Department: **UAMS Institutional Review Board**
Policy Number: **10.3**
Section: **Principal Investigator Responsibilities**
Effective Date: **January 24, 2011**
Revision Date: **August 17, 2015; February 15, 2016; July 7, 2020**

SUBJECT: Protocol Content and IRB Submissions

POLICY

Submissions must include enough information for the convened IRB or expedited IRB Reviewer to determine whether the criteria for approval of research and other applicable regulatory, policy, and ethical requirements are met. This policy describes the minimum content typically required in a human subject research protocol for the IRB to make its required determinations.

PROCEDURE

A. All protocols are to include the following elements. While heading titles may vary in order or description, and sections may be combined, the following content must be addressed.
   1. Page numbers, protocol version number, date, protocol name or descriptive identifier and the PI or Sponsor name on each page, to ensure the submitted protocol is correct and complete.
   2. Protocol title, which must match the title entered into IRB e-system.
   3. Background and Significance/Rationale, to establish the significance of the topic to be researched and to provide the conceptual framework for addressing the research question(s). This section justifies the proposed methods for intervention and assessment. When applicable, this section should include language placing the study in the context of the test article's development or proposed use.
   4. Specific Aims/Objectives, clearly stating the hypotheses to be tested and the objectives or specific aims.
   5. Study Design and Procedures, to describe 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. This section should indicate whether any study procedures are already being performed for diagnostic or treatment purposes and should address the availability of resources needed to carry out the study procedures.
   6. Study Population/Data Source, describing 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 data source and the specific data elements of interest must be described.
   7. Ethical Considerations, describing the informed consent process or justification for waiver as appropriate. For protocols not under the investigator's controls, this language must be addressed in the submission.
   8. Risks and Benefits, describing the expected risks and benefits of the study procedures and the measures taken to minimize any risks. Provisions to protect subject privacy and the confidentiality of the data should also be addressed.
   9. Statistical Plan, to 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. The language in this section also helps the IRB confirm the data being collected are relevant to the planned analysis.
   10. Data Handling and Recordkeeping, to describe the method(s) for data collection and specifies data collection tools. It should also address confidentiality, de- identification of data, data storage, any expected sharing of data, and security measures.
   11. Study Registration and Publication. Provides information on the planned dissemination of data, including plans for publications, presentations, and website registration (e.g., www.clinicaltrials.gov).
   12. References.

B. **As applicable to the research,** any or all of the following elements must be included.
   1. Safety or Efficacy Assessment, to provide 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. Description of biospecimen collection, handling, storage, sharing and/or destruction.
   4. Test Article Description and Status, to describe the investigational product or test article. If applicable, include information on formula/strength, route of administration, dosing schedule, and manufacturer/make/model (devices).
   5. Recruitment Plan, to describe how potential subjects will be identified and approached.
   6. Monitoring Plan, which may be addressed in protocol or separate monitoring plan, to escribe safety tracking plans, plans for interim data monitoring, and stoppage rules. Also identifies any special committees (i.e. DSMB) to be involved in making safety assessments.
   7. Multi-Site Protocols where UAMS is the lead site must address minimal training requirements required of investigators 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.
   8. Quality Control and Quality Assurance – Required for FDA regulated studies. This element describes any Quality Assurance or Quality Control systems to be used. If such systems are not pertinent to the study, this inapplicability should be described as well.

C. **IRB e-system Submission procedure**
   1. E-system forms, such as the new submission form or the modification form, shall be filled out completely. When submitting a modification, all parts of the form must be revised as necessary so the form remains consistent with the protocol.
   2. Additional documents to be submitted with the study are:
      a. Protocol. Note that grant application excerpts typically do not contain all of the required elements; a separate protocol should be created.
      b. Consent forms or information sheets
      c. Description of the Consent Process. This may be included in protocol, submission form, or a separate SOP but must include:
         i. The person (people) who will conduct the consent interview
         ii. The person who will provide consent or permission (e.g. subject, parent, LAR)
         iii. Any waiting period between informing the prospective subject about the study and obtaining consent.
         iv. Steps taken to minimize the possibility of coercion or undue influence. e. The language used by the person (people) obtaining consent.
         v. If non-English speakers are anticipated, the language understood by the prospective subject or LAR, and a description of how the informed consent process will accommodate the potential participants' language preferences.
      d. DHHS Model Consent and DHHS Approved Protocol, when one exists
      e. xIRB approved consent template and other xIRB approved documents
      f. HIPAA Authorization
      g. Surveys, Questionnaires or any other research-related materials that will be seen by the subject.
      h. Investigator's Brochure, Package Insert or Device Manual
      i. Letter from FDA or sponsor regarding investigational drug or device status.
      j. Advertisements, flyers or other materials used for recruitment purposes
      k. Approvals from any other required institutional committees (e.g. ACHRI, PRMC, COIC).
      l. Letters of Assurance from other research sites
      m. The PI's uploaded CV in IRB e-system.
   3. 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 IRB e-system with a description of their role and qualifications. Failure to list the personnel in IRB e-system may result in delays in access to patient information systems and audit findings.

D. The IRB previewers will ensure the above elements are addressed in the submission. Incomplete submissions, or those that do not address the above requirements, will be returned for completion with a prereview contingency letter.

REFERENCES

AAHRPP Elements II.2.E, II.2.F, II.3.A, III.1.C, III.1.D
IRB Protocol Template