Department: **UAMS Institutional Review Board**
Policy Number: **4.7**
Section: **Committee/Staff Operations**
Effective Date: **February 8, 2005**
Revision Dates: **May 27, 2020**

SUBJECT: Participant Contact

POLICY

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

PROCEDURE

A. IRB contact information shall be included on consent materials as required by IRB Policy 15.1, and as appropriate for studies in which some consent elements may be waived.
B. People who contact the IRB to inquire about studies they may be able to join shall be referred to the appropriate UAMS or Arkansas Children's contact, such as the UAMS Translational Institute or the Arkansas Children's Research Institute (ACRI).
C. Contacts regarding questions, problems, or concerns regarding research under an external IRB's oversight shall be handled internally by UAMS using the procedure below, or by ACRI under its own procedures, to the extent possible. Such contacts may also be referred to the reviewing IRB as appropriate.
D. Contacts regarding questions, problems, or concerns regarding research under the UAMS IRB's oversight shall be addressed as follows.
    1. Document each contact in the centrally available participant contact log, completing all relevant information.
    2. Address the participant's concern at initial contact if possible. Resolution could include answering the participant's query or recognizing the consent is outside the IRB's purview and refer the query to the appropriate office.
    3. If further IRB follow-up is required, record the caller's contact information on the participant contact log.
    4. Consult the IRB Director or Associate Director for guidance in how to resolve.
    5. If the participant indicates an inability to reach the study team of a study they're currently on:
        i. Provide the study team's contact information if the participant doesn't have it OR
        ii. Indicate the IRB office will contact the team on their behalf, if the participant has tried but not succeeded in reaching the team directly. Then follow up and advise the study team to contact the subject, and advise the participant they can expect to hear from the study team.
    6. For concerns, complaints, or research-related injuries, indicate the IRB chair or director will be notified and that they will get a return call. Immediately notify the chair, director, or associate director.
    7. The IRB chair, director, or associate director may contact the study team to relay the participant comment or to get more information.
    8. Update the participant log when a resolution has been reached.

E. When contacted, the IRB Chair/Director/Associate Director shall:
    1. Seek additional information as needed.
    2. Consider whether other entities need to be involved and contact them if so. These offices can include, but are not limited to:
        i. Legal Counsel
        ii. Office of Research Compliance
        iii. Institutional Official
        iv. Referral to convened IRB as an office action
    3. Continue to update contact log until situation is resolved

REFERENCES

45 CFR 46.116(b)(6) and (7)
21 CFR 50.25(a)(6) and (7)
AAHRPP Element I-4