Sheet 1: RESPONSIBILITIES OF THE OFFICE OF HUMAN SUBJECTS RESEARCH

1. INTRODUCTION

The Office of Human Subjects Research (OHSR) operates within the Office of the Deputy Director for Intramural Research (DDIR), National Institutes of Health (NIH). The NIH is part of the U.S. Public Health Service (PHS) which is an agency within the Department of Health and Human Services (DHHS).

2. HUMAN SUBJECTS RESEARCH: ETHICAL AND REGULATORY REQUIREMENTS

Federal law requires DHHS to issue regulations for the protection of human subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. These regulations are codified at Title 45, Part 46 of the Code of Federal Regulations, Protection of Human Subjects (45 CFR 46). They provide for the prospective review and approval of human subject research activities by an Institutional Review Board (IRB), a committee whose primary mandate is to protect the rights and welfare of humans who are the subjects of research. The regulations also incorporate a number of ethical principles regarding all research involving human subjects as expressed in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled The Belmont Report. All institutions, including the NIH, which receive funds from the DHHS to conduct or support research with human subjects are subject to these regulatory requirements and are to be guided by the ethical principles of The Belmont Report.

3. HUMAN SUBJECTS RESEARCH: NIH'S INTRAMURAL RESEARCH PROGRAM

The mission of the NIH is to improve human health through biomedical and behavioral research. Performing research involving human subjects is an important and necessary component of that mission, and investigators in the NIH's Intramural Research Program (IRP) conduct and/or collaborate in many such activities which take place not only on the NIH Bethesda campus and other NIH locations, but also throughout the United States and abroad.

The NIH recognizes that the involvement of human beings as subjects of research creates ethical and regulatory responsibilities for the investigators conducting such research. It has therefore organized a Human Research Protection Program (HRPP). It establishes a system of research review, approval and oversight to assist IRP investigators in understanding and complying with well-established ethical and regulatory requirements. This system is described in the NIH Manual Chapter 3014 titled, "NIH Human Research Protection Program,"
http://www1.od.nih.gov/oma/manualchapters/intramural/3014/

4. ROLE OF THE OHSR

The OHSR is responsible for NIH-wide policy development, educational activities, oversight and coordination of NIH's HRPP.

The OHSR has been established to help NIH investigators understand and comply with ethical principles and regulatory requirements involved in human subjects research and to assist various NIH components in administering and regulating human subjects research activities so as to promote both the rights and welfare of human subjects and the NIH's research mandate.

OHSR:

- Interprets 45 CFR 46 (the Federal regulations for the Protection of Human Subjects) and works with other NIH groups, as appropriate, to formulate and develop NIH policies and procedures consistent with these regulations.

- Plans, organizes and conducts educational activities for NIH personnel concerning human subject protections.

- Works closely with the NIH's Institutional Review Boards (IRBs) to promote their mandate to protect the rights and welfare of human subjects.

- Assists investigators and others in fulfilling their ethical and regulatory responsibilities when conducting collaborative human subjects research with other U.S. institutions and in foreign countries.

- Consults with investigators, upon request, to help identify and resolve ethical and regulatory issues associated with the design and conduct of their human subjects research activities.

- Maintains databases to record research activities that are exempt from 45 CFR 46 and to record serious unexpected adverse events that occur on IRP protocols.

- Maintains databases to record reliance and other agreements with research organizations and IRBs elsewhere.

- Assists, at the request of the DDIR, in the conduct of inquiries and/or investigations concerning noncompliance with 45 CFR 46 or NIH policies and procedures that concern the conduct of human subjects research.

If you have any questions about the OHSR or want more information about the NIH system of human subjects protection, please call the OHSR at 301-402-3444.