

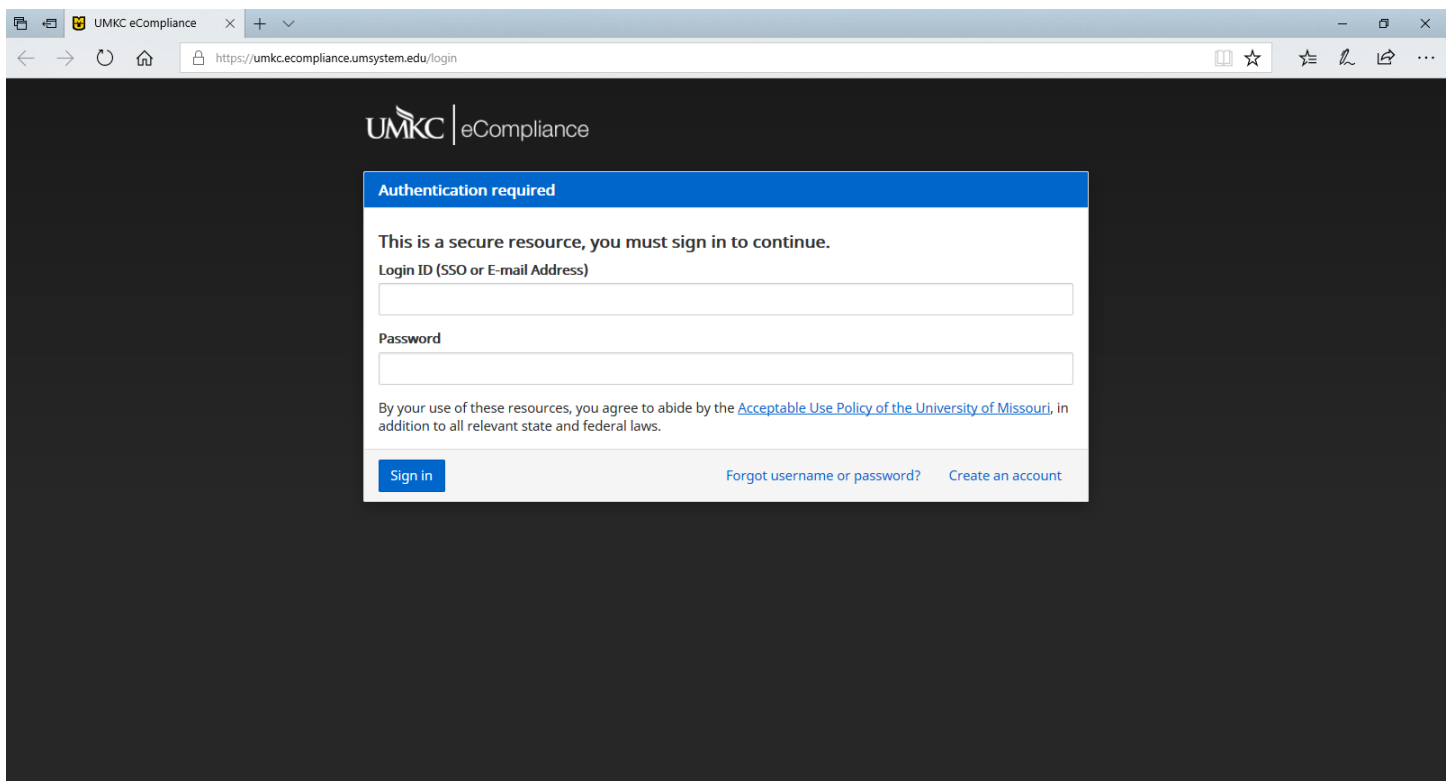
eCompliance: IRB Forms Quick User Guide University of Missouri-Kansas City

This user guide was created to help navigate the eCompliance System:

- ❖ There is one IRB application to cover exempt, expedited, and full board studies.
- ❖ The IRB application is more encompassing to cover regulatory and institutional requirements.

1. Login to eCompliance using your UMKC SSO and Password

URL: <https://umkc.ecompliance.umssystem.edu/login>



The screenshot displays a web browser window with the following elements:

- Browser tab: UMKC eCompliance
- Address bar: <https://umkc.ecompliance.umssystem.edu/login>
- Page header: UMKC | eCompliance
- Section: Authentication required
- Message: This is a secure resource, you must sign in to continue.
- Form fields: Login ID (SSO or E-mail Address) and Password
- Text: By your use of these resources, you agree to abide by the [Acceptable Use Policy of the University of Missouri](#), in addition to all relevant state and federal laws.
- Buttons: Sign in, Forgot username or password?, Create an account

2. Select the Institutional Review Board tab.

The screenshot shows the UMKC eCompliance website interface. At the top, there is a navigation bar with the UMKC logo, 'eCompliance' text, and several utility icons (notifications, IRB, Users, Admin). A search bar and 'Help' and 'My account' links are also present. Below the navigation bar is a blue banner with the text 'Welcome to UMKC eCompliance'. The main content area is divided into two sections: 'My modules' and 'All modules'. The 'My modules' section contains a list of links: 'Institutional Review Board' (with a sub-link for 'IRB Administration'), 'Project search', 'Stages', and 'Reports'. The 'All modules' section features three large blue buttons: 'Conflict of Interest', 'Institutional Review Board', and 'Lobbying Activities'. A large red arrow points upwards to the 'Institutional Review Board' button. At the bottom right of the page, there is a small copyright notice: 'UMKC eCompliance © 2018 Curators of the University of Missouri. All rights reserved.'

3. Select the primary type of research in which you are involved

The screenshot shows the UMKC eCompliance website interface, specifically the Institutional Review Board (IRB) page. The page title is 'Institutional Review Board' and the breadcrumb trail is 'IRB > Administration > Project search > Stages > Reports'. A modal dialog box is open in the center of the screen, titled 'Primary type of research'. The dialog contains the text 'Please select the primary type of research in which you are involved.' and two buttons: 'Social/Behavioral/Educational' and 'Biomedical'. Below the dialog, there is a notice: 'NOTICE: The UMKC IRB module is under construction. Please do not use unless authorized. If you have questions contact the IRB at umkcirb@umkc.edu. Thank you.' The main content area is divided into three columns of links. The first column is titled 'Prerequisites' and includes links for 'Take IRB training', 'Advisor approval', 'PI assurance', 'My personal information', and 'Upload CV/CITI training certificate'. The second column is titled 'Submission to IRB' and includes links for 'IRB forms', 'Open saved IRB project', 'Document storage', and 'Check project status'. The third column is titled 'View Approved/Archived Projects' and includes links for 'View all my approved IRB projects' and 'View all my uploaded documents'. At the bottom, there are two more sections: 'Reviewer resources' with a link for 'Screening tool' and 'Board meeting documents', and 'Researcher resources'.

4. Select IRB Forms from the eCompliance Dashboard

NOTICE: The UMKC IRB module is under construction. Please do not use unless authorized. If you have questions contact the IRB at umkcirb@umkc.edu. Thank you.

Prerequisites	Submission to IRB	View Approved/Archived Projects
Take IRB training	IRB forms	View all my approved IRB projects
Advisor approval	Open saved IRB project	View all my uploaded documents
PI assurance	Document storage	
My personal information	Check project status	
Upload CV/CITI training certificate		

Reviewer resources

- Screening tool
- Board meeting documents

Researcher resources

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5. Applications:

***Select the application type – there are more specific types of applications than previously available in eProtocol.**

Begin a new IRB form

Applications	Continuing review
<p>IRB Application Complete this form for all exempt, expedited, and full board research projects.</p> <p>IRB Reliance Request Form Complete this form to request to rely on an external IRB after pre-approval has been granted by the IRB office. Please email umkcirb@umkc.edu to start the process.</p> <p>Case Report Form Complete this form for single retrospective case reports of 3 or less individuals.</p> <p>Humanitarian Use Device (HUD) Form Complete this form for Humanitarian Use Device requests.</p>	<p>Annual Exempt Form Complete this form if you wish to renew or close your exempt study.</p> <p>Continuing Review Report Complete this form to submit the required continuing review for your Expedited or Full Board study. *If your activities are limited to data analysis AND all data have been completely de-identified, submit the Completion/Withdrawal Report below instead of completing this form.</p> <p>IRB of Record Continuing Review Complete this form only when UMKC IRB relies on another IRB (Authorization Agreement).</p>
<p>Quality improvement</p> <p>QI Determination Form Complete this form for a determination as to whether the project is Quality Improvement or Research. (This includes quality improvement studies, needs assessments, customer satisfaction surveys, etc.)</p>	<p>Amendments</p> <p>Exempt Amendment Form Complete this form to request changes to an approved Exempt study.</p> <p>Amendment Form Complete this form to request changes to an approved Expedited or Full Board study.</p>
<p>Human subjects research determination</p> <p>Human Subjects Research Determination Form Complete this form if you are questioning whether your project is human subjects research requiring IRB review. You may also contact the IRB office at 816.235.5927 or email umkcirb@umkc.edu.</p>	<p>Required reporting forms</p> <p>Completion/Withdrawal Report [Expedited and Full Board Studies Only] Complete this form if you would like to request for your project to be closed. A project may be closed when the activities are limited to data analysis AND all data have been completely de-identified. For exempt studies, submit the Annual Exempt Form to close your study.</p> <p>Death Report Complete this form to report the death of a locally enrolled participant. Please note, if you have no way of knowing a death occurred, or if an individual dies more than 30 days after s/he has stopped or completed all study procedures/interventions and required follow-up, no reporting is required.</p> <p>Event Report Complete this form to report events, including any deviations (non-compliance) or unanticipated problems (events that are unexpected, related or possibly related to the research, AND suggests the research places subjects or others at a greater risk of harm than was previously known or recognized). This form must be submitted within 5 days of becoming aware of the event.</p> <p>Inclusion/Exclusion Exception</p>

6. Navigating the IRB Application:

- a. The IRB application for exempt, expedited, and full board research starts with 4 sections.

https://umkc.ecompliance.umsystem.edu/my/irb/reviews/243540-irb-application/edit

UMKC | eCompliance

IRB #2013332 KC

IRB Application sections

1. Investigators/Project Title
2. Exempt Determination
3. Attached files
4. Submit

Investigators/Project Title

1. **Key Personnel** - List all investigators engaged in the research by clicking on the "Add an Investigator" button. This includes individuals interacting or intervening with subjects, collecting or accessing identifiable data, or consenting subjects. Please note, if individuals are performing services that are typically performed for non-research purposes, and they are only providing a service for this project, they do not need to be listed.
Principal Investigator Assurance: After you hit submit on this application, the PI will be sent an email from the system requesting the completion of the PI Assurance Form. This application will not officially be submitted to the IRB until this step is complete.
Primary Contact(s): Whoever you would like to be copied on IRB correspondence, including reminders and approvals, please be sure to add them as primary contacts when prompted under the "Add an Investigator" button. There must be at least one primary contact on this application.
Fellows and Residents: Must have a faculty member listed as the principal investigator.
Student-Initiated Projects: Students must list their faculty advisor as Principal Investigator. Students may list themselves as sub-investigator.
Significant Risk. Medical Treatment Study: For activities that require consent to be obtained by a licensed physician outside the scope of

i. Section 1 covers adding investigators and entering the title. See below.

https://umkc.ecompliance.umsystem.edu/my/irb/reviews/243540-irb-application/edit

Apps | eProtocol - University | Research Protection | CITI - Collaborative I | UAT | Office of Laboratory | keyusa - Powered by | Reporting Time Orac | Login - LibraryH3lp V

UMKC | eCompliance | IRB | Users | Admin | Search eCompliance... | Search | Help | My account

IRB Application sections

- 1. Investigators/Project Title
- 2. Exempt Determination
- 3. Attached files
- 4. Submit

2. Contact Information (Read-Only)

Principal investigator

Winders, Christopher R	
Job title	SR DIR PROGRAM/PROJECT OPS
Department	Research Services
Division	Research
Business unit	University of MO-Kansas City

Primary contact

Winders, Christopher R	
Job title	SR DIR PROGRAM/PROJECT OPS
Department	Research Services
Division	Research
Business unit	University of MO-Kansas City

3. Project Title

If the study is externally funded or internally grant funded, this title should match the title on the grant/contract.

FORM INSTRUCTION: As you work through the form, you will be checking boxes that prompt additional questions. If you realize those additional questions do not pertain to your study, go back and uncheck the box that prompted those questions.

i. Section 2 covers the investigator’s determination whether the study is exempt.

Exempt Determination

If you already know that your project is NOT exempt, please check this box to skip this entire section and additional sections will populate. If you are unsure, do not check this box and continue with #1.

IRB #2013332 KC < UMKC eComp x +

https://umkc.ecompliance.umssystem.edu/my/irb/reviews/243540-irb-application/sections/166793/edit

UMKC eCompliance

IRB #2013332 KC

IRB Application sections

1. Investigators/Project Title
2. Exempt Determination
3. Attached Files
4. Submit

Exempt Determination

If you already know that your project is NOT exempt, please check this box to skip this entire section and additional sections will populate. If you are unsure, do not check this box and continue with #1.

1. Does the project fit under any of the following exempt categories? Check the box(es) applicable to your study. A project can fall under more than one category.

[Exempt Exclusions and Limitations](#): To be exempt, the research cannot be FDA regulated, involve prisoners as subjects, or involve deception (defined as deliberately giving false information about some aspect of the research to the subject). Research with [Exempt Guidance/Charity](#) - Click to view. If needed, you may contact the IRB office for guidance (816.235.5927 or umkcirb@umkc.edu).

CATEGORY 1:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- (i) research on regular and special education instructional strategies, or
- (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Clarification: The research can only be conducted in established or commonly accepted educational settings. This includes, but is not limited to, schools and colleges. It may include other sites where educational activities regularly occur.

CATEGORY 2:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.

UNLESS: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND

- (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Clarification: (i) and (ii) mean you CAN have identifiers linked to subjects as long as any disclosures would NOT place them at risk.

Limitation with Children: Children can only be involved if their participation is limited to (1) educational tests or (2) observations of public behavior when the investigator(s) do not participate in the activities being observed.

Educational Tests: These do not have to be administered in an educational setting like category 1.

Survey & Interview Procedures: This is not meant to include activities that will influence or change a participant's social, behavioral, or educational outcomes or abilities. This activity should be limited to completing a survey or an interview/focus group.

Observation of Public Behavior: To be considered public, the subjects would not have an expectation of privacy. It would reasonably be expected that observations or recordings could take place.

CATEGORY 3:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Survey & Interview Procedures: This is not meant to include activities that will influence or change a participant's social, behavioral, or educational outcomes or abilities. This activity should be limited to completing a survey or an interview/focus group.

Observation of Public Behavior: To be considered public, the subjects would not have an expectation of privacy. It would reasonably be expected that observations or recordings could take place.

Elected or Appointed Public Officials: Applies to senior officials, such as mayor or school superintendent.

CATEGORY 4:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if

- (i) these sources are publicly available; or
- (ii) if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Clarification: Existing means it exists at the time of this IRB submission. Do not select this category if some or all of what will be collected does not yet exist.

Chart/Medical Record Reviews: Do not check this category for prospective (not yet existing) chart/medical record reviews - these are not exempt. Retrospective (existing) chart reviews may fall under this category, BUT the information must be existing.

CATEGORY 5:

Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) Public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Note: The program under study has to deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services provided under the Older Americans Act), the project must be designed to study, evaluate, or otherwise examine the program or service, and the project must be approved by the head of the federal department or agency.

CATEGORY 6:

Taste and food quality evaluation and consumer acceptance studies:

- (i) if wholesome foods without additives are consumed; or
- (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the FDA.

NONE APPLY: My project does not fall under an exempt category.

Save & continue > Save & stay on this page

- b. **Purple Arrows:** If you already know your project is not exempt, you can select the first checkbox. In addition, if after you peruse the exempt categories and determine your project is not exempt, you will check “none apply”, then “save and continue”.
- c. Additional sections will populate for expedited and full board studies after you hit “save and continue”. See below.

IRB Application sections

- 1. Investigators/Project Title
- 2. Exempt Determination
- 3. Basic Project Information
- 4. Subject Recruitment
- 5. Subject Consent
- 6. Risks and Benefits
- 7. Confidentiality and Security
- 8. Costs Associated with the Research
- 9. Completion of Required Sub-Forms
- 10. Additional forms
- 11. Attached files
- 12. Submit

IRB / My IRB Projects / IRB #2011192 HS / IRB Application: 236415

Basic Project Information

1. Select from the type of research this project would likely fall under:

Observational - Research that encompasses a range of methodologies and seeks to answer questions to improve our understanding of human health, and interactions as well as social and economic systems, organizations, and institutions.

2. Do you have any conflicts of interest with this study.

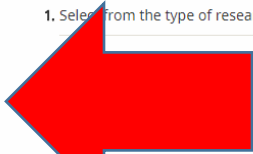
Example: Financial, personal, institutional, or other, for any study team member. If none, please indicate no conflict. We will verify your responses with existing data on file.

3. Is this study **limited to** a medical chart review or analysis of identifiable data (data that have been or will be collected solely for non-research purposes)?

Yes

No

4. Protocol Information



d. If you select an exempt category because you determined the project is likely exempt, additional questions will populate under the “exempt determination” section (captured below are just a few sample questions). There are only 4 sections for exempt research. The only document required to be uploaded to “attached files” on exempts is the funding proposal if the study is federally funded.

2. Please answer the following questions regarding your exempt project.

A. Provide a description of your project.

Text input field for project description.

B. Describe what subjects will be asked to do.

If this is an observational study or review of existing data only, please state this.

Text input field for subject description.

C. Explain how your project fits into the exempt category(ies) you selected above.

Text input field for exemption justification.

e. For expedited and full board studies, complete each section. The revised application has many dependent questions. For example, if you select “no” to this question, you will not see any additional questions regarding clinical trials (see below):

5. Is this a clinical trial?

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Click [here](#) for guidance on making this determination, if unknown.

- Yes
- No

f. If you mark “yes” to this question, additional questions will populate (see below):

5. Is this a clinical trial?

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Click [here](#) for guidance on making this determination, if unknown.

- Yes
 No

6. Has the study been registered on clinicaltrials.gov?

- Yes
 No

7. If yes, provide the NCT number here:

[Empty text input field]

8. Select the clinical trial phase:

[Empty dropdown menu]

9. Is there a clinical investigational drug brochure (CIDB)?

- Yes
 No

10. CIDB Information

+ Add new item

[Empty list area with Edit button]

11. Powertrials

g. The IRB also utilizes sub-forms. These are triggered within the "completion of required sub-forms" section (see below). An "additional forms" section will generate if you mark an item within this section that pertains to your study.

IRB Application sections sidebar with 12 items. Item 9 'Completion of Required Sub-Forms' is highlighted with a red arrow. The main content area shows a list of checkboxes for Biomedical Specific Sub-Forms and Subject Population Sub-Forms.

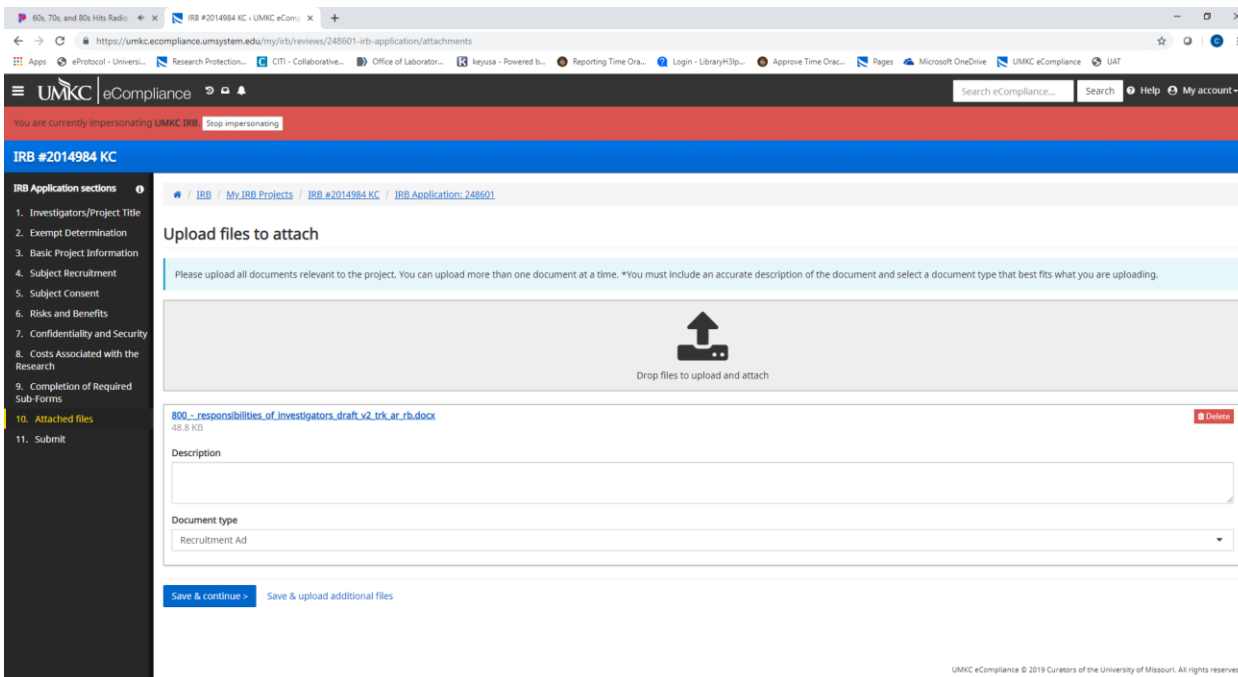
- h. The “additional forms” section is where you will access the sub-forms (a list will populate based on what you checked in the “completion of required sub-forms” section).
 - i. Click edit/update to complete the subform. You will need to “submit” the subform when completed to attach it to the application.

Additional forms are required

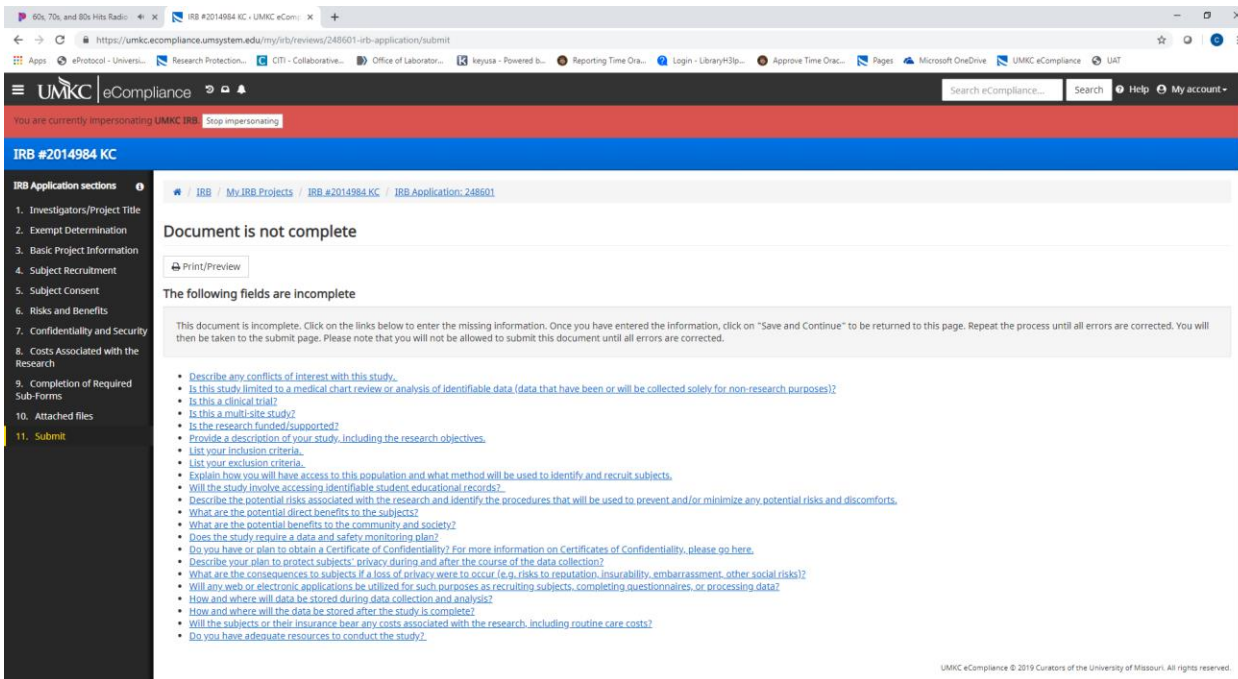
Based on the answers you have provided, you must complete the following additional forms before you can submit this IRB Application: 236415.

Complete?	Additional form	
<input type="checkbox"/>	Biohazardous Materials Subform	Edit/update
<input type="checkbox"/>	Blood/Fluid/Tissue Samples Subform	Edit/update
<input type="checkbox"/>	Children Subform	Edit/update
<input type="checkbox"/>	Cold Isotope Subform	Edit/update
<input type="checkbox"/>	Devices Subform	Edit/update
<input type="checkbox"/>	Drugs & Biologics Subform	Edit/update
<input type="checkbox"/>	Exception from Informed Consent for Planned Emergency Research Subform	Edit/update
<input type="checkbox"/>	Incompetent Persons Subform	Edit/update

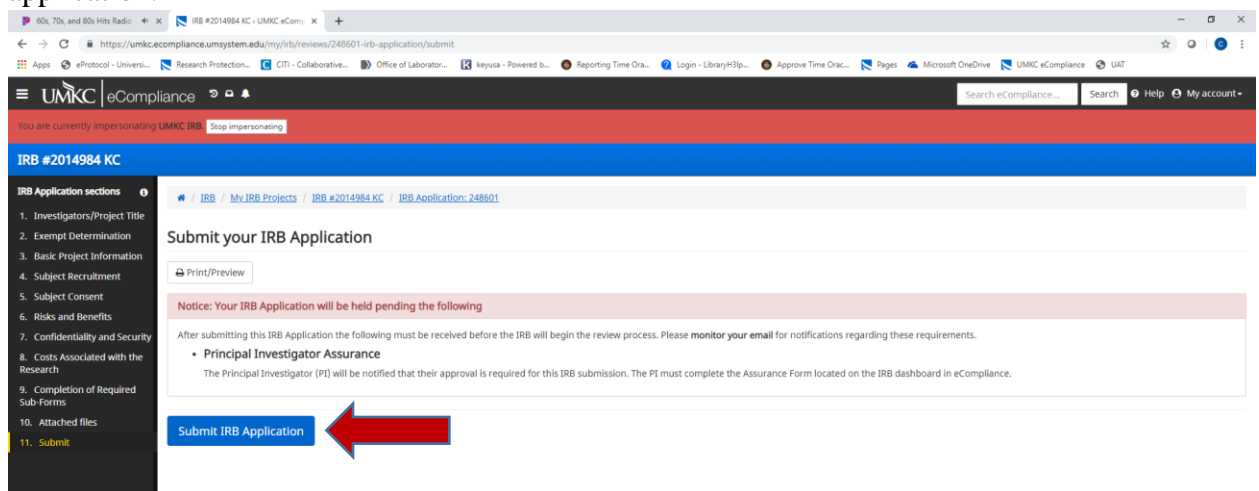
- i. Attached Files – This is where you would attach any applicable submission materials (scripts, recruitment materials, consent forms, etc.)



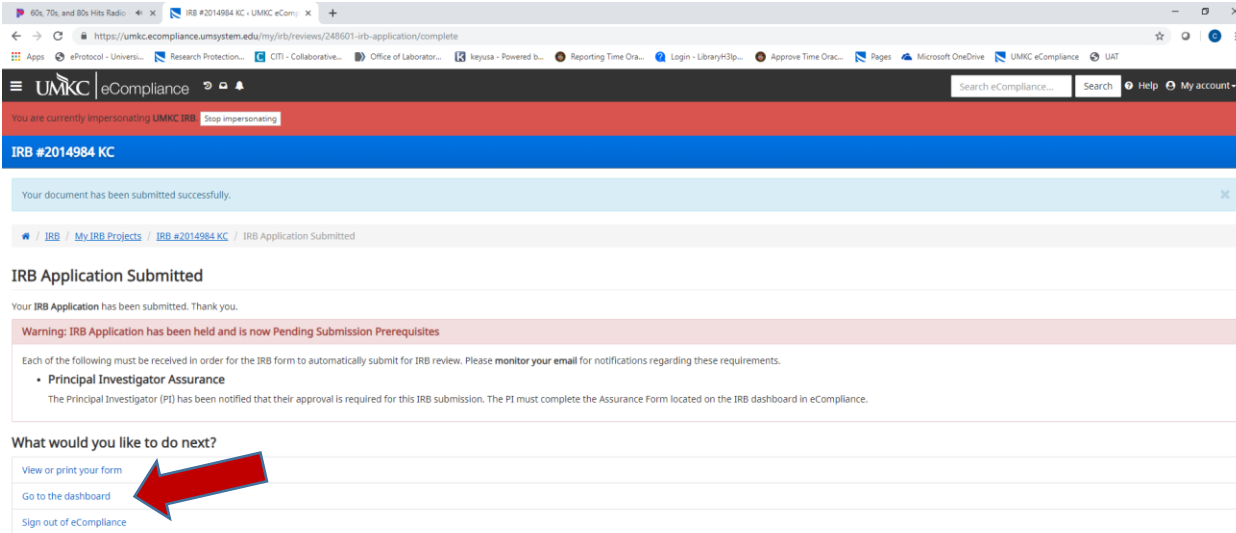
- j. Once you have uploaded all attachments click save and continue
 - If your application is not complete (missing responses to required sections) you will be directed to a page that notes your application is not complete and lists (hyperlinks to those sections)



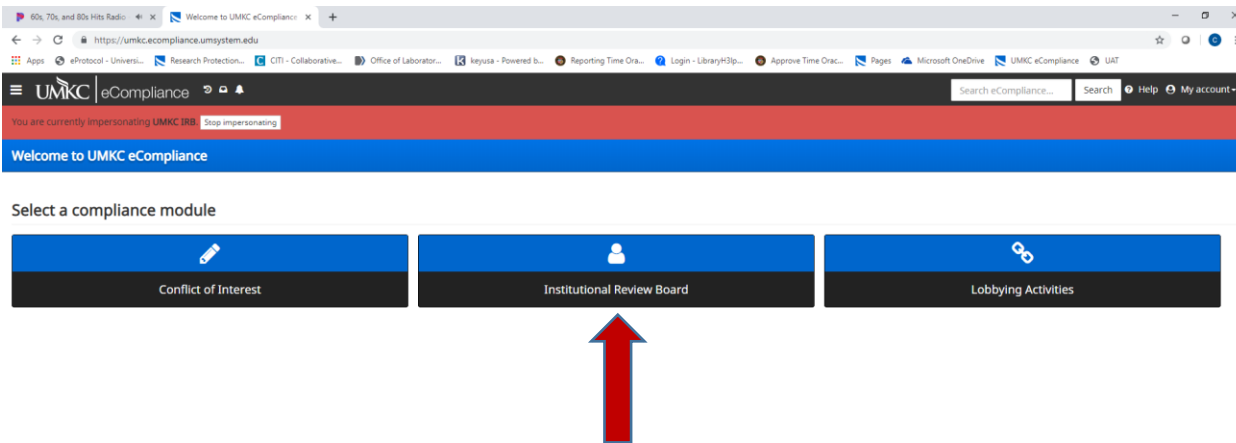
k. Once you have completed all the necessary sections/questions you will be able to submit your application.



1. With each new application you will need to submit your Principal Investigator Assurance. At this screen click “Go to Dashboard”



- m. You will be taken to the Dashboard. Here you click on Institutional Review Board



n. You will be taken to the IRB page where you can click PI Assurance

Prerequisites

- Take IRB training
- Advisor approval
- PI assurance
- My personal information
- Upload CV/CTI training certificate

Submission to IRB

- IRB forms
- Open saved IRB project
- Document storage
- Check project status

View Approved/Archived Projects

- View all my approved IRB projects
- View all my uploaded documents

Researcher resources

o. On the PI Assurance page, click Submit my decision for the application you are currently working on

Project ID	Project title	Review ID	Form	Submitted by	Submission date	
IRB #2014984 KC	eCompliance Investigator Training Prep	248601	IRB Application	UMKC IRB	05/20/2019	Submit my decision
IRB #2015044 KC	Study Title	248729	IRB Application	UMKC IRB	05/20/2019	Submit my decision

p. You will be prompted with 3 questions to respond to then click Submit my decision

PI assurance form

I understand that I am fully responsible for the conduct and supervision of the research.

Yes
 No

I understand that I am responsible for protecting the rights, safety, and welfare of the subjects enrolled in the research.

Yes
 No

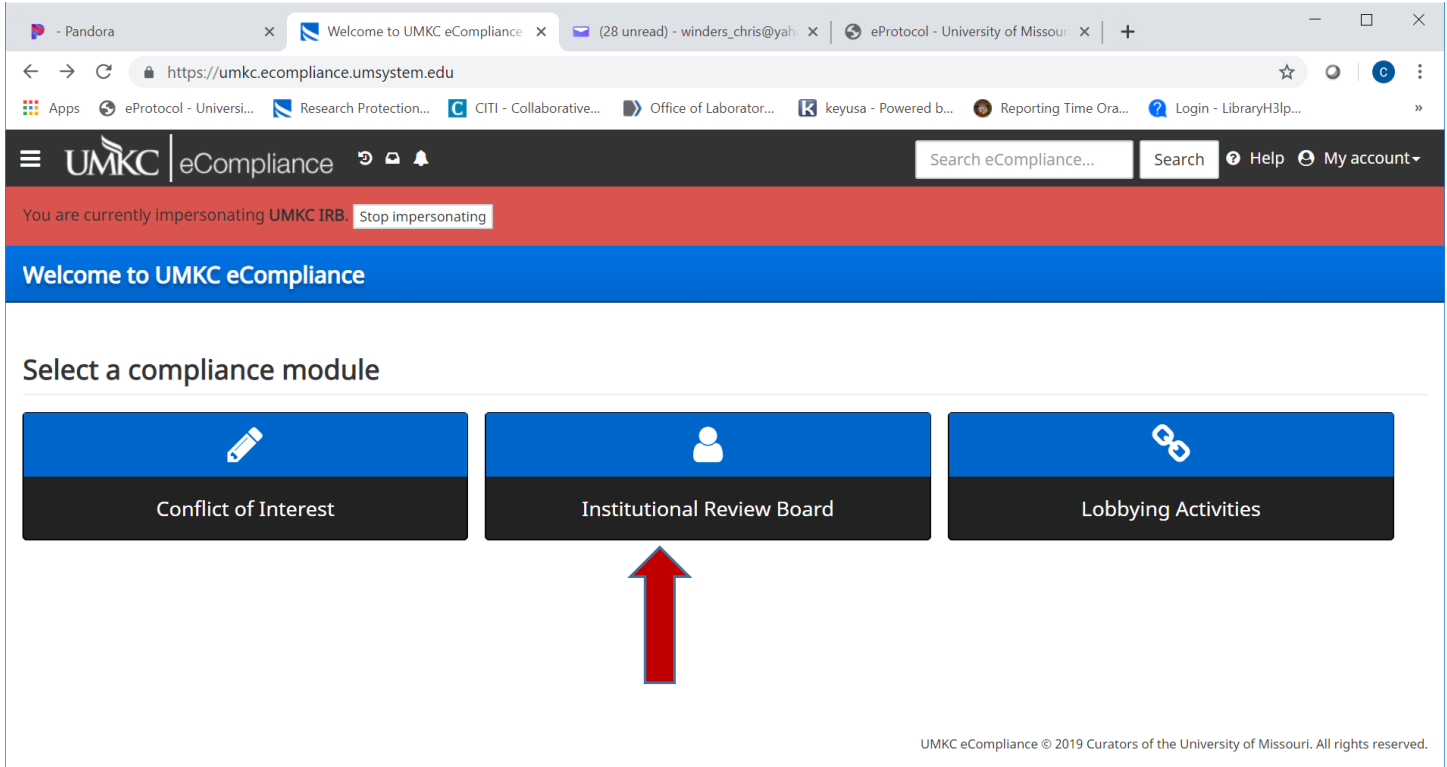
I will conduct the research in an ethical manner and in accordance with all Federal, State and Local laws and regulations, institutional policy, and requirements or determinations of the IRB.

Yes
 No

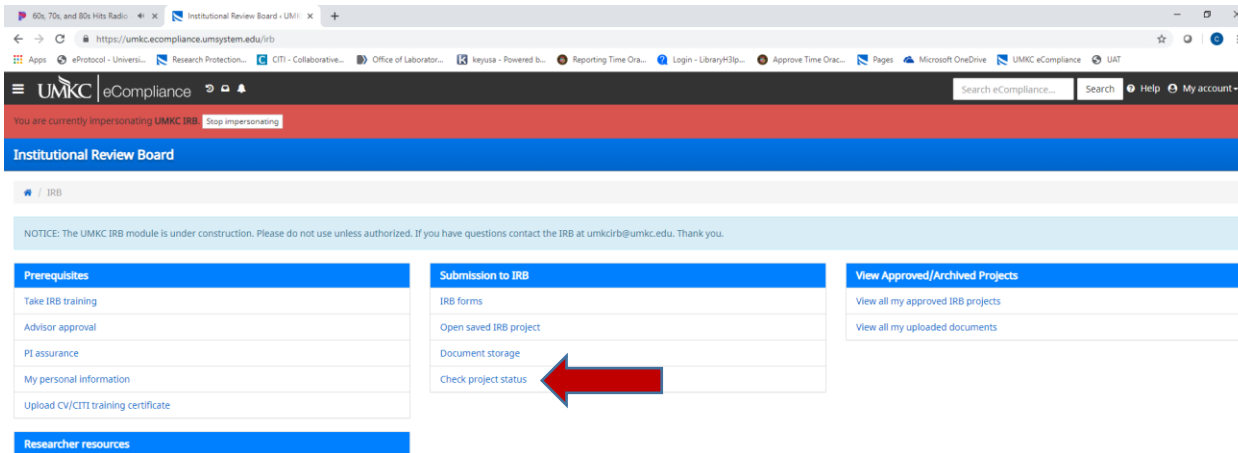
Submit my decision

7. Checking Status of Submissions

- a. From your home page click on Institutional Review Board



- b. You will be taken to the following page. Click on Check project status



c. You will be taken to this page where you can see all your projects in their various stages

Not Yet Submitted/Resubmitted

Project number	Project title	Review ID	Form	Submission date
2015049	test	248783	IRB Application	
2014876		247555	Human Subjects Research Determination Form	04/18/2019
2014875		247554	IRB Application	
2014377-AA		247537	IRB Reliance Request Form	
2015044	Study Title	248729	IRB Application	05/20/2019

Awaiting Review

Project number	Project title	Review ID	Form	Submission date
2014984	eCompliance Investigator Training Prep	248601	IRB Application	05/20/2019
2015042	dfghjkl	248726	IRB Application	05/20/2019

Under Review

Project number	Project title	Review ID	Form	Submission date
2014786	Full Board Training Protocol 04/30/2019	248108	IRB Application	04/30/2019

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