UMSL IRB Submitter Training

Introducing eCompliance for IRB Submissions

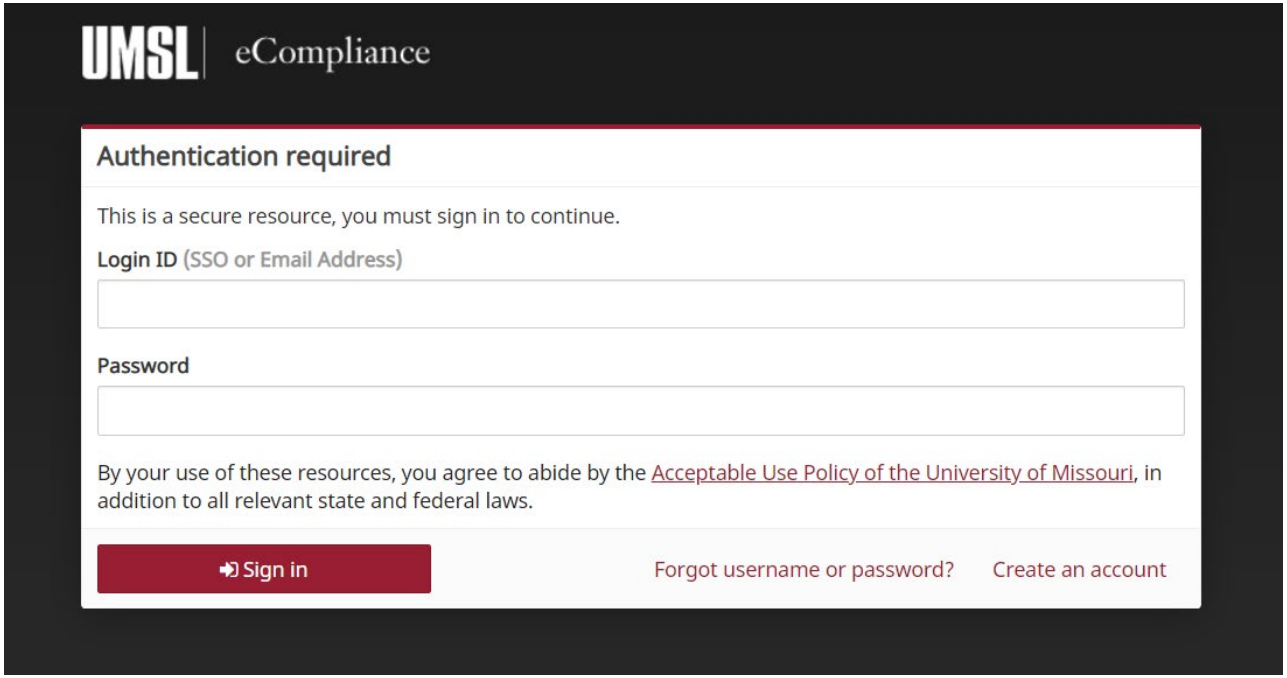
- Easy to manage your IRB submissions and approvals
- Efficient submission and review process
- One stop shop for all forms, trainings, templates, etc.
- Used by MU since 2015 and improved on an ongoing basis

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

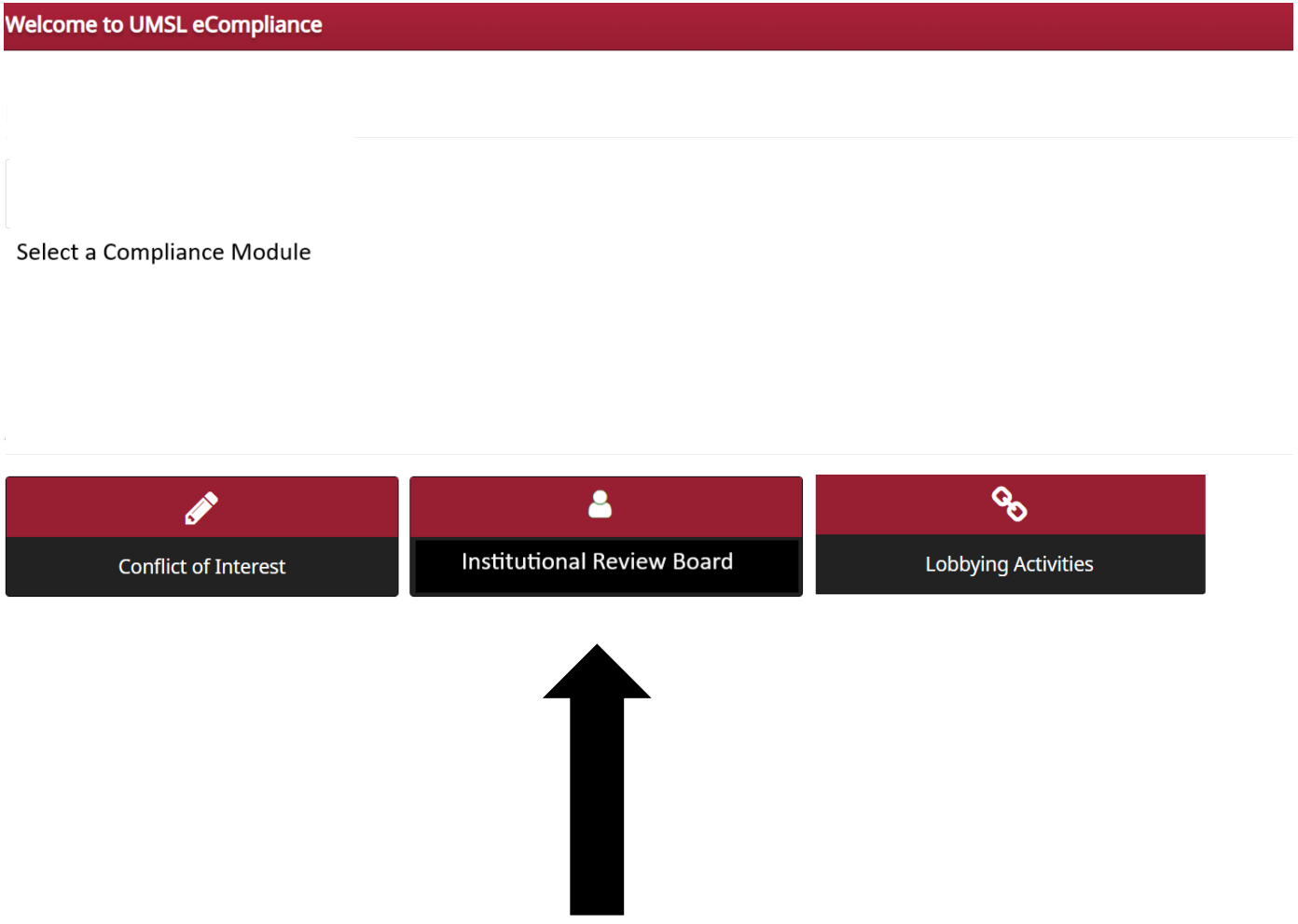
https://umsl.ecompliance.umsystem.edu/login



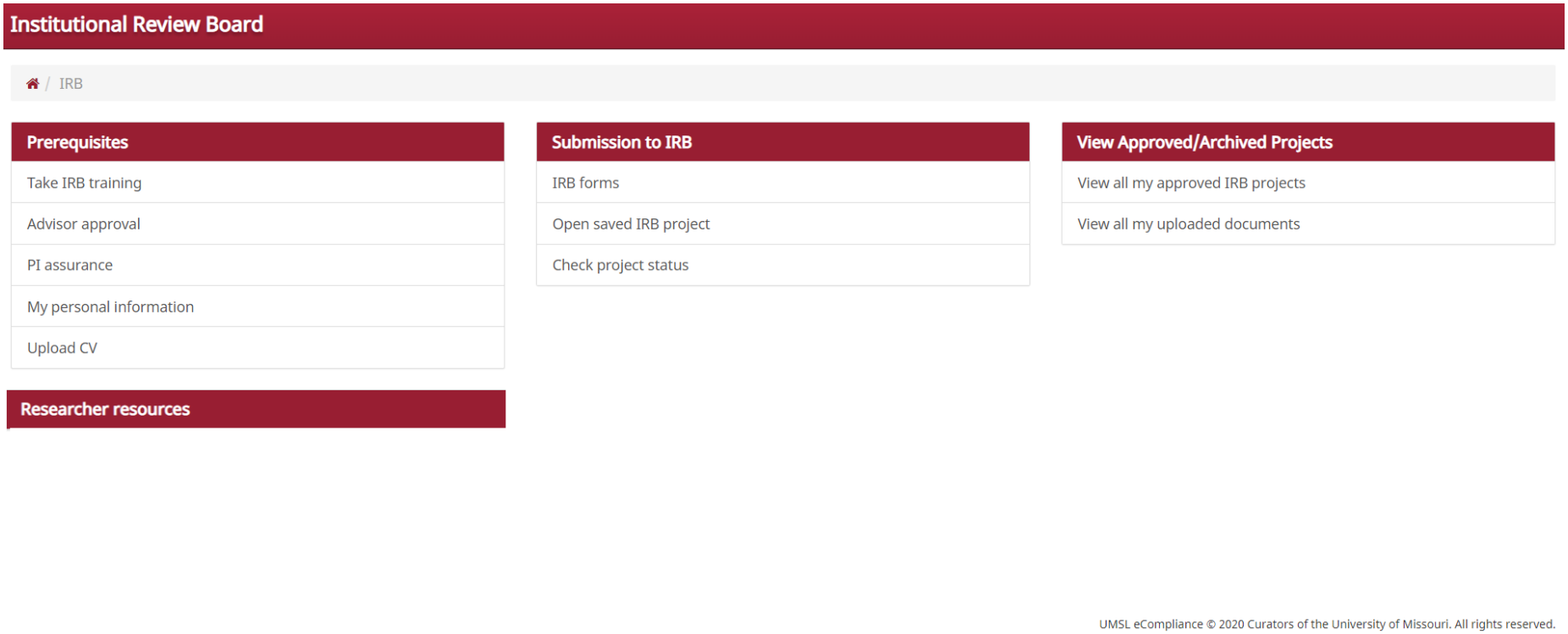
Sign in using your UMSL login information – No need to create an account.

Ready to accept submissions on July 27, 2020.

Selecting the IRB Module



IRB Dashboard



IRB Dashboard - Training

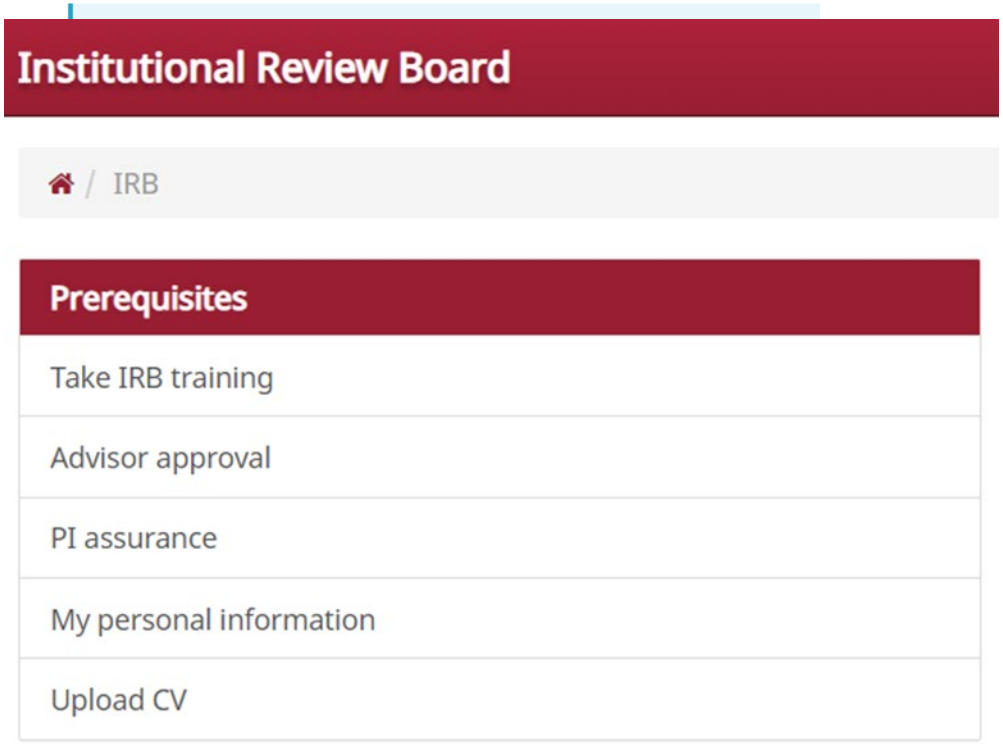
This is where you will access the CITI training – whether you need to complete the basic human subject research course or the refresher course. eCompliance is synced with the CITI program and CITI updates eCompliance within 24 hours with your training course and dates.

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

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



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.

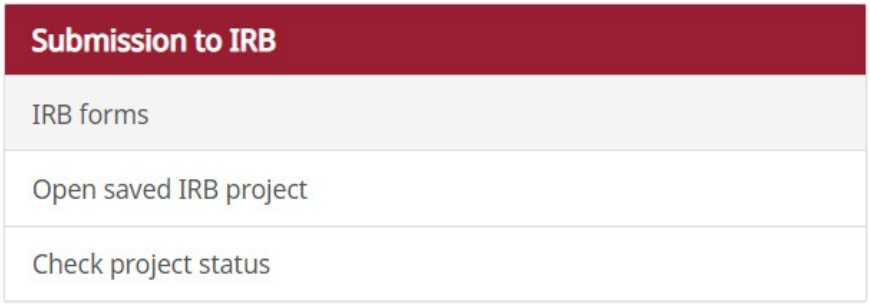
IRB Dashboard – Submission to IRB

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

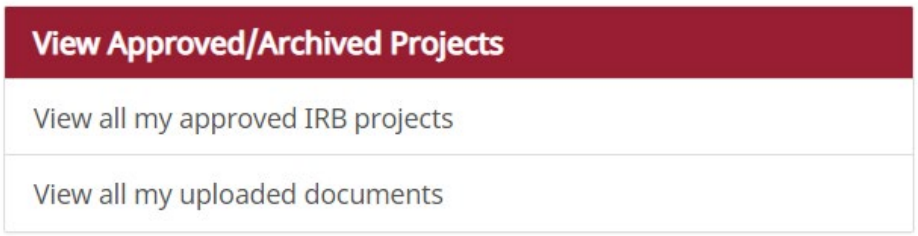
Click here to continue working on in progress submissions and projects that have been returned by the IRB office. You will be notified via email if an item is returned to you.

IRB Dashboard – Check Project Status



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

IRB Dashboard – View Approved/Archived Projects



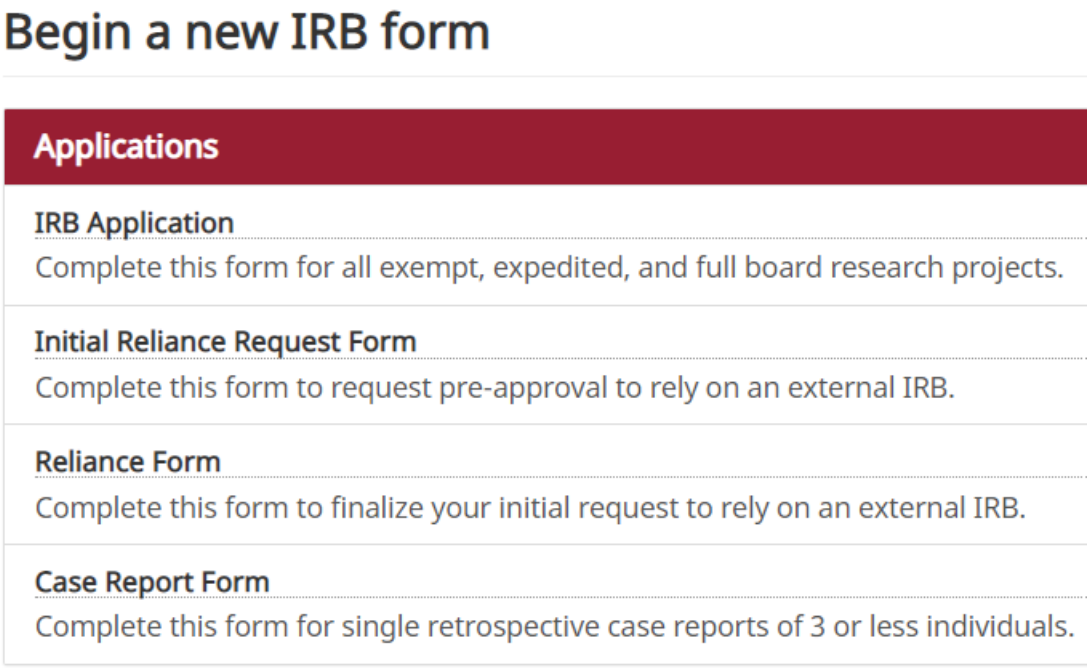
When you receive IRB approval or any other IRB determination on a submission, your study will move to this column where you can continue to access your approved and closed studies.

IRB Dashboard – Researcher Resources

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

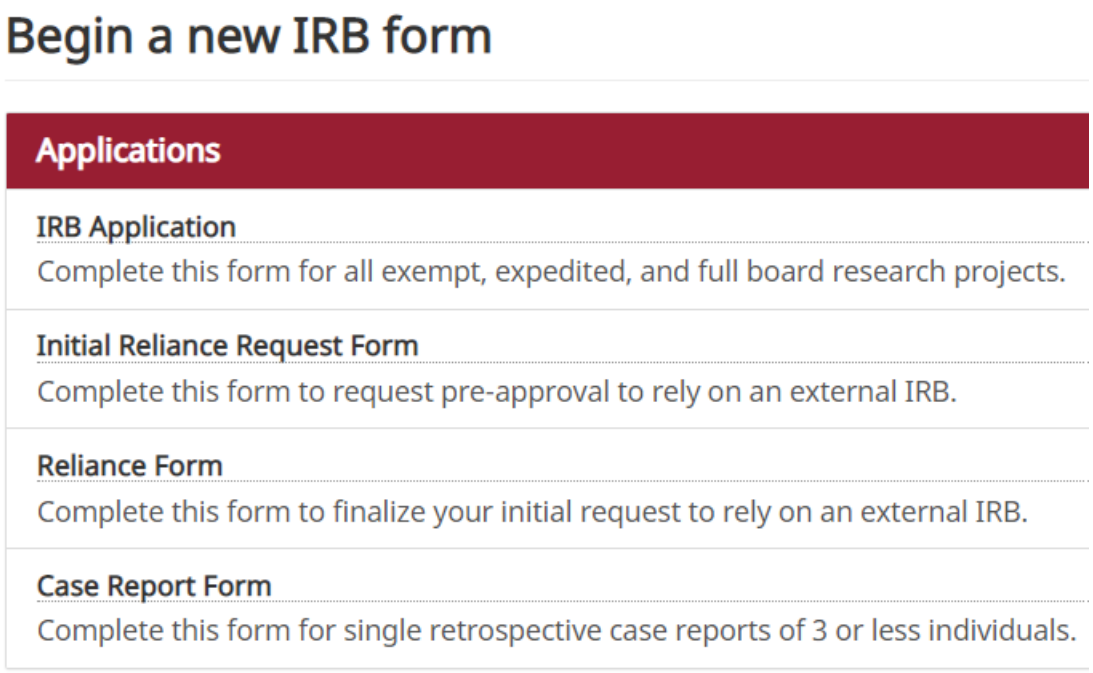
IRB Forms

IRB Forms - Applications



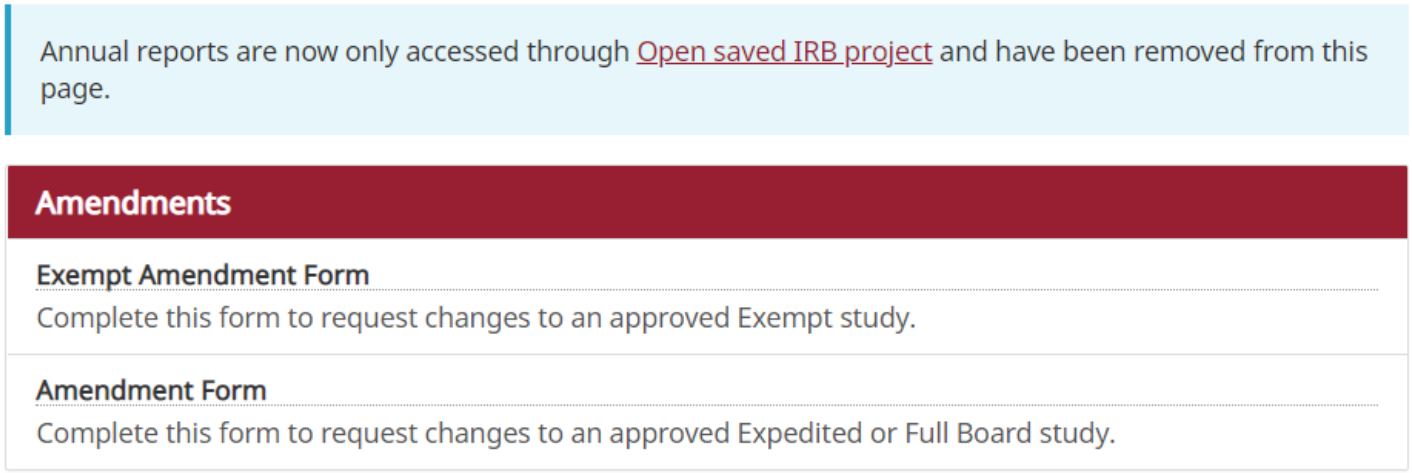
The IRB Application is submitted for all exempt, expedited, and full board studies unless one of the other applications apply.

IRB Forms - Applications



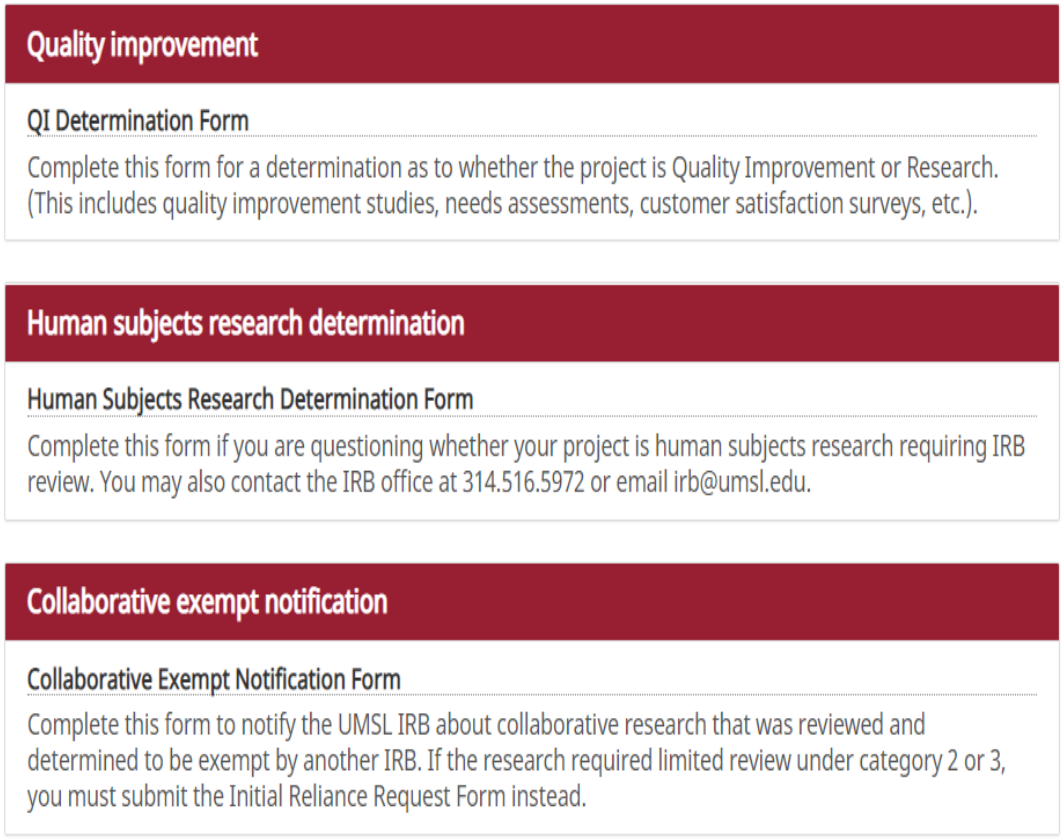
The Initial Reliance Form and Reliance Form are for studies relying on an external IRB. Consult the UMSL IRB office if you intend to use another IRB besides the UMSL IRB.

IRB Forms – Annual Reviews and Amendments



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

IRB Forms – Other Application Types

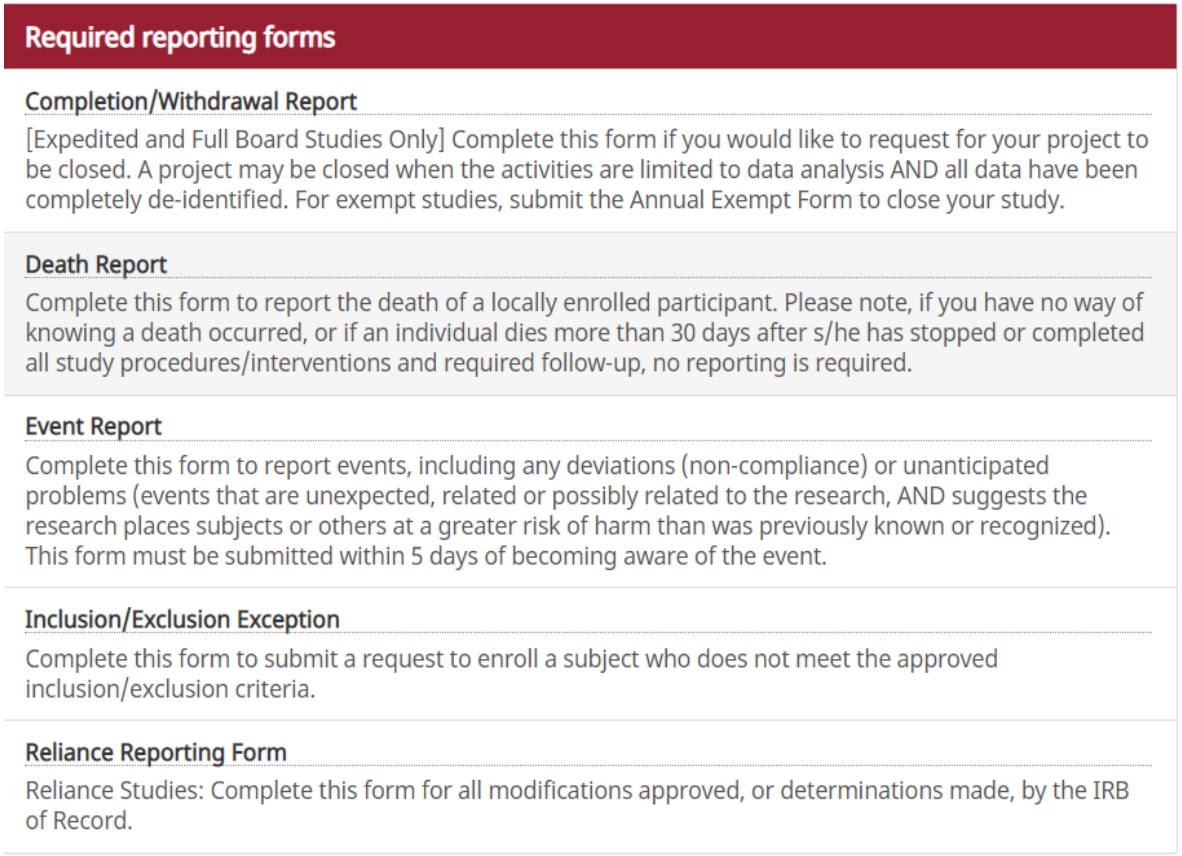


If you need a QI (not research) determination, the form is available to you.

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

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



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.

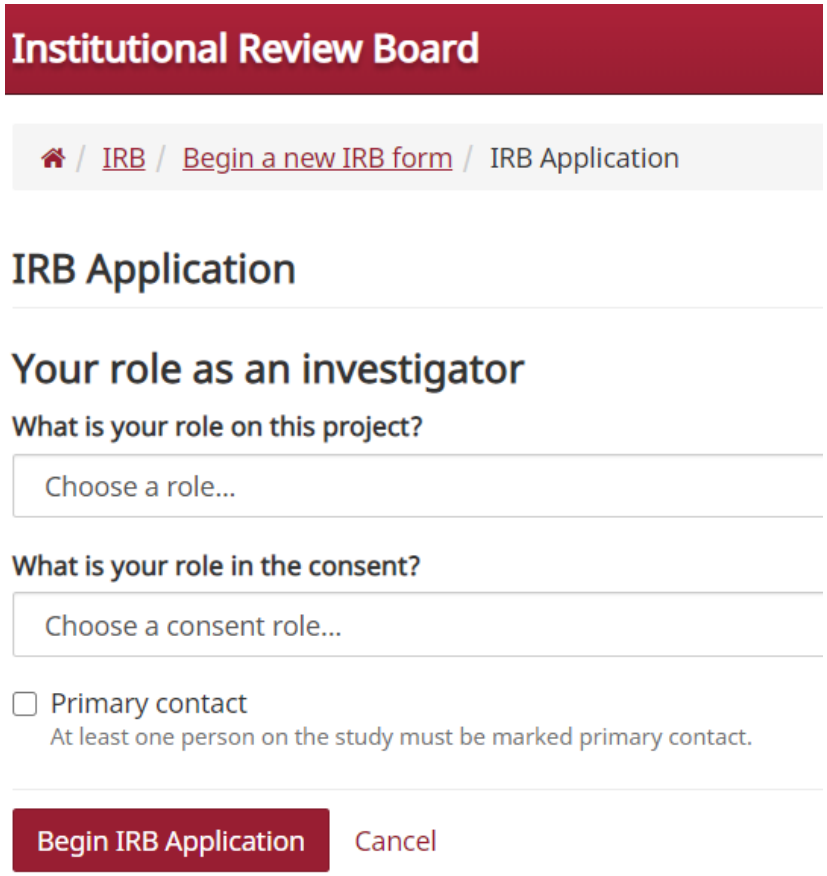
UMSL IRB as Single IRB Request Form

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

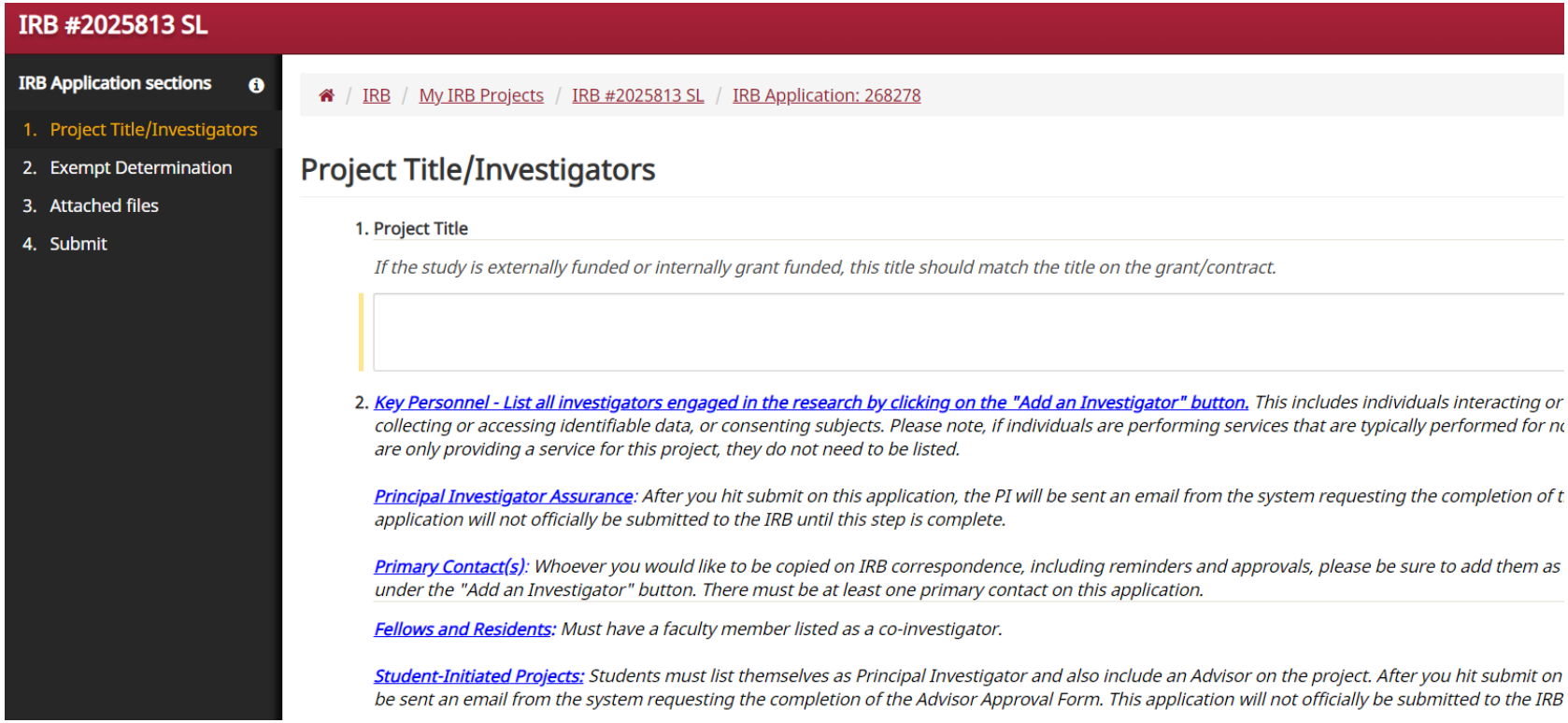


The person completing the form enters their information first – role (i.e. PI, co-investigator, research staff).

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

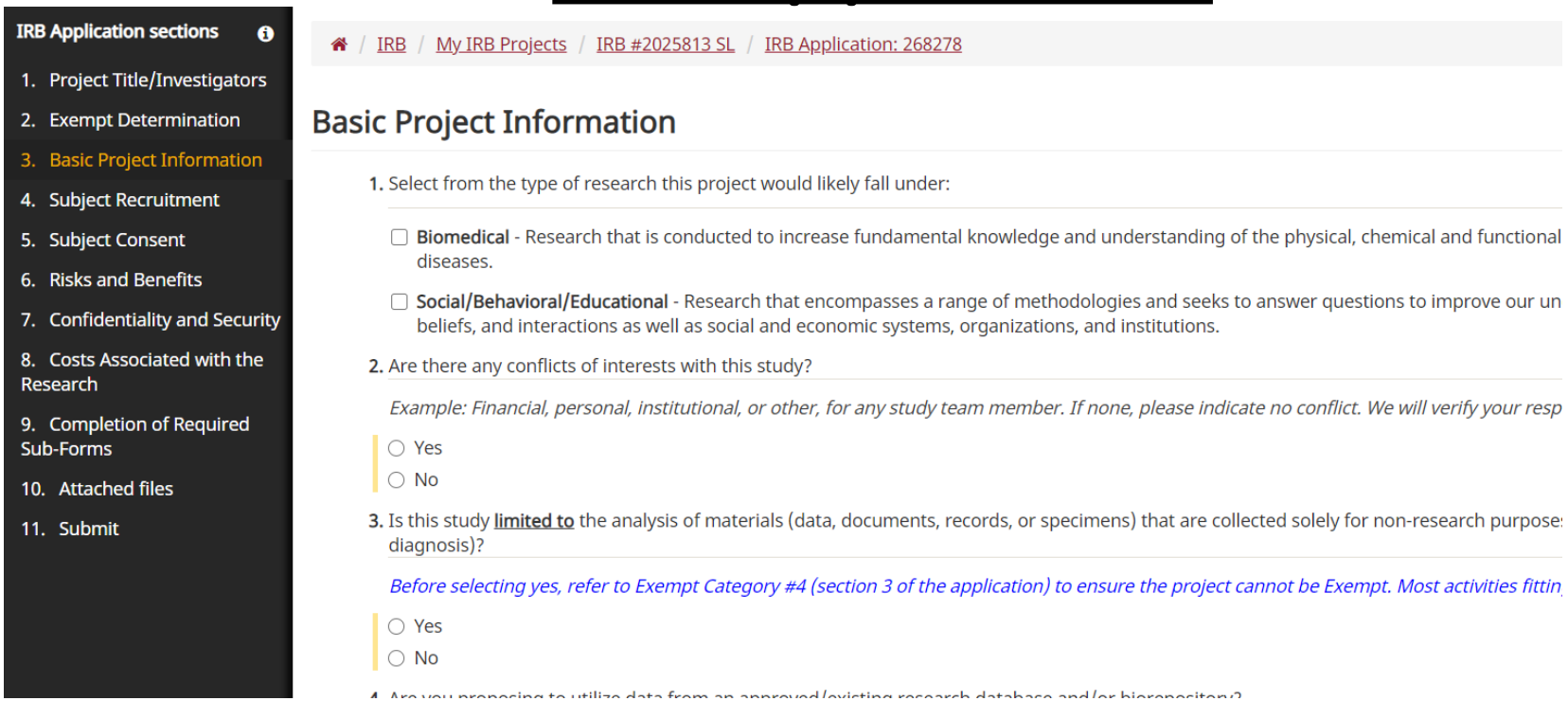
At least one person needs to be primary contact.

IRB Application



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



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