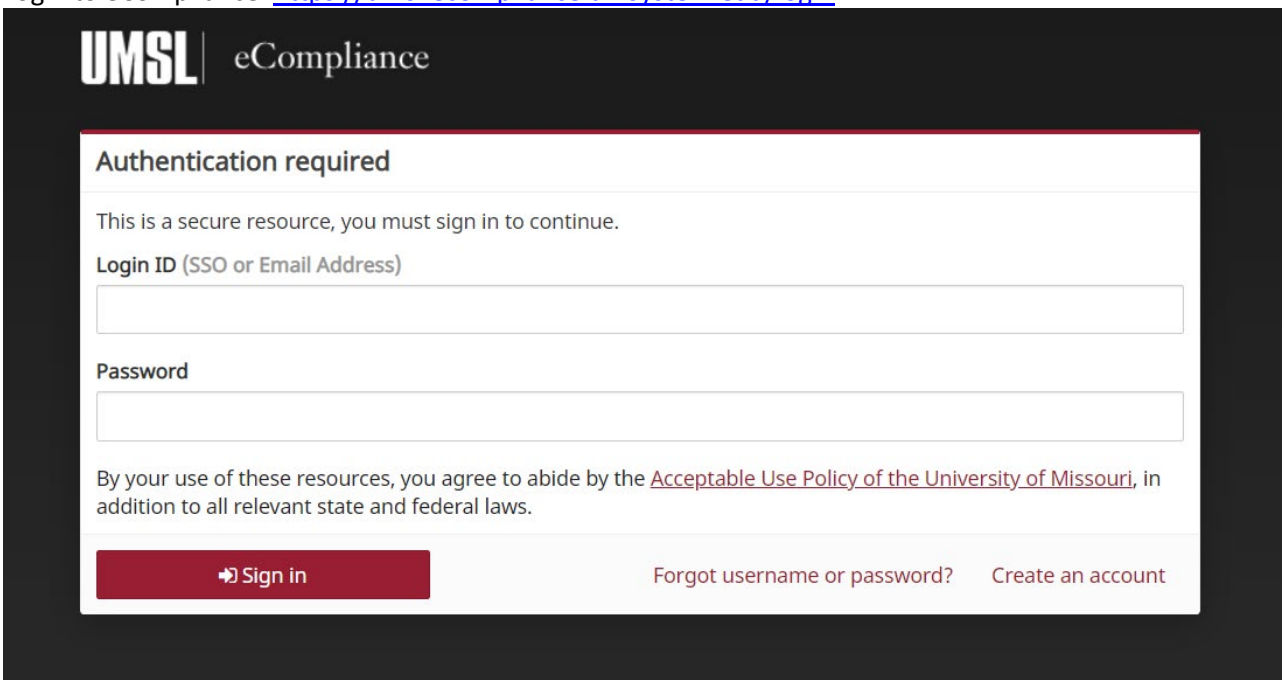
College of Nursing Research Office:
Dr. Kim Werner, wernerk@umsl.edu, 314-526-8421
Ms. Keri Jupka, kjzvf@umsl.edu, 314-516-6092

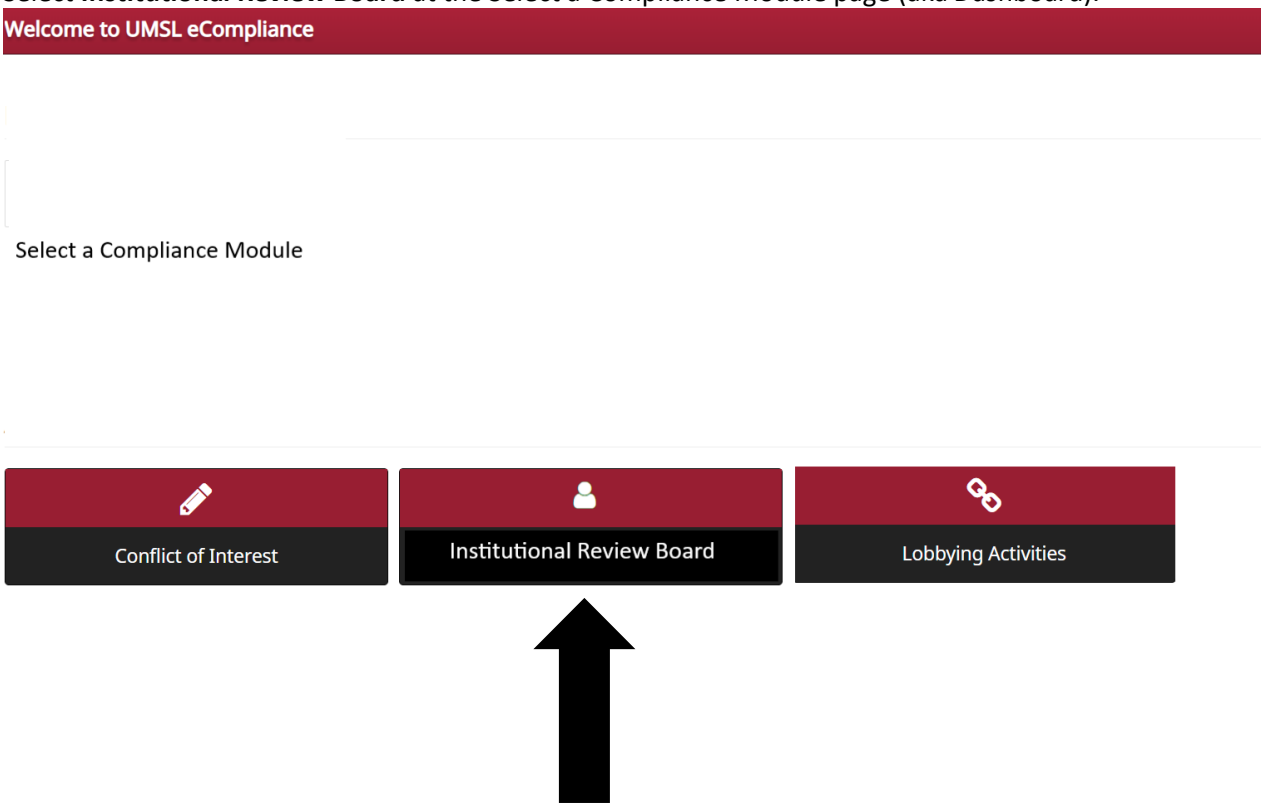
UMSL Institutional Review Board:
Ms. Danielle Hunter, irb@umsl.edu, 314-516-5972

UMSL eCompliance IRB Quick Reference Tool

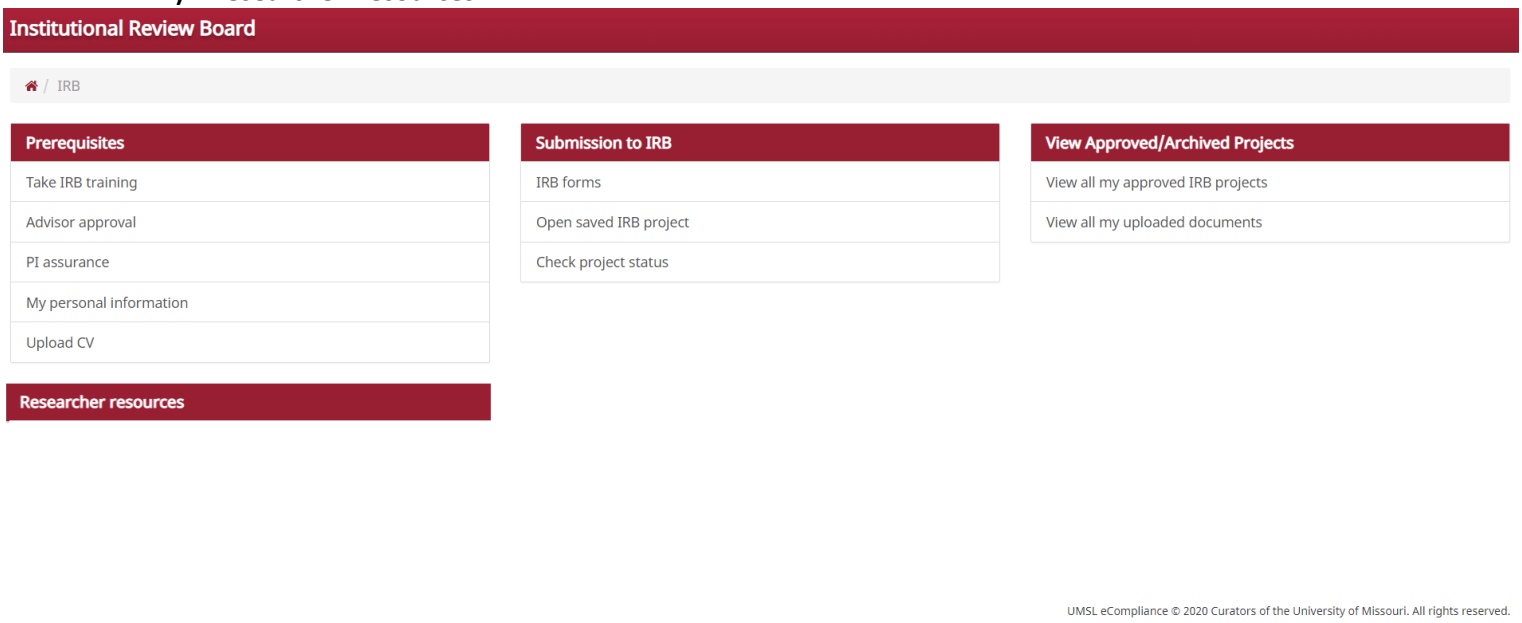
1. Login to eCompliance: https://umsl.ecompliance.umsystem.edu/login



2. Select **Institutional Review Board** at the Select a Compliance Module page (aka Dashboard).



3. You will be presented with four columns:
    1) **Prerequisites**
    2) **Submission to IRB**
    3) **View Approved/Archived Projects**
    4) **Researcher Resources**



4. **Prerequisites**: This column includes links to areas that require action before submitting the IRB application.
    1) **Take IRB Training**: Every investigator is required to complete IRB training before submitting to the IRB. This link provides instructions to complete the required training and can take you to the CITI website to complete training. We will now be requiring that all Investigators who are engaged in human subjects research have current CITI Human Studies training on file. Trainings expire every 3 years and require a refresher training for continued certification. **Please see CITI training instructions on page 9.**
    2) **Advisor Approval**: All students listed as PIs on applications must have an advisor listed. Prior to submission to the IRB, the advisor must complete this step after reviewing the application and recommending it be reviewed by the IRB. Advisors will receive an automatic e-mail that an application is awaiting advisor approval when the student completes their portion of the submission process. The studies will be listed when this link is accessed. After completed by the advisor, the application will automatically submit. **STUDENTS: Please add Dr. Kim Werner and Ms. Keri Jupka to the advisors list.**
    3) **PI Assurance:** This is required to be completed by the PI listed on an application prior to submission to the IRB. PIs will receive an automatic e-mail that an application is awaiting PI assurance when the study staff completing the application has completed their portion of the submission process. The studies will be listed when this link is accessed. After completed by the PI, the application will automatically submit to the IRB.
    4) **My Personal Information**: This link provides you with access to your personal account. If you are a university employee, the majority of your information comes from HR. If the information is incorrect, please contact HR. You can also access files that have been uploaded to your personal account, such as your CV that you may have uploaded or training certificates if you are not a university employee. The files and comments associated with this link are not specific to a project, rather specific to you.
    5) **Upload CV**: Investigators will be asked to upload their CV, so this can be uploaded at any time without being prompted. If an investigator is a student, then their Advisor should upload their CV.

5. **Submission to IRB**: This provides you access to all IRB forms, project documents, and to check your project review status. When all prerequisites have been met, this column serves as step 2 of the IRB submission process.

    1) **IRB Forms**: When you click on this link, you will be provided with a list of forms for IRB submission; sorted by Applications, Quality Improvement, Amendments, Required Reporting Forms, and Administrative Forms. Each form includes a brief description of its purpose. If you have questions on which form to complete, please contact the IRB office. **For more detailed information on what form to complete, see pages 8-9 of this document.**

STUDENTS: Once your IRB project is ready to be submitted, please contact your advisor, Keri Jupka (kjzvf@umsl.edu), Dr. Kim Werner (wernerk@umsl.edu) to reveiw and approve. DO NOT SUBMIT UNTIL APPROVAL IS CONFIRMED VIA EMAIL.

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.

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.).

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.

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.

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.

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.

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)

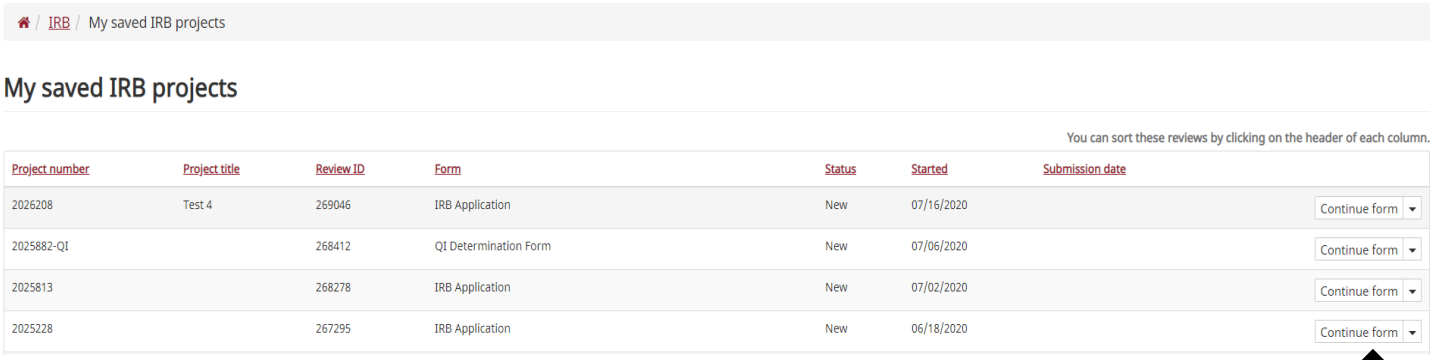
Requested Identification Numbers/Information
Complete this form to an approved study to provide your Clinicaltrials.gov. MoCode, OSPA number, or Study Short Name, if it was not previously provided.

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.

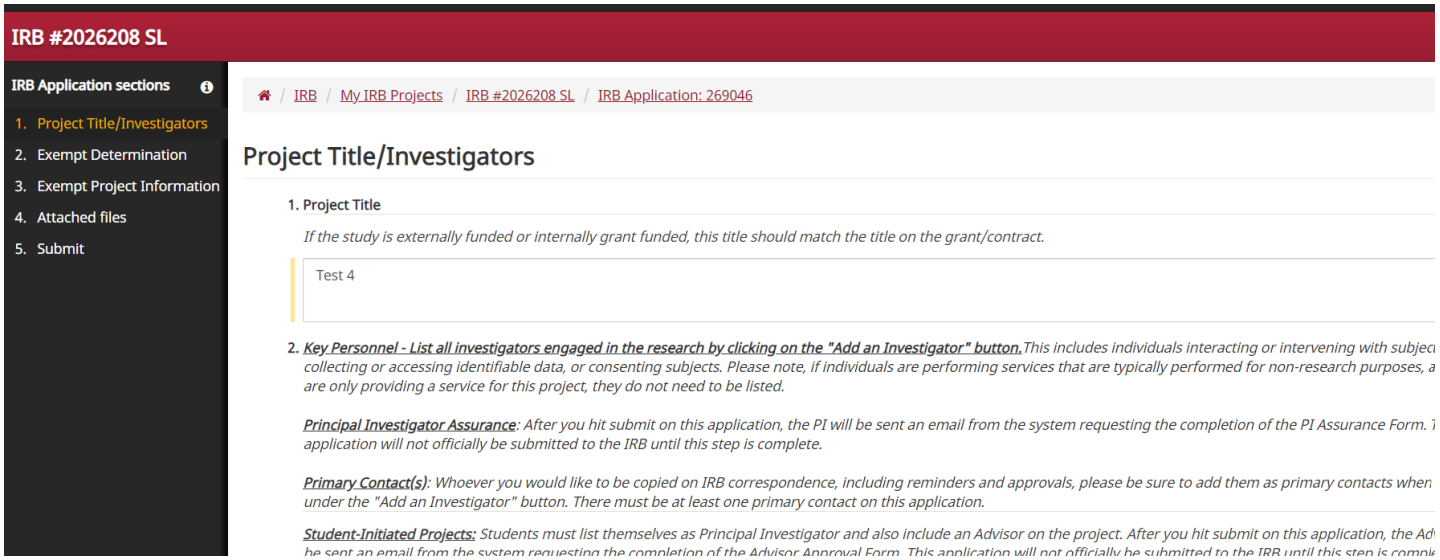
Cumulative AE Log
This is only to be used for reporting adverse events that do not require IRB review, but do require proof of IRB submission.

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

2) **Open Saved IRB Project:** If you are currently working on a form, whether it be an application, amendment, etc., you can find it here as long as it has not yet been submitted OR it has been returned to you by IRB staff for revision.



2a) When you click CONTINUE FORM, you will be presented with this page to edit your form:



3) **Check Project Status:** If you have submitted a form to the IRB office and it has not yet been approved, you can monitor the status of your submission here. Questions regarding the status should be directed to the IRB Office.

Not Yet Submitted/Resubmitted

Project number	Project title	Review ID	Form	Submission date
2025882-QI		268412	QI Determination Form	
2022275-AA		263518	Initial Reliance Request Form	
2023101	test 2	265675	Amendment Form	
2025228		267295	IRB Application	
2024524		266358	Collaborative Exempt Notification Form	
2025813		268278	IRB Application	
2026208	Test 4	269046	IRB Application	

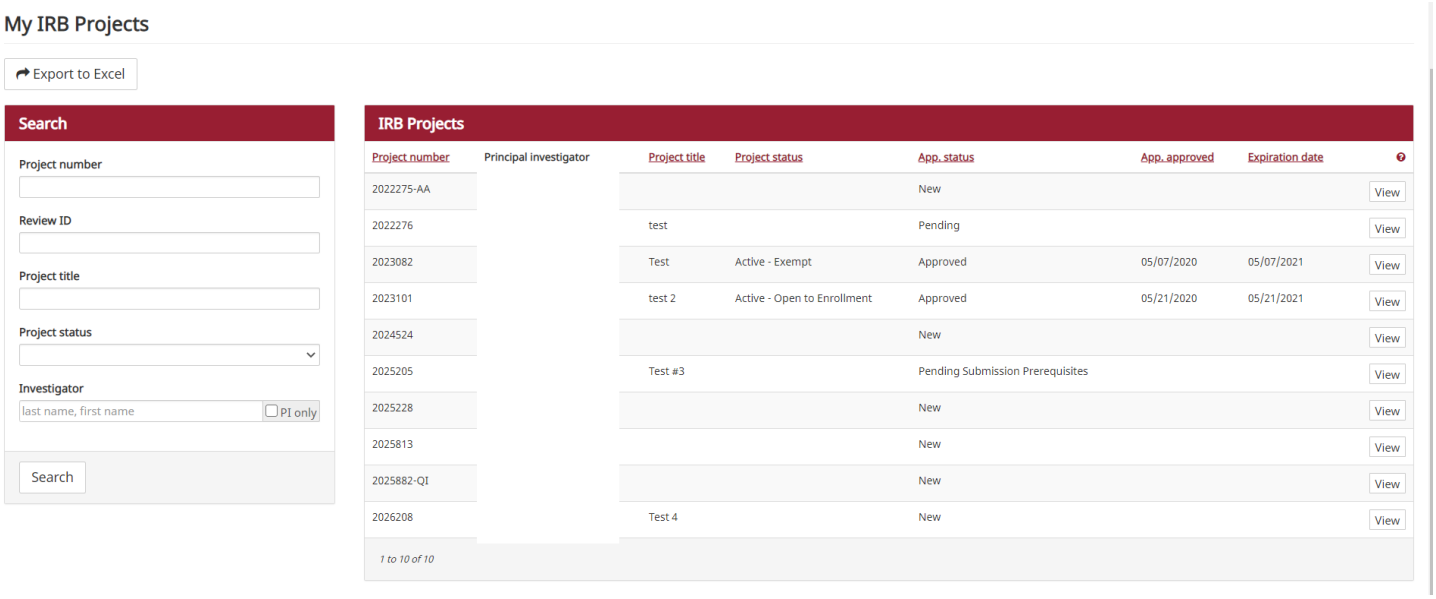
Pending Submission Prerequisites

Project number	Project title	Review ID	Form	Submission date
2025205	Test #3	267220	IRB Application	07/02/2020

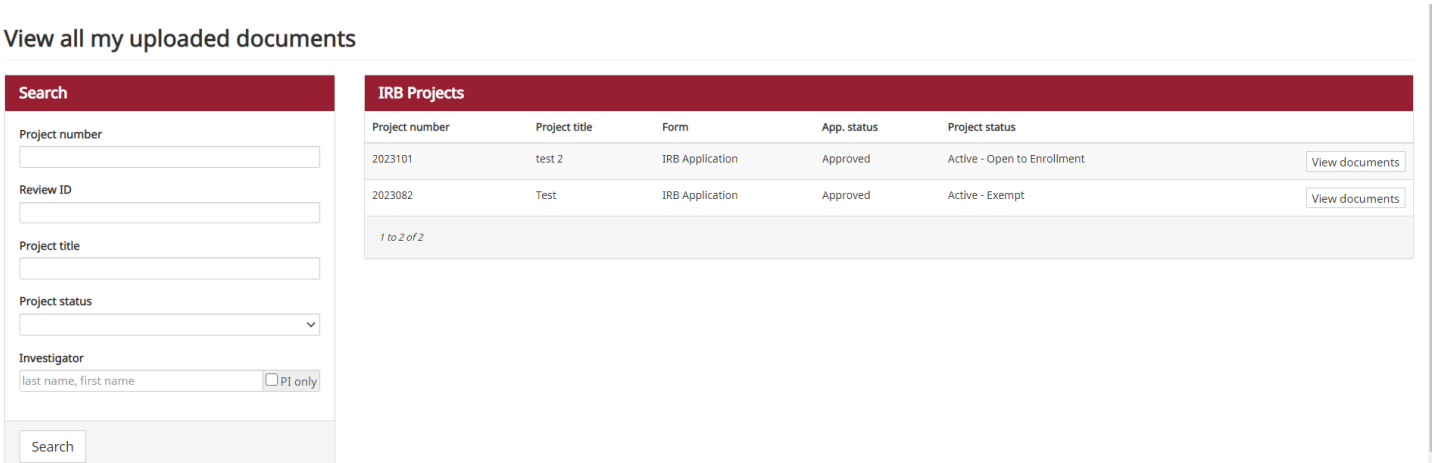
Awaiting Review

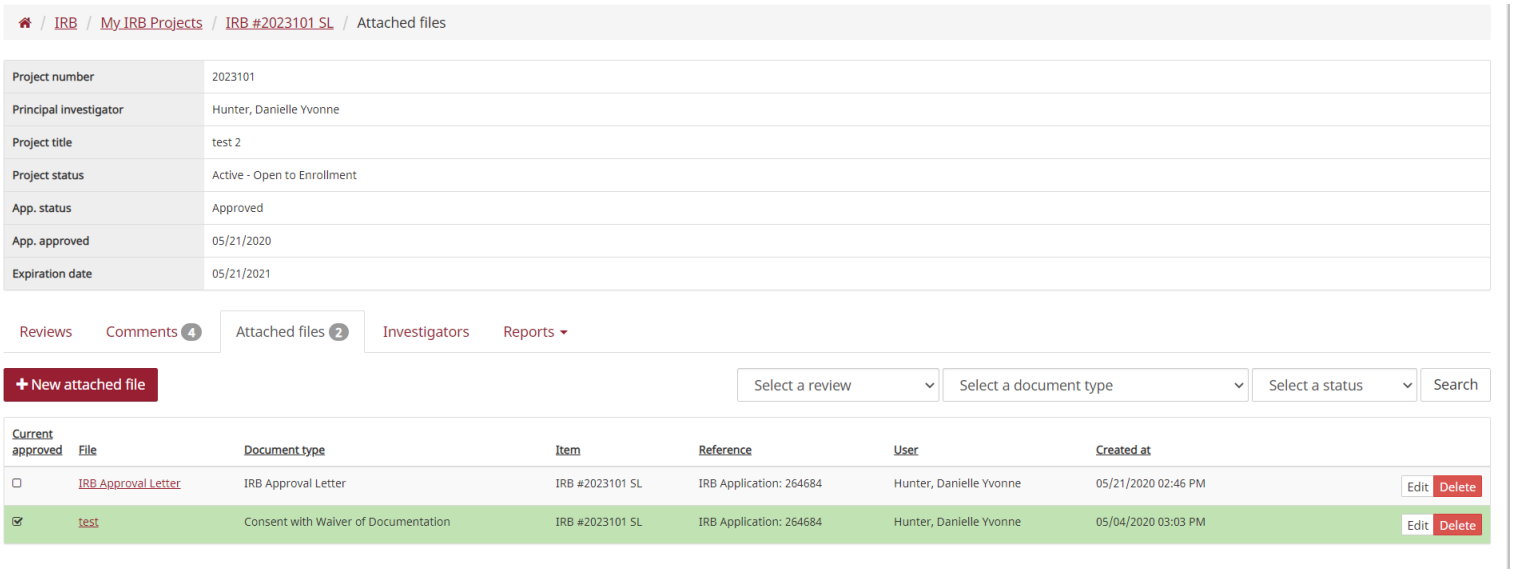
Project number	Project title	Review ID	Form	Submission date
2023082	Test	265513	Exempt Amendment Form	05/19/2020
2022276	test	263519	IRB Application	05/19/2020

6. **View Approved/Archived Projects**: In this column, you will find all projects that have received IRB approval, whether it is currently active or closed with the IRB.
    1) **View All My IRB Projects**: This link will take you to all approved studies, whether it be currently approved or closed. You can access the forms, comments, and documents.



    2) **View All My Uploaded Documents**: This link will take you the same page as above (View All My IRB Projects), but it goes directly to the attached files link where you have uploaded documents to the study. When you click View Documents, it takes you to the second snapshot.





7. **Researcher Resources:** This column will frequently be updated to include up-to-date information and direct access to the IRB website (will open in a separate window), templates, this tutorial document, etc.

Please contact Keri Jupka or Kim Werner if you have questions about which form to complete!

Applications:

1) **Exempt Application:** Submit this application for exempt, minimal risk research. For more information about what is exempt, click here to view the six categories: Exempt Categories
    a) There are additional requirements for research involving children. Not all research involving children can be exempt. This application cannot be used for medical research involving medical procedures, drugs, devices, etc. It is primarily used for social and behavioral research.
3) **IRB Application:** Submit this application for expedited and full board studies (anything that is not exempt, data analysis only, or a database/repository application).
4) **IRB Reliance Request Form:** This form is available for studies that have already received IRB approval from the lead site and you are requesting that the UMSL IRB rely on their approval. An Authorization Agreement between IRBs must be established. This application will ask that you upload all approved documents by the lead IRB ("Reviewing IRB").
5) **Case Report Form:** This form is available to those who are wanting to conduct a single retrospective case report of 3 or less individuals. These are not considered research, but require IRB oversight.
6) **Biorepository/Database Application:** This application is for studies in which the only purpose is to bank blood, tissue, and/or other specimens for future research. It can also be used for studies with the purpose of creating a database of information for future research. *The research conducted using the information/materials within the repository or database must receive separate IRB review/approval. A separate consent template is available within this application for these types of studies.

Quality Improvement Forms:

1) **QI Questionnaire:** Researchers submit this form to determine if the activity is QI only or research – which would prompt a request to submit one of the applications noted above.

Human Subject Research Determination Form:

1) **Human Subject Research Determination Form:** If you are unsure whether your project requires IRB review, submit this form for a determination.

Continuing Review Forms:

1) **Annual Exempt Form:** Prior to your project expiration date of your exempt study, you will need to submit this form to keep your study active. This form should also be used to close your study if it is completed prior to the expiration date.
2) **Continuing Review Report:** Prior to your project expiration date of your expedited or full board study, you will need to submit this form to keep your study active.
3) **IRB of Record Continuing Review:** If the UMSL IRB is relying on another IRB for a particular study and an Authorization Agreement was established between both IRBs, this form is to be used to submit the IRB's continuing approval letter with any new approved documents. This needs to be submitted prior to their IRB's expiration date.

Amendments

1) **Exempt Amendment Form:** This form is to be used when you want to make changes to your exempt study. The changes must receive IRB approval prior to initiating the changes.
2) **Amendment Form:** This form is to be used when you want to make changes to your expedited or full board study. The changes must receive IRB approval prior to initiating the changes.

Required Reporting Forms

1) **Completion/Withdrawal Report:** This form is to be completed if your project is complete or if you wish to withdraw your study because the study was never conducted. This form will provide the IRB with a final status of your study.
2) **Event Report:** You are required to report events or problems that occur on your study that were unexpected, you must submit this report so the IRB can evaluate the event or problem. You must submit this form within 5 days of becoming aware of the event.
3) **Inclusion/Exclusion Exception:** This form must be completed to enroll a subject in your study that does not meet the approved inclusion/exclusion criteria.
4) **Death Report:** If a study participant dies, this must be reported to the IRB. If the death is related to the study, complete the Event Report.

Administrative Forms

1) **Requested Identification Numbers:** If you receive your clinicaltrials.gov number or ORA number, please submit this form to provide the IRB with an update.
2) **Personnel Change Form:** If you propose to make change to the research personnel on your study, submit this form. The only exception would be a PI change which would require an Amendment.
3) **Cumulative AE Log:** Use this form for reporting adverse events that do not require IRB review, but do require proof of IRB submission. You can use this one form to log multiple adverse events.

CITI Registration and Course Completion

Go to the CITI training website by clicking "Take IRB Training"; "Sign-in to CITI program"

a. When registering you will want to affiliate with the University of Missouri-St. Louis
b. After logging in, click on View Courses.
c. Under Learner Tools, select Add a Course and respond to the questions.
d. Question 3 is where you will select either the Biomedical Research Investigator training or Social & Behavioral Research Investigator training. **DNP and PhD students, please consult with your advisor to choose the correct training for your project.**
e. Once complete, a copy of your CITI training certificate should be indicated in your eCompliance profile.

If you have questions about the IRB submission process or CITI training, please contact:
Dr. Kim Werner (wernerk@umsl.edu) or Ms. Keri Jupka (kjzvf@umsl.edu)
IRB Contact: Danielle Hunter at danielle.hunter@umsl.edu or email our general inbox at irb@umsl.edu.