

**Department:** UAMS Institutional Review Board  
**Policy Number:** 10.3  
**Section:** Principal Investigator Responsibilities  
**Effective Date:** January 24, 2011  
**Revision Date:**

**SUBJECT: Protocol Content and IRB Submissions**

**I. PURPOSE**

The purpose of this policy is to define what must be submitted to the IRB and the minimum requirements that should be included in a Protocol.

**II. POLICY**

The IRB or Experienced IRB Reviewer must have sufficient information in order to determine whether the criteria for approval of research are met.

Protocols which do not have the minimum content may be rejected. Grant applications generally will not contain sufficient information for IRB purposes. Incomplete ARIA submissions may also be rejected.

A pre-review contingency letter will be sent to the Investigator outlining the items that must be addressed.

**III. PROTOCOLS**

**A. All Protocols.** Heading titles may vary in order or description and sections may be combined in some protocols, however, all protocols must include the following content:

1. Each page should include page numbers, protocol version number, date, protocol name or descriptive identifier and the PI or Sponsor name.
2. Title of the protocol. This title should match the one entered into ARIA.
3. Background and Significance/Rationale. Establishes the significance of the topic to be researched and provides conceptual framework for addressing the hypothesis (es). Justifies proposed methods for intervention and assessment. Should include a statement placing the study in the context of the development or proposed use of the test article (if applicable).
4. Protocol Summary. Provides a brief synopsis of study, generally no more than 1-2 pages. Usually includes Background; Aims/Objectives; Study Design; Study Population; and Statistical Plan or Data Analysis.
5. Specific Aims/Objectives. This should clearly state the hypotheses to be tested and the objectives or specific aims.
6. Study Design and Procedures. Must provide details of clinical study design, including an in-depth narrative of the methodology to be employed. Flow charts or study calendars may be used to describe procedures and tests. Identify if any procedures are already being performed for diagnostic or treatment purposes.
7. Study Population/Data Source. This should include the study inclusion/exclusion criteria; expected number of subjects to be enrolled and age range of the subjects. If the study is a chart review only, the source of the data and data elements must be listed.
8. Ethical Considerations. This should include a description of the informed consent process or justification for waiver as appropriate. For protocols not under the Investigator's control, this must be addressed in the submission.

9. Risks and Benefits. This should provide the expected risks and benefits of the study procedures and the procedures taken to minimize those risks. Provisions to protect subject privacy and the confidentiality of the data should also be addressed.

10. Statistical Plan. Provide details of Statistical Considerations. In addition to proposed statistical analyses, when appropriate, this section should include a justification of the sample size and a statement regarding power based on one or more of the primary outcome measures.

11. Data Handling and Recordkeeping. Provides information on the method(s) for data collection and specifies data collection tools. Should also address confidentiality, de-identification of data, data storage, and security measures.

12. Study Registration and Publication. Provides information on the planned dissemination of data, including plans for publications, presentations, and website registration (i.e. [www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

13. References.

**B. As Appropriate to the Study.** Depending on the nature of the research, the following elements may be required for protocol review:

1. Safety or Efficacy Assessments. Provides details for how adverse events, serious adverse events, and/or unanticipated adverse device effects will be captured and reported.

2. Additional Safeguards to Protect Vulnerable Populations

3. Test Article Description and Status. Provides a brief description of the investigational product/device. If applicable, include information on formula/strength, route of administration, dosing schedule, and manufacturer/make/model (devices).

4. Recruitment Plan. Describe how potential subjects will be identified and approached.

5. Monitoring Plan. May be addressed in protocol, ARIA Submission or separate monitoring plan. Describe safety tracking plans, plans for interim data monitoring, and stoppage rules. Identifies any special committees (i.e. DSMB) that will be involved in making safety assessments.

6. Multi-Site Protocols where UAMS is the lead site must address minimal training requirements required of those from other sites, how IRB approvals from other sites will be managed and how information will be managed between the sites, including reporting unanticipated problems involving risks to subjects or others, modifications to study or documents.

7. Quality Control and Quality Assurance – Required for FDA regulated studies. Describe any Quality Assurance or Quality Control systems to be used. If such systems are not pertinent to your study, please indicate that as well.

8. Abbreviations.

#### IV. ARIA Submission

**A. Documents.** In addition to a completed ARIA Original Submission Form or Modification Form, Investigators must also submit the following documents, if applicable to the study:

1. Protocol

2. Consent Forms or Information Sheets

3. Description of the Consent Process. This may be included in protocol, submission form, separate SOP but must include:

- a. The person (people) who will conduct the consent interview
- b. The person who will provide consent or permission (e.g. subject, parent, LAR)
- c. Any waiting period between informing the prospective subject about the study and obtaining consent.
- d. Steps taken to minimize the possibility of coercion or undue influence.
- e. The language used by the person (people) obtaining consent.
- f. The language understood by the prospective subject or LAR

4. DHHS Model Consent

5. HIPAA Authorization

6. Grant Application.

7. Surveys, Questionnaires or any other research-related materials that will be seen by the subject.

8. Investigator's Brochure, Package Insert or Device Manual

9. Letter from FDA or RSC regarding test article status.

10. Advertisements, flyers or other materials used for recruitment purposes

11. Approvals from any other required institutional committees (e.g. ACHRI, PRMC, COIC).

12. Letters of Assurance from other research sites

13. A simplified CV or accurate completion of profile in ARIA providing same information.

**B. Personnel.** All individuals engaged in the research as UAMS, ACH or other institution subject to the oversight of the UAMS IRB must be listed as personnel in ARIA with a description of their role and qualifications. Failure to list the personnel in ARIA may result in delays in access to patient information systems and audit findings.