



CONFIDENTIALITY OF ADMINISTRATIVE PANEL PROCEEDINGS

ORIGINALLY ISSUED: SEPT 19, 1986 CURRENT VERSION: SEPT 27, 2016

CLASSIFICATION: STANFORD UNIVERSITY POLICY GUIDELINES

SUMMARY:

Describes procedures to protect the privacy of human subjects and the confidentiality of proprietary information in the activities of the five University Administrative Panels on Research Compliance. Updated in 1996 to clarify the confidentiality of protocols and consent forms.

RELATED RESEARCH POLICY HANDBOOK DOCUMENTS:

- 1.4, Openness in Research
- 18.3, Administrative Panels for Research Compliance

AUTHORITY:

Committee on Research

CONTACT PERSON:

Research Compliance Director

Preamble

The purpose of these Guidelines is to maintain the fundamental principle of openness in research, as set forth in Stanford's policy on Openness in Research, in ways that appropriately protect personal privacy and proprietary information. The desirability of openness with respect to the business of Administrative Panels must be limited by considerations of privacy of human subjects, the confidentiality of proprietary data, the need to encourage free discussion at Panel meetings, and the desire to promote cooperation in carrying out the purposes of the Panels.

It would be inappropriate to make any information available that would jeopardize the privacy of human subjects. Moreover, like a research proposal before it is funded, a protocol normally is considered proprietary to the principal investigator until the project is funded. Further, a protocol may contain data that are proprietary to the sponsor, which the University is contractually obligated to keep confidential. And, last, open and frank discussions of protocols should be encouraged. The incentives to do so can best be preserved by protecting the anonymity of the members of the Panels who raise questions or concerns about the risks or benefits involved in any particular protocol.

Therefore, the following policy Guidelines have been established to aid Administrative Panels in carrying out their institutional obligations.

1) Attendance at Regular Panel Meetings

Normally regular Panel meetings are closed to the public, although exceptions may be made by each Panel. Panels are encouraged to hold special public sessions on issues of unusual interest to the broader University community in those cases where a significant number of individuals have asked to meet with Panel members or where concerns have been raised about matters related to Panel business.

2) Minutes of Panel Meetings

In order to encourage open and frank discussion at Panel meetings, and to have detailed records of Panel business (including confidential issues and matters under investigation), minutes of Administrative Panels normally are not made available to others outside the University administration unless otherwise required by law or external regulations.

3) Annual Reports of Panel Activities

Chairs of Administrative Panels shall prepare annual reports to the Vice Provost and Dean of Research, summarizing the nature and volume of the Panels' activities.

4) Protocols and Human Consent Forms

Each Administrative Panel shall consider a research protocol, and, if applicable, the form used by the investigator to obtain the consent of human subjects, to be confidential documents.

Written requests to release a protocol or a consent form should be directed to the cognizant Principal Investigator, with a copy to the Research Compliance Office. Such requests must state the reason for the release of the protocol or consent form. Investigators are encouraged to grant such requests whenever possible; if a request is not granted the investigator must disclose to the requester a summary statement explaining the purpose and nature of the study. (A disclosure will not be required until the proposal for the study is funded by an external sponsor, or, in the case of a study not externally funded, until the study is initiated.)

Requests for consent forms or protocol documents associated with groups of research projects, such as those associated with particular investigators or funding agencies, will be denied.

Decisions to deny the release of a protocol or consent form may be appealed to the Vice Provost and Dean of Research, who is responsible for adjudicating disputes.

5) Implementation

Questions about interpretation or implementation of these Guidelines should be referred to the Vice Provost and Dean of Research, who is also responsible for adjudicating disputes related to any of the provisions of the Guidelines.