

UMSL IRB Submitter Training



A word cloud of terms related to IRB (Institutional Review Board) and research ethics. The words are arranged in a cluster, with varying colors and orientations. The words include: Ethics (vertical, dark blue), IRB (horizontal, light grey), Human (horizontal, orange), Subjects (horizontal, dark blue), Monitoring (horizontal, teal), Compliance (horizontal, teal), Justice (horizontal, orange), Research (horizontal, dark blue), and Respect (horizontal, light grey).

Ethics
IRB
Human
Subjects
Monitoring
Compliance
Justice
Research
Respect

Introducing eCompliance for IRB Submissions

- Easy to manage your IRB submissions and approvals
- Efficient submission and review process
- One stop shop for all forms, trainings, templates, etc.
- Used by MU since 2015 and improved on an ongoing basis

Items Covered in the Submitter Training

- eCompliance Login
- IRB Dashboard
- IRB Form Choices
- IRB Application
- IRB Submission
- Transitioning existing IRBNet approved Studies to eCompliance

eCompliance Login

<https://umsl.ecompliance.umssystem.edu/login>

UMSL | eCompliance

Authentication required

This is a secure resource, you must sign in to continue.

Login ID (SSO or Email Address)

Password

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.

[➔ Sign in](#) [Forgot username or password?](#) [Create an account](#)

Sign in using your UMSL login information – No need to create an account.

Ready to accept submissions on July 27, 2020.

Selecting the IRB Module

Welcome to UMSL eCompliance

Select a Compliance Module



Conflict of Interest



Institutional Review Board



Lobbying Activities



IRB Dashboard

Institutional Review Board

[Home](#) / IRB

Prerequisites

[Take IRB training](#)

[Advisor approval](#)

[PI assurance](#)

[My personal information](#)

[Upload CV](#)

Submission to IRB

[IRB forms](#)

[Open saved IRB project](#)

[Check project status](#)

View Approved/Archived Projects

[View all my approved IRB projects](#)

[View all my uploaded documents](#)

Researcher resources

IRB Dashboard - Training

Institutional Review Board

🏠 / IRB

Prerequisites

Take IRB training

Advisor approval

PI assurance

My personal information

Upload CV

This is where you will access the CITI training – whether you need to complete the basic human subject research course or the refresher course. eCompliance is synced with the CITI program and CITI updates eCompliance within 24 hours with your training course and dates.



We will now be requiring that all Investigators who are engaged in human subjects research have current CITI Human Studies training on file.

IRB Dashboard – Advisor Approval and PI Assurance

Institutional Review Board

🏠 / IRB

Prerequisites

Take IRB training

Advisor approval

PI assurance

My personal information


Upload CV



This is where the advisor will complete the Advisor Approval (if an advisor is listed on the IRB application (i.e. student projects)) and the PI Assurance for all IRB Applications.

IRB Dashboard – My Personal Information and Upload CV

Institutional Review Board

 / IRB

Prerequisites

Take IRB training
Advisor approval
PI assurance
My personal information
Upload CV

My personal information section is connected to the myHR system. All PIs are required to upload their CV. For student projects, the advisor would be required to upload their CV, not the student. This is a one time requirement.

IRB Dashboard – Submission to IRB

Submission to IRB
IRB forms
Open saved IRB project
Check project status



This is where you will find all forms to be submitted to the IRB. More information is found on a future slide.

IRB Dashboard – Open Saved IRB Project

Submission to IRB
IRB forms
Open saved IRB project
Check project status



Click here to continue working on in progress submissions and projects that have been returned by the IRB office. You will be notified via email if an item is returned to you.

IRB Dashboard – Check Project Status

Submission to IRB
IRB forms
Open saved IRB project
Check project status

← This is where you can monitor the status of your submission.

IRB Dashboard – View Approved/Archived Projects

View Approved/Archived Projects

[View all my approved IRB projects](#)

[View all my uploaded documents](#)

When you receive IRB approval or any other IRB determination on a submission, your study will move to this column where you can continue to access your approved and closed studies.

IRB Dashboard – Researcher Resources

Researcher resources

This is where you can quickly access the UMSL IRB website and templates.

IRB Forms

IRB Forms - Applications

Begin a new IRB form

Applications

IRB Application

Complete this form for all exempt, expedited, and full board research projects.

Initial Reliance Request Form

Complete this form to request pre-approval to rely on an external IRB.

Reliance Form

Complete this form to finalize your initial request to rely on an external IRB.

Case Report Form

Complete this form for single retrospective case reports of 3 or less individuals.



The IRB Application is submitted for all exempt, expedited, and full board studies unless one of the other applications apply.

IRB Forms - Applications

Begin a new IRB form

Applications

IRB Application

Complete this form for all exempt, expedited, and full board research projects.

Initial Reliance Request Form

Complete this form to request pre-approval to rely on an external IRB.

Reliance Form

Complete this form to finalize your initial request to rely on an external IRB.

Case Report Form

Complete this form for single retrospective case reports of 3 or less individuals.



The Initial Reliance Form and Reliance Form are for studies relying on an external IRB. Consult the UMSL IRB office if you intend to use another IRB besides the UMSL IRB.

IRB Forms – Annual Reviews and Amendments

Annual reports are now only accessed through [Open saved IRB project](#) and have been removed from this page.

Amendments

Exempt Amendment Form

Complete this form to request changes to an approved Exempt study.

Amendment Form

Complete this form to request changes to an approved Expedited or Full Board study.

Annual reports are found under the Open Saved IRB Project link.
Amendment Forms are separated by exempt vs. expedited/full board

IRB Forms – Other Application Types

Quality improvement

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.).

If you need a QI (not research) determination, the form is available to you.

Human subjects research determination

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 314.516.5972 or email irb@umsl.edu.

If you need a determination of NOT human subjects research, complete the HSR Determination Form.

Collaborative exempt notification

Collaborative Exempt Notification Form

Complete this form to notify the UMSL IRB about collaborative research that was reviewed and determined to be exempt by another IRB. If the research required limited review under category 2 or 3, you must submit the Initial Reliance Request Form instead.

The Collaborative Exempt Notification Form is for studies where another IRB already determined the study is exempt and may prevent the need to submit another exempt application to the UMSL IRB. Consult the UMSL IRB as needed.

IRB Forms – Required Reporting Forms

Required reporting forms

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.

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.

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.

Inclusion/Exclusion Exception

Complete this form to submit a request to enroll a subject who does not meet the approved inclusion/exclusion criteria.

Reliance Reporting Form

Reliance Studies: Complete this form for all modifications approved, or determinations made, by the IRB of Record.

Certain activities require post approval IRB reporting, like study closures, deaths, deviations, problems, and reliance study changes. Choose the form applicable to your study, as necessary. Help text is available on all forms to help choose the appropriate form.

IRB Forms – Administrative Forms

Administrative forms

Personnel Change Form

Complete this form if you want to make changes to research personnel. (Exception: PI or other personnel changes requiring revisions to supportive documents, and/or adding external investigators must be requested on an Amendment Form)

Requested Identification Numbers/Information

Complete this form to an approved study to provide your Clinicaltrials.gov. MoCode, OSPA number, or Study Short Name, if it was not previously provided.

Biorepository or Database Submission Form

Submit this form to establish a biorepository or database which will be used institutionally for future research. This involves the collection and storage of information and/or biospecimens over time by individuals that will be independent from the research activities. This is not project specific as those protocols should use the main IRB application and complete the database/biorepository subform.

Cumulative AE Log

This is only to be used for reporting adverse events that do not require IRB review, but do require proof of IRB submission.

HIPAA Preparatory to Research Form

Complete this form for access to PHI that is necessary to prepare a protocol or to assess the feasibility of conducting a study.

UMSL IRB as Single IRB Request Form

Submit this form to request the UMSL IRB to be the single IRB of a multi-site study.

These forms are reviewed administratively by the UMSL IRB office. For example, changes to personnel are submitted on the Personnel Change Form, unless it is a PI change, then that goes on the Amendment form. Please review the help text under each form to determine if it applies to your study.

IRB Application

IRB Application First Page

Institutional Review Board

[Home](#) / [IRB](#) / [Begin a new IRB form](#) / IRB Application

IRB Application

Your role as an investigator

What is your role on this project?

Choose a role...

What is your role in the consent?

Choose a consent role...

Primary contact

At least one person on the study must be marked primary contact.

Begin IRB Application

Cancel

The person completing the form enters their information first – role (i.e. PI, co-investigator, research staff).

Consent role options (for each person select whether they will be consenting, non-consenting, or just participating in the consent process).

At least one person needs to be primary contact.

IRB Application

IRB #2025813 SL

IRB Application sections ?

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

[Home](#) / [IRB](#) / [My IRB Projects](#) / [IRB #2025813 SL](#) / [IRB Application: 268278](#)

Project Title/Investigators

1. Project Title

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

2. **Key Personnel** - List all investigators engaged in the research by clicking on the "Add an Investigator" button. This includes individuals interacting or collecting or accessing identifiable data, or consenting subjects. Please note, if individuals are performing services that are typically performed for non 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 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 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 a co-investigator.

Student-Initiated Projects: Students must list themselves as Principal Investigator and also include an Advisor on the project. After you hit submit on be sent an email from the system requesting the completion of the Advisor Approval Form. This application will not officially be submitted to the IRB

The IRB Application is initially set up to assume the study is Exempt. As you work through the application, and you mark not exempt, the sections on the left change so the appropriate information is requested for Expedited and Full Board Studies.

IRB Application

IRB Application sections ⓘ

1. Project Title/Investigators
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. Attached files
11. Submit

[Home](#) / [IRB](#) / [My IRB Projects](#) / [IRB #2025813 SL](#) / [IRB Application: 268278](#)

Basic Project Information

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

- Biomedical** - Research that is conducted to increase fundamental knowledge and understanding of the physical, chemical and functional diseases.
- Social/Behavioral/Educational** - Research that encompasses a range of methodologies and seeks to answer questions to improve our unbeliefs, and interactions as well as social and economic systems, organizations, and institutions.

2. Are there any conflicts of interests with this study?

Example: Financial, personal, institutional, or other, for any study team member. If none, please indicate no conflict. We will verify your resp

- Yes
- No

3. Is this study **limited to** the analysis of materials (data, documents, records, or specimens) that are collected solely for non-research purpose: diagnosis)?

Before selecting yes, refer to Exempt Category #4 (section 3 of the application) to ensure the project cannot be Exempt. Most activities fittin

- Yes
- No

4. Are you proposing to utilize data from an approved/existing research database and/or biorepository?

If it is not marked as Exempt, the application expands to collect the information necessary for Expedited and Full Board studies. As you work through the form, you will be checking boxes that prompt additional questions.

Supportive documents are required to be uploaded for every application under the Attached Files section. A protocol is required for all expedited/full applications.

Assistance with IRB Applications and Submissions

We are available to assist with your submission process. Please contact the IRB office as needed.

danielle.hunter@umsl.edu

Initial Process to Transition Existing IRB Approved Studies

- If your study is no longer active, a Final Report should be submitted in IRBNet to close the project.
- All active studies must be transitioned by October 16, 2020. You must transition your study before you can submit any additional form (i.e. Amendment/Annual Report).
- Create a shell within the IRB Application in eCompliance.
- Upload to the Attached Files all supportive documentation, including your IRBNet approval letter.
- IRBNet approval and expiration dates will transfer over.

Transitioned Studies – eCompliance Acknowledgement

- An eCompliance IRB project number will generate when you start an application (7 digit number). This is your reference number with the IRB.
- If more information is required before the UMSL IRB can acknowledge the existing study, the UMSL IRB will notify you by email to provide this information.
- You will receive a letter acknowledging the eCompliance IRB approval. Keep this acknowledgement for your records to show the successful transition.

Transitioned Studies – Moving Forward

- When eCompliance acknowledges your existing IRB approved study, you will be able to access all post-approval forms and use eCompliance forms moving forward.
- You are required to report:
 - all changes prior to initiation using the appropriate amendment form
 - problems, deviations, and other potential issues
 - personnel changes
 - study closures

UMSL IRB Resources

UMSL IRB Home Page:

<http://www.umsl.edu/services/ora/Compliance/human-subjects-irb.html>



Contact our office!
314-516-5972 or
irb@umsl.edu