterials which could be re-engineered to create and release pathogens harmful to the public.

The synthesis in 2002 of an infectious polio virus using only published DNA sequence information and mail-ordered raw materials is one such case. Related to such research on "dual-use" technologies is the tension between the principle of scientific freedom and public dissemination of results and the prevention of public harm. An example from the U.S. illustrating this tension arose in 2005 when a team of scientists discovered how to synthesize the virus responsible for the 1918 influenza pandemic, which killed 50 million people worldwide. The question of whether the study should be published was considered by NIH and the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee chartered to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. Both agreed that the benefits of publication outweighed the theoretical risks. The committees' reasoning did not make explicit reference to ethical codes of conduct or human rights, though the missions identified in the NSABB Charter is to "advise on the development, utilization and promotion of codes of conduct to interdisciplinary life-scientists and relevant professional groups."

Cases such as this one raise a series of ethical questions: What are the scientists' ethical duties in such cases? Should they refrain from conducting research on technologies which have the potential to cause harm and/or have the potential to be misused? Should such research be published? To what extent do existing codes of conduct provide an answer? And how do they relate to human rights instruments?

[62] This case was provided by Aurora Plomer, School of Law at the University of Sheffield (UK).

Research on new technologies and their applications typically straddle across a range of disciplines, including physics, chemistry, biology, engineering, both professional and educational, all with their distinct ethical codes of conduct. One such example is the rise of engineering ethics in the US in the 1980s, which can be traced back to the use of the atomic bomb in World War II, the Three Mile Island disaster, the Ford Pinto case, and the explosion at Bhopal. The American Society for Engineering Education (ASEE) and the Association for Practical and Professional Ethics (APPE) both hold regular sessions on engineering ethics. In 2004, the National Academy of Engineering (NAE) sponsored a special on "Emerging Technologies and Ethical Issues in Engineering." But should a scientist who genetically engineers a novel synthetic organism be guided by the code of ethics of the American Association of Mechanical Engineering (ASME) or of the American Chemical Society?

Although there is overlap in the content of both these codes, there are also significant differences in the level of specification of the scientist's responsibilities. Furthermore, neither of these codes specifically links ethics to human rights. Nevertheless, there is considerable scope to articulate such links between, for example, duties to serve the public interest (ACS), or the use of knowledge and skill for the enhancement of human welfare (ASME), on the one hand, with Article 2 of the UDHRB or Article 15 of the ICESCR, on the other. Yet both obligations to the profession in the ACS and ASME are straightforwardly compatible with Article 18 of the UDBHR. Thus, detailed mapping of areas of convergence, divergence and links to human rights of the range of applicable codes is one of the key challenges in fast developing fields of science crossing traditional discipline boundaries.

A further question relates to the grounding of such a code of conduct in institutional frameworks. To what extent is the content of ethical codes of conduct affected by whether the organization is a professional body (with licensing and disciplinary powers) or a scientific association (with an educational mission)? We can compare, for instance, the CoE of the ASME with the Helsinki Declaration. Does the nature of a scientists' duty to his fellow scientists and society differ depending on his/her place in the discovery chain? How human rights instruments may be meaningfully embedded in existing (or future) codes of ethics depends to some extent on how the above questions are answered.

Case 3: The Association of American Geographers, Ethics, Science, and Geographic Technologies[63]

The Association of American Geographers (AAG) statement of professional ethics was first put in place in 1998, and has been updated twice, in 2005 and 2009. As with many scholarly society codes of ethics, it lays out several fundamental ethical injunctions, such as the right of informed consent, the requirement to share research results, and the need

[63] This case was assembled by Robert Albro and Douglas Richardson, with the help of Dawn Wright. It draws on some examples from the NSF-funded "Ethics Education for Geospatial Professionals" Project, which involved three universities (Penn State, Oregon State, and U of Minnesota) and the AAG (see: http://gisprofessionalethics.org).

for benefits to the community, all as part of the need to prioritize the "dignity, safety, and well-being" (Part V, b) of human subjects, described as "individuals and communities."

The AAG's statement of professional ethics, therefore, is built upon principles widespread among the ethical instruments developed internationally and domestically, particularly with regard to research with human subjects. With its emphasis upon "dignity," this code of ethics also appeals to standards consistent with human rights. In fact, it makes explicit mention both of U.S. standards, such as the Belmont Report, (part V), and of "human rights," as antecedents and guidelines. The code states categorically that working with human subjects has to include concern for "the basic human rights of affected individuals" (part V, b), and it treats "the role of human rights, social justice, or ethics of care" as equivalent in the overall pursuit of "well-being" (part VIII). Hence, human rights, while central to the AAG's ethics statement, are not the only standards considered.

Additionally, as with other scientific ethics statements, AAG's statement of professional ethics reflects the specific history, methodologies, tools, and research practices characteristic of geographers. Its statement of ethics speaks to "some of the (often overlapping) arenas in which professional geographers find themselves" (preamble). In this case, the code of ethics places specific emphasis on "respect for ecosystems, biodiversity, natural resources, climate, landforms, and the principle of sustained environmental stewardship" (part V), in ways befitting a science dedicated to the study of human interactions with the earth, its land, features, and related phenomena.

Similarly, AAG's code of ethics also gives particular attention to uses of "research involving geospatial technologies," such as geographic information systems (GIS) and global positioning systems (GPS) which introduce "special challenges" of an ethical sort, including but not limited to questions of privacy, confidentiality, data collection and analysis, community interests and ownership of information (part V, d). The code of ethics goes on to further specify a variety of potentially problematic applications, depending on context, of some geographic technologies involving automatic tracking of peoples' locations and movements; uses of images from satellite, aircraft, and ground-based sensors; and the use of geographic location, or coordinates, to link personal data. The 2009 amendment to AAG's ethics code was spurred by controversy surrounding a project conducted by the American Geographical Society (not related to the AAG), that used geographic technologies within indigenous communities in Oaxaca, Mexico, and where the question of adequate disclosure and informed consent related to detailed mapping of social information in these communities was raised.

At the same time, of course, research on and involving geographic technologies can and does generate important scientific advances as well as significant societal and environmental benefits. Hence, geospatial technologies also contribute to the human right to the benefits of science. Ethical considerations therefore also need to include the opportunities that geographic technologies provide to catalyze research, scholarship and teaching within geography and to drive innovation in science, business and society. For example, Geographic Management Systems (GMSs) enable core daily operations

management within most governmental and business organizations. GMSs build on the capacity of integrated, real-time, and mobile GPS/GIS technologies to create highly interactive real-world, real-time mapping and management environments. They permit the monitoring, modelling, and coordination of dynamic spatial activity for day-to-day operations management functions in business, government, international agencies, and non-governmental organizations. Currently evolving examples range from simple applications, such as real-time management of ambulance or fire vehicle fleets, to more complex activities such as the continuous, interactive management across space and time of extensive fixed and mobile assets and workforces, such as for major electric utility companies, governmental social services or environmental protection agencies, or international disaster and humanitarian relief operations.[64]

The ethical scenarios raised by GIS, GPS, and related geographic technologies include potential conflicts and potential benefits to society. Both must be acknowledged and analyzed. Cases of ethical concerns illustrate the special challenges of rapidly evolving new geographic technologies and include a proposed community mapping project by the L. A. police department to lay out the geographic locations of area Muslim populations as part of a counter-terror initiative, or work in environmental consulting which can involve competing pressures to include or exclude sensitive data pertinent to the negotiation of projects with communities, local, state or federal agencies. Geolocational data, derived from activities such as tracking mobile phones without the consent of users, also raises new questions about the confidentiality of databases with sensitive private information. Geographers' creation and use of new geographic technologies introduces many new ethical frontiers with respect to locational privacy and the ethical collection, management, distribution, and use of geographic data.

Yet, geographic information science and technologies are also playing essential roles in shaping the future of scientific research, not only in geography but also in most other scientific disciplines, ranging from the physical sciences and engineering to most social sciences, and even within many humanities disciplines. Integral to achieving these benefits of science to society is the ethical responsibility to guard against potential abuses of our powerful new geographic technologies.

Case 4: The American Medical Association and Public Heath Emergencies[65]

There is perhaps no profession that has a longer history of attention to the ethical requirements of its practice than medicine. By tradition, attention to the ethics of medical practice dates back at least to Hippocrates in the late fifth century BCE. Medical practice in ancient Greece differed substantially from modern medical practice. The ancient Hippocratic Oath's ban on using "the knife," in particular, could not be carried into modern medical practice. Thus the ancient oath was largely abandoned by the 1870s. In

[64] Douglas Richardson and Patricia Solís, "Confronted by Insurmountable Opportunities: Geography in Society at the AAG's Centennial," *The Professional Geographer* 56, no. 1 (2004):4-11.
[65] This case was provided by David E. Schrader, Executive Director of the American Philosophical Association.

1964 a modern version of the oath was written by Dr. Louis Lasagna of the Tufts University School of Medicine.

The American Medical Association was organized in 1847 and immediately recognized the need for some form of Code of Ethics. Again, given the changing demands facing medical practice, the original 1847 "Code of Medical Ethics" was replaced by the AMA's Principles of Medical Ethics," written in 1903 and modified in 1957, 1980, and 2001. The World Medical Association was founded in 1947. It adopted an "International Code of Medical Ethics" in 1949, revised in 1968, 1983, and 2006. The "International Code of Medical Ethics" adopts a very standard format, focusing on "Duties of Physicians in General," "Duties of Physicians to Patients," and "Duties of Physicians to Colleagues." The AMA "Principles of Medical Ethics" is rather more explicit in noting duties of physicians to the larger public.

The standard framing of issues in medical ethics tends to focus primarily on the relationship between a physician and a patient. The complexity of contemporary health care delivery, of course, complicates the issue in a variety of ways involving hospitals, insurance companies, etc. More fundamental complications arise, however, in the context of public health emergencies. The various codes of medical ethics focus very little on public health. The AMA's "Principles of Medical Ethics" Principle VII states that a "physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health." Similarly, the World Health Organization has promoted the "International Health Regulations," now adopted as binding by 194 countries. According to the World Health Organization's website, "[t]heir aim is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide."

Given the standard focus of medical ethics codes and, as a corollary, of the ethical perspective of most people involved with heath care delivery, public health emergencies create a major challenge. One of the most basic principles of ethics is the "ought implies can" principle. People can be obligated to provide only what they are able to provide. In such events as pandemic influenzas, the collective individual need for various forms of treatment may well exceed the availability of such forms of treatments. For example, estimates given in the Delaware Department of Health and Social Services Division of Public Health's "Delaware Pandemic Influenza Plan" project that an influenza outbreak on the scale of the 1918 "Spanish Flu" would involve 90 million cases of the influenza in the United States. Of those 90 million cases, 45 million would require outpatient treatment. 865,000 to 9,900,000 people would require hospitalization, and 209,000 to 1,903,000 people would die. According to the Rand Corporation, in 2006 the total number of hospital beds in the United States was a bit under 950,000.

The problem is obvious. A pandemic emergency would lead to a demand simply for hospital beds, to say nothing of other medical resources, that exceeds the available supply. Lest we think that there is any easy solution in simply constructing hospital space to serve another five to nine million patients, we must remember that the resources

required for that purpose would be, at least in large part, resources not spent satisfying other fundamental human needs.

The sobering facts about the potential demands placed on health care delivery systems by a global pandemic emergency force us to think carefully about what Human Rights standards actually require. The Constitution of the World Health Organization states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being." It is essential to note that "the highest attainable standard of health" must be relative to concrete circumstances, with the recognition that some circumstances are within human control and some are not. Changing circumstances so as to increase the availability of prenatal care in various areas of the world is surely something that is to a significant degree within human control. Stopping the global spread of a novel form of virulent influenza virus, by contract, is to a large degree beyond human control. Given this, the concrete forms of treatment that the right to "the highest attainable standard of health" may entitle "every human being" in time of what we might call normal health care challenges should be expected to be quite different from the concrete forms of treatment that the same right entitles "every human being" in times of pandemic emergencies.

The recent H1N2 influenza scare has certainly generated important attention to these issues. Two fundamental challenges involve the need for governmental agencies to move beyond innocuous generalities and for medical societies and institutions to move their members to think of ethics in ways that are able to move beyond the traditional individual physician/individual patient paradigm.

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Appendix

Guidelines for Developing Cases from U.S. Scientific Associations

For each case, please try to address the following as appropriate:

1. The length of a case should be approximately 1-page singe-spaced
2. A given case should assess the Code of Ethics (CoE) of a U. S. scientific association
3. The analysis should compare/contrast with international and domestic ethics standards as appropriate
4. The analysis should focus on evident similarities, differences, and gaps between the CoE and such standards
5. Special attention should be given to any evident implications for human rights
6. If there have been recent ethics controversies, these circumstances should be noted
7. Attention should also be given to the relationship between the discipline's CoE and any discipline-specific forms of practice as appropriate

Questions to consider while developing the case summary might include:

What are the key characteristics of a particular CoE of a given scientific association?
What motivated the formulation of the original and present CoE?
In what ways does this CoE reflect the identity/practice of the discipline in question?
Does the present CoE make explicit note of human rights?
If human rights are not mentioned, are they acknowledged in any other way?
If any, what role does or could human rights play in resolving contemporary ethical issues?
What is the immediate source of ethical concern (e. g. anthropology's engagement by the military as part of the Global War on Terror)?
What sort of ethical discussion/controversy has this concern produced?
How could human rights be applied to facilitate resolution of current or anticipated ethical concerns?
What recommendations have or will be made regarding the incorporation of human rights into the CoE?
Other?

Please Note: We expect some variation in the form of cases, given the diversity of kinds of disciplinary practice across the sciences. For additional help in developing your case, please feel free to consult the existing archive of cases, which can be used as exemplars.