

USM IRB APPLICATION CHECKLIST

(A review will not be started until application is complete.)

Applications for IRB Review must include the following elements to be considered complete:

- **Request for IRB Review** form (or other appropriate USM IRB Review form)
- **Research Proposal Summary** (must be in the same format listed below, using lay language, as brief as possible, and not to exceed 3 pages [\[Important Tips\]](#)
 - A. Introduction
 - References/Brief Literature Review
 - Should show thoughtful consideration of the research topic, particularly if the study involves greater than minimal risk
 - Should be current and should reflect recent advances or changes in the field of inquiry.
 - B. Specific Aims
 - C. Methods of Data Collection and Analysis (Qualitative and Quantitative)
 - D. Description of the subject population, research setting, subject recruitment procedures
 - E. Informed Consent procedure
 - F. Provisions for subject and data confidentiality
 - G. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)
 - H. Statement of potential research benefits to subjects (Monetary compensation is not a benefit of participation)
 - I. Investigator experience (Attach a current copy of your C.V.)
- **Copies of all Informed Consents/Assents**
- **Copies of all advertisements/flyers** used for recruitment of subjects
- **Copies of all questionnaires, guiding questions, survey instruments, tests, etc.**
- **Other pertinent documentation** [\[Supplementary Information\]](#)
 - Debriefing scripts/forms
 - Grant application (complete application, including grant face page)
 - Section of the thesis or dissertation that describes the human subjects portion of the research
 - Complete Research Proposal (if study needs Full Board Review or if requested by IRB)
 - Letters of cooperation from any cooperating groups, schools, etc.
 - For research conducted in foreign countries, documentation of local approval (e.g. approval by a local ethics review committee) AND the informed consent document(s) to be used in the foreign country.
 - Other institution IRB approvals of research studies to be conducted by USM faculty/staff/students or at USM facilities when the Principal Investigator is from the other institution.

Important Tips

- Title document "Proposal Summary"
- Use headings: A. Introduction, B. Specific Aims, etc
- Provide brief, thoughtful responses under each topic heading, using lay language
- Demonstrate preparation by referring to research context or by including brief literature summary
- Describe only data collection activities involving human subjects
- List each human subjects data collection activity separately with appropriate methodology
- Use informed consent and other templates provided on ORC website as **guidance** for *individualizing your documents*
- Check document for **grammar and spelling**

Supplementary Information

- Grant application, including face page (if project is funded)
- Complete Research Proposal (for thesis or dissertation or for any study requiring Full Board Review)
- Debriefing scripts/forms, when applicable
- Letters of cooperation/authorization from cooperating groups/agencies, including HIPAA authorization and Business Associate Agreement; school permission requiring FERPA or PPRA; permission to use archived data, etc.
- For research to be conducted in foreign countries, documentation of local approval **AND** translations of informed consent documents to be used
- For research conducted by researcher from an institution other than USM or by USM researcher in cooperation with other institutions, copy of other institutional IRB approval letter
- Check document for **grammar and spelling**