

The key features of the Federalwide Assurance (FWA) for domestic (U.S.) institutions are the following:

- a) the identifying information for the institution filing the FWA, the Human Protections Administrator (or a reliable point of contact) at the institution, and the institutional official signing the FWA;
- b) a list of the institution's legal components where human subjects research will be conducted (legal components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution, for example, ABC University can list its XYZ University Hospital, KLM School of Public Health, and EFG Institute for International Studies as components);
- c) a statement of ethical principles to be followed in protecting human subjects of research;
- d) an applicability statement indicating that the institution commits to comply with the Terms of the FWA for Institutions within the United States (see section A of the Terms of the FWA at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>) for all federally conducted or supported human subjects research covered by the FWA; the institution also may voluntarily extend the Common Rule or 45 CFR part 46 to all research regardless of the source of support;
- e) the designation of one or more IRBs that will review the research covered by the FWA (these IRBs must be registered [<http://www.hhs.gov/ohrp/assurances/index.html#registernew>] with OHRP before the FWA can be approved); and
- f) the signature of an official authorized to represent the institution.

The FWA is signed by a high-level individual within the institution, for example, the Chief Executive Officer, Chief Operating Officer, President, or Chancellor, committing the institution to abide by the Terms of Assurance whenever it is engaged in human subjects research covered by the assurance. This person is considered to be the "signatory official" for the purposes of the FWA.

Website: <http://ohrp.cit.nih.gov/search/asearch.asp>

Useful OHRP information:

Policy and Guidance page -- <http://www.hhs.gov/ohrp/policy/index.html>

FAQ'S: [http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html)

## **2. Have an Institutional Review Board (IRB) which must:**

- Have a statement of principles governing institution's discharge of its responsibilities.
- Designate of one or more IRBs established in accordance with requirements of 45 CFR Part 46 with sufficient staff and meeting space.
- Have a list of IRB members identified by name-board consisting of at least 5 members (one must be an expert in scientific area and one must be not affiliated with the institution).
- Have written procedures for review of protocols and for handling problems that arise. ( Note: Additional instructions from DHHS-May 2000, require that grant proposal application and protocol be reviewed side by side to ensure consistency between the award and actual work that is done)

## **3. The IRB must review and approve the protocol for every project involving human subjects prior to any dollars being spent on any activity involving human subject research. Protocols must be reviewed and renewed annually.**

Michigan State U. has put together a very comprehensive website on Human Subject Research which has links to all the specific regulations for various federal agencies.

[http://www.humanresearch.msu.edu/regs/regs\\_index.htm](http://www.humanresearch.msu.edu/regs/regs_index.htm)

### **Terminology from UVA VP for Research:**

The definitions below pertain to usage within the context of the UVA Institutional Review Board for the Social and Behavioral Sciences Policies and Procedures, and may therefore differ from general interpretations or definitions. Some of the definitions have been extracted from the Glossary of Terms available in the IRB Guidebook provided by the OHRP.

<http://www.virginia.edu/vprgs/irbsbsterminology.html>

Other Useful links: <http://www.niaid.nih.gov/ncn/qa/default.htm>

### **HIPAA PATIENT PRIVACY RULE**

The Health Insurance Portability and Accountability Act of 1996 (Public L. 104-191, Subtitle F)  
Implementing Regulation: 45 CFR Parts 160 & 164; *Privacy Rule overrides state laws*  
Administering Agency: Dept. of Health and Human Services (HHS)

#### **Key Points:**

- The Privacy Rule establishes minimum Federal standards for protecting the privacy of individually identifiable health information. The Rule confers certain rights on individuals, including rights to access and amend their health information and to obtain a record of when and why their PHI has been shared with others for certain purposes.
- The Privacy Rule establishes conditions under which covered entities can provide researchers access to and use of PHI when necessary to conduct research. The Rule is not intended to impede research.
- Compliance with the Privacy Rule is required on and after April 14, 2003, for most **covered entities**. (Small health plans have an extra year to comply.)

Frequently asked questions: [http://privacyruleandresearch.nih.gov/pr\\_02.asp](http://privacyruleandresearch.nih.gov/pr_02.asp)

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER I--ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF  
AGRICULTURE

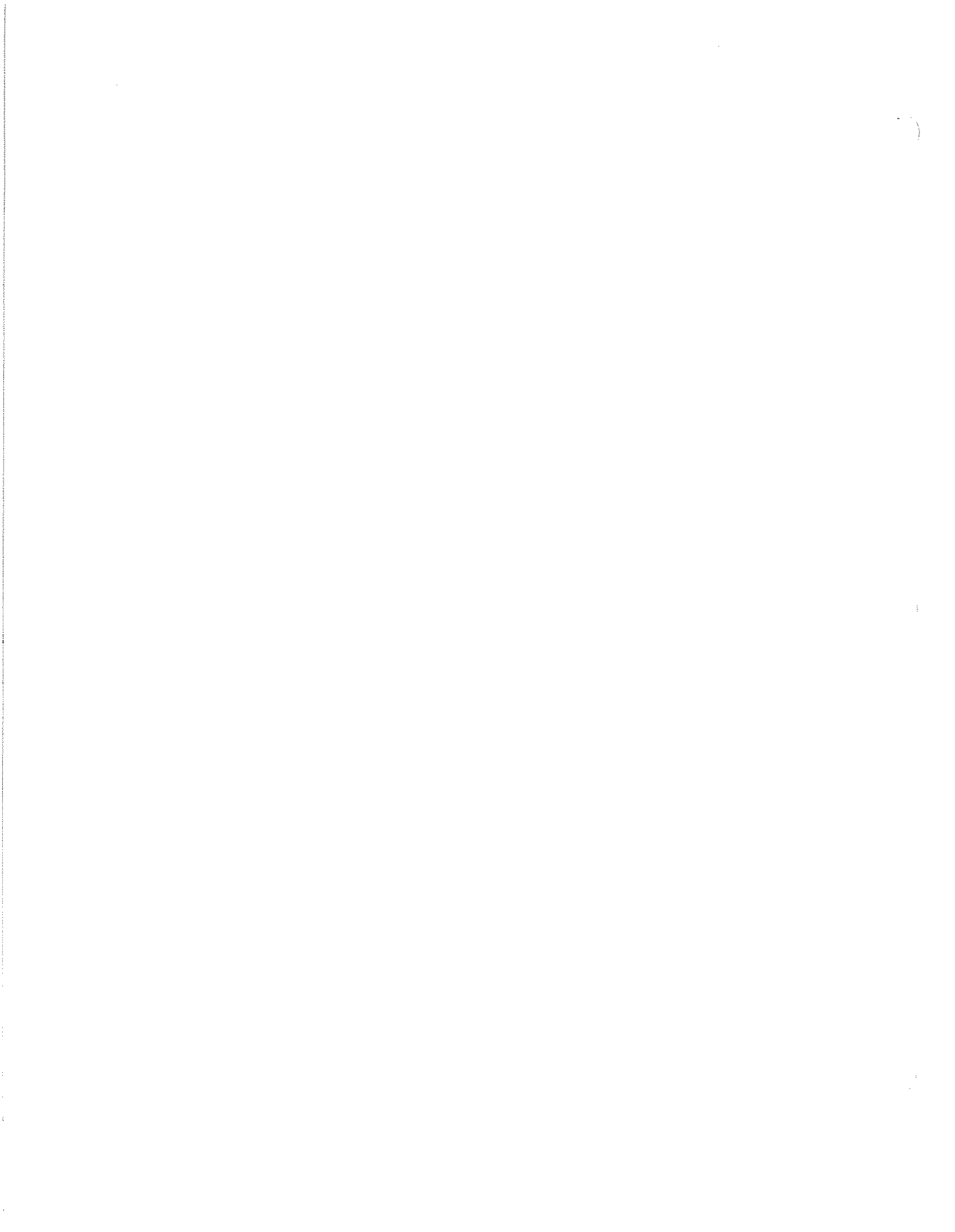
PART 1--DEFINITION OF TERMS--Table of Contents

Sec. 1.1 Definitions.

Animal means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes: Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber, With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

For the complete Act see:

<http://www.nal.usda.gov/awic/legislat/usdalegl.htm>



# PROTECTION OF HUMAN SUBJECTS

July 12, 1974- the **National Research Act- Public Law 93-348** created the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (might also be know as the Public Health Service Act)

**Belmont Report-** A statement of ethical principles governing research involving human participants issued by the National Commission for the Protection of Human Subjects in April, 1979

Implementing Regulation: **Title 45- Public Welfare; Part 46 Protection of Human Subjects**

August 19, 1991 **45 CFR part 46-** Protection of Human Subjects-DHHS

**45CFR Part 690** Federal Policy for the Protection of Human Subjects-NSF

**Common Rule** for the Protection of Human Subjects-is the term used by 17 federal agencies who have adopted the same regulations governing human subjects of research. (see FAQ)

## FOREIGN COUNTRIES:

June, 1964 **Declaration of Helsinki -World Medical Association**-statement of ethical principles to provide guidance to individuals participating in medical research involving human subjects and includes research involving identifiable data.

Council for International Organizations of Medical Sciences (CIOMS)-Officially connected to World Health Organization published *International Ethical Guidelines for Biomedical Research Involving Human Subjects-1982*

Common Rule 101 & 114-discuss incorporating Foreign IRB when they exist and what to do when they do not exist. This regulation is primarily applicable to biomedical research as the concept of social and behavioral science review boards is not standard in most foreign countries. (see FAQ's)

## **Title 45- Public Welfare; Part 46 Protection of Human Subjects (NIH)**

### **§46.101 To what does this policy apply?**

- (a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

What research categories are exempt?

- Research conducted in educational settings involving normal educational practices.
- Research involving educational tests unless human subjects are identifiable or disclosure of results could place subjects at risk for criminal or civil liability, etc.
- Research involving the collection of existing data, if sources are publically available and/or subjects cannot be ID.
- Research conducted by or approved by Agency heads to examine its public service programs
- Taste and food quality evaluation and consumer acceptance studies as long as food is deemed to be safe by FDA

UVA requires the determination of exemption to come from the IRB office. Please refer to the UVA website for more information about the exemption process:

<http://www.healthsystem.virginia.edu/internet/hic/general-information/exempt.cfm>

There exists an Expedited Review process when research poses little risk to humans, see:

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

#### DEFINITIONS:

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

**Vulnerable populations**-Pregnant females, fetuses, human in vitro fertilization, prisoners, the cognitively impaired.

### **NIH Grants Policy Manual in section on Human Subjects requires institutions:**

**1. File an Assurance of Compliance with the Office for Protection from Research Risks (OPRR) who is responsible for approving Assurance (Note: A list of institutions with assurances can be found on website.) Assurances must be renewed every 3 years.**

- *MPA-Multiple Project Assurance*
- *SPA-Single Project Assurance*
- *CPA-Cooperative Project Assurance*
- *FWA-Federal Wide Assurance*

Note\* Effective 12/31/05 all MPA's & CPA's will be deactivated; SPA's will remain in effect for all non-competitive renewals of existing HHS awards.