Completing the Required Study Proposal Document – Section 6: Participants

In this section of the proposal document, Investigators should provide detailed information about the individuals who will be recruited and enrolled in the research study. Information that should be provided includes:

a. Target Population – Describe in detail who will be the study participants. Identify any specific groups of people that will be targeted, such as adults, children, students, or patients. Include a maximum number (e.g., “up to, rather than “at least”) for the anticipated sample size.

b. Inclusion/Exclusion – List any criteria that will be used to include or exclude potential participants (e.g. age or health restrictions).

c. Benefits – List any potential benefits that participants may receive for participating in the study. If there are no direct benefits to the participants, indicate there will be no direct benefits. Be sure to also identify the benefits to society and the field of study. Note that compensation is not considered a study benefit.

d. Risks – Identify any potential risks that participants may incur by participating in the study. Consider the potential risks that might result from their participation in study interventions and data collection methods. Describe any potential risks relating physical injury, emotional or psychological discomfort, criminal or civil liability, financial standing, employability, or reputation. Address how those risks will be mitigated and any plans to notify the participant and/or IRB if harms occur.

e. Recruitment – Describe in detail the methods you will use to recruit participants. Be specific about both the process you’ll use to inform potential participants about the study and how they can contact you with their interest. List and upload any materials that you intend to use (e.g. flyers, scripts, emails, etc.).

f. Obtaining Informed Consent – Provide specific information about the informed consent process. Describe which members of the research team will be obtaining informed consent, when and where the consent process will occur, and how the participant will indicate their consent to be in the study (e.g. written, verbal). Ensure that the process includes the opportunity for the participants to ask questions and that they will receive a copy of the consent form. If you are requesting to waive the requirement for documentation (i.e. handwritten signature) or to waive informed consent altogether, be sure to explain how the study meets the criteria for the requested waiver. If the study involves deception be sure to also describe the procedures that will be used to debrief participants.

New Name, Same Office

We’d like to announce that the Office of Research Support (ORS) will now be known as the Office of Research Support & Compliance (RSC). All contact information such as phone numbers and email addresses for our office and staff will remain unchanged.

Upcoming IRB Meeting

The next Full Board Meeting is:
**Monday, March 27, 2017**

The deadline to upload required documents are:
**Wednesday March 8, 2017**

Visit the IRB Meeting Deadlines and Dates page for the full 2016-2017 schedule.

[https://research.utexas.edu/ors/human-subjects/meeting-dates-and-deadlines/](https://research.utexas.edu/ors/human-subjects/meeting-dates-and-deadlines/)
IRB Contacts

Have questions about the IRB process or your study status? Contact your IRB Program Coordinator.

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Quality Improvement Visits

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) requires the IRB to conduct regular quality improvement efforts. Researchers may be randomly selected to participate in a brief, 30-minute Quality Improvement (QI) visit to discuss an active protocol. These visits are also an opportunity for researchers to ask questions about continuing reviews, protocol changes, and any other IRB topics.

Upcoming RSC Educational Sessions & Workshops

IRB 201 – IRB Intro
March 8, 2017
POB 2.404B
2:00 PM – 3:00 PM

This educational session addresses general IRB processes, background information, the levels of review, and how to submit.

Want to Chat with an IRB Coordinator?

Stop by one of the currently scheduled office hours for your department.

Communication Sciences and Disorders with Katharine Menke:
Fridays 11:00 AM – 12:00 PM, CMA 4.114C

Department of Kinesiology and Health Education with William Grant:
Thursdays 3:00 PM – 4:00 PM, BEL 718

College of Education with Peter Piliere:
Fridays 1:00 PM – 2:00 PM, SZB 536

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March 17, 2006