

CHARGE TO THE ADMINISTRATIVE PANEL ON
HUMAN SUBJECTS IN NONMEDICAL RESEARCH
BY THE VICE PROVOST AND DEAN OF RESEARCH

CHG-2

(August 2015)

GENERAL CHARGE

The Administrative Panel on Human Subjects in Nonmedical Research is 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 the Panel on human subjects in nonmedical research is the prospective and continuing review and approval of all Stanford University research involving human participants, except research reviewed by the Administrative Panels on Human Subjects in Medical Research. Its 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 Panel is 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 University facilities or by Stanford University 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 Panel may approve research protocols with or without modifications, or may withhold approval of all or any portion of a protocol.

The Panel is assigned the authority to, and shall review, suspected or alleged protocol violations, participant complaints, potential violations of applicable external regulations or STANFORD HRPP 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 Panel also has the authority to take action based on its 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, the Vice Provost and Dean of Research, and others as required by the STANFORD HRPP, and external regulations.

Upon request, the Panel shall review and comment on proposed external regulations dealing with human subjects in nonmedical research. When appropriate, the Panel 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.

GUIDELINES

A number of the important policies discussed in the HRPP Manual to aid the Panel in the exercise of its 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)): "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 the Panel. Any member of the Panel may, upon request, obtain full Panel review of such protocols. Approval of a protocol may be granted at a convened meeting of a quorum of the Panel (i.e., a majority of the voting members) 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 the Panel 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 Panel is appointed by the Vice Provost and Dean of Research. The members of the Panel include: Stanford University faculty and staff, student(s) when nominated by the ASSU Committee on Nominations (either upperclassmen or preferably graduate students with previous human subject research 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 the Vice Provost and Dean of Research and the Office of the General Counsel. Membership is explained in Chapter 6 of the HRPP Manual.

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

REPORTING OBLIGATIONS

The Panel reports 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 nonmedical research and providing oversight for the HRPP.

PANEL MEETINGS

The Panel shall meet as necessary to conduct business. The Chair of the 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 Panel through the Research Compliance Office.