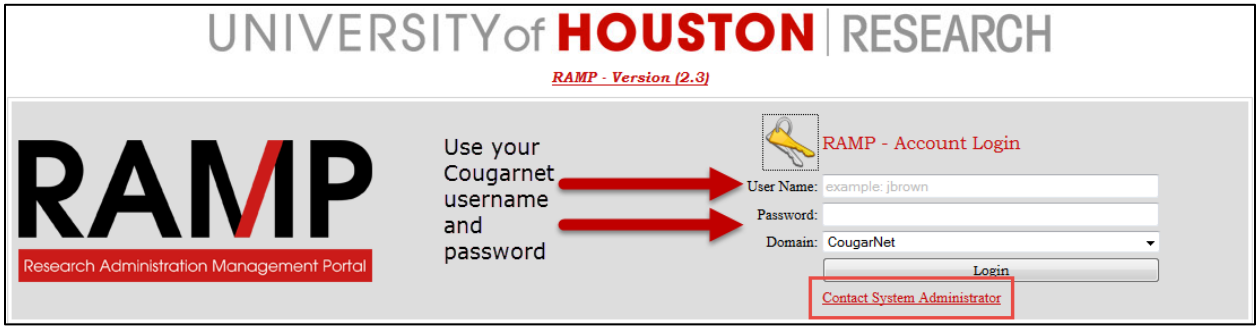
Create an IRB Application for Archival Data (Data that has already been collected.)

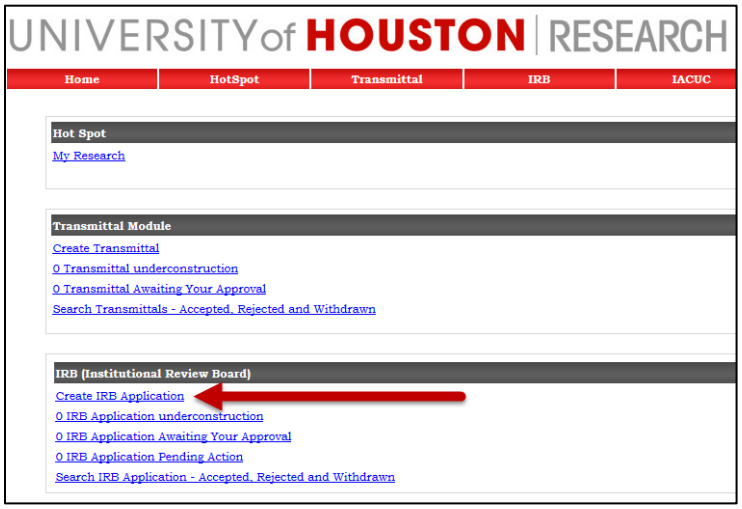
NOTE: Before you can be approved for a research study, you must complete Human Subjects training. Send your advisor a copy of your completion certificate before accessing RAMP.

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

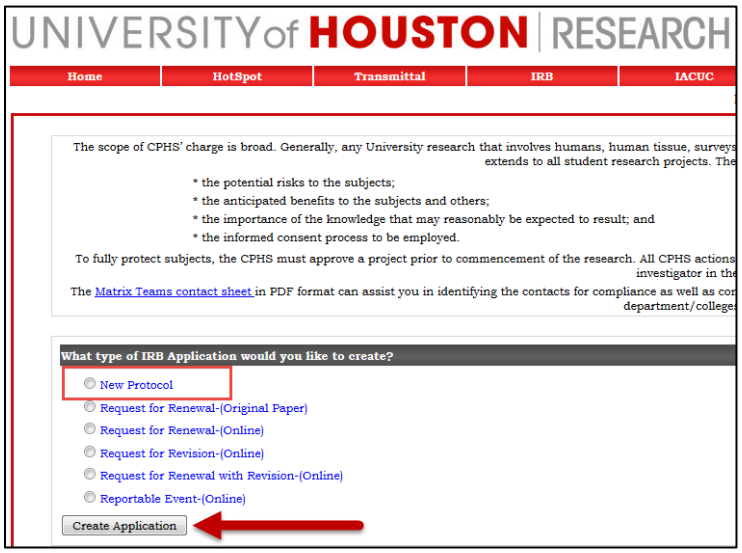
Contact the System Administrator by clicking the link if your login does not work.



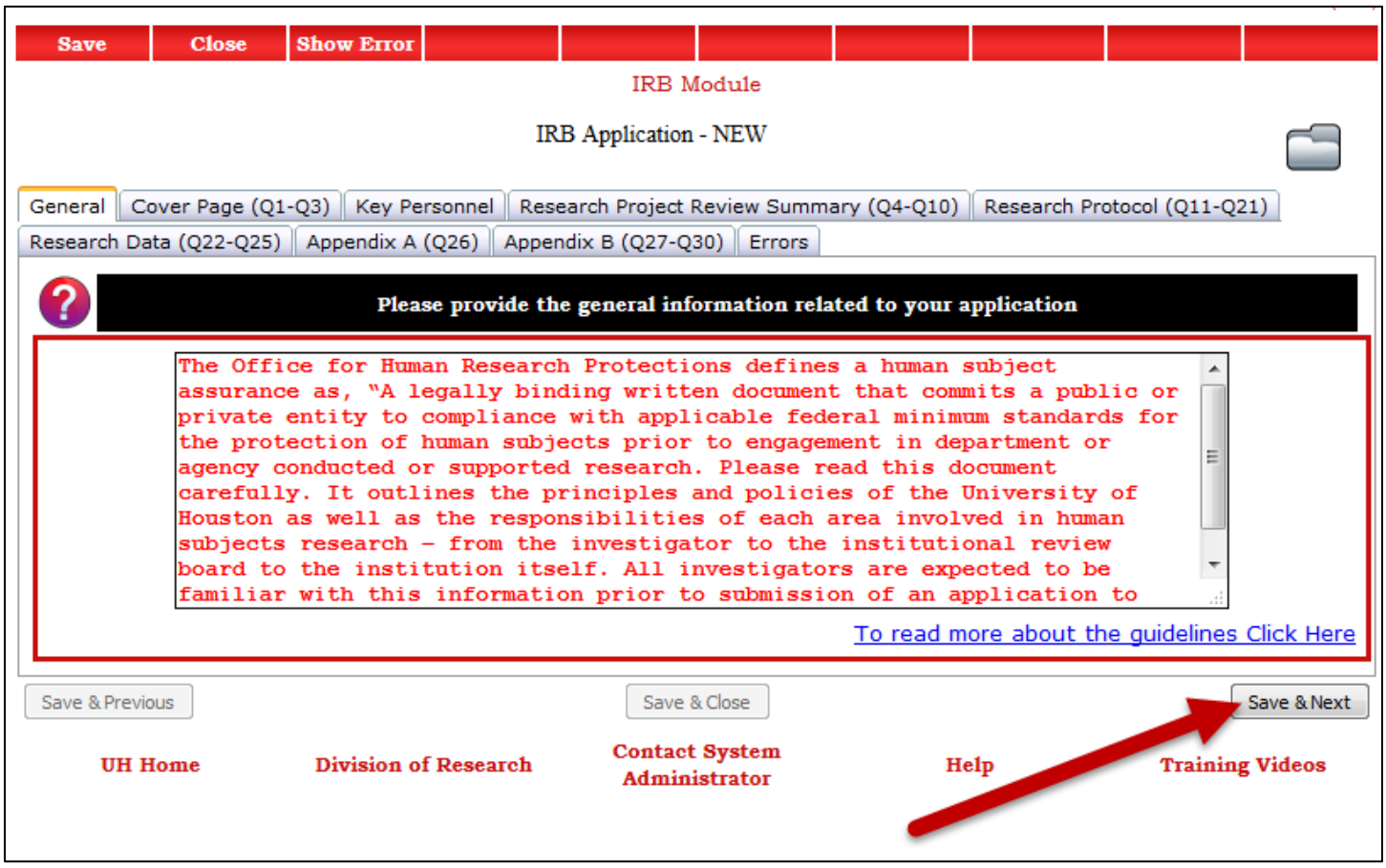
Click the link to "Create IRB Application."



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



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

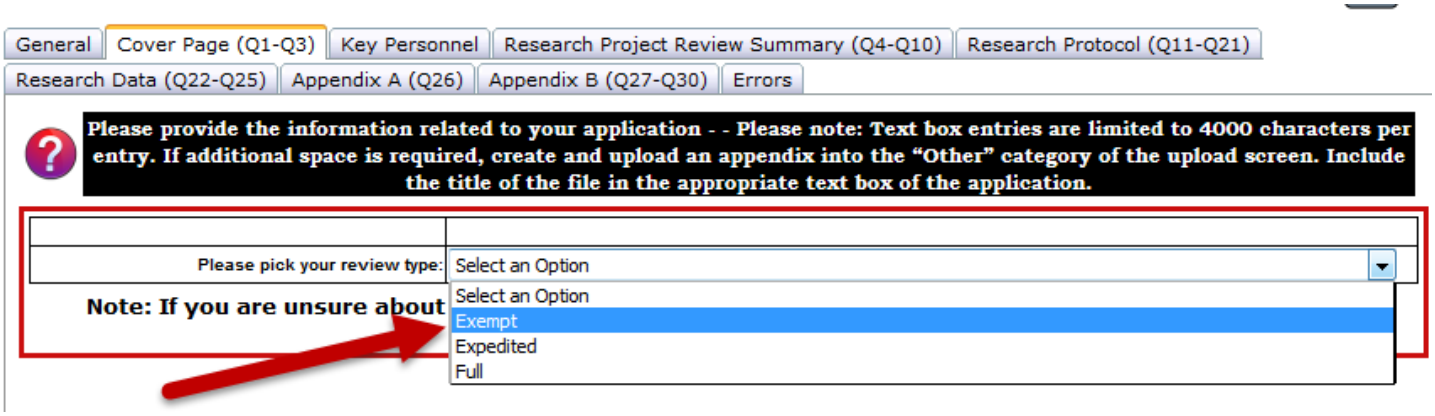


For the questions below, the directions are *italicized* and in red.

At the top, choose your review type:

Choose Exempt and for the exemption code, choose 4. Research involving the collection/study of data.

This section is difficult to see and easy to miss.



Cover Page (Q1-Q3)

1. Title: *Provide a descriptive title for your study.*

2. Research reason: *Choose unfunded research, doctoral dissertation*
   2.01) If the project is funded or proposed for funding, please indicate if UH is/will be: *Enter: N/A*
3. 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, the name of your committee chair and the name of your methodologist*

Research Project Review Summary (Q4-Q10)

4. State the specific research hypotheses or questions to be addressed in this study *List all hypothesis/research questions to be studied.*
5. What is the importance/significance of the knowledge that may result? *Describe your research is important.*
6. 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: *Enter:: N/A - Data Analysis only*
   6.04) Exclusion Criteria: *Enter: N/A - Data Analysis only*
   6.05) Justification: *Enter: N/A - Data Analysis only*
   6.06) Determination: *Enter: N/A - Data Analysis only*
7. 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.*
8. 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): *Enter the type of research that was conducted to generate the data set.*
9. Location(s) of Research Activities: *If your study uses archival data from an organization or institution, select other. Please provide letter of approval from the specified site. (Attach the letter(s) of approval in Appendix.)*
10. 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
    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. *Choose this option.*

Research Protocol (Q11-Q21)

11. Describe the research study design. *Briefly describe the research methods and the variables to be studied. Include a description of the data collection techniques and/or the statistical methods to be employed. At the end, enter "ALL DATA TO BE ANALYZED WAS PREVIOUSLY COLLECTED AT (enter the site where the data was collected), the source of the data. THIS IS A STUDY OF DE-IDENTIFIED DATA. (This means you do not have data that can traced to a specific person. The data does not contain names or personal identifiers.)*
12. Describe each task subjects will be asked to perform. *Enter: N/A. This is a secondary analysis of data already collected. See attached permission letter for data use.*

13. Describe how potential subjects will be identified and recruited? *Enter: N/A. This is a secondary analysis of data already collected.*
14. Describe the process for obtaining informed consent and/or assent. *Enter: N/A. This is a secondary analysis of data already collected.*
15. 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. *Enter description of the measurement instrument used to collect the data.*
16. 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. *Enter: N/A. This is a secondary analysis of data already collected.*
17. Approximately how much time will be required of each subject? *Enter: N/A. This is a secondary analysis of data already collected.*
18. Will Subjects experience any possible risks involved with participation in this project?
    18.01) Risk of Physical Discomfort or Harm *Choose No*
    18.02) Risk of Psychological Harm (including stress/discomfort) *Choose No*
    18.03) Risk of Legal Actions (such as criminal prosecution or civil sanctions) *Choose No*
    18.04) Risk of Harm to Social Status (such as loss of friendship) *Choose No*
    18.05) Risk of Harm to Employment Status *Choose No*
    18.06) Other Risks *Choose None*
19. Does the research involve any of these possible risks or harms to subjects? Check all that apply. *Leave blank.*
20. What benefits, if any, can the subject expect from their participation? *Enter: N/A. This is a secondary analysis of data already collected.*
21. What inducements or rewards (e.g., financial compensation, extra credit, and other incentives), if any, will be offered to potential subjects for their participation? *Enter: N/A. This is a secondary analysis of data already collected.*

Research Data (Q22-Q25)

22. Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, patient or student ID numbers, etc.? *Choose No*
23. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? *Choose No*
24. Will anyone outside the research team have access to the links or identifiers? *Choose No*
25. Where, how long, and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept? The data pertaining to data analyses only will remain on UH property for a minimum of 3 years following completion of the study. The study is complete when all data analysis is finished. All materials, including electronic documents, will be stored on a secure media storage device not connected to the internet in my advisor's, Dr. (put your advisor's name here), office and will only be accessible to the investigators. The data will be kept for 3 years upon completion of the project.

Remember to upload a copy of the letter from the organization that "owns" the collected data that describes the data set and says that you have permission to use it for this research study. A sample is included on the next page.

To upload, click the folder icon on the far right side of the screen.

To upload a document, click the green arrow button.

For the permission letter, choose the "Letter of Cooperation" folder.

Sample of the permission letter from the organization that owns the data:

(Use organization's letterhead.)

Date

(Addressed to your advisor/committee chair

His/her UH address)

Dear -----,

This letter is to verify that (your name), a doctoral student in the Executive Doctor of Education Program in Professional Leadership with an Emphasis in Health Science Education in the College of Education at the University of Houston, has permission from (whoever is in charge of the unit that collected the data), the owner of the requested data set, to utilize the data obtained from (name of the specific survey, questionnaire, interviews, etc.) for the purpose of analysis in his/her doctoral thesis.

(Describe any limitations for the use of the data set.)

(Also describe any characteristics of the data set that are pertinent such as whether the research was reviewed internally by the organization, whether it is delimited, etc.).

(Letter should be signed by someone with signature authority in the unit that collected the data or a supervisor of the unit that collected the data)

(Their title, address, and all contact information should be included.)