

Approved by IRB Executive Committee: February 6, 2008
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AAHRPP Element V.I.B

POLICY

The University of Utah IRB makes available contact information, a Participant Survey, an IRB Service Survey and a Reporting of Complaints or Concerns Form on the IRB website. The IRB will investigate all complaints or concerns received regarding human subject research conducted under its jurisdiction.

All complaints or concerns will be handled in a confidential manner. This includes any reporting of an alleged violation of investigator compliance.

Complaints that are substantiated will be further investigated through a directed audit conducted by an IRB administrator and other IRB staff or member(s), and actions will be taken as deemed appropriate by the IRB.

Complaints of a sensitive nature may be brought to the IRB Executive Committee for discussion and recommendation.

PROCEDURES

1. Complaints received by research staff will first be handled according to
 - 1.1. SOP 901 on Unanticipated Problem Involving Risks to Participants or Others;
and
 - 1.2. SOP 903 on HRPP and Non-Compliance.
2. The Research Compliance Administrator, IRB Director, IRB Administrator, or designee will attempt to find a suitable resolution and response to the complaint or concern in a timely manner.