Office of Sponsored Programs & Research Integrity

Institutional Review Board 101

The Human Subjects Protocol Submission Process Simplified

University of Central Missouri

What is it?

An Institutional Review Board (IRB):

- Examines all research proposals involving with human subjects and/or data;
- Assesses the level of risk to participants involved in your research proposal as well as the ethical boundaries;
- Reviews proposed consent forms and considers any special populations in a study such as; pregnant women, children, prisoners, and institutionalized individuals; and,
- Approves or requires revisions be made to proposals.

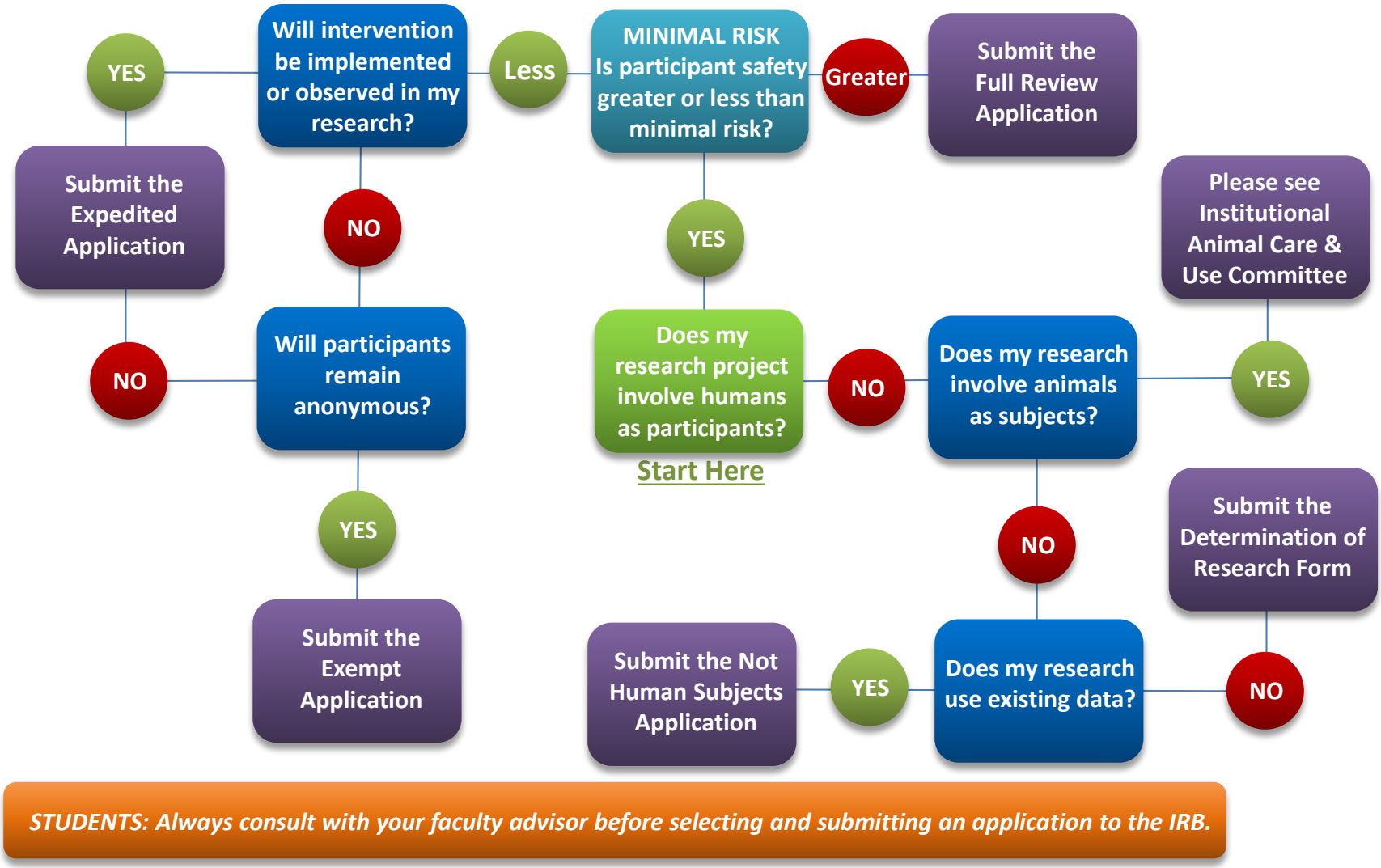
WARNING

- If you collect data **BEFORE** your research is approved by the IRB, **per federal regulations, IRB will immediately terminate your project and confiscate all data.** This is done to protect research participants and maintain federal compliance.

Who sits on an IRB?

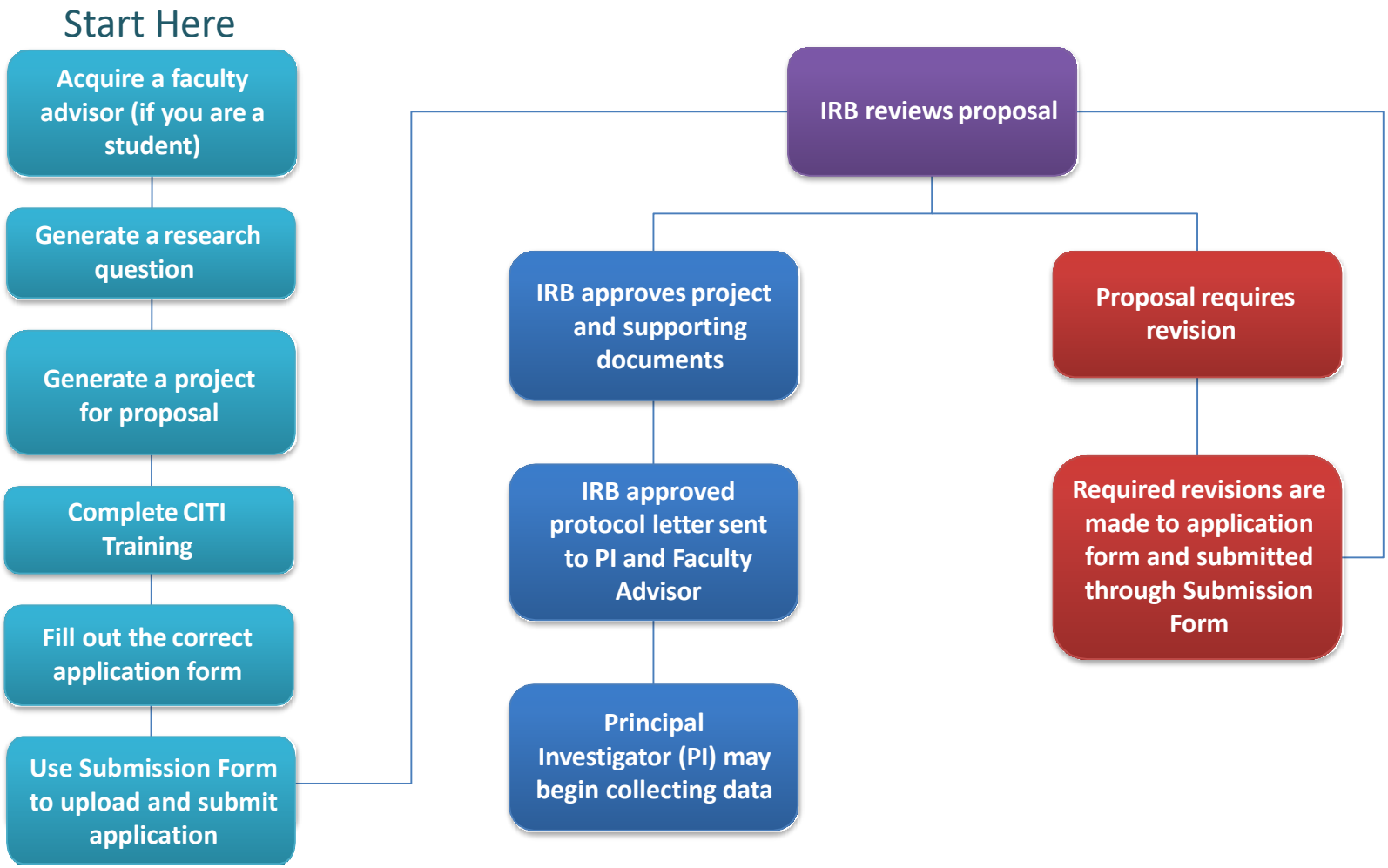
- An IRB consists of representatives from the community, faculty/staff from various departments (scientific and nonscientific), a student representative, and guidance from the Research Compliance Officer (ex-officio, non-voting).
- A current list of IRB members can be found on the Office of Sponsored Programs & Research Integrity website.

Which IRB application do I use?



STUDENTS: Always consult with your faculty advisor before selecting and submitting an application to the IRB.

What is the process?



How do I fill out an application?

The Not Human Subjects, Exempt, Expedited, and Full Review application forms have similar requirements.

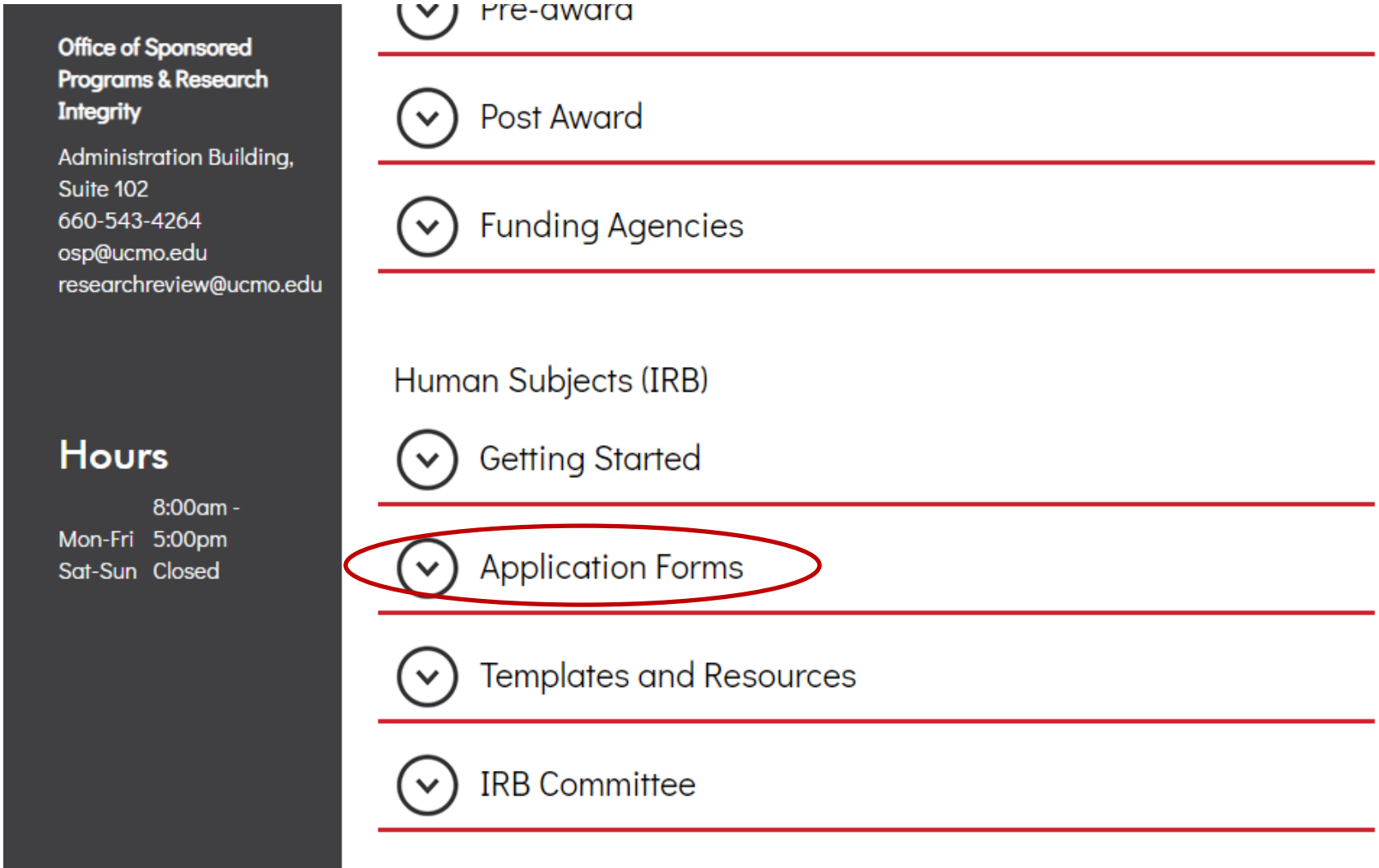
The following example is for an Expedited application.

Step 1: Get Application Form

Go to ucmo.edu/osp and, in the left menu, select *Forms & Resources*.

Step 2: Get Application Form

Select the “Application Forms” dropdown to view all eligible forms.



Step 3: Get Application Form

Select the appropriate application form, download, and save to your computer.

Application Forms

Below are the different application forms for Human Subjects research. Please complete the appropriate form for your research and use the Submission Form to submit protocol applications to the IRB for review. Please use the IRB application guide to determine which form to complete.

Submission Form: Use this form to attach and submit your IRB application and supporting documents.

Non-Human Subjects: If your research project does not fall under human or animal subjects, but is using existing data, this form needs to be completed for back up documentation of research compliance.

Exempt: This form is for research that will likely qualify as exempt, such as minimal interaction, low risk to participants, and/or de-identifiable data collection.

Expedited/Full: Researcher with more extensive interactions with participants, higher risk interactions, and collecting identifiable data will need to undergo a full review.

External IRB: If you already have an IRB from another institution, you must complete the Submission Form, select "External Protocol" in the Review Type field, and upload the original application, support items, and the external IRB's approval letter.

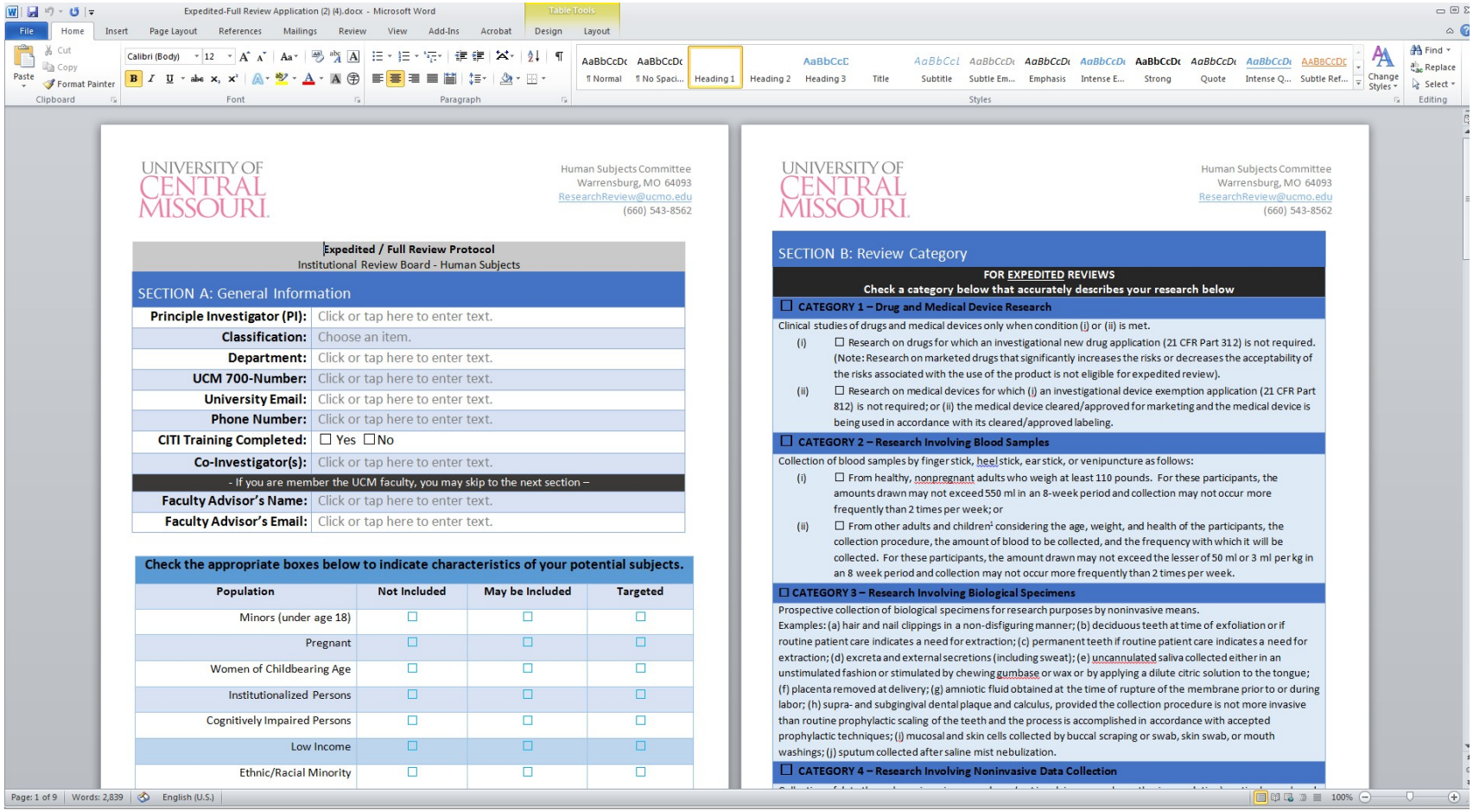
Renewals: Renewing a protocol extends the end date of the research project. Use the Submission Form to renew your protocol by selecting "Renewal" in the *Review Type* field and upload the original application form.

Amendments: To amend an active protocol, use the Submission Form and select Amendments in the *Review Type* field and provide a description of the proposed changes in the *Comments* box.

Protocol Closeout Form: Use this form after all research is complete and your are ready to close your protocol.

Step 4: Fill Out Application

The application will be completed in Word.



UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
Warrensburg, MO 64093
ResearchReview@ucmo.edu
(660) 543-8562

Expedited / Full Review Protocol
Institutional Review Board - Human Subjects

SECTION A: General Information	
Principle Investigator (PI):	Click or tap here to enter text.
Classification:	Choose an item.
Department:	Click or tap here to enter text.
UCM 700-Number:	Click or tap here to enter text.
University Email:	Click or tap here to enter text.
Phone Number:	Click or tap here to enter text.
CITI Training Completed:	☐ Yes ☐ No
Co-Investigator(s):	Click or tap here to enter text.
- If you are member the UCM faculty, you may skip to the next section –	
Faculty Advisor's Name:	Click or tap here to enter text.
Faculty Advisor's Email:	Click or tap here to enter text.

Check the appropriate boxes below to indicate characteristics of your potential subjects.

Population	Not Included	May be Included	Targeted
Minors (under age 18)	☐	☐	☐
Pregnant	☐	☐	☐
Women of Childbearing Age	☐	☐	☐
Institutionalized Persons	☐	☐	☐
Cognitively Impaired Persons	☐	☐	☐
Low Income	☐	☐	☐
Ethnic/Racial Minority	☐	☐	☐

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SECTION B: Review Category

FOR EXPEDITED REVIEWS
Check a category below that accurately describes your research below

☐ **CATEGORY 1 – Drug and Medical Device Research**

Clinical studies of drugs and medical devices only when condition (i) or (ii) is met.

(i) ☐ Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(ii) ☐ Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **CATEGORY 2 – Research Involving Blood Samples**

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(i) ☐ From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(ii) ☐ From other adults and children[1] considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ **CATEGORY 3 – Research Involving Biological Specimens**

Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ **CATEGORY 4 – Research Involving Noninvasive Data Collection**

Step 5: Fill Out Application

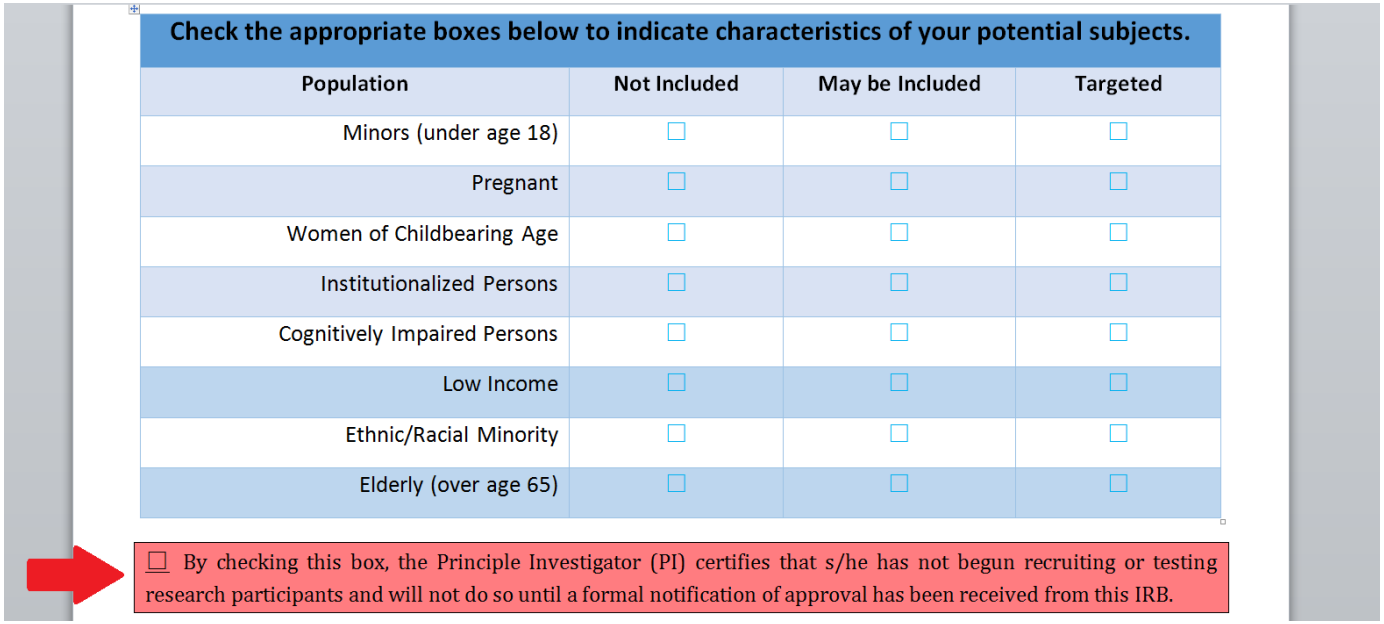
Complete Section A: General Information.

SECTION A: General Information	
Principle Investigator (PI):	Click or tap here to enter text.
Classification:	Choose an item.
Department:	Click or tap here to enter text.
UCM 700-Number:	Click or tap here to enter text.
University Email:	Click or tap here to enter text.
Phone Number:	Click or tap here to enter text.
CITI Training Completed:	☐ Yes ☐ No
Co-Investigator(s):	Click or tap here to enter text.
- If you are member the UCM faculty, you may skip to the next section –	
Faculty Advisor's Name:	Click or tap here to enter text.
Faculty Advisor's Email:	Click or tap here to enter text.

Step 6: Fill Out Application

Check all appropriate boxes.

Note that unless you have data from a professional indicating your subjects are, without a doubt, not pregnant or not cognitively impaired, you must check "May Be Included" for the Pregnant, Women of Childbearing Age, and Cognitively Impaired categories. Without testing or data from a professional, you will not know if a subject is pregnant or cognitively impaired.



Check the appropriate boxes below to indicate characteristics of your potential subjects.

Population	Not Included	May be Included	Targeted
Minors (under age 18)	☐	☐	☐
Pregnant	☐	☐	☐
Women of Childbearing Age	☐	☐	☐
Institutionalized Persons	☐	☐	☐
Cognitively Impaired Persons	☐	☐	☐
Low Income	☐	☐	☐
Ethnic/Racial Minority	☐	☐	☐
Elderly (over age 65)	☐	☐	☐

☐ By checking this box, the Principle Investigator (PI) certifies that s/he has not begun recruiting or testing research participants and will not do so until a formal notification of approval has been received from this IRB.

Step 7: Fill Out Application

Complete Section B: “Review Category”

Check the appropriate category for your project based off the descriptions provided.

SECTION B: Review Category

FOR EXPEDITED REVIEWS
Check a category below that accurately describes your research below

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(i) ☐ Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(ii) ☐ Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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(ii) ☐ From other adults and children[1] considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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☐ **CATEGORY 4 – Research Involving Noninvasive Data Collection**

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing where appropriate given the age, weight, and health of the individual.

☐ **CATEGORY 5 – Non-research or Research Involving Archived Data**

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

☐ **CATEGORY 6 – Research Involving Audio or Video Recordings**

Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **CATEGORY 7 – Psychological, Sociological, or Behavioral Research**

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

☐ **CATEGORY 8 – Continuing Review of Previously Approved Research**

Continuing review of research previously approved by the convened IRB as follows:

(i) ☐ where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up participants; or

(ii) ☐ where no participants have been enrolled and no additional risks have been identified; or

(iii) ☐ where the remaining research activities are limited to data analysis.

☐ **CATEGORY 9 – Continuing Review of Drug or Medical Device Research**

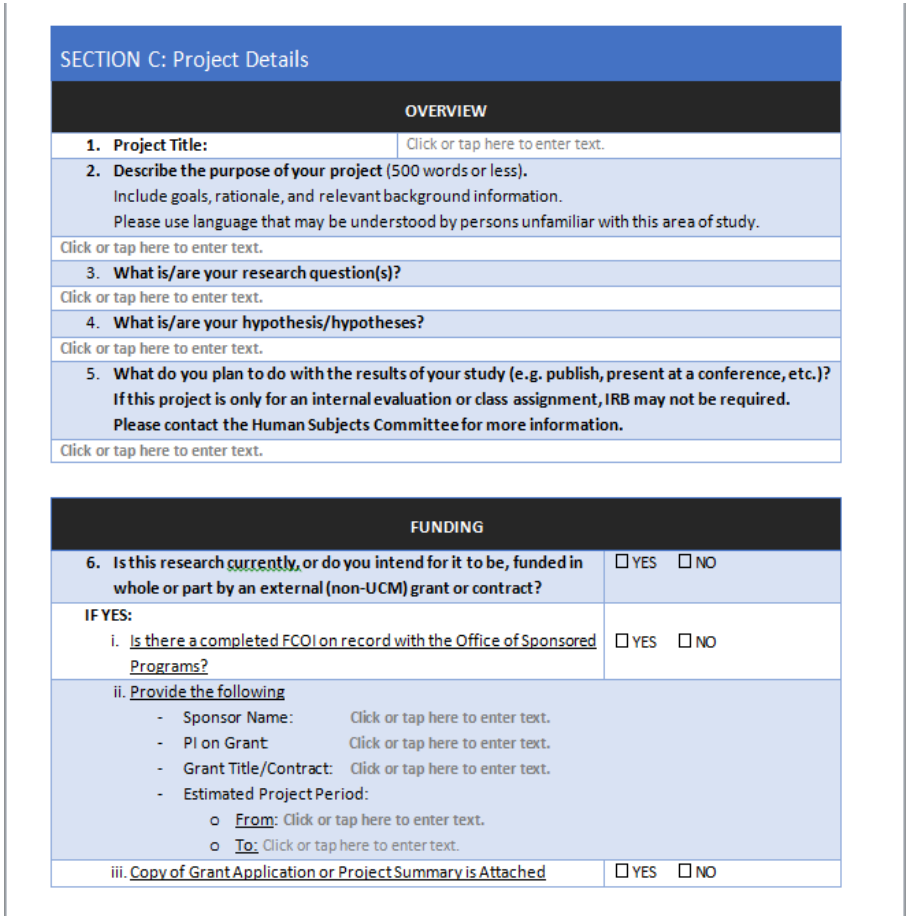
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

☐ **FULL BOARD REVIEW:**

Any research or training project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board IRB review. Research involving more than minimal risk requires full board review.

Step 8: Fill Out Application

Complete Section C: “Project Details”
This section is multiple pages.



SECTION C: Project Details

OVERVIEW	
1. **Project Title:**	Click or tap here to enter text.
2. **Describe the purpose of your project** (500 words or less). Include goals, rationale, and relevant background information. Please use language that may be understood by persons unfamiliar with this area of study.	
Click or tap here to enter text.	
3. **What is/are your research question(s)?**	
Click or tap here to enter text.	
4. **What is/are your hypothesis/hypotheses?**	
Click or tap here to enter text.	
5. **What do you plan to do with the results of your study (e.g. publish, present at a conference, etc.)?** **If this project is only for an internal evaluation or class assignment, IRB may not be required.** **Please contact the Human Subjects Committee for more information.**	
Click or tap here to enter text.	

FUNDING	
6. **Is this research currently, or do you intend for it to be, funded in whole or part by an external (non-UCM) grant or contract?**	☐ YES ☐ NO
IF YES: i. Is there a completed FCOI on record with the Office of Sponsored Programs?	☐ YES ☐ NO
ii. Provide the following - Sponsor Name: Click or tap here to enter text. - PI on Grant Click or tap here to enter text. - Grant Title/Contract: Click or tap here to enter text. - Estimated Project Period: o From: Click or tap here to enter text. o To: Click or tap here to enter text.	
iii. Copy of Grant Application or Project Summary is Attached	☐ YES ☐ NO

Step 9: Fill Out Application

Continued Section C: "Project Details"

PARTICIPANT POPULATION

7. **Describe the participant population you will target for this research** (e.g., sex, age range, ethnic background, health status, or other targeted demographics).

Click or tap here to enter text.

8. **How many participants will you need to complete your study?** Click or tap here to enter text.

RECRUITMENT

9. **Describe your recruitment process. Include how, where, when, and who will contact potential research participants.**

Click or tap here to enter text.

10. **Attach all applicable recruitment materials. Check all that apply.**

☐Recruitment Scripts ☐Letter/Cover Letter
☐Flyers ☐Advertisements
☐Recruitment Emails ☐Other: Click or tap here to enter text.

11. **Will you be directly emailing or mailing participants?** ☐NO ☐YES

IF YES, how are you obtaining emails and\or mailing addresses?

Click or tap here to enter text.

12. **Will participants be compensated for their participation?** ☐NO ☐YES

IF YES, describe how participants will be compensated – include the amounts and method of distribution:

Click or tap here to enter text.

RISKS & BENEFITS

13. **What are the risks and inconveniences to the participants? Describe all known anticipated psychological, physical, sociological, financial, economic risk to participants.** Examples include, but are not limited to: loss of confidentiality, identifiable links to individual participants, experiencing guilt for lying in a study requiring deception, emotions distress, physical injury or discomfort.

Click here to enter text.

14. **How will you minimize these risks and their impact to the participants?**

Click or tap here to enter text.

15. **Describe your plan for an emergency situation. Even if you feel this situation is unlikely, please have a plan in case of emergency (e.g., the researcher will carry a cell phone, etc.).**

Click or tap here to enter text.

16. **Describe the potential benefits to your participants and/or society.**

Click or tap here to enter text.

METHOD OF DATA COLLECTION

17. **Check all that apply.** *Attach copies of all data collection tools to be used.*

☐Questionnaire/Survey ☐Interviews (attach scripts, questions)
☐Observations ☐Existing Data
☐Other: Click or tap here to enter text.

18. **Indicate all biomedical procedures that apply to your research:**

☐ Physical Activity ☐ Body Mass Index
☐ Venipuncture ☐ X-rays
☐ Magnetic resonance imaging (MRI) ☐ Anthropomorphic evaluations
☐ Electrocardiograms (EKGs) ☐ Intravenous catheter insertion
☐ Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
☐ Other: Click here to enter text.

19. **If applicable, describe any procedures being performed already for diagnostic or treatment purpose.**

Click here to enter text.

20. **Describe the research methods or procedures you will use to collect your data. That is, what exactly are your participants going to do?**

Your response should include a step-by-step description of each procedure, including the frequency and duration of each procedure. If analyzing existing data, describe how you will obtain and analyze these data.

Click or tap here to enter text.

21. **Where will the study take place?** I.e., where will participants be observed, complete surveys, etc.?

Click or tap here to enter text.

22. **Does your study include plans to recruit participants from or collect data at an external site?** (I.e., off UCM campus – for example, at an elementary school, hospital, etc.) ☐NO ☐YES

IF YES, name and describe the external site(s) below.
You must also attach a written acknowledgement indicating that you have permission to use the named facility and/or personnel.

Click or tap here to enter text.

Step 10: Fill Out Application

Final Pages of Section C: "Project Details"

INFORMED CONSENT

The consent document(s) must contain all the required elements of consent. We recommend you use the appropriate template(s) available on the UCM website.

23. **How will you obtain consent?**
Describe your process for obtaining informed consent from your participants – include how, when, and where the consent process will take place, and who will collect it.

Click or tap here to enter text.

24. **Which of the following will you use to present the informed consent?** *(Attach all.)*

☐Paper Consent Form	☐ Minor's Assent Form (Must also include Parental Consent)
☐Web-based Consent Form	☐Parental Consent Form (Must also include Minor's Assent)
☐Cover Letter	☐Other: Click or tap here to enter text.
☐Verbal Consent Script	

25. Will you inform your participants of the full nature and purpose of your study before (during consent) or after (during debriefing) they complete your study?	☐Before - During Consent ☐After - During Debriefing
26. Will non-English-speakers be included in your study?	☐NO ☐YES

***IF YES**, include translated versions of your consent documents.*

PARTICIPANT PRIVACY & CONFIDENTIALITY

27. **Describe any procedures you will use to protect the privacy of your participants during data collection.**
(E.g., participants will complete surveys in the privacy of their own homes; interviews will be performed at a location of their choosing, etc.)

Click or tap here to enter text.

28. **During data collection, will you collect or have access to identifiable information about your participants?**

☐NO – Data collection will be anonymous (*The investigators will not collect or have access to identifiable information about the study's participants*)

☐YES – Data collect will be confidential (*The investigators will collect or have access to identifiable information about the study's participants*)

29. **How will you handle identifiable information?**

☐ Identifiable information will not be collected

☐ Identifiable information will be coded and investigators will not have access to a code key

☐ Identifiable information will be coded and investigators will have access to a code key

☐ Identifiable information will be collected and will be de-identified for analyses

☐ Identifiable data will be collected and will remain identifiable for analyses

30. **How will the collected data be secured?**

☐Locked in a cabinet or office

☐Password protected PC, hard disk drive, or other secure electronic storage

☐Encrypted online or cloud storage

☐All data will be destroyed (shredded/deleted/etc.) after use

☐Other: Click or tap here to enter text.

31. **Who will have access to the data?**

Click or tap here to enter text.

Step 11: Fill Out Application

Complete Section D: “Principal Investigator and Faculty Advisor Agreement”

Carefully read the “Please note” section, as students are required to work with their faculty advisor on the IRB protocol application.

UNIVERSITY OF CENTRAL MISSOURI

Human Subjects Committee
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researchreview@ucmo.edu
(660) 543-8562

Section D: Principal Investigator and Faculty Advisor Agreement

I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.

I agree to conduct the research involving human participants as presented in this protocol application as approved by the University of Central Missouri's Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB and the Research Compliance Officer of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol. I understand that the University of Central Missouri owns the research data. If I choose to transfer to another institution, I will need departmental approval to take the data with me.

If a student researcher, I additionally certify that my faculty advisor has an electronic copy of this application as submitted. My advisor has agreed to:

- *Oversee this research by communicating regularly with me;*
- *Assist with the resolution of any problems or concerns encountered during the research;*
- *Assure my research complies with Human Subjects Regulations in the Code of Federal Regulations*
- *Assure that the UCM IRB is notified in the event of an adverse event or protocol deviation.*

Please note:
Failure to work with your advisor as described above will be considered a breach of professional ethics which falls under the academic honesty policy. The consequences of violating standards of academic honesty are extremely serious, costly and may result in the loss of academic and career opportunities.

☐ **By checking this box, I certify that I have read and agree to the agreement above**

Principal Investigator (Print Name): Click or tap here to enter text. **Date:** Click or tap to enter a date.

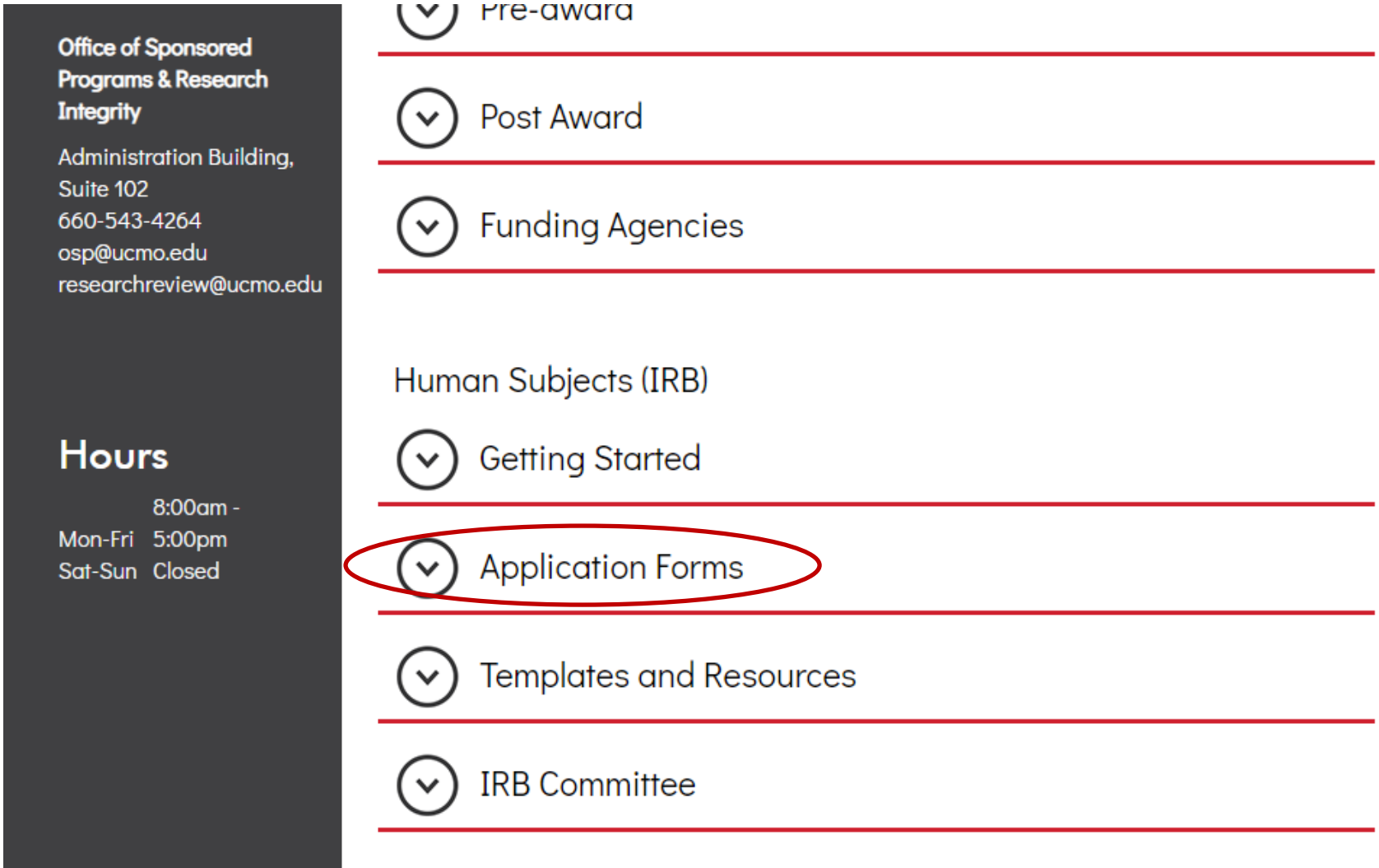
If an unanticipated problem or adverse event should occur, you must immediately notify the IRB by email at researchreview@ucmo.edu and call (660) 543-8562.

Step 12: Submit Application

Go to ucmo.edu/osp and, in the left menu, select *Forms & Resources*.

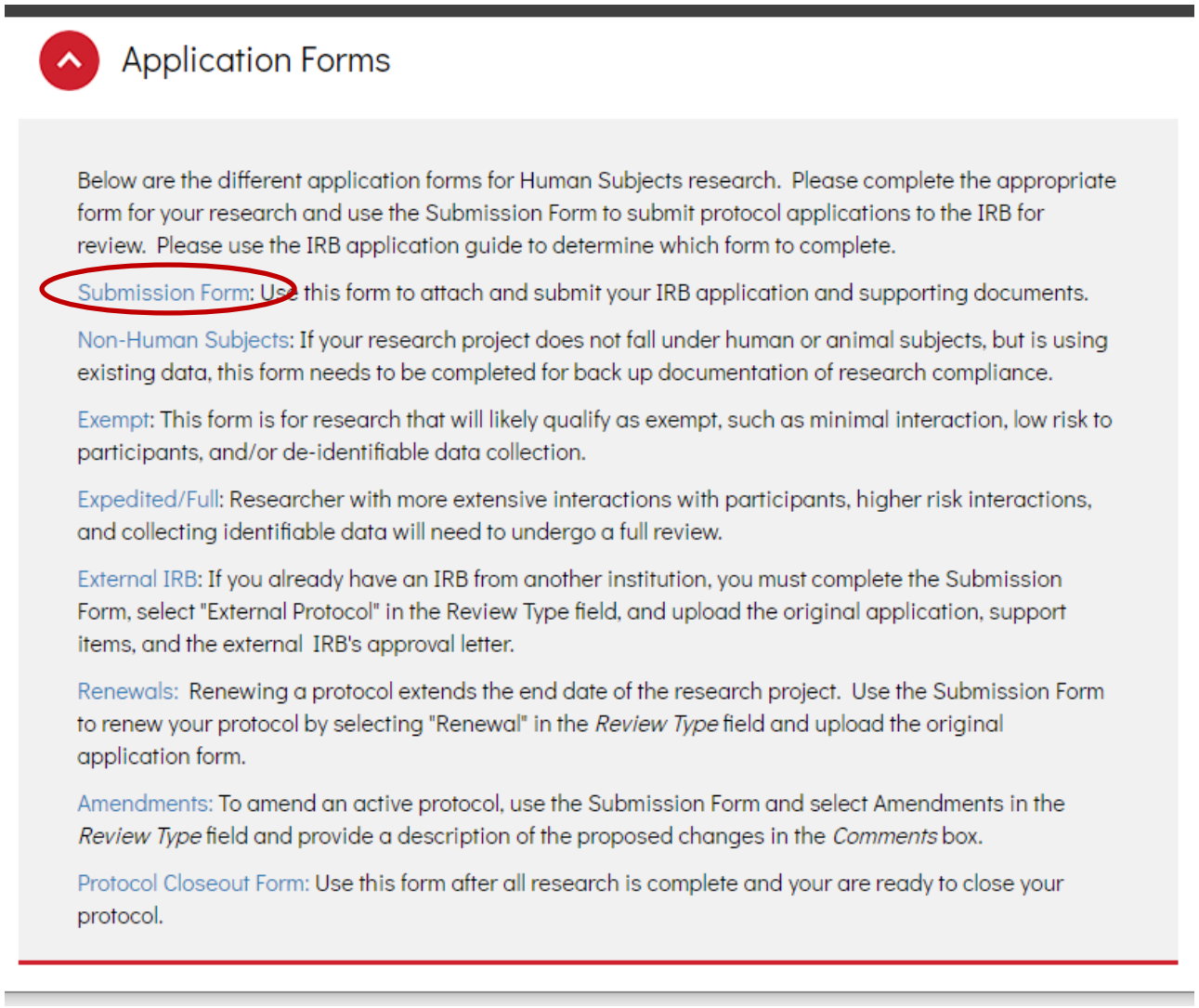
Step 13: Submit Application

Select the “Application Forms” dropdown to view all eligible forms.



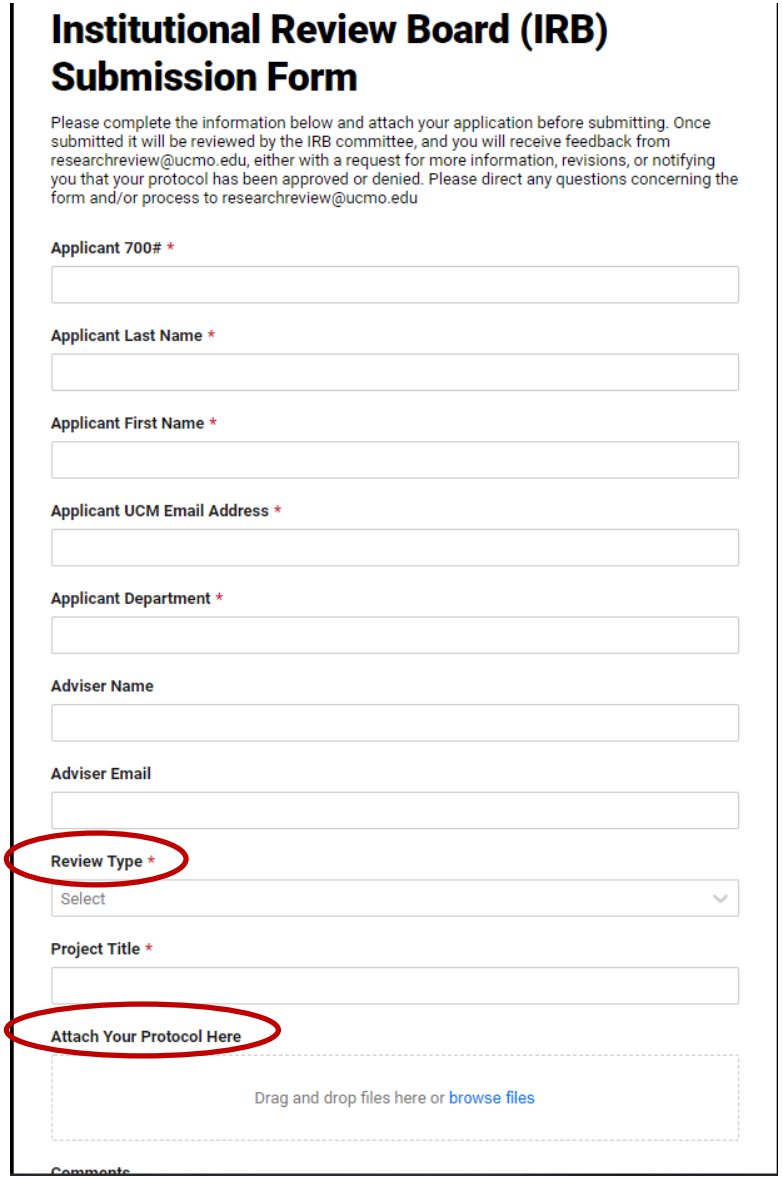
Step 14: Submit Application

Select the “Submission Form” to upload your application.



Step 15: Submit Application

Complete the required fields, select the appropriate “Review Type” and drag and drop or click “Browse Files” to upload the application and all supporting documents to the *Submission Form*.



Institutional Review Board (IRB) Submission Form

Please complete the information below and attach your application before submitting. Once submitted it will be reviewed by the IRB committee, and you will receive feedback from researchreview@ucmo.edu, either with a request for more information, revisions, or notifying you that your protocol has been approved or denied. Please direct any questions concerning the form and/or process to researchreview@ucmo.edu

Applicant 700# *

Applicant Last Name *

Applicant First Name *

Applicant UCM Email Address *

Applicant Department *

Adviser Name

Adviser Email

Review Type *

Select

Project Title *

Attach Your Protocol Here

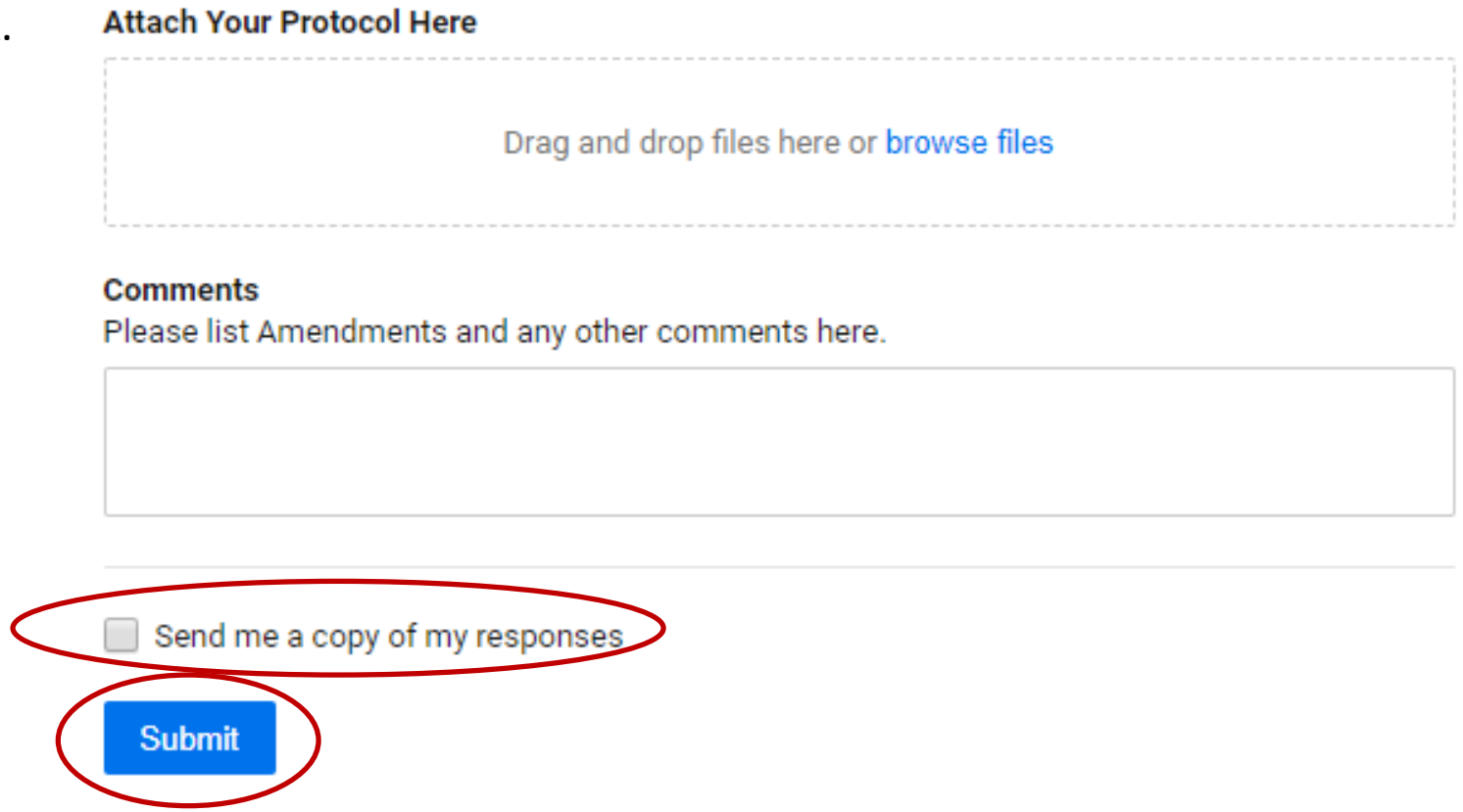
Drag and drop files here or browse files

Comments

Step 16: Submit Application

Review all information on the Submission Form and make sure all required support documents are uploaded.

Once you have confirmed that everything is correct, you may click the Submit button. Please note, if you would like a courtesy email of your submission, you must click the box.



CITI Training

- OSPRI pays for the CITI institutional license, so it is **free** for all UCM employees and students.
- Before your protocol application can be approved by IRB, you must complete the Responsible Conduct of Research (RCR) module of CITI training.
- Although it requires moderate response effort, it is paramount that you understand the material presented in the training
- The next slide explains how to access the training

Getting Access to CITI Training

The following are basic learner login instructions for first time use of the CITI site.

- Researchers need to go to www.citiprogram.org to register for CITI online training.
- Once there, click on “Register” button in the upper right corner
- Under “Select Your Organization Affiliation,” type in University of Central Missouri
- Check that you agree to the terms and check to affirm that you are affiliated with UCM before clicking the “Continue to Create Your CITI Program Username/Password” button.
- Create a unique username and password and select the learner group.
- After going through registration, you should be ready to complete training modules.
- Please contact citisupport@med.miami.edu in should you have any issues registering.

Quick Tips

- Acquire a faculty advisor from the start
- Work in conjunction with your advisor through every step of this process
- Conduct a basic literature review before submission
- The Office of Sponsored Programs and Research Integrity will be your point of contact for this process
- Plan on 2-4 weeks wait time for approval
- Check your employee or student email frequently for IRB communications

Contacts

Office of Sponsored Programs & Research Integrity
Administration Building, Suite 102

For questions regarding the application process, please email**: researchreview@ucmo.edu**

Program Administrator and Research Compliance Officer: **Kathy Schnakenberg**
Phone: **660-543-8562**
E-mail: **schnakenberg@ucmo.edu**