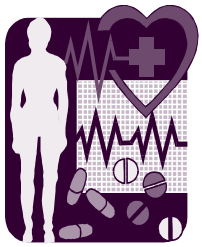
WILLIAM PATERSON UNIVERSITY
Office of Sponsored Programs

The STAR Report

Fall 2000 Volume 3, No. 1

Human Subject Research @ WPU



The Ethical Foundations for the Protection of Human Subjects

There are several well known historical events that lead to the development of ethical standards concerning the use of human subjects in biomedical and behavioral research. Nazi atrocities in Concentration Camps during World War II are perhaps the most widely known. There were other atrocities as well, several of which occured here in the United States.

These American situations included the misuse of prisoners and hospital patients, the deception of volunteers in psychatric studies, the exposure of soldiers to radiation and LSD, and the widely publicized Tuskegee Syphilis Study. In this last instance, African-American men who had been diagnosed with syphilis were intentionally not treated so that the progress of their disease could be tracked for decades.

World War II resulted in the most well known international document concerning human rights: the Nuremburg Code (1947). Later, the international medical community developed the Helsinki Declaration (1964). In these, the two central ethical foundations were established: subjects must volunteer and the research must do no harm.

The Belmont Report

In the 1970's, a blue-ribbon commission was formed to develop guidelines for research. The Belmont Report (1979) defined the three guiding principals that have become the foundation of all US regulations: **Respect of Persons, Beneficence** and **Justice.**

After publication of the Belmont Report, all Federal agencies developed and implemented differnt policies. By 1991 most agencies agreed to let the Department of Health and Human Services regulations — formally known as 45 CFR Part 46 — be the standard or "Common Rule" they would all follow. Only the FDA has its own regulations, and these are very closely alligned with the DHHS regulations.

45 CFR Part 46 "The Common Rule"

The WPU IRB Policy

William Paterson University's human subject research policy is based on 45 CFR Part 46. The IRB committee is the local representative of the DHHS. It has faculty, a non-scientist, and an outside member. They review research protocols submited by faculty, some students and outside researchers using WPU, they follow approved research over time, and they provide training and advice to the WPU community. The Committee is chaired by a WPU faculty member and its activities are coordinated through the OSP.

Following last year's gene-research scandals, new regulations have gone into effect that require local IRB's to provide annual compliance reports to the DHHS concerning human subject research and ongoing training programs for faculty and staff involved in research as well as key administrators.

The Protocol Review Process

All faculty, staff and some students conducting research involving living human subjects or human material must submit protocols – complete descriptions of the proposed research – for review, approval and continuing review by the IRB. This applies to all behavioral and biomedical research that is not part of a classroom activity. Faculty who fail to submit research protocols to the IRB may find themselves without the support of the University if there are adverse medical or legal outcomes.

The Faculty/Staff Review Process

The review process begins with the submission of a complete **Research Protocol**. This includes three original signed Protocol Face Sheets (Appendix A), the research protocol, informed consent statement(s), and data collection tool(s). The protocol must include information on the background, purpose and expected outcome of the study, the subject population, the location and duration of the study, and the research design and methodology. For subjects, the protocol must include details concerning the recruitment and selection process, potential risks and methods to protect subjects, participation consent procedures, and an analysis of the risks/benefit ratio.

The purpose of the **Informed Consent Statement** is to provide a potential subject with enough of a description of the procedures, risks, benefits, and duration of their involvement for them to choose whether or not to participate. It must be written in clear terms and in a manner appropriate for the subject. The name(s) and telephone number(s) of the investigator(s), as well as that of the Associate Vice President and Dean for Graduate Studies and Research, must be included as well. The document must include the IRB's Protocol Number, its initial and subsequent approval dates.

After a protocol is received, it is sent to one of the IRB committee members to determine if the study qualifies for an exempted, expedited or full committee review.

- If it is exempted from Committee review and if the protocol is acceptable, an approval letter is sent to the researcher. At WPU, full IRB committee evaluates all exempted protocols.
- If it qualifies for an expedited review, it is sent to another IRB committee member for review for a second opinion. A letter is sent to the researcher either approving the protocol or requesting changes or additional information. The full IRB committee reviews all expedited protocols.
- If the study requires full committee review, it is placed on the agenda for the next meeting. The researcher may be invited to the meeting. After the meeting, a letter is sent to the researcher either approving the protocol or requesting changes or additional information.

After approval, if there are any substantive changes to the research plan, subject population, Informed Consent Statement, or data collection tools are needed, they must be submitted to the IRB for review and approval before they are put into effect.

The Student Review Process

On a limited basis, the IRB reviews research undertaken by undergraduate and graduate students for coursework that is undertaken outside the classroom. Research that crosses these four thresholds are recommended for review: 1) the study involves a vulnerable population, 2) the study focuses on an extremely sensitive topic or proposes a research plan that is outside the normal range of projects for the course the research is required for, 3) the respondent is identified, 4) the study poses an identifiable and potentially significant risk to the subject or researcher. Whether or not student research surpasses these thresholds is determined by the instructor as an agent

IRB & Policies Forms On The Internet

WPU Homepage
(www.wpunj.edu)
⬇
Academics
⬇
Colleges & Departments
⬇
Office of Sponsored Programs
⬇
Institutional Review Board

The OSP has developed a very complete website to support the activities of the IRB and to provide easy access to WPU policies and forms, Federal policies and websites, and related sites. Follow this flow chart or just use this URL to the WPU IRB site:

http://www.wpunj.edu/sponprog/IRB/

for the IRB. (Should there be an adverse or problematic outcome, the instructor will be supported by the IRB.)

Students submit a complete and signed **Student Research Protocol Review Request Form** that must include the data collection tool and Informed Consent Statement. In reviewing a student's Research Protocol, the IRB is primarily concerned with the research plan, data collection instrument and informed consent statement within the context of the research topic or hypothesis.

The selection of the research topic is entirely between the student and his/her instructor or sponsor.

Student reviews are completed within three business days, and student researcher and his/her instructor are sent a letter that approves their research, approves their research with conditions, or requests changes or additional information before a decision can be made.

Under the new Federal mandates, the Continuing Review of approved research has become much more important. All approved research that is longer than one year in duration must have a status report submitted to the IRB prior to its approval anniversary date. The report will be reviewed by a member of the IRB committee—and if necessary by the full committee–-and a letter sent to the researcher extending the IRB's approval, requesting additional information, or instructing that the research be discontinued pending further review.

Continuing Review of Approved Research

The IRB is developing its process for on-site auditing of research projects, and expects to begin randomly selecting studies for auditing in the Spring 2001 semester.

Review Categories

Exempted research studies pose no risks to subjects:

* Research in established educational settings involving normal educational practices
* Use of educational tests, surveys or interviews, or observation of public behavior
* Use of existing data, documents, records or specimens collected before study began
* Research by an agency of its clients about its services, practices, resources or plans
* Taste tests

Expedited research studies pose only a minimal amount of risks to subjects:

* Research on drugs or devices that do not need a IND or ID from the FDA
* Collection of blood by venipuncture, finger stick, or another method within pre-set limits
* Collection of biologicial specimens by non-invasive means, like mucosal swabing
* Collection of data through non-invasive, like an x-ray, physical sensors, or ultrasound
* Use of existing materials or data collected for non-research purposes
* Research on individual or group characteristics or behavior or employing surveys, interviews, oral histories, or focus groups
* Collection of voice, video, digital or image recordings

Full Committee Review is used for all other types of research, and any research involving a vulnerable population.

Vulnerable Populations

"The Common Rule" identifies **Children, Prisoners, Fetuses, and Pregnant Women** as populations deserving special consideration and attention. The WPU IRB includes other populations who may feel coersion because of the circumstances of the research, such as nursing home and hospital patients or employees.

Watch for Special IRB Workshops in 2001!

The WPU IRB Committee

Dr. Dorothy Feola, Chair	Education
Dr. Kate Makarec	Humanities & Social Sciences
Dr. Reginal Grier	Business
Dr. James Manning	Science and Health
Dr. Barbara Bohny	Science and Health
Dr. Nina Jemmott	Graduate Studies and Research
Mr. Martin Williams	Sponsored Programs
Open	Humanities and Social Sciences
Open	Outside Representative

Newsletters, books and directories available through the OSP

The OSP subscribes to *ACUO News, Notes and Deadlines, the NSF Bulletin*, and AASCU's Grants Resource Center *Reports* and *Bulletins*, as well as other weekly or occaissional papaper and electronic publications from funding agencies and other third-party services. These are collected and sent to anyone interested through our weekly *Dates, Updates and Insights* electronic "newsletter," aka DUI.

The OSP maintains a library of books, pamphlets and guides for supporting the grants process, including files on agencies and programs; manuals on budgeting, project evaluation, and program design; and, policy documents from state and federal agencies, such as the *New Jersey Core Curriculum Standards.*

Published directories include two CD-ROMs -- *FCSearch* from the Foundation Center, and the *Catalog of Federal Domestic Assistance — The Grants Register 2000,* the *New Jersey Grants Guide,Foundation Grants to Individuals*, and the *Guide to Federal Funding for Education.*

Through its website, the OSP provides:

- Access to two excellent online databases that provide direct access to thousands of funding opportunities: **GrantSearch** and **Grant Select** (both described in detail in the Fall 1999 Star Report)
- Links to Federal agencies, Foundations and National Health Charities
- Guides and resources to help in the development and writing of proposals
- WPU and Federal Policies regarding
- Electronic Forms
- And Much More

"Good Morning, this is the Office of Sponsored Programs. How may I help you?"

The OSP is a service oriented resource for the faculty and staff of the University. It provides access to programs, services and resources that support the grant process, from identifying funding opportunities and defining ideas through to putting a completed package in the mail and then helping finalize the contract and reporting on outcomes.

Office: 107 Raubinger Hall
Hours: Monday through Friday 8:30-4:30

Phone: 973-720-2852
Fax: 973-720-3573

Homepage:
http://www.wpunj.edu/sponprog/osphome.html

Workshops and Specialized Training
call for details

⇒ **Grants Landscape** **October 12**

⇒ **Effectively Using the Internet in Developing and Writing Grants** **November 9**

⇒ **Writing Proposals for Service and Educational Programs** **December 1**

⇒ **Writing Proposals for Research Projects** **December 8**

IRB Workshops for Faculty or Students

⇒ **By appointment through the OSP**

Office of Sponsored Programs

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Caryn Terry	Program Assistant
Dorothy Muriuki	Graduate Assistant
Nina Jemmott	Associate V. P. and Dean of Graduate Studies and Research