

CHARGE TO THE ADMINISTRATIVE PANELS ON
HUMAN SUBJECTS IN MEDICAL RESEARCH
BY THE VICE PROVOST AND DEAN OF RESEARCH
(August 2015)

GENERAL CHARGE

The Administrative Panels on Human Subjects in Medical Research are assigned the authority and responsibility to perform, in an independent and autonomous manner, the key functions of the Human Research Protection Program (HRPP) of Stanford University and its affiliates, (together referred to as "STANFORD") including Stanford University Hospital and Clinics, the Lucile Packard Children's Hospital at Stanford, and the Veterans Administration Palo Alto Health Care System (VAPAHCS) with its associated Palo Alto Veterans Institute for Research (PAVIR). Some functions are described in this General Charge. A full description of their duties and responsibilities is contained in the HRPP Manual accessed at http://humansubjects.stanford.edu/hrpp/hrpp_entire.pdf.

The primary function of each panel on human subjects in medical research is the prospective and continuing review and approval of all STANFORD research involving human participants, except research reviewed by the Administrative Panel on Human Subjects in Nonmedical Research. Their objective is to ensure that the rights and welfare of research participants are adequately protected and that all activities involving human subjects are in compliance with applicable STANFORD policies and external regulations.

The Panels are assigned the authority and responsibility for reviewing all protocols involving human subjects (as defined below and in Chapter 1 of the HRPP Manual) that are conducted at STANFORD facilities or by STANFORD faculty, staff, students or visiting scientists at any location. This includes the authority to observe the informed consent process and all aspects of the conduct of the research. All protocols that involve human subjects shall be reviewed at intervals appropriate to the degree of risk but not less than once per year when federally funded, or up to three years in select cases of nonfederal low risk studies. The Panels may approve research protocols with or without modifications, or may withhold approval of all or any portion of a protocol.

The Panels are assigned the authority to, and shall review, suspected or alleged protocol violations, participant complaints, potential violations of applicable external regulations or STANFORD policies and other potential non-compliance, and unanticipated problems involving risks to participants or others, as outlined in Chapter 3 of the HRPP Manual. The Panels also have the authority to take action based on their reviews, including the authority to suspend or terminate a protocol or an investigator's privilege to conduct human subject research, as outlined in Chapter 9 of the HRPP Manual. In cases of suspension or termination, the Panel will immediately notify the affected investigator(s), the relevant school dean or appropriate institutional official (e.g., the ACOS for Research and Development at the VAPAHCS), the Vice Provost and Dean of Research, and others as required by the HRPP Manual, STANFORD policies and external regulations (e.g., Food and Drug Administration).

Upon request, the Panels shall review and comment on proposed external regulations dealing with human subjects in medical research. When appropriate, the Panels will formulate draft policies and procedures for approval by the appropriate University bodies and

promulgation by the Vice Provost and Dean of Research.

DEFINITIONS

Human subject: 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.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Per FDA:

Human subject: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Clinical investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of 21 CFR 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of the FDA.

GUIDELINES

A number of the important policies discussed in the HRPP Manual to aid the Panels in the exercise of their responsibilities are summarized below:

1. Research projects shall be reviewed in such a manner as to provide for the protection of the participant against undue or unnecessary invasion of privacy, disrespect for human dignity, and physical, psychological or social harm. In most cases, this will involve approval of a clearly-worded consent form to assure that the participant is fully informed of the risks inherent in participation and of the benefits which might be reasonably expected.

2(a). Conflict of Interest — Human subject research protocols shall be reviewed for potential conflicts of interest involving possible financial gain from research results versus obligations to human participants. This review process is set out in Chapter 3 of the HRPP Manual.

2(b). Under the Common Rule (45 CFR 46.107(e); 21 CFR 56.107 (e): "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB." The standards for determining if a conflict exists and the steps to take if it does are set out in Chapter 6 of the HRPP Manual.

3. All research protocols involving the use of human participants shall be available for review by any member of an assigned Panel. Any member of that Panel may, upon request, obtain full Panel review of such protocols. Approval of a protocol may be granted at intervals appropriate to the degree of risk but not less than once per year when federally funded, or up to three years in select cases of nonfederal low risk studies. Except for life-threatening emergencies and protocols qualifying for expedited or exempt review, all protocols must be

approved at a convened meeting of a quorum of the Panel (i.e., a majority of the voting members, including at least one member whose primary concerns are in non-scientific areas) with the affirmative vote of a majority of those present. The IRB review process and requirements are discussed in Chapter 7 of the HRPP Manual.

4. The activities of these Panels are subject to the Research Policy Handbook (RPH 18.4) "Confidentiality of Administrative Panel Proceedings."

DECISIONS OF THE IRB

If an investigator has concerns with respect to procedures or decisions of the IRB, the investigator may discuss his/her concerns with the Vice Provost and Dean of Research. The details and process for such discussions are set forth in Chapter 6 of the HRPP Manual. As this document makes clear, neither the Vice Provost and Dean of Research, nor the Provost, nor any other STANFORD official or committee may approve a protocol that has not been approved by the decision of one of the Panels, nor apply undue pressure on the Panel to reverse a decision (as further provided in Chapter 3 of the HRPP Manual).

MEMBERSHIP

The Panels are appointed by the Vice Provost and Dean of Research. The members of each panel include: STANFORD faculty and staff, one student when nominated by the ASSU Committee on Nominations (who is an upperclassman or preferably a graduate student with previous human subject research or medical experience), a member whose primary concerns are in non-scientific areas, a member of the local community not otherwise affiliated with the University, and any others who may be invited to serve when their expertise is required.

Non-voting ex officio members include but are not limited to representatives of the: Office of Vice Provost and Dean of Research, the VA Palo Alto Health Care System, Office of the General Counsel, Department of Environmental Health & Safety (Biosafety Officer, Radiation Safety Officer), and Office of the Dean of School of Medicine. Membership is explained in Chapter 6 of the HRPP Manual.

The term of membership on the Panels is a 12-month renewable period beginning October 1 through September 30.

REPORTING OBLIGATIONS

The Panels report to the Vice Provost and Dean of Research, who is the institutional official responsible for assuring compliance with University policies and external regulations on the use of human subjects in medical research and providing oversight for the HRPP.

PANEL MEETINGS

The Panels shall meet as necessary to conduct business but not less than monthly. The Chair of each Panel shall submit an annual report of Panel activities and deliberations to the Office of the Vice Provost and Dean of Research.

STAFF SUPPORT

The Office of the Vice Provost and Dean of Research shall provide the necessary staffing and administrative assistance for the Panels through the Research Compliance Office.