TITLE: **Review of Not Otherwise Approvable Research**

PURPOSE: Review research that is not otherwise approvable under the regulations.

RESPONSIBILTIES: Organizational Official or Designee

PROCEDURES:

When research is not subject to regulations because the research is not supported or conducted by a federal department or agency, the DHHS and the FDA will not conduct a review of the research to determine whether it can be approved. The University of Arizona will conduct its own review that parallels the regulatory process when the IRB determines that research involving children, pregnant women, or fetuses as subjects is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects health or welfare.

The Principal Investigator is responsible for all costs incurred by implementing the following process. This includes, but is not limited to, expert time, advertising, and meeting space rental.

Panel Formation

Identify a panel of five (5) or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates to review the protocol.

Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.

Inform potential panel members that they will be asked to provide individual written recommendations and that their reports, as well as their identities, will be publicly available during the public review and comment period.

Public Notification

Publish in a form accessible to the public:

- A request for written comments, including an Internet link to the protocol, relevant sections of grant applications, parental permission and assent documents, and relevant excerpts from the IRB minutes and correspondence.
- The date and location of the expert panel meeting, to be held a minimum of four (4) weeks after the notice is posted.
- Note that the panel meeting will be open to the public and that the public will have an opportunity to comment at the panel meeting.
- Note that written comments on posted materials must be submitted at least one (1) week before the day of the panel meeting to be considered by the panelists. This allows the public three (3) weeks to comment on posted materials.
- Indication that the panelists' reports/recommendations (see below) will be posted two (2) weeks after the panel meets.

- Invite comments for up to thirty (30) days after the meeting of the convened panel for review and consideration by the panel.

Open the meeting to the public.

Post Meeting

After the convened panel discussion occurs and public comments are received, each panel member writes an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

Post panel reports on the University of Arizona's website for informational purposes for thirty (30) days after the panel meeting.

Review the panel deliberations, reports, public comments, and make one of the following recommendations within 90 days of the convened panel meeting:

- The University of Arizona approves support of the research as submitted;
- The University of Arizona approves support of the research, but with required and/or recommended modifications; or
- The University of Arizona disapproves support of the research.

Inform the IRB and the investigator.

Post the decision on the University of Arizona's website.

MATERIALS:

None.

REFERENCES:

- 45 CFR §46.207, 45 CFR §46.407
- 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

REVIEW/REVISIONS: From 10/01/2010: Clarified that the Principal Investigator incurs all costs of the review panel.

From 08/01/2011 version: Renumbered from P&P-044.