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# Yale University Institutional Review Boards Procedure

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## Procedure 700 PR.2 Soliciting and Responding to Research Participant Feedback and Concerns

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### Overview

This procedure defines the process for IRB solicitation, receipt and response to questions, concerns, complaints, and input from current, former, or future research participants or their designated representatives, the community and research personnel. The Institutional Review Boards (IRBs) provide opportunities for prospective, current and former research participants and/or their designated representatives to discuss their concerns, complaints, and input and to answer questions concerning research and their rights as research participants. All issues raised must be treated with due respect and confidentiality.

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### Community Awareness

The following methods may be used to inform the research community of the IRB's interest in feedback on the research process:

- The Authorization Section of all written informed consent documents includes language that notifies research participants of the availability of the IRB to discuss their concerns, complaints, and input, to answer questions concerning research when the research staff cannot be reached, or when they wish to speak to someone other than the research staff, and their rights as research participants (see template consent forms at <http://info.med.yale.edu/hic/forms/index.html> and <http://www.yale.edu/hsc/Investigator/forms.htm> )
  - Posters and fliers informing the community of the availability of the IRB to discuss their concerns, complaints, and input, and to answer questions concerning research and their rights as research participants are in the IRB offices, at Yale School of Medicine, Yale New Haven Hospital, student centers and other locations deemed appropriate. A list of poster/flier locations is maintained by the IRB, reviewed periodically and amended as appropriate.
  - Participant information is posted on the IRB website;
  - IRB brochures are available at the IRB offices and in community locations such as local libraries, select research affiliate offices, and student centers. A list of locations of brochures is maintained by the IRB and the brochures are replenished periodically
  - Community presentations informing the community about research are conducted and include contact information for the IRB.
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### Responding to Concerns, Questions, Complaints or other Input

- Calls and correspondence received by the IRB or research staff from potential, current or past research subjects are treated with respect and confidentiality.
- Issues raised may be the result of misunderstanding of the research process on the part of the caller. The IRB staff member or research personnel who takes the call should clarify the issue or error in the course of the discussion. No further action is required in these cases.

- Other issues may require an IRB designee, such as the Compliance Manager, to review the protocol file and follow-up with the Principal Investigator or research staff to determine the validity of the complaint. Follow-up with research staff will not be conducted in a way that identifies the complainant without prior consultation with the complainant. Complainant concerns should be discussed with the IRB Chair and/or Director.
- Other than inquiries requiring only education or clarification, the nature of the concern and its resolution should be documented or referenced in the IRB protocol files.
- Concerns that suggest investigator noncompliance must be handled in accordance with IRB policy 700 Noncompliance.
- IRB staff will review complaints and concerns to identify patterns of research behavior that require intervention and conduct the appropriate educational or other appropriate response.

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## **Evaluation**

The IRB reviews all outreach materials and venues periodically and revises the documents or locations as deemed appropriate.

Communications with research participants and community members are reviewed on a case by case basis to determine if there are areas of repeated concern or lack of clarity, and outreach materials are revised as appropriate.