

**Institutional Review Board (IRB) Resource Guide**

**Overall Process for Submitting an IRB Application**

**\*\* If you are planning to conduct human subject research you will need to submit an IRB application.**

The IRB process ensures researchers protect the health, safety, and confidentiality of human subjects. The Federal Definition of Research is defined as: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102 9D0].

**Overall Process for submitting a New IRB application:**

1. Form 1 is required and submitted with all applications. **See** Form 1 resource guide and four examples of form 1 that were submitted and approved.
2. You will need to submit either Form 2 and 3. Select the form that best meets the criteria for your study. Once you identify the correct form and select the criteria on that form submit that form with your IRB application. **See** Form 2 and 3 resource guide.
3. CITI training certificates: Each member of the research team who is **engaged** in the research must complete and submit the following CITI certificates:
	1. Human Subject Researcher
	2. Responsible Conduct for Research
	3. Conflict of Interest
	4. Export Compliance

**Engagement** implies those who will either obtain consent, collect data, work with identifiable data, or interact with the participants during the study. If someone on your team is only consulting on the design or reviewing aggregated data that has been de-identified is not considered engaged in the research.

\*\*If a team member is from another institution with an IRB and has competed that institution’s CITI training will need to include those certificates their institution requires.

1. Supporting documents must also be included, they can be attachments to the submission email or included as appendices within Form 1.
	1. **Such as:** Recruitment emails or scripts sent to the participants, recruitment flyers, Letter of Support from the institution/department/unit where the study is being conducted, and all surveys or instruments the participants will complete.
2. Review Forms 4 through 13 to identify if any of these forms relate to your study. For example: if recruitment is conducted via telephone, submit Form 12. Asking for a waiver of consent submit Form 8. Asking for a waiver of written consent (obtaining consent electronically) submit Form 11.
3. Email irb@uah.edu with the required forms
4. Once submitted you will receive confirmation and an IRB protocol number. Please include this protocol number in all emails to the IRB.
5. Your application will be reviewed. If any content is missing, or needs more detail you will receive a comment sheet of items that need to be addressed.
6. If you receive a Comment Sheet you will make these edit/changes/additions in form 1 that were identified on the comment sheet. You must highlight these changes/edits in yellow
7. Once you have made the necessary edit/changes/additions identified on the comment sheet, resubmit to the IRB stating the protocol number in the email and attach the necessary forms.
8. If all comments are satisfied you will receive an approval letter.
9. Approval process takes about 3 weeks.

**Overall Process for submitting an Extension to an Approved IRB application:**

This is form is only needed if you need to extend your study beyond the time frame it was approved. You will need to submit **Form 5: UAH Institutional Review Board Application for Extension of Approval.**

* You will complete this form and also submit the current consent form you are using.