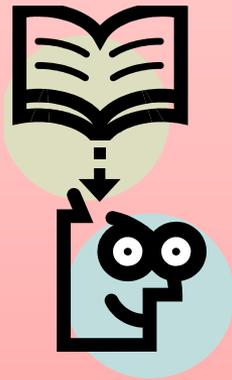


# University of Central Missouri Institutional Review Board 101



# What is it?

## An Institutional Review Board (IRB):

- Examines all research proposals dealing with human subjects;
- 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.

# IMPORTANT

The next slide is sooooooooooooo important.

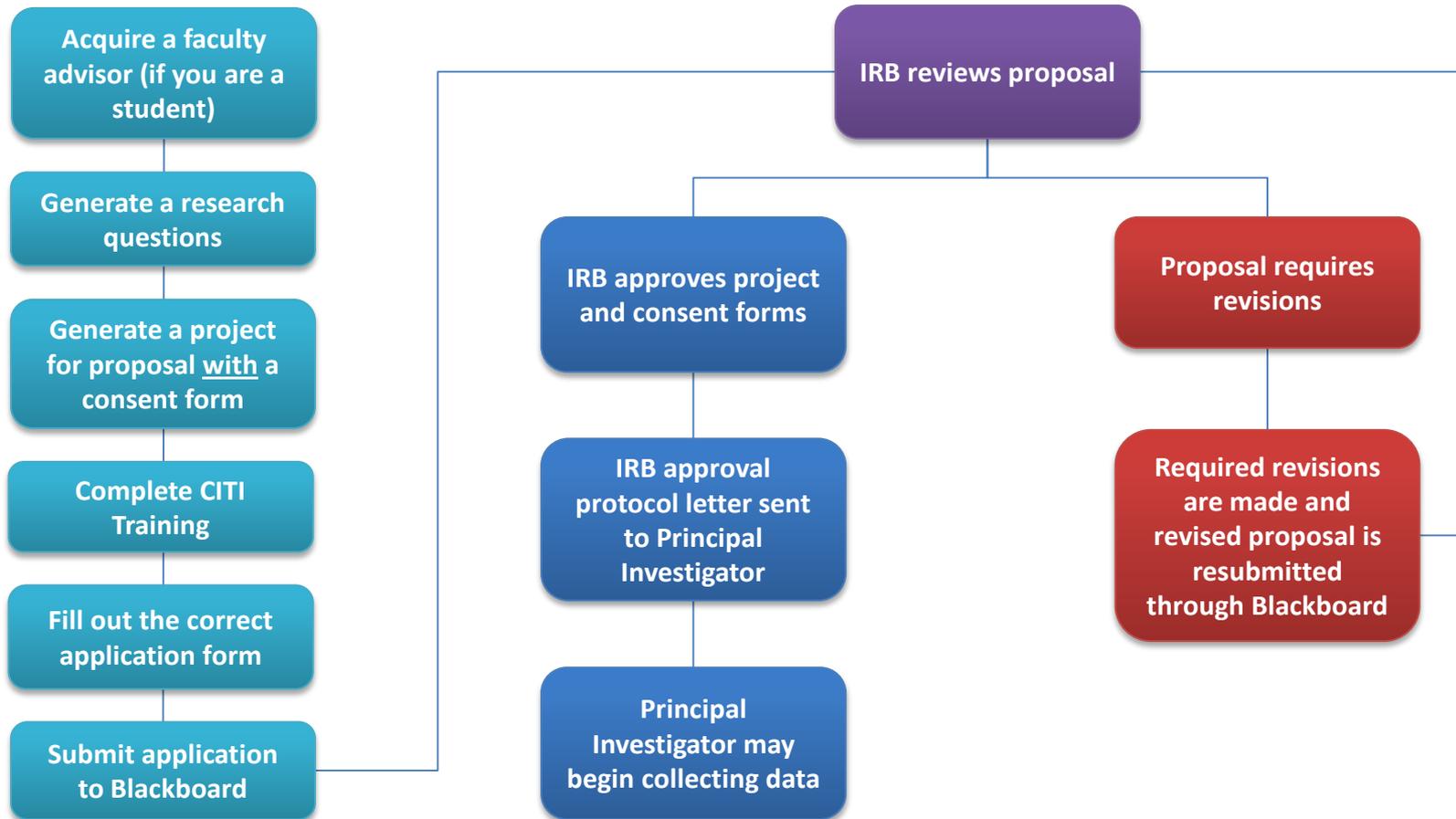
- If it is found that you collected data BEFORE being approved by the IRB, **the IRB will immediately terminate your project and confiscate all data.**



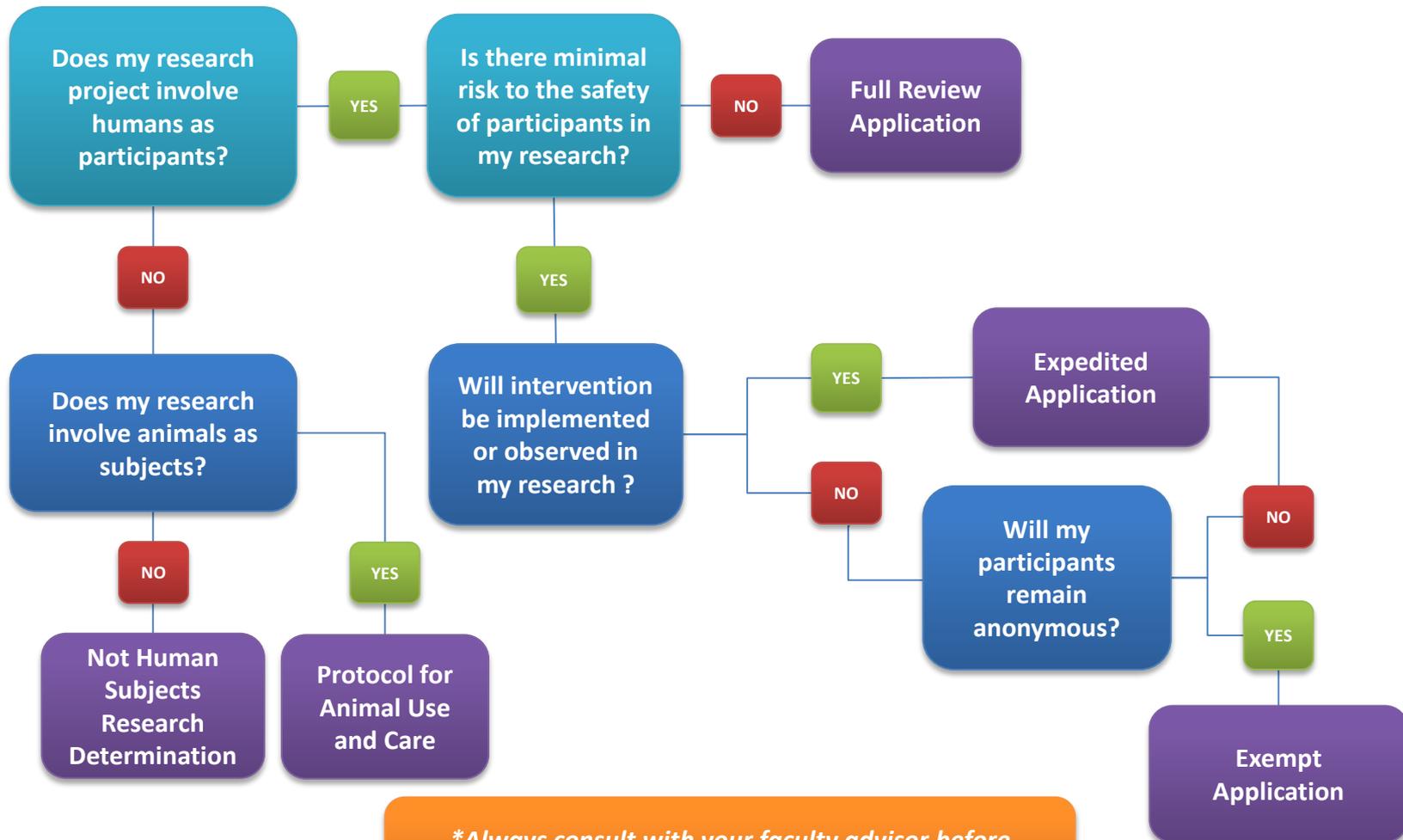
# Who sits on an IRB?

- An IRB consists of representatives from the community, medical professionals, professors from various departments, a student representative, and representatives from the Office of Sponsored Programs and Research Integrity.

# What is the process?



# Which application do I use?



*\*Always consult with your faculty advisor before choosing and submitting an application for review.*

The next section will show you  
how to enroll on Blackboard.

# Enrolling on Blackboard

1. Go to the UCMO Blackboard login page and log in

The screenshot shows the Blackboard login interface for the University of Central Missouri. At the top, the university logo and name are on the left, and the word "BLACKBOARD" with the code "app003" is on the right. The main content area is divided into several sections:

- Blackboard Login:** A red header section containing a welcome message, instructions to enter a network username and password, and a "Login" button. It also includes a "Forgot Your Password?" link and a "Create Your Blackboard Profile" section with links to new features and SIS integration.
- Links:** A red header section with "Quick Links" such as Username/Password, Logging In, Blackboard Tests, Uploading Documents, Browser Check, Internet Speed Test, Create Blackboard Profile, and Plagiarism Help. It also lists "UCM DMCA Agent" and "UCM Home".
- Compatibility Check:** A red header section showing system requirements. It features three icons: a yellow warning icon for "Browser: Chrome 56.0 Platform: Windows 7 64-bit", a green checkmark for "Java Script", and another green checkmark for "Cookies". A link to the full "Browser Check" is provided.
- UCM Technology Support:** A red header section with the "TSC" logo (Technology Support Center), contact information (Phone: (660) 543-4357, Hours: 24/7, email: tsc@ucmo.edu), and links for "Bb Self Help", "Faculty Help", and "Student Help".
- Blackboard Student:** A red header section featuring a pencil icon, a badge for "Available on the App Store", and a badge for "ANDROID APP ON Google play".

# Enrolling on Blackboard

## 2. Click on “My Community”

The screenshot displays the Blackboard user interface. At the top, a navigation bar contains three tabs: 'My Learning', 'My Community', and 'Browser Check'. The 'My Community' tab is highlighted with a red circle. Below the navigation bar, there is a 'Personalize Page' button with a dropdown arrow. The main content area is divided into four sections:

- My Announcements:** A red header with a dropdown arrow. The content area shows two lines of text: "No Institution Announcements have been posted in the last 7 days." and "No Course or Organization Announcements have been posted in the last 7 days." A "more announcements..." button is located at the bottom right of this section.
- My Courses:** A red header with a dropdown arrow. The content area displays the message: "You are not currently enrolled in any courses."
- Courses: Quick View:** A red header with a dropdown arrow. The content area displays the message: "You are not currently participating in any courses."
- My Tasks:** A red header with a dropdown arrow. The content area shows "My Tasks:" followed by "No tasks due." and a "more tasks..." button at the bottom right.

# Enrolling on Blackboard

## 3. Click on “Browse Organization Catalog”

The screenshot displays the Blackboard user interface with a top navigation bar containing 'Add Module' and 'Personalize Page' buttons. The main content area is divided into several sections:

- Organization Search:** A search box with a 'Go' button.
- My Organizations:** A section titled 'Organizations where you are: Participant' listing 'Human Subjects Committee'.
- Organization Catalog:** A section containing a folder icon for 'Student Support' and a link for 'Browse Organization Catalog', which is circled in green.
- Institution Discussion Boards:** A section stating 'No Discussion Boards have been selected for display.'
- Discussion Board Creation:** A section with the text 'Request the creation of an institution discussion board. Click here to send a request email.'

# Enrolling on Blackboard

4. Type “human subjects” in the space provided and click “Go”

Organization Catalog |

### Browse Organization Catalog

Search Catalog Organization  Contains  AND Creation Date

**Browse Categories**  
*Select a category to see only courses belonging to that category*

# Enrolling on Blackboard

## 5. You will see this screen

### Browse Organization Catalog

Search Catalog Organization Name ▾ Contains ▾ human subjects AND Creation Date Before ▾ 03/28/2017  Go

#### Browse Categories

Select a category to see only courses belonging to that category

--unspecified category-- ▾ Go

Organization ID ▲	Organization Name	Leader Names	Description	Textbooks
60HumanSubjectsCommittee1204	Human Subjects Committee			

Displaying 1 to 1 of 1 items [Show All](#) [Edit Paging...](#)

# Enrolling on Blackboard

6. Click the drop down arrow that appears when the mouse hovers over “60HumanSubjectsCommittee1204”

Organization Catalog | ?

### Browse Organization Catalog

Search Catalog Organization Name  AND Creation Date Before

Browse Categories  
Select a category to see only courses belonging to that category

Organization ID ▲	Organization Name	Leader Names	Description	Textbooks
60HumanSubjectsCommittee1204	Human Subjects Committee			

Displaying 1 to 1 of 1 items |

# Enrolling in Blackboard

## 7. Click “Enroll”

Organization Catalog | 

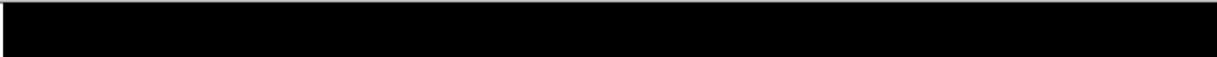
### Browse Organization Catalog

Search Catalog Organization Name ▾ Contains ▾ human subjects AND Creation Date Before ▾ 03/28/2017  Go

### Browse Categories

Select a category to see only courses belonging to that category

--unspecified category-- ▾ Go

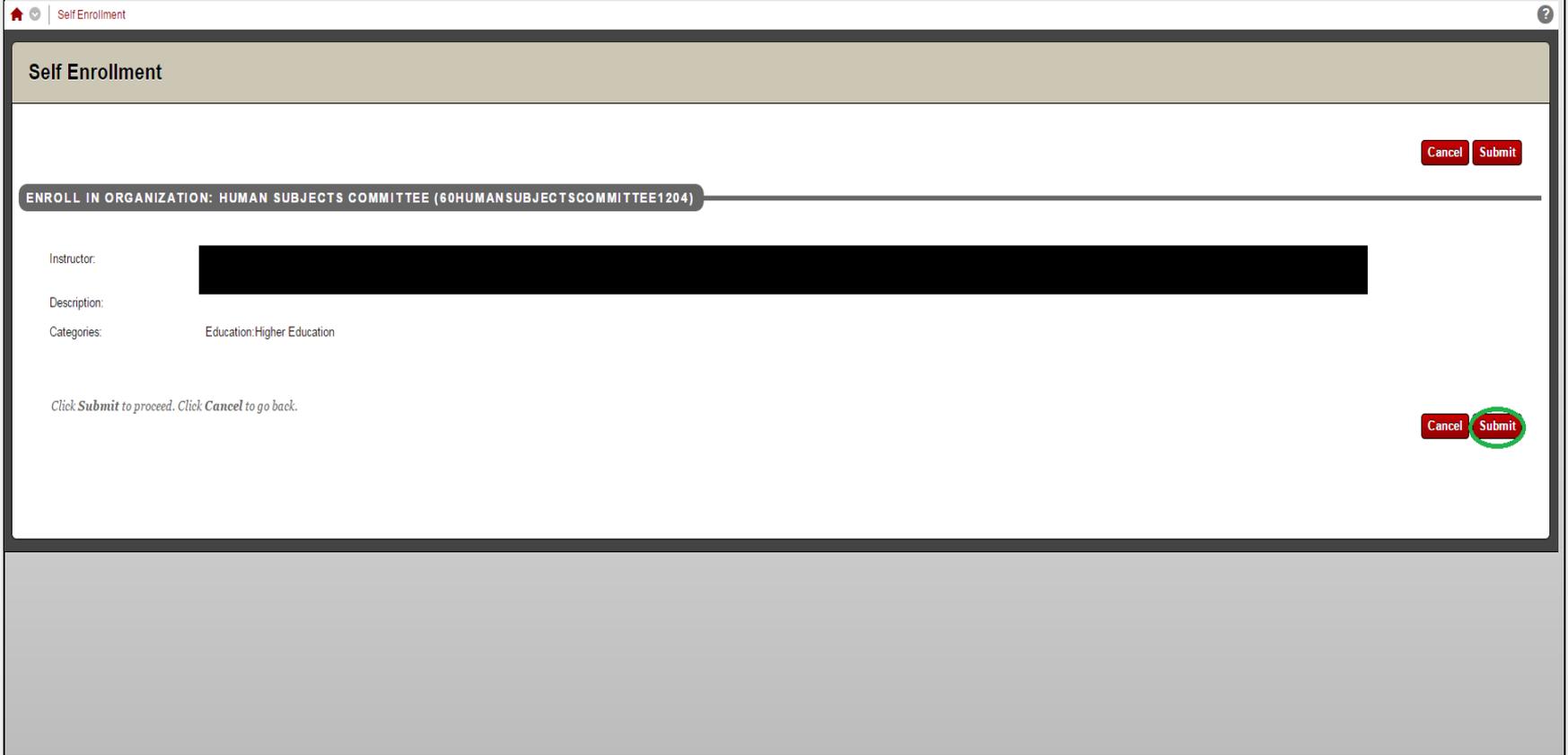
Organization ID ▲	Organization Name	Leader Names	Description	Textbooks
60HumanSubjectsCommittee1204	Human Subjects Committee			

Displaying 1 to 1 of 1 items | [Show All](#) [Edit Paging...](#)

 Enroll

# Enrolling on Blackboard

## 8. Click “Submit”



The screenshot shows the Blackboard Self Enrollment interface. At the top, there is a navigation bar with a home icon, a user icon, and the text "Self Enrollment". Below this is a header section titled "Self Enrollment". The main content area features a progress bar with the text "ENROLL IN ORGANIZATION: HUMAN SUBJECTS COMMITTEE (60HUMANSUBJECTSCOMMITTEE1204)". Below the progress bar, there are fields for "Instructor:" (redacted with a black bar), "Description:" (empty), and "Categories:" (Education: Higher Education). At the bottom left, there is a note: "Click **Submit** to proceed. Click **Cancel** to go back." At the bottom right, there are two buttons: "Cancel" and "Submit". The "Submit" button is highlighted with a green circle, indicating it is the next step in the process.

You are now enrolled.

In the next section you will learn  
how to fill out an application

# Filling out an Application

Since the Not Human Subjects, Exempt, Expedited, and Full Review applications all have similar requirements, the following example will be an Expedited application.

# Filling out an Application

1. After logging in to your UCMO Blackboard account, click on “My Community”. You will see this screen. Click on “Human Subjects Committee”

The screenshot displays the Blackboard 'My Community' interface. At the top, there is a navigation bar with 'Add Module' on the left and 'Personalize Page' with a list icon on the right. Below this, the page is organized into several modules:

- Organization Search:** A search box with a 'Go' button.
- My Organizations:** A section titled 'Organizations where you are: Participant' containing a link to 'Human Subjects Committee', which is circled in green.
- Organization Catalog:** A section containing a 'Student Support' folder icon and a 'Browse Organization Catalog' link.
- Institution Discussion Boards:** A section with the message 'No Discussion Boards have been selected for display.'
- Discussion Board Creation:** A section with the text 'Request the creation of an institution discussion board. Click here to send a request email.'

# Filling out an Application

## 2. Click on “Applications”

The screenshot displays the 'Organization Home' dashboard for the Human Subjects Committee. On the left, a vertical navigation menu lists several options: Organization Home, Applications (highlighted with a green circle), Revisions, Amendments and Renewals, Final/Renewal Report (Project Status), Satisfaction Survey, IRB Training Information, Tools, and Bb Help. The main content area is titled 'Organization Home' and features three primary sections: 'My Announcements', 'My Tasks', and 'What's New'. The 'My Announcements' section shows a message: 'No Course or Organization Announcements have been posted in the last 7 days.' with a 'more announcements...' link. The 'My Tasks' section shows 'My Tasks:' and 'No tasks due.' with a 'more tasks...' link. The 'What's New' section displays a notification card with a user profile icon, 'Edit Notification Settings', and 'Actions' buttons, and the text 'No Notifications'. Below this, a 'Needs Attention' section also shows a notification card with 'No Notifications'. Both notification cards indicate they were last updated on March 27, 2017 at 12:28 PM.

# Filling out an Application

## 3. Click “Expedited-Full Review Application (2).docx”

Applications

**Application Instructions**

All researchers begin by selecting the type of review and submitting their application and all supporting documents. Please submit all forms in one submission.

Please save all files with your last name in the beginning (ex. Doe\_application, Doe\_consent etc.)

CITI training will be entered in the grade book when we receive notification that you have passed.

Upon completion of the review and CITI training you will receive an email regarding the application status.

Official letters and date stamped consents/assents will be sent to the PI's email address.

If you have any questions please email [researchreview@ucmo.edu](mailto:researchreview@ucmo.edu) or Kathy Schnakenberg at [schnakenberg@ucmo.edu](mailto:schnakenberg@ucmo.edu)

**Not human subject determination**

Attached Files: [Final Not HS determination 2015.docx](#) (80.974 KB)

Submit your Not Human Subjects Determination application here.

Please attach all attachments on one submission.

**Exempt application**

Attached Files: [Exempt Application.docx](#) (177.155 KB)

Exempt research is where the subjects are usually anonymous, no intervention and minimal risk. Attach materials including surveys, consent, letters of permission and recruitment wording.

**Note: Please combine all documents into one attachment**

**Expedited application**

Attached Files: [Expedited-Full Review Application \(2\).docx](#) (83.63 KB)

These are typically for research which has identifiable information, an intervention and minimal risk. Attach materials including surveys, consent, letters of permission and recruitment wording.

**Note: Please combine all documents into one attachment**

[https://ucmo.blackboard.com/webapps/blackboard/content/listContent.jsp?course\\_id=\\_83449\\_1&content\\_id=\\_3013221\\_1&mode=reset](https://ucmo.blackboard.com/webapps/blackboard/content/listContent.jsp?course_id=_83449_1&content_id=_3013221_1&mode=reset)

# Filling out an Application

## 4. You will open this Word document...

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

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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Women of Childbearing Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Institutionalized Persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cognitively Impaired Persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Income	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethnic/Racial Minority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**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 (j) 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<sup>2</sup> 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) uncanalated 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**

Page: 1 of 9 | Words: 2,839 | English (U.S.) | 100%

# Filling out an Application (Section A)

## 5. Complete “Section A: General Information”

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

# Filling out an Application (Check Boxes)

**6. Check the 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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Women of Childbearing Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Institutionalized Persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cognitively Impaired Persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Income	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethnic/Racial Minority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Elderly (over age 65)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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.

# Filling out an Application (Section B)

## 7. 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

#### 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<sup>2</sup> 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) unannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base 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

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.

# Filling out an Application (Section C)

## 8. Complete “Section C: Project Details”.

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?	<input type="checkbox"/> YES <input type="checkbox"/> NO
IF YES:	
i. <u>Is there a completed FCOI on record with the Office of Sponsored Programs?</u>	<input type="checkbox"/> YES <input type="checkbox"/> 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. <u>Copy of Grant Application or Project Summary is Attached</u>	<input type="checkbox"/> YES <input type="checkbox"/> NO

*Continued...*

# Filling out an Application (Section C continued)

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.	
<input type="checkbox"/> Recruitment Scripts	<input type="checkbox"/> Letter/Cover Letter
<input type="checkbox"/> Flyers	<input type="checkbox"/> Advertisements
<input type="checkbox"/> Recruitment Emails	<input type="checkbox"/> Other: Click or tap here to enter text.
11. Will you be directly emailing or mailing participants?	<input type="checkbox"/> NO <input type="checkbox"/> 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?	<input type="checkbox"/> NO <input type="checkbox"/> 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.	
<input type="checkbox"/> Questionnaire/Survey	<input type="checkbox"/> Interviews (attach scripts, questions)
<input type="checkbox"/> Observations	<input type="checkbox"/> Existing Data
<input type="checkbox"/> Other: Click or tap here to enter text.	
18. Indicate all biomedical procedures that apply to your research:	
<input type="checkbox"/> Physical Activity	<input type="checkbox"/> Body Mass Index
<input type="checkbox"/> Venipuncture	<input type="checkbox"/> X-rays
<input type="checkbox"/> Magnetic resonance imaging (MRI)	<input type="checkbox"/> Anthropomorphic evaluations
<input type="checkbox"/> Electrocardiograms (EKGs)	<input type="checkbox"/> Intravenous catheter insertion
<input type="checkbox"/> Collection of blood samples by finger stick, heel stick, ear stick or venipuncture	
<input type="checkbox"/> 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.)	<input type="checkbox"/> NO <input type="checkbox"/> 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.	

# Filling out an Application (Section C continued)

INFORMED CONSENT									
<p>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.</p>									
<p><b>23. How will you obtain consent?</b> Describe your <u>process</u> for obtaining informed consent from your participants – include how, when, and where the consent process will take place, and who will collect it.</p> <p>Click or tap here to enter text.</p>									
<p><b>24. Which of the following will you use to present the informed consent? (Attach all.)</b></p> <table border="0"> <tr> <td><input type="checkbox"/> Paper Consent Form</td> <td><input type="checkbox"/> Minor's Assent Form (Must also include Parental Consent)</td> </tr> <tr> <td><input type="checkbox"/> Web-based Consent Form</td> <td><input type="checkbox"/> Parental Consent Form (Must also include Minor's Assent)</td> </tr> <tr> <td><input type="checkbox"/> Cover Letter</td> <td><input type="checkbox"/> Other: Click or tap here to enter text.</td> </tr> <tr> <td><input type="checkbox"/> Verbal Consent Script</td> <td></td> </tr> </table>		<input type="checkbox"/> Paper Consent Form	<input type="checkbox"/> Minor's Assent Form (Must also include Parental Consent)	<input type="checkbox"/> Web-based Consent Form	<input type="checkbox"/> Parental Consent Form (Must also include Minor's Assent)	<input type="checkbox"/> Cover Letter	<input type="checkbox"/> Other: Click or tap here to enter text.	<input type="checkbox"/> Verbal Consent Script	
<input type="checkbox"/> Paper Consent Form	<input type="checkbox"/> Minor's Assent Form (Must also include Parental Consent)								
<input type="checkbox"/> Web-based Consent Form	<input type="checkbox"/> Parental Consent Form (Must also include Minor's Assent)								
<input type="checkbox"/> Cover Letter	<input type="checkbox"/> Other: Click or tap here to enter text.								
<input type="checkbox"/> Verbal Consent Script									
<p><b>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?</b></p> <table border="0"> <tr> <td><input type="checkbox"/> Before - During Consent</td> </tr> <tr> <td><input type="checkbox"/> After - During Debriefing</td> </tr> </table>		<input type="checkbox"/> Before - During Consent	<input type="checkbox"/> After - During Debriefing						
<input type="checkbox"/> Before - During Consent									
<input type="checkbox"/> After - During Debriefing									
<p><b>26. Will non-English-speakers be included in your study?</b> <input type="checkbox"/> NO <input type="checkbox"/> YES</p> <p><i>IF YES, include translated versions of your consent documents.</i></p>									



PARTICIPANT PRIVACY & CONFIDENTIALITY	
<p><b>27. Describe any procedures you will use to protect the privacy of your participants during data collection.</b> (E.g., participants will complete surveys in the privacy of their own homes; interviews will be performed at a location of their choosing, etc.)</p> <p>Click or tap here to enter text.</p>	
<p><b>28. During data collection, will you collect or have access to identifiable information about your participants?</b></p> <p><input type="checkbox"/> NO – Data collection will be <u>anonymous</u> (The investigators will not collect or have access to identifiable information about the study's participants)</p> <p><input type="checkbox"/> YES – Data collect will be <u>confidential</u> (The investigators will collect or have access to identifiable information about the study's participants)</p>	
<p><b>29. How will you handle identifiable information?</b></p> <p><input type="checkbox"/> Identifiable information will not be collected</p> <p><input type="checkbox"/> Identifiable information will be coded and investigators <u>will not</u> have access to a code key</p>	

<p><input type="checkbox"/> Identifiable information will be coded and investigators <u>will</u> have access to a code key</p> <p><input type="checkbox"/> Identifiable information will be collected and will be de-identified for analyses</p> <p><input type="checkbox"/> Identifiable data will be collected and will remain identifiable for analyses</p>
<p><b>30. How will the collected data be secured?</b></p> <p><input type="checkbox"/> Locked in a cabinet or office</p> <p><input type="checkbox"/> Password protected PC, hard disk drive, or other secure electronic storage</p> <p><input type="checkbox"/> Encrypted online or cloud storage</p> <p><input type="checkbox"/> All data will be destroyed (shredded/deleted/etc.) after use</p> <p><input type="checkbox"/> Other: Click or tap here to enter text.</p>
<p><b>31. Who will have access to the data?</b></p> <p>Click or tap here to enter text.</p>

# Filling out an Application (Section D)

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

### 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 Office 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**

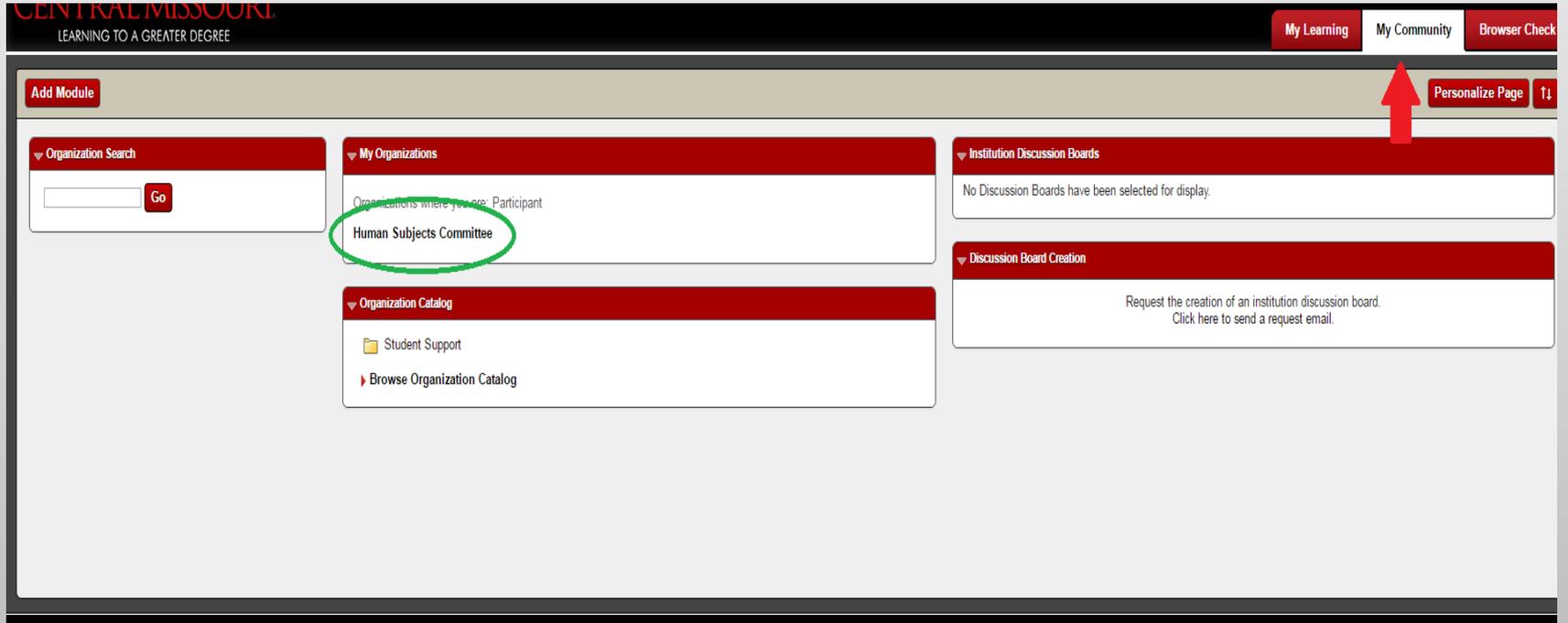
**Principal Investigator (Print Name):** Click or tap here to enter text. **Date:** Click or tap to enter a date.

**If an unanticipated problem or adverse event should occur, you must immediately complete and submit the IRB Incident Report Form to [ResearchReview@ucmo.edu](mailto:ResearchReview@ucmo.edu), and contact 660 542 8562.**

Now you will learn how to submit an  
Expedited Application for review on  
Blackboard

# Submitting an Application

1. Log in to your UCMO Blackboard account. Access the “Human Subjects Committee” through “My Community”.



The screenshot displays the Blackboard user interface for Central Missouri State University. At the top, the header includes the university name and logo, the tagline "LEARNING TO A GREATER DEGREE", and navigation tabs for "My Learning", "My Community", and "Browser Check". Below the header is a navigation bar with an "Add Module" button and a "Personalize Page" button with a red arrow pointing to it. The main content area is divided into several sections:

- Organization Search:** A search box with a "Go" button.
- My Organizations:** A section titled "My Organizations" with a dropdown arrow. It lists "Organizations where you are: Participant" and "Human Subjects Committee", which is circled in green.
- Organization Catalog:** A section titled "Organization Catalog" with a dropdown arrow. It contains a folder icon for "Student Support" and a link for "Browse Organization Catalog".
- Institution Discussion Boards:** A section titled "Institution Discussion Boards" with a dropdown arrow. It contains the text "No Discussion Boards have been selected for display."
- Discussion Board Creation:** A section titled "Discussion Board Creation" with a dropdown arrow. It contains the text "Request the creation of an institution discussion board. Click here to send a request email."

# Submitting an Application

## 2. Click on “Applications”

The screenshot displays the 'Organization Home' page of the Human Subjects Committee. On the left sidebar, the 'Applications' menu item is highlighted with a green circle. The main content area is divided into four sections: 'My Announcements', 'My Tasks', 'What's New', and 'Needs Attention'. Each section shows 'No [category] have been posted in the last 7 days.' and includes a 'more [category]...' link. The 'What's New' and 'Needs Attention' sections also show 'No Notifications' and 'Last Updated: March 27, 2017 12:28 PM'.

**Organization Home**

Human Subjects Committee

- Organization Home
- Applications**
- Revisions
- Amendments and Renewals
- Final/Renewal Report (Project Status)
- Satisfaction Survey
- IRB Training Information
- Tools
- Bb Help

**My Announcements**

No Course or Organization Announcements have been posted in the last 7 days.

[more announcements...](#)

**My Tasks**

My Tasks:

No tasks due.

[more tasks...](#)

**What's New**

 [Edit Notification Settings](#) [Actions](#)

No Notifications

Last Updated: March 27, 2017 12:28 PM

**Needs Attention**

 [Edit Notification Settings](#) [Actions](#)

No Notifications

Last Updated: March 27, 2017 12:28 PM

# Submitting an Application

## 3. Click “Expedited Application”

**Human Subjects Committee**

- Organization Home
- Applications**
- Revisions
- Amendments and Renewals
- Final/Renewal Report (Project Status)
- Satisfaction Survey
- IRB Training Information
- Tools
- Bb Help

### Applications

**Application Instructions**  
All researchers begin by selecting the type of review and submitting their application and all supporting documents. Please submit all forms in one submission.  
**Please save all files with your last name in the beginning (ex. Doe\_application, Doe\_consent etc.)**

CITI training will be entered in the grade book when we receive notification that you have passed.  
Upon completion of the review and CITI training you will receive an email regarding the application status.  
Official letters and date stamped consents/assents will be sent to the PI's email address.  
If you have any questions please email [researchreview@ucmo.edu](mailto:researchreview@ucmo.edu) or Kathy Schnakenberg at [schnakenberg@ucmo.edu](mailto:schnakenberg@ucmo.edu)

---

**Not human subject determination**  
Attached Files: [Final Not HS determination 2015.docx](#) (60.974 KB)  
Submit your Not Human Subjects Determination application here.  
**Please attach all attachments on one submission.**

---

**Exempt application**  
Attached Files: [Exempt Application.docx](#) (177.155 KB)  
Exempt research is where the subjects are usually anonymous, no intervention and minimal risk. Attach materials including surveys, consent, letters of permission and recruitment wording.  
**Note: Please combine all documents into one attachment**

---

**Expedited application**  
Attached Files: [Expedited-Full Review Application \(2\).docx](#) (183.63 KB)  
These are typically for research which has identifiable information, an intervention and minimal risk. Attach materials including surveys, consent, letters of permission and recruitment wording.  
**Note: Please combine all documents into one attachment**

# Submitting an Application

4. Click on “Browse Computer” and select your application file.

Human Subjects Committee

- Organization Home
- Applications
- Revisions
- Amendments and Renewals
- Final/Renewal Report (Project Status)
- Satisfaction Survey
- IRB Training Information
- Tools
- Bb Help

## Upload Assignment: Expedited application

Cancel Save Draft Submit

### ASSIGNMENT INFORMATION

Points Possible  
4  
View Rubric

These are typically for research which has identifiable information, an intervention and minimal risk. Attach materials including surveys, consent, letters of permission and recruitment wording.

**Note: Please combine all documents into one attachment**  
[Expedited-Full Review Application \(2\).docx](#)

### ASSIGNMENT SUBMISSION

Text Submission Write Submission

Attach File Browse My Computer Browse Content Collection

### ADD COMMENTS

Comments

# Submitting an Application

## 5. Click “Submit”

The screenshot shows a web application interface for submitting an application. On the left is a vertical sidebar with navigation buttons: Organization Home, Applications, Revisions, Amendments and Renewals, Final/Renewal Report (Project Status), Satisfaction Survey, IRB Training Information, Tools, and Bd Help. The main content area is divided into three sections:

- ASSIGNMENT INFORMATION:** Shows 'Points Possible' as 4 with a 'View Rubric' button. Below is a note: 'These are typically for research which has identifiable information, an intervention and minimal risk. Attach materials including surveys, consent, letters of permission and recruitment wording.' A note below that says: 'Note: Please combine all documents into one attachment' followed by a link: 'Expedited-Full Review Application (2).docx'. At the top right of this section are buttons for 'Cancel', 'Save Draft', and 'Submit' (highlighted with a green circle).
- ASSIGNMENT SUBMISSION:** Contains two rows of options. The first row has 'Text Submission' and a 'Write Submission' button. The second row has 'Attach File' and two buttons: 'Browse My Computer' and 'Browse Content Collection'.
- ADD COMMENTS:** Features a 'Comments' section with a dropdown menu (set to 'All') and a large text input area. A 'Character count 0' indicator is at the bottom right of the input area.

At the bottom of the page, a note reads: 'When finished, make sure to click **Submit**. Optionally, click **Save as Draft** to save changes and continue working later, or click **Cancel** to quit without saving changes.' To the right of this note are buttons for 'Cancel', 'Save Draft', and 'Submit' (highlighted with a green circle).

# CITI Training

- Before your proposal can be formally approved, you must complete CITI training.
- Although it requires moderate response effort, it is paramount that you understand the material presented in the training
- The next slide will show you how to access the training

# CITI Training

The UCM Human Subjects/Animal Use Programs will be instituting a responsible conduct of research (RCR) training requirement which will apply to all new proposals submitted for Human Subjects or Animal Use review on or after August 16, 2011. This training requirement will be provided online through the Collaborative Institutional Training Initiative Web-based Training Program (CITI Program).

We are offering several RCR programs including social and behavioral, physical science, or the humanities. There is also an advanced program for research administrators. Select one program most appropriate for your research. These programs have 10 modules which take between 2-4 hours to complete. The programs are flexible and allow one to log in and out at any time saving previous work. **Make a copy of your training certificate when completed and submit with your Human Subjects/Animal Use application.**



*The following are basic learner instructions to logon to your CITI site for the first time:*

*User should be instructed to go to [www.citiprogram.org](http://www.citiprogram.org) to register for CITI online training.*

*Once there, they simply click on "New Users Register Here".*

*Under "Select your institution or organization" page they should select UCM in the "Participating Institutions" drop down box.*

*Next they should proceed to create their own username and password and select the Learner group.*

*After going through registration process they should be ready and setup as CITI Learners.*

*Please contact [citisupport@med.miami.edu](mailto:citisupport@med.miami.edu) in case of any question.*

**THIS IS ALL FREE.  
FOR YOU.  
NO CHARGE.**

# Quick Tips

- Acquire a faculty advisor
- Work in conjunction with your advisor for every step of this process
- Conduct a 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 e-mail frequently for IRB communications

# Contacts

For questions regarding the application process: **[researchreview@ucmo.edu](mailto:researchreview@ucmo.edu)**

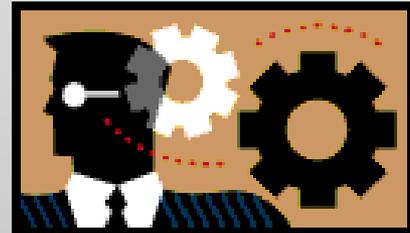
Program Administrator and Research Compliance Officer: **Kathy Schnakenberg**

Phone: **660-543-8562**

E-mail: **[schnakenberg@ucmo.edu](mailto:schnakenberg@ucmo.edu)**

# References

UCM Human Subjects Review Committee. (2014, November 20). Retrieved from  
<https://www.ucmo.edu/graduate/human/>



# Presentation Created by:

Sawyer Harmon

Research Review Student Worker

Office of Sponsored Programs and Research Integrity

University of Central Missouri

March 2017

# *Acknowledgements*

Kathy Schnakenberg

Sarah Craig