

**Department:** UAMS Institutional Review Board  
**Policy Number:** 4.7  
**Section:** Committee/Staff Operations  
**Effective Date:** February 8, 2005  
**Revision Dates:** NA

**SUBJECT: Participant Phone Calls**

**Purpose:**

The purpose of this policy and procedure is to describe how IRB staff should respond to participant phone calls.

**Policy:**

Current, prospective, or past research participants can call and discuss any problems, concerns, or questions regarding research conducted at UAMS. All calls should be treated as confidential. Each IRB staff member is expected to know general information regarding the rights of research participants and be able to answer general questions.

**Materials:**

Participant Contact Form

**References**

None

**Procedure:**

1. IRB Staff Members will:
  - 1.1. Document each phone call received from a participant with the Participant Contact Form ("Form"). Note on the Form the date, who called, the facts presented to them, information provided, open questions, and actions promised.
  - 1.2. Request the participant's contact information in case there is a need to call them back after seeking assistance.
  - 1.3. Answer the participant's questions when possible.
  - 1.4. Forward the Form to the Director for assistance if unable to answer participant's questions.
  - 1.5. For concerns, complaints, research-related injuries, inform the participant that the Director or IRB Chair will contact them, and immediately forward the Form to the Director or IRB Chair.
  - 1.6. If the participant cannot reach the study team, use the ARIA database or UAMS e-phone book to locate contact information, and attempt to connect the study

team and participant. Staff members will not forward the participant to a phone number unless the study team has been directly contacted and they expect the call.

1.6.1. If staff member is able to connect the study team and the participant, Staff member will ask the team to notify them upon resolution.

1.6.2. If staff member cannot connect the study team and participant and the request is not urgent, arrangements will be made to contact the study team at another time and follow-up with the participant. Otherwise, the staff member will immediately notify the Director/designee.

1.7. Track unresolved issues and follow up as needed with the Study Team to obtain a resolution.

1.8. Indicate on the Form when a clear resolution has been reached.

1.9. Once resolved, submit Forms to the Director/designee for review.

2. Director/Designee will:

2.1. Review Forms.

2.2. Document on the form any additional communications or actions noting who was present, facts presented to him/her, information provided, and actions promised.

2.3. Notify the UA System General Counsel's Office of research related injuries, and other concerns and complaints on a case-by-case basis.

2.4. If the situation involves serious risks to participants, consider asking for a directed audit, with ongoing reporting to the IRB.

2.5. Track unresolved issues and follow up as needed to obtain a resolution.

2.6. File Forms.

3. IRB Chair will:

3.1. Review Forms provided by IRB staff

3.2. Document on the form any additional communications or actions noting who was present, facts presented to him/her, information provided, and actions promised.

3.3. Track unresolved issues and follow up as needed to obtain a resolution.

3.4. Once resolved submit Forms to the Director/designee for review and filing.