IRB Submission Guidelines and Checklist

The purpose of this document is to help researchers to prepare their submissions to the IRB. Please Use this checklist to ensure a complete submission package. You don't need to submit this checklist to the IRB. Please contact the Office of Research Integrity (ORI) for assistance.

ORI/IRB contact: <u>orihelp@bsu.edu</u> HRPP manager: Sena Lim: slim2@bsu.edu

What to expect after submitting your IRB submission through IRBNet?

- 1) The ORI staff will pre-review your 'locked' (or) IRB submission package.
- 2) If necessary, you will be contacted to provide additional information or modify your documents. Your project will be 'unlocked' (1) so that you can edit your IRBNet package.

NOTE: You have to re-lock your project () after you address the requests. If your project is not re-locked, The ORI staff will not be notified that your project is ready.

- 3) Your 'locked' (or (or (lab) IRB submission package will be reviewed by the IRB for a decision. One of the following options will happen.
 - a. The ORI staff will upload the IRB approval letter in IRBNet on the project's 'Reviews' page. You will also receive a notification from IRBNet.
 - b. If necessary, the ORI staff unlock your project () and send an email for minor modifications. You have to re-lock your project () after you address the requests. If all requests are well addressed, The ORI staff will upload the IRB approval letter in IRBNet on the project's 'Reviews' page. You will also receive a notification from IRBNet.
 - c. The ORI staff will upload a deferred letter in IRBNet on the project's 'Reviews' page. You also receive a notification from IRBNet. If you receive the deferred letter, you need to submit a new package as a "revision."

Tips for your IRB submission

- Please read the new submission guidance and IRBNet manual before you start your IRB application.
- Use the checklist below to complete your application.
- All supplementary documents are available in the IRBNet Templets and Forms.
- Contact the ORI staff if you have questions before submitting.
- Please review all documents and application thoroughly and electrically sign on your project on IRBNet.

1. New Project Submission Checklist

Bold forms are mandatory, and other documents required for new project submission will be project-specific. All documents are located in the templates and forms library on IRBNet. The ORI staff may send back your package if it is incomplete.

✓	Documents /Actions	Document name/type(s)	Notes
	Complete CITI training		https://www.citiprogram.org Social/behavioral basic/refresh course or biometric basic/refresh course
	Link CITI certificate to your profile and your team member profile		Reference Manual: Linking CITI certificate to IRBNet in the library.
	IRB application Form	Wizard Form	Use the Wizard form option.

Data Storage and Security Plan	Data Storage and Security Plan	Reference Guidance: Data security.
Consent Document	Adult Consent Form Child Assent Form Parental Permission Form	Templates and supplementary language guidance are available in the IRBNet library.
Recruitment Materials	Advertisement Flyer Recruitment message/ email Phone or verbal script	Samples/Templates are available in the IRBNet library.
Data Collection	Data Collection Instruments Survey Screening Interview Focus group script Validated assessment Stimulus (any format)	Upload ALL scales, assessments, measurement, and stimulus. Save the Qualtrics survey as a pdf format and submit it to the IRB, if applicable.
Reliance agreement Request/ Individual Investigator Agreement (IIA)	Reliance agreement Request Individual Investigator Agreement (IIA)	If this is a multi-site /collaborative study or you are working with a non-BSU member, you need to upload one of the documents.
Letter of support	Letter of support	A sample is available in the IRBNet library.
COVID-19 Safety Plan	COVID-19 Safety Plan	If the study is involved in in-person activities, you must submit this form.
Others	FERPA Media permission	All documents related to your study should be submitted to the IRB.
Sign the package		Sign the package is under Project Administration on the left blue box.

2. Modification/Amendment Submission Checklist

✓	Document/works	Document type	notes
	Revised Wizard Form	Wizard form	You may need to create a clone and
			revise the form.
	All revised documents		You must highlight ALL changes you
			have made.
	IRB amendment/	IRB amendment/modification	Explain your changes
	modification form	form	

3. Revision Submission Checklist (if your study has been deferred)

✓	Document/works	Document type	notes
	Revised Wizard Form	Wizard form	You may need to create a clone and revise the form.
	All revised documents		You must highlight ALL changes you have made.
	A word document explaining your revision		You can copy and paste the list of IRB requests and add your responses to each item.