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# Yale University Institutional Review Boards Guidance

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## 700 GD.2 Interdepartmental Collaboration on Research Subject Complaints

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### Overview

Human research participants may at times not be satisfied with their participation in a research project and may complain, either to the research team or to other University offices, including the HRPP. At times, a complaint may intertwine issues that involve a scope outside of the research, for example, involving clinical issues or HIPAA privacy issues. This procedure describes the process for investigation and follow-up of research subject complaints that span multiple departments. Complaints may be made by a research participant, parents of a child participant, or by the person who represents a participant unable to provide autonomous consent.

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### Point Person

The HRPP Compliance Manager serves as the point person responsible for coordinating the review of a complaint. In the event the HRPP Compliance Manager is not available, the HRPP Director, a Chair or Vice Chair of one of the Yale Institutional Review Boards (IRB) may assume this responsibility. Coordination of the response does not necessarily mean unrestricted access to information discovered in the course of the review for either the Point Person or the individual making the complaint. Unrestricted access to information and authority for final resolution of the complaint is determined by the nature of the complaint, and may rest with the Deans' Office, Office of the General Counsel, or other entity, as appropriate. Similarly, individual cases may be required to be coordinated outside of the HRPP. In such cases, the coordinating entity (Deans' Office, General Counsel) will ensure that information pertaining to the human subject is made available to the Point Person, to the extent that it is relevant.

In the case of a complaint involving the Compliance Manager or the HRPP itself, the point person coordinating the review will be a designee of the Associate Vice President for Research Administration.

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### Goals

The Point Person will:

- Manage and coordinate communications between the various departments or responsible authorities, the PI, the research team and/or the research subject
- Ensure that all aspects of the complaint are addressed by the appropriate parties
- Ensure, with the assistance of the departments or responsible authorities, that the process of review by the various constituents proceeds in a timely fashion

- Ensure that a fully coordinated and comprehensive response is provided to the complainant, the PI and/or the research team in a timely fashion

The departments or responsible authorities will

- ensure that full and accurate information is shared among those parties involved, to the extent that they are able to share information within the confines of privacy and privilege.

General Counsel will

- advise on these issues when necessary

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## **Collaborating Departments and Authorities**

Departments and authorities that may need to be involved in reviewing complaints include:

- Clinical (Yale New Haven Hospital, Yale Medical Group)
- The Deans' Offices of the Schools of Nursing and Medicine (for Scientific Misconduct and related issues)
- Legal/Risk Management
- HIPAA
- HRPP/IRB
- Radiation Safety Committees (RSC and YURSC)
- Radioactive Drug Research Committee (RDRC)
- Yale Cancer Center (YCC)
- Yale Center for Clinical Investigation (YCCI)

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## **Committee Review**

Committees that may be involved in the review of an issue include:

- Quality Assurance Compliance and Safety Committee (QUACS)
- YCC's Protocol Review Committee (PRC)
- Pediatric Protocol Review Committee (PPRC)
- Radiation Safety Committee (RSC) and Radioactive Drug Research Committee (RDRC)
- Yale IRBs

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## **Department/Committee Contacts**

Contact persons for departments and committees include, but may not be limited to: Ronald Vender, MD (YMG), Thomas Lynch, MD (YCC), Margaret Grey, PhD (YSN), Ravinder Nath, PhD (RSC and RDRC), Susan Bouregy, PhD (HIPAA Privacy), Stuart Warner, JD (YNHH), Robert Bienstock, JD (Yale University Associate General Counsel), Linda Mayes, MD (Scientific Misconduct), HRPP Compliance Manager, HRPP Director, IRB Chair or Vice Chair, as appropriate.

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## **Reporting**

The HRPP Compliance Manger will report progress on interdepartmental complaints to the HRPP Steering Committee at all convened meetings. If there are no current complaints under investigation, that report will be made to the Committee.

As appropriate, the HRPP Compliance Manager will report information on the complaint, its progress and resolution, to the cognizant IRB.

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