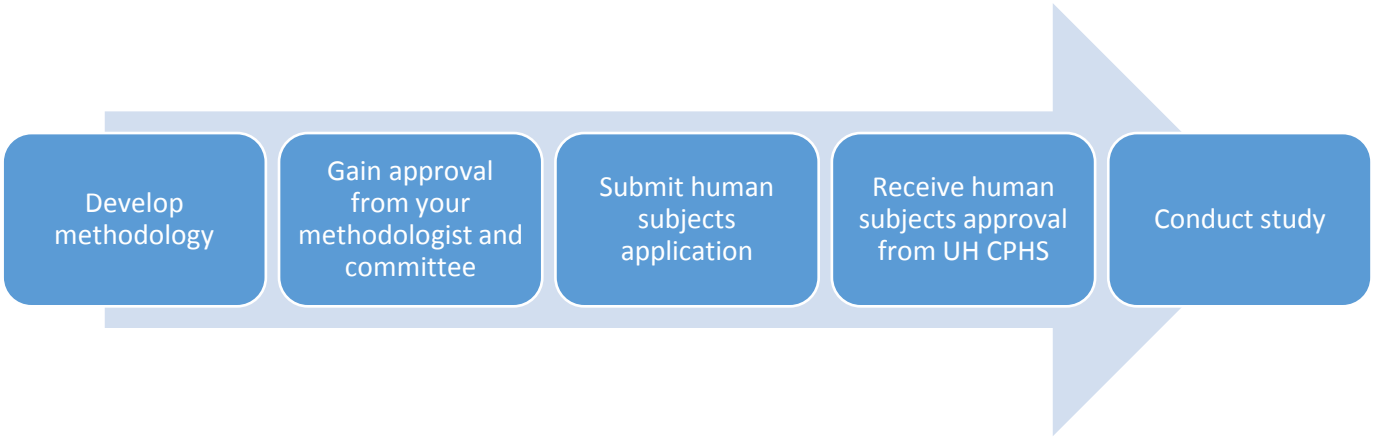
UH Human Subjects and Institutional Review Board Information

After you develop the methodological approach for your study for Chapter 3 and your methodologist and advisor approve it, you will submit a human subjects application to the UH Committee for the Protection of Human Subjects (CPHS) to obtain permission to conduct your study and gather/use the data.



Please note that you may not collect or use any data until your human subjects application has been approved by the UH Committee for the Protection of Human Subjects.

HUMAN SUBJECTS TRAINING

You must complete the web-based *Course in the Protection of Human Research Subjects* through the Collaborative Institutional Training Initiative (CITI). There is no cost to you for this training. This training consists of eight modules that include readings, case studies, and quizzes. You must score 80% to receive a completion report. Once you have completed this training, you should send your advisor a screenshot of the completed report page. The UH CPHS also receives a copy of the report and will not approve a human subjects application until this training is completed.

http://www.uh.edu/research/compliance/irb-cphs/hs-training/

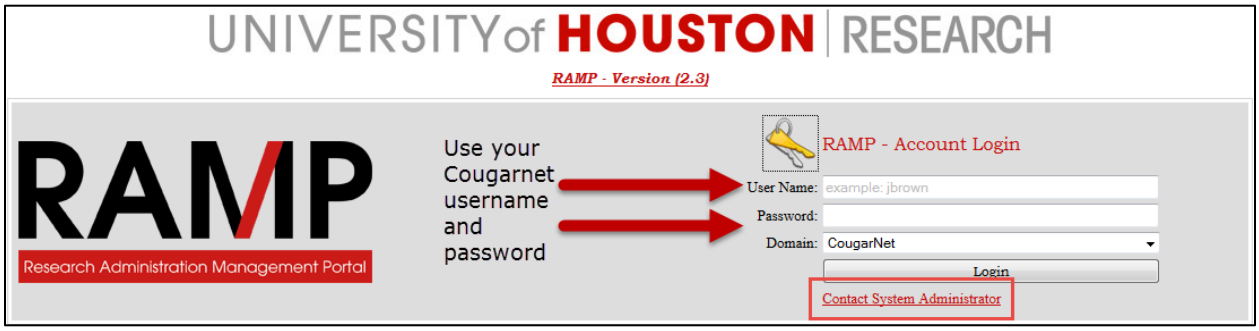
RAMP

When you are ready to submit your Human Subjects application in the UH online system, RAMP, you will enter the responses to specific questions about your study. However, before you submit the actual application, you will work with your committee to finalize your methodology. Create the first draft of the answers to the questions below and then submit this draft to your advisor.

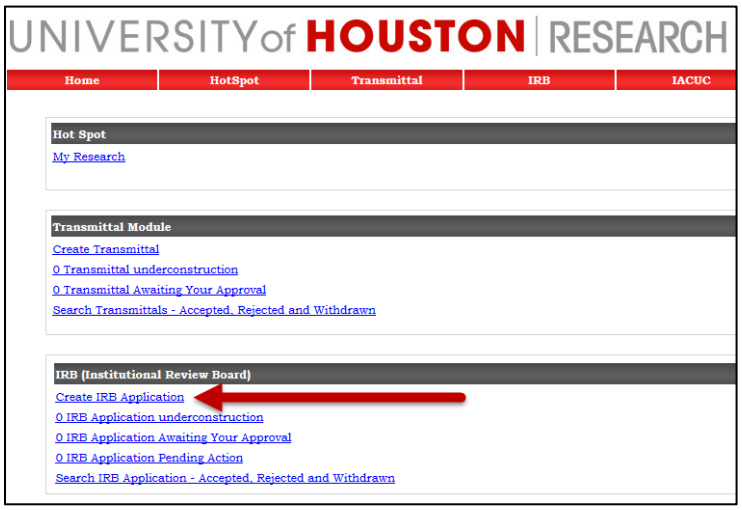
Copy the 25 questions shown below into a new Word document. This will allow you to begin answering them with specific information about your research study. Please note that help "prompts" for how you should answer these questions are shown in red beside each question. If you don't know the answer, provide your best estimate or best idea.

Access RAMP, Research Administration Management Portal: https://ramp.research.uh.edu

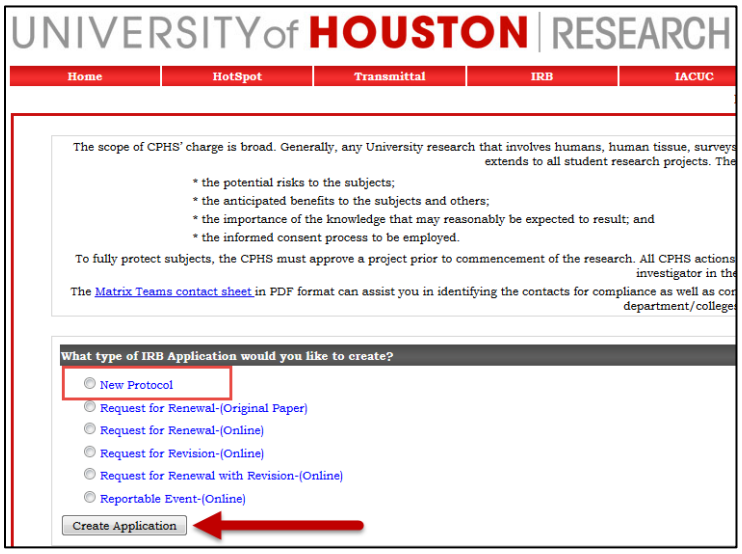
Contact the System Administrator by clicking the link if your login does not work.



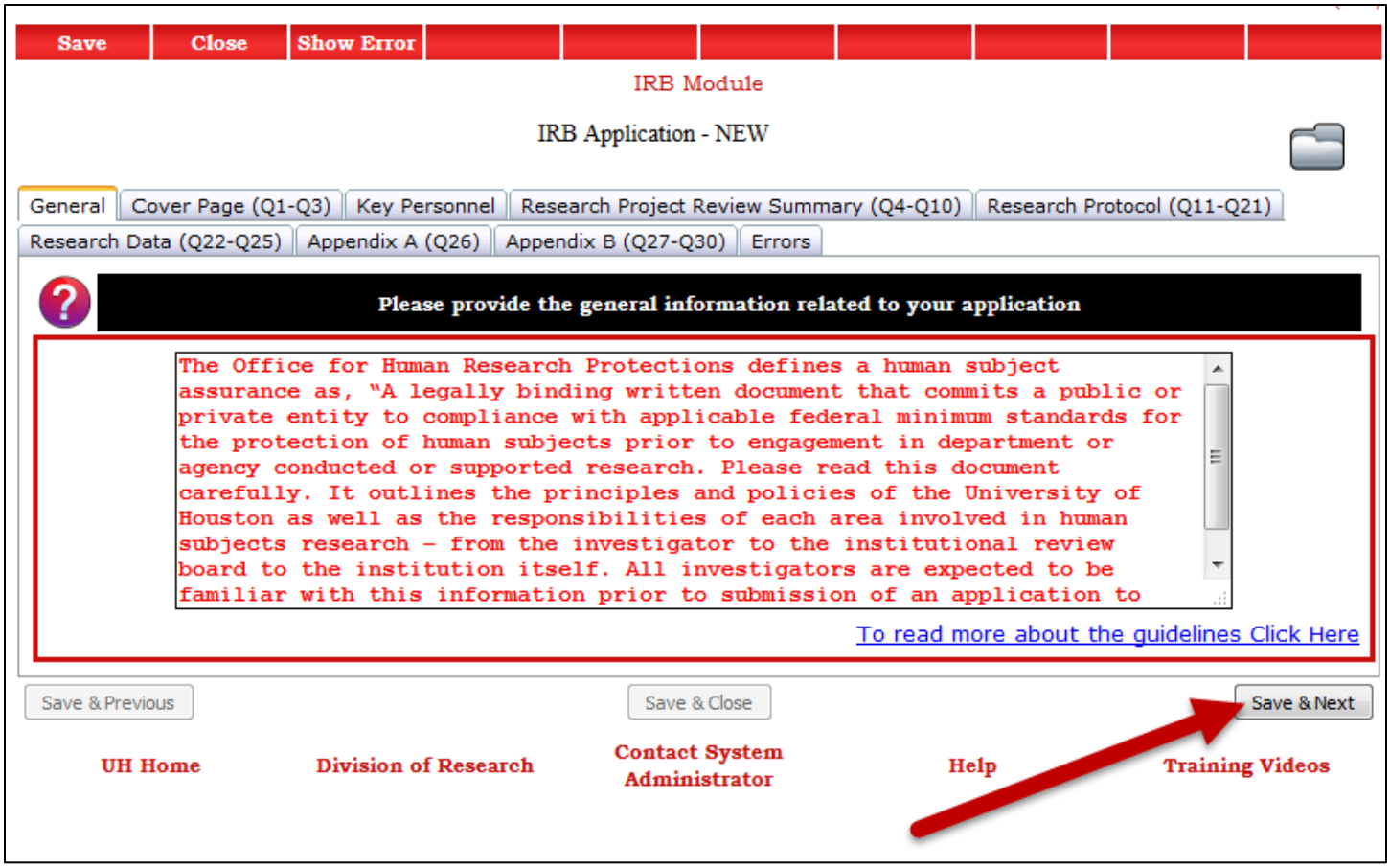
Click the link to "Create IRB Application."



Click the radio button for "New Protocol" then click "Create Application."



Read the information and click *"Save & Next."*

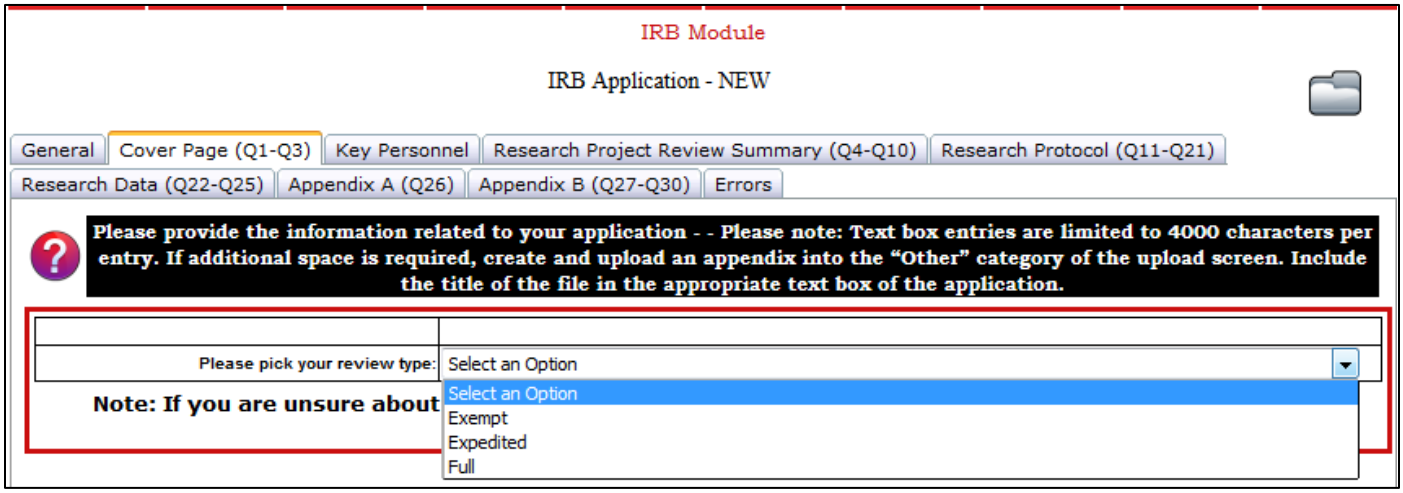


For the questions below, the directions are *italicized* and in red.

At the top, choose your review type:

Choose Exempt, Expedited or Full for Review Type. If you are not sure what type is appropriate for your study, access the description s here (http://www.uh.edu/research/compliance/irb-cphs/categories/) and talk with your advisor and methodologist.

This section is difficult to see and easy to miss.



1. Title of your study: *This is a tentative title for your thesis as well as your application.*
2. Choose the
3. Research reason: *unfunded research, doctoral dissertation.*
   Your response for this question is doctoral dissertation.
4. If this application supports a proposal for funding, please search for funded research project. (Proposal Abstract or Statement of Work must be uploaded with this application). *Leave blank*

Key Personnel: *add your name, your committee chair and methodologist*

Research Project Review Summary (Q4-Q10)

5. State the specific research hypotheses or questions to be addressed in this study.
   List all of your research questions.
6. What is the importance/significance of the knowledge that may result?
   Why is your research important?
7. Type of Subject Population (check all that are appropriate)
   6.01) Expected maximum number of participants: *List the number of participants in your data set*
   6.02) Age of proposed subject(s) (check all that apply): *Choose the age of your participants (adults 18yrs-64yrs) in your data set*
   6.03) Inclusion Criteria: *Describe the criteria by which a participant is eligible to take part in the study. Provide definitions of criteria.*
   6.04) Exclusion Criteria: *The criteria set that would keep a participant from being part of the study.*
   6.05) Justification: *Justification for the defined inclusion /exclusion criteria. Why are certain people being excluded? Why are others not included?*
   6.06) Determination: *How will you determine participants are eligible to be part of the study? Who will be deciding which people will be included and what resources, records or other information will they be using?*
8. If this study proposes to include children, this inclusion must meet one of the following criterion for risk/benefits assessment according to the federal regulations (45 CFR 46, subpart D). Check the appropriate box: *Leave blank unless children (under age of 18) are included in your subject population.*
9. If the research involves any of the following, check all that are appropriate: Interview, Clinical Studies, Survey/Questionnaire, Behavioral Observation, Study of Existing Data, Study of Human Biological Specimens, For Venipuncture and Biological, Data Analyses Only, Other (explain)
   Select all of the methodological approaches you will use.
10. Location(s) of Research Activities: List the location of your research activities.
    Please provide letter of approval from the specified site. (Attach the letter(s) of approval in Appendix.)
11. Informed Consent of Subjects: Your study protocol must clearly address one of the following areas: Informed Consent. Signed informed consent is the default. A model consent is available on the CPHS website and should be used as a basis for developing your informed consent document. If applicable, the proposed consent must be included with the application. (http://www.research.uh.edu/PCC/CPHS/Informed.html) ATTACH COPY OF PROPOSED CONSENT DOCUMENT

In most instances, this will be your choice.

Cover Letter. You may request a waiver of documented informed consent with Appendix A - Request for Waiver of Documentation of Consent. ATTACH COPY OF PROPOSED COVER LETTER AND APPENDIX A.

No informed consent. You may request a waiver of informed consent with Appendix B - Request for Waiver/Modification of Informed Consent. If applicable, a copy of the modified consent document is required. ATTACH APPENDIX B.

Research Protocol (Q11-Q21)

12. Describe the research study design.
    Describe the research methods to be employed and the variables to be studied. Include a description of the data collection techniques and/or the statistical methods to be employed.
13. Describe each task subjects will be asked to perform.
    This should include all proposed tasks subjects will be asked to complete. E.g.: Questionnaire Survey Focus Group and/or Interview. Be sure to include whether or not you will audio or video record or photograph participants.
14. Describe how potential subjects will be identified and recruited?
    Attach a script or outline of all information that will be provided to potential subjects. Include a copy of all written solicitation, recruitment ad, and/or outline for oral presentation.
15. Describe the process for obtaining informed consent and/or assent.
    How will investigators ensure that each subjects participation will be voluntary (i.e., free of direct or implied coercion)?
16. Briefly describe each measurement instrument to be used in this study (e.g., questionnaires, surveys, tests, interview questions, observational procedures, or other instruments) AND attach to the application a copy of each (appropriately labeled and collated). If any are omitted, please explain.
    Describe the data collection instrument or method. Upload copies of the instrument or questions in the uploaded files section of RAMP.
17. Describe the setting and mode for administering any materials listed in question 15 (e.g., telephone, one-on-one, group). Include the duration, intervals of administration, and amount of time required for each survey/procedure. Also describe how you plan to maintain privacy and confidentiality during the administration.
18. Approximately how much time will be required of each subject?
    Provide both a total time commitment as well as a time commitment for each visit/session.
    If you are using archival data, state that the data has already been collected by (the group, company or institution that collected the data).
19. Will Subjects experience any possible risks involved with participation in this project?
    18.01) Risk of Physical Discomfort or Harm
    18.02) Risk of Psychological Harm (including stress/discomfort)
    18.03) Risk of Legal Actions (such as criminal prosecution or civil sanctions)
    18.04) Risk of Harm to Social Status (such as loss of friendship)
    18.05) Risk of Harm to Employment Status

18.06) Other Risks

The answer is usually no.

20. Does the research involve any of these possible risks or harms to subjects? Check all that apply.
21. What benefits, if any, can the subject expect from their participation?

    The benefits should be direct to the participants such as improved physical condition or improvement in performance in a particular academic area. If the benefit is gaining some general knowledge about the study topic or primarily to the field, state: "There will be no direct benefit to participants however the study might provide insight into ….."
22. What inducements or rewards (e.g., financial compensation, extra credit, and other incentives), if any, will be offered to potential subjects for their participation?

    Indicate what inducements or rewards the participants will gain by participating in the study. If no inducements or rewards are expected note as such.

Research Data (Q22-Q25)

23. Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, patient or student ID numbers, etc.?

    Could any of the participants be identified or contacted via data collected. Include justification. If you have consent forms with signatures, you will have direct identifiers.

    If you are using archival data, state that the data is deidentified (any identification of the participants has been removed before you received the data.
24. Will you retain a link between study code numbers and direct identifiers after the data collection is complete?

    If study code numbers are used and a link between the study codes and direct identifiers will be retained <u>after data collection</u> is complete then "Yes" should be selected.
25. Will anyone outside the research team have access to the links or identifiers?

    Your response is usually "no."
26. Where, how long, and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept? *Investigators must confirm their understanding of UHs data retention policy which requires all study data must be retained at UH for a minimum of 3 years after completion of study. Describe how you will protect data in all formats.*

    This is the suggested wording: All materials, including electronic documents, will be stored on a secure media storage device not connected to the Internet in Dr. (use your chair's name)'s office on the UH campus and will only be accessible to the investigators. The data will be kept for 3 years upon completion of the project.