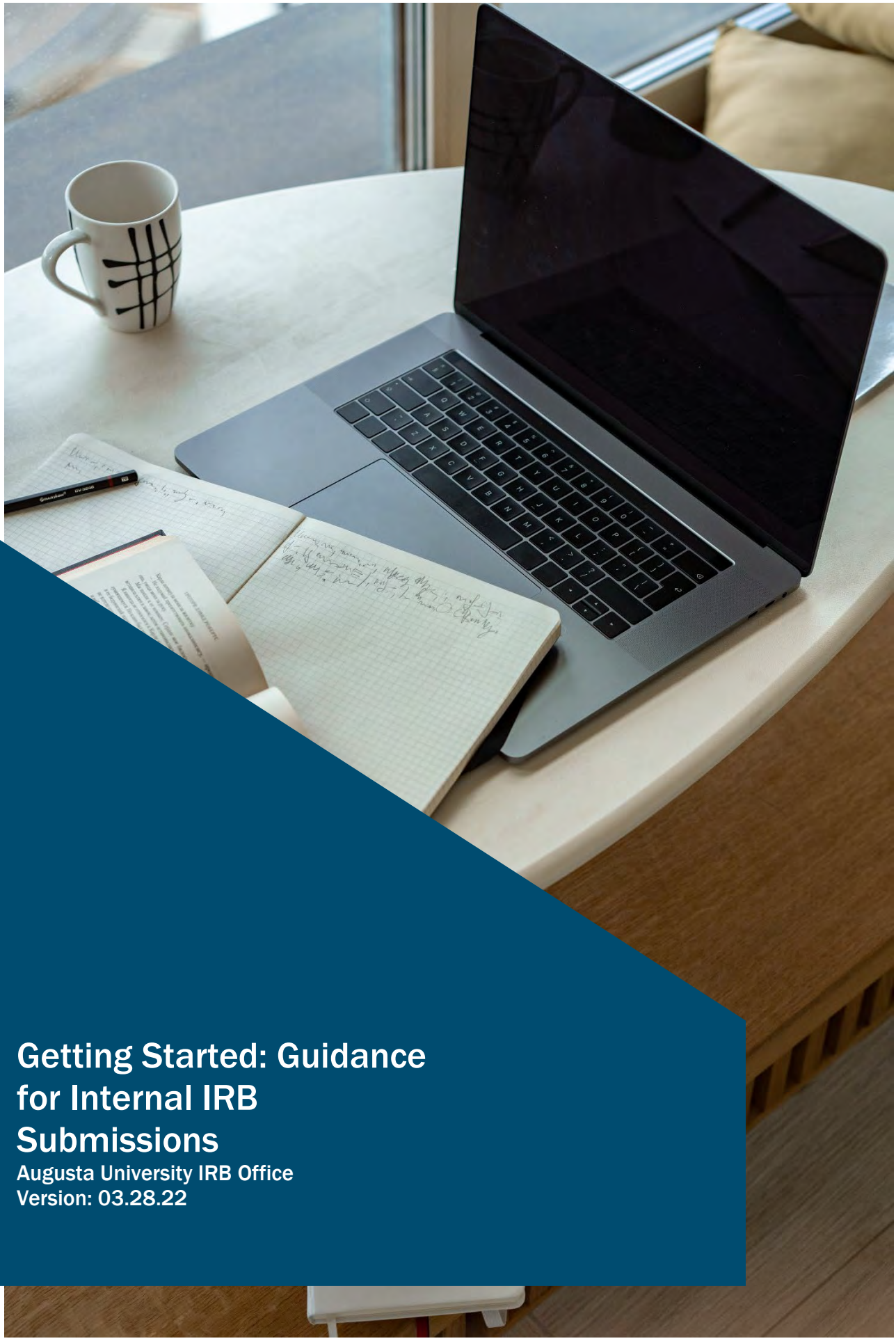

Getting Started: Guidance for Internal IRB Submissions

Augusta University IRB Office
Version: 03.28.22

AUGUSTA UNIVERSITY
Institutional Review Board Office

Table of Contents

Submitting a Human Subject Determination Request

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Ensure you have an active IRBNet Account? If not, please register at www.irbnet.org. This is the platform used for all IRB submissions.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Scope of Work. This template can be found in the IRBNet Forms and Templates Library.	☐	☐	
Human Subject Determination Form. Please use the most current form. This document can be found in the IRBNet Forms and Templates Library.	☐	☐	
Data Collection Form, if applicable.	☐	☐	
Grant, if applicable.	☐	☐	

Submission Step-by- Step

1. Log in to IRBNet at www.irbnet.org.
2. Click the tab that says Create New Project.
3. On the Designer page, upload the Scope of Work and Human Participant Research Determination Form by clicking the 'Attach new document' link.
4. Sign this package as the Principal Investigator.
5. Submit this Package.
   a. Choose Augusta University (AU) IRB Office, Augusta, GA.
   b. Submit as 'Other'

Please Read:

A Human Subject Determination Request (HSD) is an IRBNet submission for individuals who are unsure if their project meets the federal definition of **Human Subject Research.** An HSD is NOT the same as an **Exempt Study Submission**. If you believe your study is an **Exempt Research Project**, please review the IRB Exempt Policy and follow the Submitting a New Exempt Study Guidance.

Version Date: 06.14.21, 03.28.22

HIPAA AUTHORIZATION WAIVER REQUEST

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Required Documents	Yes	No	Comments
Supplemental Form: Waiver of HIPAA Authorization	☐	☐	
A memo detailing the request for waiver of HIPAA authorization to include a list of identifiers needed, where these identifiers will be obtained from (i.e.: patient's medical record), and the reason for the request.	☐	☐	

Note: If this is being submitted with a Human Subject Determination Request- remember to upload the Supplemental Form: Human Research Determination Request Form (New Regulations/2018 Regulations).

Submission Step-by- Step

1. Create a new package via Project History
2. Ensure the submission type is Other
3. Ensure the required documents are uploaded in your package on the Designer page.
4. Obtain Required Signatures:
5. Principal Investigator
6. Faculty Sponsor, if applicable
7. Submit the Package

For assistance, please contact the IRB Office at 706-721-3110 or IRB@augusta.edu.

Please Read:

The IRB at Augusta University also serves as the AU Privacy Board for HIPAA-related research. A Privacy Board is a review body established to act upon requests for a waiver or an alteration of the HIPAA Authorization requirement under the HIPAA Privacy Rule for uses and disclosures of protected health information (PHI) for a particular research study. A waiver of HIPAA authorization should be requested when there is a need to access or collect protected health information for research purposes to include recruitment.

Submitting a New Study (General)

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Complete your CITI Training? Please review the CITI Program Guidance. ALL AU Investigators are required to complete this training before submitting to the IRB.	☐	☐	
Create an IRBNet Account? Create an account at www.irbnet.org. This is the platform used to submit projects to the IRB.	☐	☐	
Upload a copy of your CV/Resume to your IRBNet User Profile? Make sure the date you last updated your CV/Resume is visible in the header or footer of your document.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Protocol Template. Available in IRBNet Forms and Templates or Protocol Builder.	☐	☐	
Core Data Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page.	☐	☐	
Data Collection Form (ex. - survey, questionnaire, Excel spreadsheet, interview script) – Please ensure you put a version date in the footer of this document.	☐	☐	
Applicable Supplemental Forms (indicated on the last page of the Core Data Form)	☐	☐	
Attestation Forms: • Research Data Storage. Must be signed by the PI and Faculty Sponsor if applicable • Conflict of Interest Attestation. All study team members listed on the Core Data Form must sign this form. This document must be signed using DocuSign or with a wet signature.	☐	☐	
Informed Consent Document. Please use the AU Templates located in IRBNet.	☐	☐	
Sponsor's Protocol	☐	☐	
Advertisements. Templates available in IRBNet.	☐	☐	
Drug and Device Information	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and click Create a New Project.
2. Upload your study's required documents. Review the table to the left of this column for required documents.
3. Share your package with all study team members listed on the Core Data Form as well as the Department Approver. (Click Share this Package, click blue word Share, Click Select Organization, Search for User, Grant needed access).
4. Link all study team member training and credentials records. (On the Designer page, navigate to the Link/Un-Link Training Records link) Each team member must have a CV/Resume and a valid CITI.
5. Obtain Required Signatures.
    a. Principal Investigator
    b. Department Chair
    c. Faculty Sponsor (for AU Students and Residents)
6. Review your checklist to ensure all required Documents are in your package.
7. Click Submit. Remember to follow all prompts. New research studies should be submitted as 'New Project.

For a demonstration for submitting a New Study Review the Submitting a New Study Training Video located on the IRB Office Website.

Version Date: 06.14.21, 03.28.22

Additional Guidance:

Your study may need additional approvals before you submit to the IRB. Please review the below chart.

☐ Radiation Safety Committee Approval, for studies involving radiation outside of standard of care (for more information email radiationsafetyoffice@augusta.edu)	☐ Stem Cell Committee Approval, for studies involving stem cells for research purposes (evaluated on a case-by-case basis at this time)	☐ Biosafety Committee Approval, for studies involving any of the following: Introduction/Exposure to Biological Materials, Gene Transfer. Stem Cells, and/or Select Agents and Toxins (for more information email BIOSAFETY@augusta.edu)	☐ PRMC Approval for Oncology studies (excluding Chart Review studies) (for more information navigate to this website https://www.augusta.edu/cancer/research/documents/prmcinitialsubmissionformv2252021.docx	☐ Education Research Review Approval for studies involving use of MCG students or their data for research purposes (for more information or to see if your study requires this type of approval navigate to this website https://www.augusta.edu/mcg/coffice/evaluation-services/edresearch.php)

IRB Submission Process:

YOUR STUDY IS SUBMITTED TO THE IRB

The IRB Office Analyst will review your study for completeness. If there are issues, they will unlock your package and send an email through IRBNet with a list of stipulations.

Be sure to complete revisions or requests for information in a timely manner.

Review the Responding to Package Unlocks Guidance for assistance or contact the IRB Office.

THE STUDY IS FORWARDED TO THE IRB REVIEWER

Once your study has been reviewed by the Analyst and there are no stipulations to address, it is forwarded to the IRB.

Once the IRB completes their review, a letter is prepared and sent to the study team.

THE IRB SENDS COMMUNICATION TO THE STUDY TEAM

IF your study is approved, you will receive an approval letter or Exempt letter. This letter is located in the Reviews tab of your project. Remember to read this letter carefully.

If the IRB reviews your submission and they request revisions or need more information, you will receive letter detailing their stipulations. Be sure to review this letter and respond in a separate Response/Follow -Up package. Follow the Submitting a Response/Follow Up Package guidance or contact the IRB Office if you have questions.

Submitting a New Study for Social-Behavioral and Educational Research

This is a general guide that helps investigators submit a research study for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Complete your CITI Training? Please review the CITI Program Guidance. **ALL** AU Investigators are required to complete this training before submitting to the IRB. Social-Behavioral and Educational Researchers typically complete CITI Group 7. Read the CITI guidance thoroughly to make sure you select the appropriate module.	☐	☐	
Create an IRBNet Account? Create an account at www.irbnet.org. This is the platform used to submit projects to the IRB.	☐	☐	
Upload a copy of your CV/Resume to your IRBNet User Profile? Make sure the **date** you **last updated** your CV/Resume is visible in the header or footer of your document.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Protocol Template. Available in IRBNet Forms and Templates or on Protocol Builder.	☐	☐	
Core Data Form. This is a ***Wizard*** document located on the Designer Page. To access this document, go to the Designer Page and click ***Start a Wizard***	☐	☐	
Data Collection Form (ex. - survey, questionnaire, Excel spreadsheet, interview script). Be sure put a **version date** in the footer of Word documents.	☐	☐	
Applicable Supplemental Forms indicated on the last page of the Core Data Form.	☐	☐	
Attestation Forms: • Research Data Storage. Must be signed by the PI and Faculty Sponsor, if applicable • Conflict of Interest Attestation All study team members listed on the Core Data Form must sign this form. This document must be signed using DocuSign or with a wet signature.	☐	☐	
Informed Consent Document or Consent Information Sheet, ***if applicable***. Please use the AU Templates located in the IRBNet Forms and Templates library. There are templates for both **Paper and Web-based surveys** as well as a **Consent Template**.	☐	☐	
Sponsor's Protocol, *if applicable.*	☐	☐	
Advertisements, *if applicable.* Templates available in IRBNet.	☐	☐	

Submission Step-by- Step

1. **Log into IRBNet and click Create a New Project.**
2. **Upload your study's required documents.** Review the table to the left of this column for required documents.
3. **Share your package with all study team members listed on the Core Data Form as well as the Department Approver. (**Click Share this Package, click blue word Share, Click Select Organization, Search for User, Grant needed access**).**
4. **Link all study team member training and credentials records. (**On the Designer page, navigate to the Link/Un-Link Training Records link) Each team member must have a CV/Resume and a valid CITI Training complete.
5. **Obtain Required Signatures.**
   a. **Principal Investigator**
   b. **Department Chair**
   c. **Faculty Sponsor (for AU Students and Residents)**
6. **Review your checklist to ensure all required Documents are in your package.**
7. **Click Submit.** Remember to follow all prompts. New research studies should be submitted as 'New Project.'

For a demonstration for submitting a New Study Review the Submitting a New Study Training Video located on the IRB Office Website.

Version Date: 06.14.21, 03.28.22

Additional Considerations:

Research that involves the use of MCG students or their data for research purposes must have **Education Research Review Approval** before the study is submitted to the IRB. See the link below. https://www.augusta.edu/mcg/coffice/evaluation-services/edresearch.php)	For **Research that Involves Online Surveys**, be sure to use **Qualtrics**. Augusta University has a university account available to all AU affiliates. See the link below to register. https://augusta.ca1.qualtrics.com/homepage/ui Once at the above site click on "Don't have an account?" **no passcode is required.**	If an investigator wishes to use **student or educational records for research purposes**, they must comply with **FERPA regulations**. Be sure to visit the AU registrar's office website and review the IRB Policy – Research Conducted in Public Schools.	**Investigators must have permission to conduct research at non-affiliated sites.** If you plan on conducting research at a non-affiliated location, upload a copy of permission from the site's director, supervisor, etc. Contact the IRB Office if you are unsure.	Read the IRB Policy – Exempt Review and/or IRB Policy – Expedited Review to ensure your study meets federal regulations as well as Augusta University guidelines.

IRB Submission Process: Once you meet all package requirements, you are ready to begin the IRB submission process.

YOUR STUDY IS SUBMITTED TO THE IRB

The IRB Office Analyst will review your study for completeness. If there are issues, they will **unlock** your package and send an email through IRBNet with a list of stipulations.

Be sure to complete revisions or requests for information in a timely manner.

Review the **Responding to Package Unlocks Guidance** for assistance or contact the IRB Office.

THE STUDY IS FORWARDED TO THE IRB REVIEWER

Once your study has been reviewed by the Analyst and there are no stipulations to address, it is forwarded to the IRB.

Once the IRB completes their review, a letter is prepared and sent to the study team.

THE IRB SENDS COMMUNICATION TO THE STUDY TEAM

IF your study is approved, you will receive an **Approval** letter or **Exempt** letter. This letter is located in the Reviews tab of your project. Remember to read this letter carefully.

If the IRB reviews your submission and they request revisions or need more information, you will receive a **Modifications Required Letter** detailing their stipulations. Be sure to review this letter and respond in a separate Response/Follow -Up package.

Follow the **Submitting a Response/Follow Up Package** guidance or contact the IRB Office if you have questions.

Submitting a New Exempt Study

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Complete your CITI Training? Please review the CITI Program Guidance. ALL investigators conducting research at AU are required to complete this training *before* submitting to the IRB.	☐	☐	
Create an IRBNet Account? Create an account at www.irbnet.org. This is the platform used to submit projects to the IRB.	☐	☐	
Upload a copy of your CV/Resume to your IRBNet User Profile? Make sure the date you last updated your CV/Resume is visible in the header or footer of your document.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Core Data Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page.	☐	☐	
Data Collection Form (ex. - survey, questionnaire, Excel spreadsheet, interview script) – Please ensure you put a version date in the header or footer of this document.	☐	☐	
Applicable Supplemental Forms (indicated on the last page of the Core Data Form)	☐	☐	
Attestation Forms: • Research Data Storage. Must be signed by the PI and Faculty Sponsor if applicable • Conflict of Interest Attestation. All study team members listed on the Core Data Form must sign this form. This document must be signed using DocuSign or with a wet signature.	☐	☐	
Advertisements/Recruitment Scripts. Advertisement templates available in IRBNet. Any recruitment script or emails sent to potential participants must be included with your submission. Remember to add the version date to this document.	☐	☐	

Submission Step-by- Step

1. Log in to IRBNet and click Create a New Project.
2. Upload your study's required documents.
3. Share your package with all study team members listed on the Core Data Form as well as the Department Approver. (Click Share this Package, click blue word Share, Click Select Organization, Search for User, Grant needed access).
4. Link all study team member training and credentials records. (On the Designer page, navigate to the Link/Un-Link Training Records link) Each team member must have a CV/Resume and a valid CITI.
5. Obtain Required Signatures.
    a. Principal Investigator
    b. Department Chair
    c. Faculty Sponsor (for AU Students and Residents)
6. Please review the Required Documents section thoroughly to ensure all required documents are uploaded to your package.
7. Click Submit.

Version Date: 06.14.21, 03.28.22

Additional Guidance:

Your study may need additional approvals before you submit to the IRB. Please review the below chart.

☐ Radiation Safety Committee Approval, for studies involving radiation outside of standard of care (for more information email radiationsafetyoffice@augusta.edu)	☐ Stem Cell Committee Approval, for studies involving stem cells for research purposes (evaluated on a case-by-case basis at this time)	☐ Biosafety Committee Approval, for studies involving any of the following: Introduction/Exposure to Biological Materials, Gene Transfer. Stem Cells, and/or Select Agents and Toxins (for more information email BIOSAFETY@augusta.edu)	☐ PRMC Approval for Oncology studies (excluding Chart Review studies) (for more information navigate to this website https://www.augusta.edu/cancer/research/documents/prmcinitialsubmissionformv2252021.docx	☐ Education Research Review Approval for studies involving use of MCG students or their data for research purposes (for more information or to see if your study requires this type of approval navigate to this website https://www.augusta.edu/mcg/coffice/evaluation-services/edresearch.php)

IRB Submission Process:

YOUR STUDY IS SUBMITTED TO THE IRB

The IRB Office Analyst will review your study for completeness. If there are issues, they will unlock your package and send an email through IRBNet with a list of stipulations.

Be sure to complete revisions or requests for information in a timely manner.

Review the Responding to Package Unlocks Guidance for assistance or contact the IRB Office.

THE STUDY IS FORWARDED TO THE IRB REVIEWER

Once your study has been reviewed by the Analyst and there are no stipulations to address, it is forwarded to the IRB.

Once the IRB completes their review, a letter is prepared and sent to the study team.

THE IRB SENDS COMMUNICATION TO THE STUDY TEAM

IF your study is approved, you will receive an approval letter or Exempt letter. This letter is located in the Reviews tab of your project. Remember to read this letter carefully.

If the IRB reviews your submission and they request revisions or need more information, you will receive letter detailing their stipulations. Be sure to review this letter and respond in a separate Response/Follow -Up package. Follow the Submitting a Response/Follow Up Package guidance or contact the IRB Office if you have questions.

Submitting a New Chart Review Study

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Complete your CITI Training? Please review the CITI Program Guidance. ALL investigators conducting research at AU are required to complete this training *before* submitting to the IRB.	☐	☐	
Create an IRBNet Account? Create an account at www.irbnet.org. This is the platform used to submit projects to the IRB.	☐	☐	
Upload a copy of your CV/Resume to your IRBNet User Profile? Make sure the date you last updated your CV/Resume is visible in the header or footer of your document.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Core Data Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page.	☐	☐	
Data Collection Form (ex. - Excel spreadsheet or Word Document with data points) – Please ensure you insert a version date in the header or footer of all Word documents.	☐	☐	
HIPAA Authorization Waiver Request. Located in the IRBNet Forms and Templates Library.	☐	☐	
Attestation Forms: • Research Data Storage. Must be signed by the PI and Faculty Sponsor if applicable • Conflict of Interest Attestation. All study team members listed on the Core Data Form must sign this form. This document must be signed using DocuSign or with a wet signature.	☐	☐	

Submission Step-by- Step

1. Log in to IRBNet and click Create a New Project.
2. Upload your study's required documents. Review the table to the left of this column for required documents.
3. Share your package with all study team members listed on the Core Data Form as well as the Department Approver. (Click Share this Package, click blue word Share, Click Select Organization, Search for User, Grant appropriate access level).
4. Link all study team member training and credentials records. (On the Designer page, navigate to the Link/Un-Link Training Records link) Each team member must have a CV/Resume and a valid CITI.
5. Obtain Required Signatures.
    a. Principal Investigator
    b. Department Chair
    c. Faculty Sponsor (for AU Students and Residents)
6. Please review the Required Documents section thoroughly to ensure all required documents are uploaded to your package.
7. Click Submit. Remember to follow all prompts. New research studies should be submitted as 'New Project.'

Version Date: 10.13.21, 03.28.22

Additional Guidance:

PRIVACY AND CONFIDENTIALITY CONSIDERATIONS:

Confidentiality refers to the treatment of identifiable data. Since you are collecting PHI for your chart review study, it is important to ensure data is protected. Your protocol must include:

- How you will store the data. Remember, the Human Research Box Folder is a mechanism for storing HIPAA protected data.
- How you will lessen the potential risk of loss of confidentiality. *Coding* data is one way investigators provide additional protection against a breach in confidentiality.

CODED VS. DE-IDENTIFIED DATA:

Data is considered *coded* when identifying information (such as name or social security number) has been replaced with a number, letter, symbol, or combination thereof (i.e.: the code); and a key to decipher the code exists.

Data is *de-identified* when direct identifiers were removed from previously collected data. If you are reviewing patient records, this definition does not apply to your study.

For additional guidance see the Investigator Guide to Data.

OTHER CONSIDERATIONS

Investigators must also be aware that your study may require additional approvals *before* you submit to the IRB.

Contact the IRB Office during study planning for more information.

Contact Information:

706-721-3110; IRB@augusta.edu

You may also visit the IRB Office website to request training or submit an inquiry using the Ask Andy Feature.

IRB Submission Process:

YOUR STUDY IS SUBMITTED TO THE IRB

The IRB Office Analyst will review your study for completeness. If there are issues, they will unlock your package and send an email through IRBNet with a list of stipulations.

Be sure to complete revisions or requests for information in a timely manner.

Review the Responding to Package Unlocks Guidance for assistance or contact the IRB Office.

THE STUDY IS FORWARDED TO THE IRB REVIEWER

Once your study has been reviewed by the Analyst and there are no stipulations to address, it is forwarded to the IRB.

Once the IRB completes their review, a letter is prepared and sent to the study team.

THE IRB SENDS COMMUNICATION TO THE STUDY TEAM

IF your study is approved, you will receive an approval letter or Exempt letter. This letter is located in the Reviews tab of your project. Remember to read this letter carefully.

If the IRB reviews your submission and they request revisions or need more information, you will receive letter detailing their stipulations. Be sure to review this letter and respond in a separate Response/Follow -Up package. Follow the Submitting a Response/Follow Up Package guidance or contact the IRB Office if you have questions.

Responding to Package Unlocks

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Read your message from the IRB Office Analyst? Be sure to read the email from the analyst thoroughly and ask questions for clarification. Analysts will provide a detailed list of items needed for your project.	☐	☐	

Things to Remember	
When submitting to the IRB, your study's first stop is with the IRB Office Analyst.	I. Whenever there are stipulations, the IRB Analyst will **unlock** your package.
At this time, the Analyst reviews your project for completion and they may have stipulations for you to address before your project is forwarded to the IRB or IRB Chair.	II. Be sure to revise all documents or provide the information or supplemental forms needed for your project. ***Supplemental forms and templates are in the IRBNet Forms and Templates library.***
Stipulations will be sent via email through IRBNet. It is important that you check your email and submit your revisions in a timely manner to avoid delay in the review of your study.	
Remember, if you have questions or concerns regarding stipulations from the Analyst, you may reach out to the Analyst directly or call the IRB Office at 706-721-3110.	

Helpful Tips:

STACKING DOCUMENTS:

On the Designer Page:

1. Click the pencil icon next the appropriate document in the *Documents from Previous Packages* Section.
2. Upload the revised document. This will stack the revised document.
3. To revise the Core Data Form, click the pencil icon. This will open up the Wizard. Once revisions are saved, the Core Data Form will be 'Stacked.'

For a picture tutorial, review the Guidance: How to Revise/Stack Previously Submitted Documents

TRACKED CHANGES:

All Word documents being revised should be revised using Track Changes.

To turn on track changes in Word, navigate to the REVIEW tab and click "Track Changes" *before* you begin making any changes.

Also, be sure to update the version dates!

For additional guidance see: Guidance: How to Revise/Stack Previously Submitted Documents (found in IRBNet, under forms and templates).

QUESTIONS REGARDING YOUR STIPULATIONS

If there are questions or concerns regarding your stipulations, contact the IRB Office for assistance *before* marking your revisions complete. .

We are here to help!

Contact Information:

706-721-3110; IRB@augusta.edu

You may also visit the IRB Office website to request training or submit an inquiry using the Ask Andy Feature.

Version Date: 06.14.21, 03.28.22

Submitting a Response Follow-Up Package for IRB Request for Revisions or More Information

When a package is reviewed by the IRB and additional action is required, researchers receive a formal letter indicating Modifications Required, Approved with Conditions or Information Required noting these changes. This document guides researchers on how to submit revised documents back to the IRB in a Response/Follow-up Package.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Read your letter from the IRB? Please read this letter carefully *before* revising any documents, the letter may contain specific instructions.	☐	☐	
For revised Word documents, did you complete your revisions using Tracked Changes ***and*** update the version date? Review the Helpful Tips on page 2 of this guidance or contact the IRB Office for assistance.	☐	☐	
Complete the Stipulation Response Letter? The Stipulation Response Template is on page 3 of this guidance.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Stipulation Response Letter. The template is located below. It can also be found in the IRBNet Forms and Templates library. Please upload this letter in a separate document.	☐	☐	
Revised documents. Documents such as the Protocol, Core Data Form, Advertisements, Surveys/Questionnaires, and scripts must be stacked.	☐	☐	
Documents or Supplemental Forms Requested by the IRB, if applicable.	☐	☐	
If you are required to link study personnel training, be sure to share the project with the study personnel and link their training on the Designer Page.	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. Upload and/or stack required documents on the Designer Page. Review the Helpful Tips section of this guidance to learn more about stacking documents.
4. Obtain required Signatures:
    a. Principal Investigator
    b. Faculty Sponsor, if applicable
5. Click Submit.

IMPORTANT:

It is important read your letter from the IRB thoroughly and respond only to the items listed. If you have questions about your stipulations or are unsure on how to respond, you may contact the IRB Office or follow up with the IRB analyst for assistance.

Helpful Tips:

STACKING DOCUMENTS:

On the Designer Page:

1. Click the pencil icon next the appropriate document in the *Documents from Previous Packages* Section.
2. Upload the revised document. This will stack the revised document.
3. To revise the Core Data Form, click the pencil icon. This will open up the Wizard. Once revisions are saved, the Core Data Form will be 'Stacked.'

For a picture tutorial, review the Guidance: How to Revise/Stack Previously Submitted Documents

TRACKED CHANGES:

All Word documents being revised should be revised using Track Changes.

To turn on track changes in Word, navigate to the REVIEW tab and click "Track Changes" ***before*** you begin making any changes.

Also, be sure to update the version dates!

For additional guidance see: Guidance: How to Revise/Stack Previously Submitted Documents (found in IRBNet, under forms and templates).

QUESTIONS REGARDING YOUR LETTER

If after reviewing your letter from the IRB and you have questions, contact the IRB Office for assistance *before* submitting this package.

We are here to help!

Contact Information:

706-721-3110; IRB@augusta.edu

You may also visit the IRB Office website to request training or submit an inquiry using the Ask Andy Feature.

Stipulation Response Letter Template

Protocol and Package Number: Click here to enter text.
Protocol Title: Click here to enter text.
PI Name: Click here to enter text.

Date: Click here to enter text.

Dear IRB Committee,

I am in receipt of the IRB Letter, dated Click here to enter text. indicating Modifications Required for the above-referenced protocol and package. Please see my response below

***** List each stipulation individually and include a response below it.***

1. Revision(s) required:

Response from PI:

2. Revision(s) required:

Response from PI:

3. Revision(s) required:

Response from PI:

Thank you for your review of my submission,

PI Name: Click here to enter text.

Exempt to Expedited Review

Regarding the EXEMPT REVIEW request submitted to the IRB, the IRB Designated Reviewer determined that your submission qualifies for EXPEDITED REVIEW. The updates below are required to be completed by the date listed in the published Modifications Required letter.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

When an IRB Designated Reviewer Determines that your Exempt Review Request Qualifies for Expedited Review….

1. Create a New Package for this project in IRBNet. Be sure to read the Modifications Required Letter carefully.
2. In Designer, select the Pencil icon next to the previously submitted Core Data Form and use the "Jump To" dropdown box to select "Review Information". Update the selected Level of Review to indicate Expedited Request (minimal or no known risk).
3. For Expedited Review, you are required to complete a protocol template. The template is located in the IRBNet Forms and Templates library. Information related to the protocol that was previously stated in the Core Data Form should be transferred into the template.
4. Review the Form Complete page of the Core Data Form to determine if any supplemental forms/documentation is required for your submission.
5. If your research involves consenting participants, complete and upload the appropriate consent form template.

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. Upload and/or stack required documents on the Designer Page. Review the Submitting a Response Follow Up Package for IRB Request for Revisions or More Information guidance document. Also, please be sure to review the Modifications Required letter for additional information.
4. Obtain required Signatures:
    a. Principal Investigator
    b. Faculty Sponsor, if applicable
5. Click Submit.

IMPORTANT:

It is important read your letter from the IRB thoroughly and respond only to the items listed. If you have questions about your stipulations or are unsure on how to respond, you may contact the IRB Office or follow up with the IRB analyst for assistance.

Version Date: 03.28.22

Submitting an Amendment

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
For personnel changes, did you ensure new team members have an active IRBNet account, have completed their CITI training and uploaded a copy of their CV/Resume to their IRBNet User Profile? Follow the CITI Program Guidance.	☐	☐	
For revised Word documents, did you complete your revisions using Tracked Changes ***and*** update the version date? Review the Helpful Tips on page 2 of this guidance or contact the IRB Office for assistance.	☐	☐	
Review the Amendments Policy? Review it here. It is available on the Tools for Researchers Website.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Amendment/Modification Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page.	☐	☐	
For *personnel changes*, new study team members must sign the Conflict of Interest Attestation.	☐	☐	
Revised Protocol and/or Sponsor's Protocol, if applicable.	☐	☐	
Revised Core Data Form, if applicable.	☐	☐	
Revised and/or new Advertisements, if applicable.	☐	☐	
Revised Informed Consent Documents or Assent Documents, if applicable.	☐	☐	
Revised Drug/Device Information, if applicable.	☐	☐	
Revised Supplemental Forms, if applicable.	☐	☐	

Submission Step-by- Step

1. Select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. Complete the Amendment/Modification Wizard document and upload applicable forms.
4. Remember to stack** revised documents appropriately. Review the 'Helpful Tips' section to learn more about stacking documents.
5. For personnel changes, be sure to Share your project with new team members and link their CITI training and CV/Resume. When removing personnel, update the Core Data Form and un-share the project with them.
6. Obtain required signatures:
    a. Principal Investigator
    b. Faculty Sponsor, if applicable
    c. For PI changes, the Department Chair and the previous PI must sign (unless the PI is no longer with the institution).
7. Click Submit.

Helpful Tips:

STACKING DOCUMENTS:

On the Designer Page:

1. Click the pencil icon next the appropriate document in the *Documents from Previous Packages* Section.
2. Upload the revised document. This will stack the revised document.
3. To revise the Core Data Form, click the pencil icon. This will open up the Wizard. Once revisions are saved, the Core Data Form will be 'Stacked.'

For a picture tutorial, review the Guidance: How to Revise/Stack Previously Submitted Documents

TRACKED CHANGES:

All Word documents should be revised using Track Changes.

To turn on track changes in Word, navigate to the REVIEW tab and click "Track Changes" ***before*** you begin making any changes.

Be sure to update the version dates!

For additional guidance see: Guidance: How to Revise/Stack Previously Submitted Documents (found in IRBNet, under forms and templates).

QUESTIONS REGARDING YOUR AMENDMENT

We are here to help!

Contact Information:

706-721-3110; IRB@augusta.edu

You may also visit the IRB Office website to request training or submit an inquiry using the Ask Andy Feature.

ADDING A NEW STUDY PERSONNEL:

Remember to ensure the new study team member has completed the appropriate CITI training modules, has an active IRBNet account, and has uploaded their CV/Resume to their User Profile. *Be sure to link their training and credentials records to the new package.*

The new study team member is required to complete the Conflict of Interest Attestation Form.

You must share the project with the new study team member. To do so, click the "Share this project" link located on the left-hand side of your screen, and follow instructions.

Revise appropriate documents such as the Core Data Form, the protocol, or informed consent document if applicable.

REMOVING A STUDY TEAM MEMBER:

Remove the study team member from the Core Data Form and other documents if applicable. Remember to click the pencil icon when updating the Core.

Un-share the package with the research team member. Navigate to the Project Overview Page and click the study team member's name. From there, change their access level to 'No Access,' then click 'Save.'

CHANGING THE PRINCIPAL INVESTIGATOR

On the Project Overview page, click the yellow 'Edit' link to update the Principal Investigator's name and credentials.

Update all required documents:

- Core Data Form
- Conflict of Interest Attestation form (the new PI must sign)
- Research Data Storage Attestation form (the new PI is required to complete and sign this form.
- Update Informed Consent and Assent documents, if applicable
- Protocol Template

Follow instructions for adding new personnel.

Changing a Principal Investigator

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Ensure the new PI has an active IRBNet account, has completed their CITI training, and uploaded a copy of their CV/Resume to their IRBNet User Profile?	☐	☐	
Ensure the new PI has signed the Conflict of Interest Attestation Form and Research Data Storage Form?	☐	☐	
Update the PI's name and credentials on the Project Overview page? On the Project Overview page, click Edit, located directly above the PI name. Update this section using the new PI's information.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Amendment/Modification Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page.	☐	☐	
Update the Protocol. Please remember to stack this document. Revisions must be completed using Tracked Changes. You may contact the IRB Office if you have questions.	☐	☐	
Update the Core Data Form. Please stack this document.	☐	☐	
Update Advertisements, if applicable.	☐	☐	
Upload the Sponsor's Protocol or Grants, if applicable.	☐	☐	
Update Informed Consent Documents or Assent Documents, if applicable.	☐	☐	
Update Drug/Device Information, if applicable.	☐	☐	
Update other applicable supplemental forms.	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. Complete the Amendment/Modification Wizard document and upload applicable forms. This is a Wizard document located on the Designer Page.
4. Remember to stack revised documents appropriately. See the helpful tips section below to learn more about Stacking.
5. Share this project with the PI and link their CITI training and CV/Resume. Remember to update the Core Data Form.
6. Obtain required signatures:
    a. The new PI
    b. The previous PI
    c. The Department Chair
    d. The Faculty Sponsor, if applicable.
7. Click Submit.

Helpful Tips:

STACKING DOCUMENTS:

On the Designer Page:

1. Click the pencil icon next the appropriate document in the *Documents from Previous Packages* Section.
2. Upload the revised document. This will stack the revised document.
3. To revise the Core Data Form, click the pencil icon. This will open up the Wizard. Once revisions are saved, the Core Data Form will be 'Stacked.'

For a picture tutorial, review the Guidance: How to Revise/Stack Previously Submitted Documents

TRACKED CHANGES:

All Word documents being revised should be revised using Track Changes.

To turn on track changes in Word, navigate to the REVIEW tab and click "Track Changes" ***before*** you begin making any revisions.

Also, be sure to update the version dates!

For additional guidance see: Guidance: How to Revise/Stack Previously Submitted Documents (found in IRBNet, under forms and templates).

QUESTIONS REGARDING YOUR AMENDMENT

We are here to help!

Contact Information:

706-721-3110; IRB@augusta.edu

You may also visit the IRB Office website to request training or submit an inquiry using the Ask Andy Feature.

Submitting a Reportable Event

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Complete the purpose of the report page? Be sure to indicate the type of problem and whether or not Administrative Notification is necessary.	☐	☐	
Provide details in the Event Summary?	☐	☐	
Complete the Additional Action page? If there are additional actions, such as a consent revision, please be sure to submit an Amendment.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Reportable Event Form. This is a *Wizard document* located on the Designer Page. To access this document, click 'Start a Wizard' on the Designer Page.	☐	☐	
Upload applicable documentation.	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. On the Designer page, complete the Reportable Event form.
4. Obtain package signatures:
   a. PI
   b. Faculty Sponsor, if applicable.
5. Click Submit.

Please review the IRB Policy – Reportable Events thoroughly. If you have any questions or concerns, contact the IRB Office at 706-721-3110 or IRB@augusta.edu.

When completing the Reportable Event Form, please be sure to include the following:

- Date of report
- Date of occurrence
- Participant ID (if applicable)
- Note whether it was a VA patient
- Select the type of report (initial, follow-up or final)
- Enter the date of pi notification
- Enter the date of sponsor/funding source notification
- Describe the problem (e.g. Date of occurrence or discovery, time line, cause, action taken, changes made, outcome)
- Event severity (mild, moderate, severe)
- Event relatedness (definite, probable, possible, not related, unknown)
- Outcome (resolved or ongoing)

Version Date: 06.14.21, 03.28.22

Submitting an Annual Report

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Ensure all study team members have up-to-date CITI training? Appropriate CITI training must be linked your study. This means that training has not expired and it has a status of 'Accepted.'	☐	☐	
Ensure all information is correct? This includes an accurate count of participants consented or records/charts reviewed.	☐	☐	
Ensure that Unanticipated Changes have been reported to the IRB, if there are any?	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Annual Report Form. This is a *Wizard Document*. On the *Designer page*, click Start a Wizard and select the Annual Report Form.	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. Complete the Annual Report Form. This is a Wizard document located on the Designer Page.
4. Link the Training and Credentials of all research team members listed on the Core Data Form. (on the Designer page, click the blue "Link/Un-Link Training Records") - Each study member must have a valid CITI linked.
5. Obtain Required Signatures:
    a. Principal Investigator
    b. Faculty Sponsor, if applicable
6. Submit the package:
    a. Click 'Submit this Package'
    b. Ensure the submission type is "Other"
    c. Click 'submit'

Please Read

The only studies eligible for Annual Report are studies that have a date indicated on the approval letter as NEXT REPORT DUE DATE.

The IRB Office is unable to process amendments/personnel changes or reportable events with the Annual Report. Please DO NOT upload additional documents to this package.

To ensure timely review of your submission, please submit your Annual Report at least 45 days prior to the Next Report Due date.

Version Date: 06.14.21, 03.28.22

Completing the Annual Report Form

Current Status of Project

What is the current status of the project?

- Research not started at any location
- Open to Enrollment of new participants/Continuing to Collect Data
- Closed to Enrollment
- Closed – if all activities associated with the study are completed. If closed, submit a Continuing Review Report as a separate package in IRBNet.

Current Number of Subjects Enrolled

Provide the current number of subjects enrolled, records (including patient medical records/charts) reviewed, or specimens collected since the study began. Be specific. (i.e. 50 patient charts reviewed; 15 subjects enrolled)

Please select the statement below that most accurately reflects the current status of the study.

- Accrual is temporarily closed
- Accrual is permanently closed
- Clinical interventions, surveys, or similar participant interactions continuing
- Remaining activities limited to collection of participant long-term follow-up data
- Remaining activities limited to analysis of specimens/data already collected

Study Assessment Information: CITI Training

Are all project team members current with CITI training?

Conflict of Interest Status

Has there been a change in the Conflict of Interest (COI) status for any project team member in which they now have a conflict?

Unanticipated Problems

Have there been any unanticipated problems, protocol deviations, or complaints from subjects since the project received initial IRB approval or the last annual report submission?

Changes to Project

Are there any changes to the project that need to be made? This includes changes to the protocol or previously submitted documents, project team changes, funding changes, etc. Submit a separate amendment to the IRB to address these revisions.

Submitting a Continuing Review Report

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Ensure all study team members have up-to-date CITI Training?	☐	☐	
Ensure your enrollment numbers are accurate? Remember, if you have exceeded your IRB approved enrolment numbers, you must submit a Reportable Event and an Amendment to increase the number of subjects.	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Continuing Review Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page. Please review the Helpful Tips section on page 2 for guidance.	☐	☐	
New Publications or Literature about your research since the last Continuing Review.	☐	☐	
Data Safety Monitoring Reports (those not required to be reported as Reportable Events), if applicable.	☐	☐	
IND Safety Report Summary (if applicable)	☐	☐	
FDA Annual Report (if applicable)	☐	☐	
Multi-site Reports and/or Approval Letters (if applicable)	☐	☐	
Additional applicable documentation	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. Complete the Continuing Review Form. This is a Wizard document located on the Designer Page.
4. Upload all required documents. Review the table to the left of this column for required documents.
5. Link all Study Team Members' CITI training.
6. Obtain Required Signatures
    a. Principal Investigator
    b. Faculty Sponsor, if applicable
7. Click Submit. Remember to follow all prompts. Continuing Review

PLEASE READ:

The only studies eligible for Continuing Review are studies that have an EXPIRATION DATE listed in the Approval Letter. Be sure to read the IRB Policy –Continuing Review to stay compliant with federal regulations and AU IRB guidelines.

You may submit amendments with your Continuing Review Report. Please be sure to follow the guidance for submitting an Amendment.

To ensure timely review of your submission, please submit your Annual Report at least 45 days prior to the Next Report Due date.

Version Date: 06.14.21, 03.28.22

Completing the Continuing Review Form

<table>
<tr><th>Information to prepare before completing the Form:</th><th>Study Progress section of the Continuing Review form.</th><th>Check your Numbers!</th></tr>
<tr><td rowspan="2">Current study status

Enrollment status Are you still enrolling participants or collecting data?

<u>Subject Accrual Numbers:</u>
Active participants are individuals who are enrolled in a study but have not yet completed study activities. They have not withdrawn from the study nor are they in follow-up status.
Enrolled means that consent was obtained; in the event consent was not required enrolled means that their data was included in research data collection.
Follow –up means that a participant was enrolled and began study activities, but the study team has not been able to reach these individuals to complete their study activities.
Screen Failure refers to participants who did not meet the inclusion criteria for a study.
Withdrawals refer to participants who decided on their own to discontinue research activities as well as participants who were removed from the study.
Individuals who did not meet inclusion criteria would not be considered “withdrawn.” See Screen Failure.</td><td rowspan="2">Include the number of subjects, specimens or charts reviewed since the last continuing review.

Provide a summary of your progress with this research to date, including any:

❖ Modifications (amendments) since the last
❖ Continuing Review.
❖ Interim findings and benefits experienced by research participants since your last Continuing Review Report.

If the research has not started, give an explanation as to why the research has not started.

If the research is still open to accrual, provide information on if any changes were made due to COVID, i.e. Remote consent, virtual interactions, etc.</td><td>Total Participants Consented = Participants Active + Participants in Follow-up + Withdrawals + Screen Failures</td></tr>
<tr><td>Participants Completed/Charts Reviewed/Samples Collected = Total Consented/Enrolled - Participants Active - Participants in Follow-up
- Withdrawals - Screen Failures</td></tr>
</table>

Submitting a Re-activation Request

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Ensure each research team member has up-to-date CITI Training?	☐	☐	
Confirm enrolment numbers?	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Re-activation Form. This form is entitled *Request to Open a LAPSED Study* in the IRBNet Forms and Templates Library.	☐	☐	
Continuing Review Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page.	☐	☐	
Data Safety Monitoring Reports (those not required to be reported as Reportable Events), if applicable	☐	☐	
IND Safety Reports Summary, if applicable	☐	☐	
Additional applicable documentation	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Complete the required documents and upload them on the Designer Page. Review the table to the left of this column for required documents.
3. Link all study team member training.
4. Obtain Required Signatures
   a. Principal Investigator
   b. Faculty Sponsor, if applicable.
5. Click Submit.

Data to Prepare Before Completing the Form:

Current study status

Enrollment status

Enrollment numbers since the last continuing review:

- Participants in Screening:
- Participants Active

Cumulative enrolment numbers from the start of the study:

- Withdrawals
- Total Participants Consented
- Screen Failures
- Participants Completed
- Number of Males Consented
- Number of Females Consented

Number of Racial Minorities Consented:

- White:
- Black or African American:
- Asian: American Indian or Alaska Native:
- Hispanic or Latino:
- Native Hawaiian or Pacific Islander:
- Other:

Submitting a Study Closure Report

Use this checklist to ensure your study is ready for IRB review. An incomplete submission may result in delayed review of your project or withdrawal. Supplemental forms and templates are located in the IRBNet Forms and Templates Library.

For Assistance, contact the IRB Office at 706-721-3110 or IRB@AUGUSTA.EDU.

Did you…	Yes	No	Comments
Ensure your enrolment numbers are accurate?	☐	☐	
Required Documents	**Yes**	**No**	**Comments**
Continuing Review Form. This is a *Wizard* document located on the Designer Page. To access this document, click *Start a Wizard* on the Designer Page. ❖ You MUST start a new Wizard from scratch for study closures. ❖ The Study Status for this submission should be '*Closed*.' ❖ Be sure to provide a detailed summary of your project in the Study Progress section!	☐	☐	
Data Safety Monitoring Reports (those not required to be reported as a Reportable Event), if applicable.	☐	☐	
IND Safety Report Summary, if applicable	☐	☐	
Publications, if applicable	☐	☐	

Submission Step-by- Step

1. Log into IRBNet and select the appropriate project.
2. Click 'Create a New Package.' The option to create a new package is located on the left-hand side of your screen under Project Administration.
3. On the Designer page, complete and upload the required documents and forms.
4. Obtain Required Signature
   a. Principal Investigator
   b. Faculty Sponsor, if applicable.
5. Click Submit.

Data to Prepare Before Completing the Form:

Current study status – Select *Closed – Final Continuing Review Report (CRR), all research activities and all identifiable data analysis is complete, request closure of IRB File*

Enrollment status: no longer enrolling participants

Enrollment numbers since the last continuing review:

- ❖ Participants in Screening:
- ❖ Participants Active

Cumulative enrolment numbers from the start of the study:

- ❖ Withdrawals
- ❖ Total Participants Consented
- ❖ Screen Failures
- ❖ Participants Completed
- ❖ Number of Males Consented
- ❖ Number of Females Consented

Number of Racial Minorities Consented:

- ❖ White:
- ❖ Black or African American:
- ❖ Asian: American Indian or Alaska Native:
- ❖ Hispanic or Latino:
- ❖ Native Hawaiian or Pacific Islander:
- ❖ Other:

Version Date: 06.14.21, 03.28.22