MU eCompliance IRB Quick Reference Tool

1. Login to eCompliance: https://ecompliance.missouri.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**

Welcome to the eCompliance IRB module!
If you have any questions about the eCompliance system, please see the [IRB quick reference](mailto:irb@missouri.edu) or call 573.882.3181.

### Prerequisites
- Take IRB training
- Advisor approval
- PI assurance
- My personal information
- Upload CV/CITI training certificate

### Submission to IRB
- IRB forms
- Open saved IRB project
- Document storage
- Check project status

### View Approved/Archived Projects
- View all my IRB projects
- View all my uploaded documents

### Researcher resources
- IRB Home Page (Office of Research Website)
- Templates (Consent/HIPAA)
- Choosing the Right IRB
- eCompliance Tutorial Document

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.

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**IRB training**

**CITI Program**

The University of Missouri is a subscriber to the Collaborative IRB Training Initiative (CITI) Program. All investigators are required to complete IRB Training through the CITI website in order to receive IRB Certification.

For more information see:
- [MU CITI Program Information](#)
- [CITI Program Website](#)

First time users of the CITI website will need to register a CITI account and choose from the following:

- **Campus IRB users** will choose one of the Campus learner groups:
  - SBR: social behavioral research
  - IRB Member - Members of the board (IRB)

- **HS/IRB users** will choose one of the HS learner groups:
  - Biomedical: for all researchers doing primarily biomedical research
  - SBR (social behavioral research): those researchers doing only social behavioral research (ie MINH)
  - Biomedical/SBR: those researchers who do mixed social behavior and biomedical research (ie, social behavioral research that adds a biomedical component, MRI, blood draw etc.)
  - IRB Member - Members of the IRB Board only

<table>
<thead>
<tr>
<th>Course</th>
<th>Expiration date</th>
<th>Certificate of training</th>
</tr>
</thead>
<tbody>
<tr>
<td>CITI IRB Training</td>
<td>02/07/2017</td>
<td>CITI Completion Reports are available on the CITI website.</td>
</tr>
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</table>
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.

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. [HSIRB users: This process used to be handled prior to the approval letter being sent. This has been moved to the beginning of the process in an effort not to hold up the approval process.]

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/CITI Training Certificate**: If you are prompted to upload a CV during an application review or upload a CITI training certificate, you will do that here. Please note, most investigators will be asked to upload their CV, so this can be uploaded at any time without being prompted.

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, Continuing Review, 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. **Please note, any form that starts with HS are Health Sciences IRB forms only. For more detailed information on what form to complete, see page 9 of this document.**
### Applications

- **Exempt Application**
  - Complete this form for Exempt, minimal risk research. (Contact the IRB if you are unsure whether your research is exempt.)

- **IRB Application**
  - Complete this form for all expedited and full board research.

- **Data Analysis Application**
  - ONLY complete this form for research involving the analysis of existing data, including reviews of medical records. (The data must exist at the time of the IRB submission.)

- **IRB Reliance Request Form**
  - Complete this form for NCI CIRB reliance and for other studies that will rely on another IRB approval.

- **HS Case Report Form**
  - Complete this form for single retrospective case reports of 3 or less individuals.

- **HS Humanitarian Use Device (HUD) Form**
  - Complete this form for Humanitarian Use Device requests.

- **Repository/Database Application**
  - ONLY complete this form for banking blood, tissue, and/or other specimens, to allow for future research. It is also used for creating a database of information, to allow for future research. (A separate submission would be required to use the identifiable data within the repository or database).

### Quality Improvement

- **QI Questionnaire**
  - 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 your project is human subjects research requiring IRB review. (If you already know your project is subject to IRB review, please submit an IRB application.)

### Continuing Review

- **Annual Exempt Form**
  - Complete this form if you wish to renew your exempt study.

- **Continuing Review Report**
  - Complete this form to submit the required continuing review for your Expedited or Full Board study.

- **IRB of Record Continuing Review**
  - This is ONLY to be used for research where MU IRB relies on another IRB (Authorization Agreement).

### 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**
  - Complete this form if your project is complete or if you wish to withdraw your project because the project was never conducted.

- **Event Report**
  - Complete this form to report any unanticipated events (deviations or unanticipated problems) at this site. This form must be submitted within five days of becoming aware of the event.

- **HS Inclusion/Exclusion Exception**
  - Complete this form to submit a request to enroll a subject who does not meet the approved inclusion/exclusion criteria.

- **HS On Site Death Report**
  - Complete this form to report the death of a study participant. If the death is related to the study, complete the Event Report as well.

- **Misc Reporting Form**
  - Complete this form for any miscellaneous item that requires reporting to the MU IRB. (This form may be used when the MU IRB is relying on another IRB and updates are required to be reported.)

- **Emergency Use of a Test Substance Form**
  - Submit this form to request emergency use of a test article. If time did not allow the IRB to be contacted in advance for a determination, this form must be submitted within 5 working days of the test article administration and 30 days from the test article administration. (Contact the IRB office immediately to notify us of this emergency request (573.882.3101))

### Administrative Forms

- **HS Requested Identification Numbers**
  - Complete this form to an approved study to provide your Clinicaltrials.gov number or OSPA number, if it was not previously provided.

- **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 must be requested on an Amendment Form.)

- **HS Monitoring Reports**
  - Use this form to submit all reports from monitors that review the on-site study. The report is required to be submitted within one week of receipt.

- **HS 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.
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.

My saved IRB projects

You can sort these reviews by clicking on the header of each column.

<table>
<thead>
<tr>
<th>Project number</th>
<th>Project title</th>
<th>Review ID</th>
<th>Form</th>
<th>Status</th>
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<td>202005</td>
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<td>HS Cumulative AE Log</td>
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<td></td>
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<td></td>
<td>202704</td>
<td>IRB Application</td>
<td>new</td>
<td></td>
</tr>
</tbody>
</table>

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

**IRB #2002005 HS**

Sections

1. Investigators
2. Protocol Changes: OH, EB, and ID
3. Financial Conflict of Interest
4. Locating of Research
5. Project Information
6. Subject Recruitment
7. Consent Process
8. Confidentiality and Security
9. Risks and Benefits
10. Costs Associated with the Research
11. Subforms
12. Attached Files
13. Submit

Investigators

1. Project title (do not use all capitals)

   Provide the full title of the project.

2. Study Staff (students, fellows & residents must have a faculty member as a co-investigator)

   [Add an Investigator]

<table>
<thead>
<tr>
<th>Role</th>
<th>Investigator</th>
<th>Department</th>
<th>IRB training date</th>
<th>Primary contact</th>
<th>Consent personal role</th>
<th>Veterans personal</th>
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<tbody>
<tr>
<td>Adviser/Co-</td>
<td>John Doe</td>
<td>Institutional Review Board</td>
<td>05/05/01</td>
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<tr>
<td>Investigator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Authorized to Obtain Consent</td>
<td>Yes</td>
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</table>

3. Contact Information

   Principal investigator

   Primary contact

4. Is this application submitted by an outside entity utilizing MU IRB as their IRB of record?

   The answer is YES if MU has entered into a formal collaborative agreement with the outside entity to be their IRB of record. If you are unsure, please contact the IRB office at 573-882-3181.

   - [ ] Yes
   - [x] No
3) **Document Storage:** If you are currently working on a submission, you can find a direct link to the documents here. If you received a request to upload a document(s) and not edit the actual IRB form itself, you can add the document(s) here.

3a) When you click VIEW/UPLOAD DOCUMENTS, you will be presented with this page to add/edit new documents:

4) **Check Project Status:** If you have submitting 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.
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 call the office 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) **Data Analysis Application**: Submit this application for health record review requests, studies only involving analysis of existing data, and transfer studies (you are transferring from another institution) where the activities are limited to data analysis.

5) **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 MU 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”).

6) **HS 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.

7) **HS Humanitarian Use Device (HUD) Form**: This form is available for studies utilizing an HUD. This is not considered research, but requires IRB approval.

8) **Repository/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. This form should also be used to close your study if it completed prior to the expiration date.
3) **IRB of Record Continuing Review:** If the MU 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) **HS 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) **HS On-Site 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.

5) **Misc Reporting Form:** This form should be used for reportable items that do not require reporting via an Amendment. For example, this form may be used when the MU IRB is relying on another IRB and updated are required to be reported. Typically, the IRB will direct you to complete this form, if it is necessary.

6) **Emergency Use of a Test Substance Form:** Submit this form to request emergency use of a test article.

**Administrative Forms**

1) **HS Requested Identification Numbers:** For an HSIRB approved study, if you receive your clinicaltrials.gov number or OSPA 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) **HS Monitoring Reports:** When a monitor comes on-site to review your study, this report must be submitted within one week of receipt. Their report must be uploaded to this form.

4) **HS Cumulative AE Log:** For an HSIRB approved study, 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.