Sheet 2: INSTITUTIONAL REVIEW BOARD LEADERSHIP

1. ROLE OF THE NIH'S INSTITUTIONAL REVIEW BOARDS (IRBS) AND IRB CHAIRS

The NIH's Human Research Protection Program (HRPP) is a system of research review, approval and oversight to assure that the rights and welfare of research subjects are protected. The NIH, in cooperation with its Institutes and Centers (ICs), has established IRBs that are responsible for the review and approval of research activities involving human subjects. The IRBs' primary mandate is to protect the rights and welfare of humans who are the subjects of research. All NIH IRBs follow the NIH Standard Operating Procedures for IRBs. The position of IRB Chair is of singular importance, and requires commitment, dedication, knowledge, and leadership (see 2 (b) below)**.**

2. ORIENTATION OF NEW IRB CHAIRS

At the time of appointment, new IRB Chairs will meet with the Director, OHSR to discuss the following points:

(a) The ethical and regulatory requirements for human subject protections

Chairs will be provided with the materials listed at the end of this information sheet. They will be expected to understand and promote the ethical principles outlined in The Belmont Report, and to have a thorough knowledge of the Federal regulations (45 CFR 46 and 21 CFR 50 and 56) and NIH/Clinical Center (CC) policies and procedures governing research involving human subjects. The NIH Manual Chapter 3014, "NIH Human Research Protection Program," is the guide to the roles, responsibilities and authorities of IRBs, research investigators, the OHSR, the Deputy Director for Intramural Research (DDIR), the Director, Clinical Center, and others in the NIH community. The Chair will be expected to provide expertise to her/his IRB on the content of this manual chapter, federal regulations and NIH policies that protect human subjects.

(b) Leadership requirements

Attributes that have been found to promote effective leadership for an IRB Chair include:

- The ability to conduct meetings of the IRB in an efficient, expeditious and fair manner. Attentiveness to the details and requirements of the Federal regulations and NIH/CC policies in the context of NIH IRP protocol review. Application of the requirements to foster ethically and scientifically sound biomedical research.
- The promotion of methodical and systematic IRB review by applying IRB review standards.
- The ability to set a tone of openness that encourages dialogue in IRB meetings.
- Respect for the diverse backgrounds, perspectives and sources of expertise of all IRB members, especially for the contributions of the non-scientists, and the ability to foster such respect among the IRB members.
- The confidence and courage to uphold IRB judgments that may not always be popular with principal investigators.
- Investment of adequate time, interest and commitment to provide guidance and expertise to IRB members, scientists and others in her/his IC.

(c) IRB administration and resources

OHSR will familiarize IRB Chairs with the IRB record keeping requirements discussed in the federal regulations and NIH IRB Standard Operating Procedures. The Chair will be responsible for assuring that he/she receives appropriate and sufficient administrative support, meeting space and other necessary resources to function efficiently, and will report deficiencies in this support to the IC Director or other appropriate IC official for correction. The Chair should encourage the IC Protocol Administrator to participate in educational activities and meetings that will improve the effectiveness and efficiency of the IRB administration.

(d) Interaction between IRB Chairs and OHSR

The Director and staff of OHSR will be available to consult with IRB Chairs at any time during their term of office.

RESOURCE MATERIALS:

1. Levine, Robert. Ethics and Regulation of Clinical Research.
2. The NIH Federal Wide Assurance, FWA 0005897.
3. The Belmont Report.
4. Federal Regulations for the Protection of Human Subjects (45 CFR 46).
5. NIH Manual Chapter 3014, "NIH Human Research Protection Program."
6. NIH Standard Operating Procedures for IRBs.
7. Clinical Center Medical Administrative (MAS) Issuances relevant to clinical research in the Clinical Center, especially MAS 93-1
   http://intranet.cc.nih.gov/mec/mas/.
8. Relevant forms and information sheets issued by the OHSR, see **http://ohsr.od.nih.gov/**.
9. Office for Human Research Protections (OHRP) videos on the ethics and regulations of clinical research. Please call OHSR at 301 402-3444 for more information.
10. OHRP's IRB Guidebook "Protecting Human Research Subjects". This publication is available for review and copying in OHSR, or can be accessed through the OHRP website, **http://www.hhs.gov/ohrp/irb/irb_guidebook.htm**.
11. The DDIR's booklet entitled "Conduct of Research in the Intramural Research Program at NIH", **http//:www.nih.gov/campus/irnews/guidelines.htm#anchor123606**.