

Summer Student Research Program

Project Description

FACULTY SPONSOR'S NAME AND DEGREE: Professor Stanley H. Weiss, MD

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PROJECT TITLE (200 Characters max):

Revising Regulations for Protecting Human Subjects Who Participate in Research

HYPOTHESIS:

Well researched and reasoned recommendations can help change regulations for the protection of human subjects participating in research

PROJECT DESCRIPTION (Include design, methodology, data collection, techniques, data analysis to be employed and evaluation and interpretation methodology)

This project offers a student a rare opportunity to become intimately familiar and perhaps have a major impact on policy and practical issues related to the protection of human subjects in research.

In July 2011, the Office of the Secretary, Health and Human Services and the Food and Drug Administration released Advance Notice of Proposed Rulemaking (ANPRM) seeking comment on the notice: "Human Subject Research Protections: Enhancing Protections for Research Subjects and Reducing the Burden, Delay and Ambiguity for Investigators."

As Chair of the Joint Policy Committee of the Societies of Epidemiology (JPC-SE), Dr. Weiss was senior author and submitter of two formal comments to this ANPRM.^{1,2} One represented the official response to the ANPRM of six of the epidemiological organizations of the JPC-SE as well as having 19 individual signatories from the JPC-SE. The other comment submitted by Dr. Weiss was authored by seventeen senior epidemiologists, ethicists, geneticists and minority health experts from within and outside the United States.

A key issue recommended by the JPC-SE involves the formal differentiation of "practice" from "research." If certain activities now labeled as "research" were instead (and in our view more properly) classified as "practice," then these regulations could be rewritten so that such activities would not fall under the Common Rule. They then would not require written consent or a waiver of consent by an IRB even when data are identifiable.

A key recommendation in the other comment Dr. Weiss submitted (co-signed by seventeen authors) is that the principle of benefit to individuals and the principle of protection of the public require that the Common Rule be amended to explicitly require certain considerations of societal effects of research.^{2,3} We argue that an IRB or regulators should weigh in where a project has potential to help an individual subject but contains the possibility of **harm** to society or a subgroup of society. We proposed a way to deal with this is to require a new additional section for all projects undergoing IRB review, attesting to whether or not there are any plausible public health risks. These latter issues have already been included by Dr. Weiss into a draft manuscript.

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The JPC-SE expects to present more information on these recommendations to the federal government in the coming months. In addition, a survey was previously conducted (with support from the National Academy of Sciences) to examine the practices and knowledge of epidemiologists about the Health Insurance Portability and Accountability Act (HIPAA) and the Family Educational Rights and Privacy Act (FERPA). The key findings about HIPAA were published (RB Ness, JAMA⁵). Dr. Weiss is in the process of analyzing the FERPA-related dataset for publication.⁶

Dr. Weiss is seeking a student to work with him and other senior staff to conduct more extensive literature reviews, participate in conference calls and meetings and to write reports. The student will be expected to develop a manuscript for publication. The student must have excellent writing skills. In order to participate in data analysis, a relevant quantitative background will be strongly advantageous, particularly knowledge of SAS and MS Excel.

SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:

- 1) Joint Policy Committee of the Societies of Epidemiology, Public Comment to Notice "Human Subject Research Protections: Enhancing Protections for Research Subjects and Reducing the Burden, Delay and Ambiguity for Investigators." Document ID: HHS-OPHS-2011-0005-1066. Submitting Author SH Weiss, October 26, 2011.
www.regulations.gov/#!documentDetail:D=HHS-OPHS-2011-005-1066
- 2) Public Comment on Notice "Human Subject Research Protections: Enhancing Protections for Research Subjects and Reducing the Burden, Delay and Ambiguity for Investigators." Document ID: HHS-OPHS-2011-0005-1070. Submitting Author SH Weiss, October 26, 2011.
www.regulations.gov/#!documentDetail:D=HHS-OPHS-2011-005-1070
- 3) SH Weiss. Role of research, and limitations Imposed by current funding and regulatory issues. Changes and greater consistency are both needed. At: "Special Symposium - Protecting Patients and Participants: Does It Matter Whether It's Research or Public Health Practice?" at the 135th American Public Health Association Annual Meeting & Exposition in Washington, DC 2007, Session 4129.0: Tuesday, November 6, 2007.
- 4) RB Ness, EB Andrews, JA Gaudino, AB Newman, CL Soskolne, T Sturmer, DE Wartenberg, SH Weiss. The Future of Epidemiology. Academic Medicine Vol. 84, No. 11. November 2009
- 5) RB Ness. Influence of the HIPAA privacy rule on health research. JAMA 2007; 298(18):2164-2170.
- 6) SH Weiss, JA Gaudino, EO Alleyne, M Quick, RB Ness, J Middaugh, DM Rosenblum. Has FERPA, the school privacy law (a.k.a. the "Buckley amendment"), affected epidemiologists? 137th American Public Health Association Annual Meeting & Exposition, November 7-11, 2009.

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IS THIS PROJECT SUPPORTED BY EXTRAMURAL FUNDS?

Yes or No

(IF YES, PLEASE SUPPLY THE GRANTING AGENCY'S NAME)

THIS PROJECT IS: Clinical Laboratory Behavioral
 Other, Public Health.

THIS PROJECT IS CANCER-RELATED

Please explain Cancer relevance

THIS PROJECT IS HEART, LUNG & BLOOD- RELATED

Please explain Heart, Lung, Blood relevance

THIS PROJECT EMPLOYS RADIOISOTOPES

THIS PROJECT INVOLVES THE USE OF ANIMALS

PENDING APPROVED IACUC PROTOCOL #

THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS

PENDING APPROVED IRB PROTOCOL # 0120070193 (Exempt)

(Only the portion of the project related to the FERPA survey involved human subjects.)

Protocol Title: Survey of Epidemiologists on the Impact of HIPAA and FERPA

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS ENTERING FRESHMAN
SOPHOMORES ALL STUDENTS
FIRST AND SECOND YEAR NJMS MEDICAL STUDENT

THIS PROJECT IS WORK-STUDY: Yes or No

THIS PROJECT WILL BE POSTED DURING ACADEMIC YEAR
FOR INTERESTED VOLUNTEERS?: Yes or No

WHAT WILL THE STUDENT LEARN FROM THIS EXPERIENCE?

We expect the student will have the opportunity to assist Dr. Weiss and project staff in a critical literature review of protection of human subjects issues. We also expect the student will participate in conference calls and other meetings with a diverse group of epidemiologists, ethicists, geneticists and minority health experts from within and outside the US. The student will gain an appreciation for controversial issues surrounding the protection of human subjects and this experience should have a positive impact on the student's involvement in practice and research *vis a vis* the protection of human subjects into the future. The student is expected to take a substantial role in synthesizing data and/or opinions, resulting in a manuscript suitable for publication.