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HHS Provides Guidance on Financial Relationships and Interests in Research Involving Human Subjects

On May 12, 2004, the Department of Health and Human Service (DHHS) Secretary Tommy G. Thompson released new guidance for protecting research subjects from possible harm caused by financial conflicts of interest that might occur in research studies. This replaces the prior draft from January 2001. This guidance suggests points to consider in determining whether specific financial interest in research affect the rights and welfare of human subjects and the actions that could be considered to protect those subjects. In some cases, financial interests might become conflicting interest, affecting the rights and welfare of human subjects.

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Inside this Issue

CDC to co-sponsor an International Conference on Health and Human Rights Entitled: "Lessons Learned from Rights Based Approaches to Health"

During the past year, members from the CDC Health and Human Rights Workgroup, the Social Determinants of Health Workgroup, the Measures of Racism Workgroup, and the Gay, Lesbian, Bisexual, Transgender and Questioning Population Workgroup have been collaborating with other Atlanta-based organizations, including Emory Institute of Human Rights, CARE-USA, the Carter Center, the World Health Organization, and Doctors for Global Health, to organize and sponsor an international conference on health and human rights. The conference is entitled "Lessons Learned from Rights Based Approaches to Health" and will be held April 14-16, 2005. Featured speakers include former U.S. President Jimmy Carter and United Nations Special Rapporteur on the Right to Health Paul Hunt, along with other leaders in the fields of health and human rights.

Background

The highest attainable standard of health is one of the fundamental rights of every human being, incorporated in Article 12 in the International Covenant on Economic, Social and Cultural Rights. Poverty, inequity, civil conflict, discrimination and violence are all factors in denial of the basic rights of individuals and groups and also constitute significant barriers to their achievement of health and well-being. Scholars and practitioners in the growing field of health and human rights recognize three main areas of theory and practice which, when applied to policy and programs in the field, can result in "advancing human well-being beyond what could be achieved through an isolated health or human rights-based approach"[1]. These three major linkages between health and human rights are: (a) the impact, both

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Ethical Dilemmas in Public Health

A CDC investigator designed and implemented a study on family planning service. He hired local health workers to collect data on family planning service, such as how clinic staff answered patients' questions or whether clinic staff followed safe practice (e.g., washing hands between exams). Some of the health workers had serious concern about when they should intervene on behalf of the clients when clinic staff made mistakes during their routine practice.

What guidelines should the investigator give to the health workers for safeguarding client safety and welfare?

The investigator should make it clear that the safety and welfare of the client comes first and that there might be a time when they need to intervene for the clients' safety.

When should the health care workers intervene on behalf of the clients?

The investigator and health workers have a responsibility to observe and note any mistakes made by the clinic staff. However, it is not desirable or possible to intervene in every case, but the investigator should check with local authorities to learn of when it is necessary to intervene for the patient's safety and should give guidance to the health workers of when they should intervene.

Special Series: Historical Perspective on Ethical Principles in Human Subjects Research: The Belmont Report[1]

On November 16th, 2004, the Office of Human Research Protection (OHRP) will hold a commemorative event celebrating the 25th anniversary of the Belmont Report. The event will take place at 2:30 P.M. in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201.

On July 12, 1974, the National Research Act (Public Law 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. The Commission was comprised of lawyers, doctors, professors, and presidents from various universities, firms, hospitals and civic councils. It was held over a four day period in February of 1976. The report determined a distinction between research and practice as well as the identification and remarks about the application on three basic principles relevant to research involving human

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Update: Human Subjects Activity (HSA) Training Calendar 2004-2005

Month	Topic/Presenter	Date/Time	Place
October '04	**Collaborative Research:** Assurances, Deferrals, & IIAs (Fran Sanden)	**10/4/04 (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**
November '04	**How to Write a Protocol** (Joy Herndon, Kendra Hatfield-Timajchy, Fran Sanden)	**11/4/04 (11a - 1p) Note: This is a Thursday**	**1 West Ct Sq (Decatur), CR 5106**
December '04	**How to Write & Respond to an IRB Report** (Pam Galusha)	**12/6/04 (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**
January '05	**The CDC IRB Process: What to Expect, Including Form Usage** (Fran Sanden & Pam Galusha)	**1/10/05 (11a-1p)**	**1 West Ct Sq (Decatur), CR 5106**
February '05	**Genomics in HS Research** (TBA)	**2/7/05 (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**
March '05	**Adverse Events, Clinical Trials & GCP Basics** (TBA)	**3/7/05 (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**
April '05	**Specimen Storage** (TBA)	**4/4/05 (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**
May '05	**Data Management** (TBA)	**5/2/05 (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**
June '05	**Informed Consent** (Fran Sanden)	**TBA (11a - 1p)**	**1 West Ct Sq (Decatur), CR 5106**

Please RSVP via email to Fran Sanden at fsanden@cdc.gov if you plan to attend. This will help insure enough handout materials.

CDC Human Subjects Activity (HSA) Announcement

The CDC Human Subjects Activity (HSA) recently launched a new website. The website address is http://intranet.cdc.gov/od/hsa/.

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This guidance provides institutional review boards (IRBs), institutions, and investigators with some possible approaches in assuring that this does not happen.

As institutions, IRBs, and researchers consider potential financial conflicts of interest, they can refer to the guidance for possible mechanisms to manage such conflicts. These mechanisms include:

- Separating institutional responsibility for research activities from management of the institution's financial interests;
- Establishing conflict of interest committees or identifying other bodies or persons and procedures to address financial interests in research;
- Using independent organizations to hold or administer the institution's financial interest;
- Determining whether methods for managing conflicts of interest are adequate for protecting the rights and welfare of human subjects and whether other actions are needed to minimize risks to subjects;
- Determining the kind, amount, and level of detail of information to be provided to research subjects regarding funding and financial interests; and
- Using special measures to modify the informed consent process when a potential or actual financial conflict exists.

The guidance is available at http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finalguid.pdf

In preparing this guidance, the department considered public comments on an earlier draft guidance published in March 2003.

HHS (www.hhs.gov/ohrp/) new website! Reconstructed to be more user-friendly.

positive and negative, of public health policies and practice on human rights, (b) the recognition and assessment of the impact of human rights violations on health and well-being, and (c) the proposition that the promotion and protection of health is fundamentally linked to the promotion and protection of human rights[2]. Abstracts about other explicit linkages between health and human rights are encouraged.

In embracing a rights-based approach to development programming, conference partner organizations are committed to using theoretical frameworks and practical experiences from the health and human rights field to strengthen the effectiveness of our own health interventions. The host organizations' portfolio of programs includes interventions in social determinants of health, HIV/AIDS, economic development and globalization, children's health, reproductive health, mental health, infectious disease, violence, and refugee and internally displaced populations in approximately 60 countries throughout Asia, Africa, Latin America, Eastern Europe, and the Middle East. In taking a rights-based approach to design and implementation of programs, sponsoring and participating organizations and individuals have the potential to make a substantive contribution to the growing body of practical work in rights-based approaches to health.

Goals

The conference will focus on examples of successful and promising rights-based health programming, research, and advocacy. Conference plenary, panel, and roundtable sessions will emphasize linkages between human rights theory and health practice. Specific conference goals include:

- Sharing evidence-based models of rights based approaches to health, with a special emphasis on case studies and field examples;
- Building awareness on and capacity for rights based approaches to health programming;
- Facilitating networking and collaborating opportunities among professionals;
- Advancing rights based health agendas from basic awareness to evidence-based practice.

Participants

The primary audience for the conference will include public health and development professionals who have, at minimum, a basic understanding of relations between health and human rights. The conference proceedings will benefit middle and senior level program managers, and community level practitioners, from the public, nongovernmental, and private sectors.

Conference Topics

The conference panels will be organized around the following health topics. When submitting your abstract proposal, please specify which of the following topics it fits within:

- Children's Health
- Conflict and War
- Economic Development & Globalization
- Education
- Nutrition
- HIV/AIDS
- Humanitarian Aid
- Infectious Disease
- Mental Health
- Other
- Water and Sanitation
- Poverty and Other Social Determinants of Health
- Racism and Other Systems of Injustice
- Refugee and Internally Displaced Populations
- Reparations for Human Rights Abuses
- Sexual and Gender Minorities
- Sexual and Reproductive Health
- Violence

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Call for Abstracts

Conference cosponsors invite individuals to submit abstracts within the conference theme of *Lessons Learned from Rights Based Approaches to Health*. Each proposal must explicitly outline its relevance to health, human rights, and the interrelationship between the topics. Although evidence-based lessons learned (i.e., case studies and field examples) are of particular interest to the selection committee, a diverse array of abstracts will be accepted for presentation. Examples of acceptable abstracts include research and program frameworks, assessment strategies, methodologies, curricula and evaluation programs. Additional information is available from the conference website at http://humanrights.emory.edu.

CDC staff are encouraged to submit abstracts to present at the conference.

For more information, please contact Aun Lor at 404-498-6012 or alor@cdc.gov.

References

1. Mann, J. M., Gruskin, S., Grodin, M. A., Annas, G.J., "Health and Human Rights," in Mann *et al*, ed., *Health and Human Rights: A Reader* (New York: Routledge, 1999), pp. 11
2. Mann et al, *Ibid*.

ADS Staff Update

Please help us welcome Sarah Boos, who recently joined EPO as an ORISE fellow. Sara was born and raised in Decatur, Georgia. She graduated from Georgia State University with a BS in Biology and minor in Chemistry. She is working on a GIS certification and looks forward to earning a masters degree in public health. Sarah is currently assisting Dr. Robin Ikeda and Dr. Stephen B. Thacker on various projects, and helping Aun Lor with the ADS newsletter and the planning of a future health and human rights Conference co-sponsored by CDC, Emory University, CARE USA, the World Health Organization and Doctors for Global Health.

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subjects. Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the department's policy.

Research vs. Practice

The boundaries between research and practice can be hazy as they often occur together. The Belmont Report defines "Practice" as "interventions that are designed solely to enhance the well-being of an individual patient or client and which has a reasonable expectation of success." It's purpose being to provide diagnosis, preventative treatment or therapy to individuals. On the contrary "research" is defined as an activity to test the hypothesis, permit conclusions, and thereby develop or contribute to the generalized knowledge.

Respect for Persons, Beneficence, Justice

The basic ethical principles that were defined by the Commission include respect for persons, beneficence, and justice. Respect for persons covers two moral requirements, to acknowledge autonomy and protect those with diminished autonomy. Beneficence is defined as an obligation, in a strong sense, to treat individuals in an ethical manner. Beneficence is also expressed as "do not harm", and "maximize possible benefits, while minimizing possible harms."

"Justice" is defined in the sense of "fairness in distribution" or "what is deserved" as just ways to distribute risks and benefits. The following formulations were used: to each person an equal share; to each person according to individual need; to each person according to individual effort; to each person according societal contributions; and to each person according to merit.

Applications

The applications set by the council led to the consideration of the following requirements: informed consent, assessment of risk and benefits, and the selection of subjects. Informed consent requires subjects be given the opportunity to chose what shall or shall not happen to them. Three elements are factored into informed consent: information, comprehension, and voluntariness. Assessment of risk and benefits presents both an opportunity and responsibility to gather systematic and comprehensive information about proposed research. This includes the nature and scope of risks and benefits, the systematic assessment of risks and benefits, and the selection of subjects. This allows the investigator to examine whether the proposed research is properly designed, the review committee to determine if the risks present to the subjects are justified, and the prospective subjects whether or not to participate.

References

1. The Belmont Report - http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

OHRP Update

The Office for Human Research Protections (OHRP) has issued guidance on research involving coded private information or human biological specimens. The document also references pertinent requirements of the HIPAA Privacy Rule that may be applicable to research involving coded private information or specimens. You can find the guidance document, Guidance on Research Involving Coded Private Information or Biological Specimens at http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.

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