

**ENSURING RESEARCH COMPLIANCE
AND
ETHICAL STANDARDS**



GRAMBLING
STATE UNIVERSITY®
Institutional Review Board

Operating under an HHS provided Federal Wide Assurance (FWA) number and is committed to complying with all Federal regulations and maintaining policies and procedures for the protection of human participants.



NAVIGATING THE NEW IRB SYSTEM

- In order for the IRB review to provide protections for all subjects, reviews must be carried out in a consistent and systematic manner. Several specific written procedures are required by federal regulation for all IRBs acting as an IRB of record for an organization holding a Federal Wide Assurance (FWA). Researchers also benefit from the transparency generated when the IRB follows written procedures so that all parties know how reviews will be conducted and what information is required by the IRB. In an effort to streamline and make the GSU-IRB protocol management process more efficient, various online and cloud-based solutions and platforms have been researched. The Sitero Mentor IRB Protocol Management Platform was selected and is a cost-effective solution that will provide the targeted support that the GSU-IRB critically needs.

SITERO MENTOR IRB

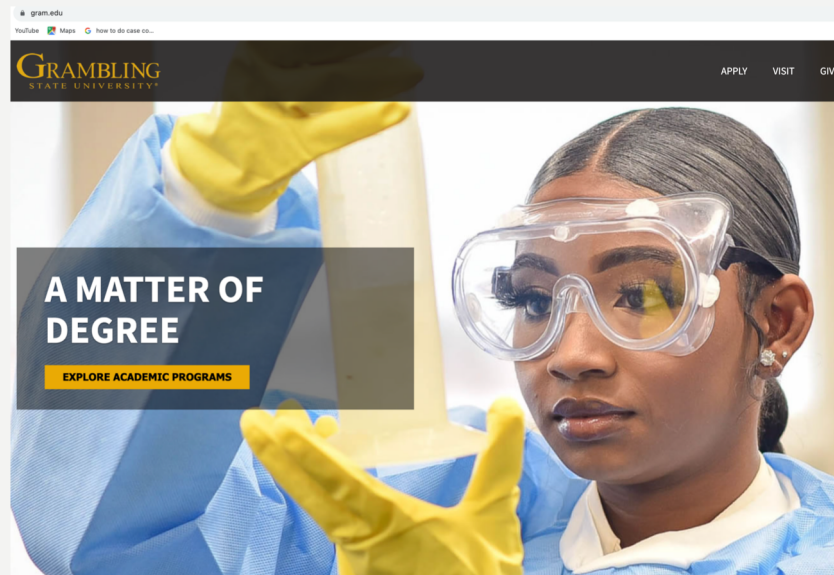
- **NEXT GENERATION IRB SOFTWARE PLATFORM**
 - Sitero Mentor's online IRB software streamlines our IRB processes with automated documentation and workflows

SITERO MENTOR IRB

- Cloud-based
- Integrated with our institution's Single Sign-On (SSO)
- Includes all forms
- Routes Protocols to proper level of review
- Sends automatic reminders and other notifications
- Cost - effective

HOW TO ACCESS SITERO MENTOR

- You will need your gsumail email address and password.
 - Go to www.gram.edu.
 - Click on Faculty & Staff:



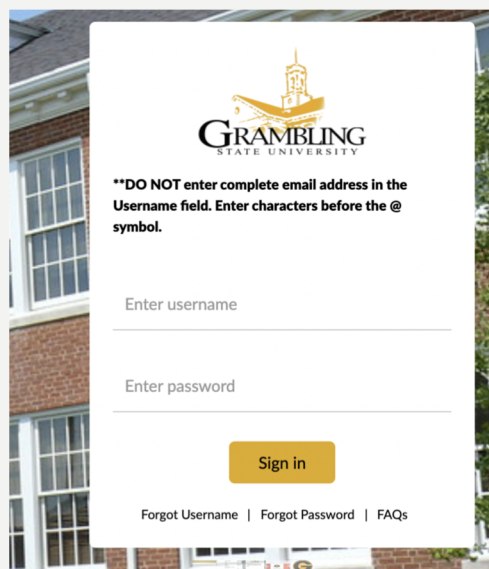
HOW TO ACCESS SITERO MENTOR

- Then click on GSU Portal:

General Information University Calendar Academic Calendar Campus News University Holidays Dining Services KGRM Radio COVID-19 Guidelines	Campus Information Campus Map Directory Library Faculty Senate University Police Federal Drug-Free Schools and Campuses Regulations Notice	Teaching Aids Canvas Distance Learning Academic Support IBM Academic Initiative
Resources & Support Faculty Handbook Information Technology Human Resources DocuSign Forms and Documents	Policies & Procedures University Policies & Procedures Policy & Procedure Template Policy & Procedure Process Flow Chart	Sites BannerWeb GSUNet GSU Portal Bookstore Office 365 Communications Request Portal AirPortal Ricoh Print Services Facilities Work Order Request

HOW TO ACCESS SITERO MENTOR

- Before entering the GSU Portal, you will need to log-in with GSU credentials. (Your username is the word that comes before @gsumail.gram.edu (if a student) OR before @gram.edu (if faculty or staff). Your password is the same as your @gsumail.gram.edu or @gram.edu password).

A screenshot of the Grambling State University login portal. The page features the university's logo at the top, which includes a stylized building and the text "GRAMBLING STATE UNIVERSITY". Below the logo, there is a warning message: "**DO NOT enter complete email address in the Username field. Enter characters before the @ symbol." This is followed by two input fields: "Enter username" and "Enter password". A yellow "Sign in" button is positioned below the password field. At the bottom of the form, there are links for "Forgot Username", "Forgot Password", and "FAQs". The entire login form is overlaid on a background image of a brick building with large windows.

GRAMBLING
STATE UNIVERSITY

****DO NOT enter complete email address in the Username field. Enter characters before the @ symbol.**

Enter username

Enter password

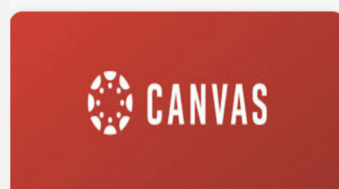
Sign in

[Forgot Username](#) | [Forgot Password](#) | [FAQs](#)

HOW TO ACCESS SITERO MENTOR

- After you enter your credentials, you may be asked to reset your password or to set up 2-factor authentication. Follow instructions on the screen.
- Once logged in, you should see the app for the IRB platform:

My Apps



Canvas

Canvas is a cloud-based Learning Management System that makes teaching and learning easier. Our tools are designed to be used online, on mobile and on tablet. But most of



GSU-IRB

Mentor Application

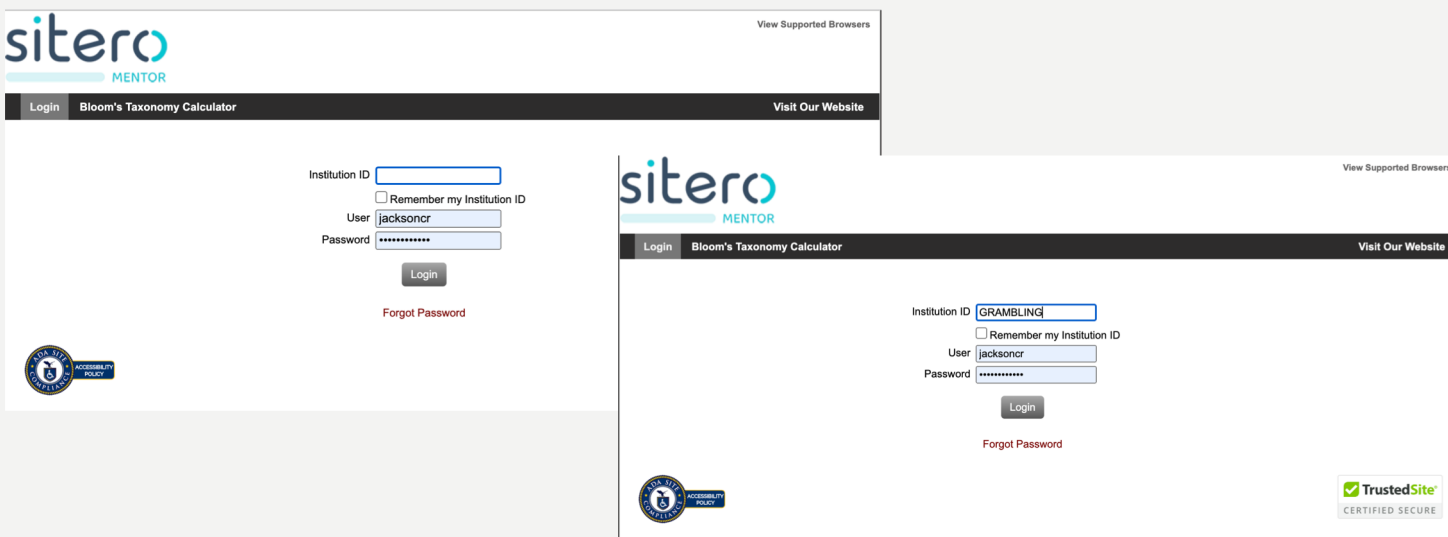


Office 365

Microsoft Office 365 (often called Microsoft 365 or Office 365) is a Web-based version of. Microsoft's Office suite of enterprise-grade productivity applications

HOW TO ACCESS SITERO MENTOR

- After clicking on the GSU-IRB app, you will see:

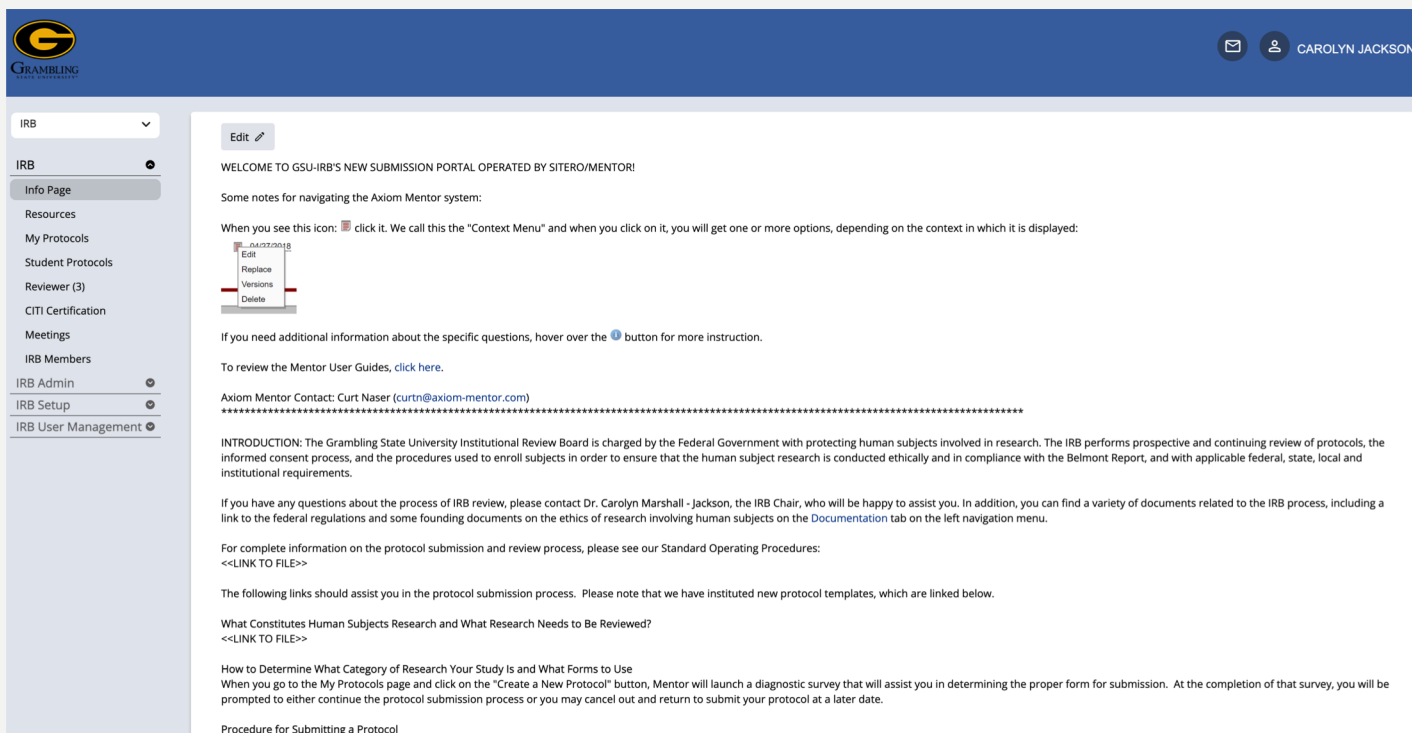


The image displays two screenshots of the Sitero Mentor login interface. Both screenshots show the Sitero logo and the text 'MENTOR' at the top. Below the logo is a navigation bar with 'Login' and 'Bloom's Taxonomy Calculator' links. The main content area contains a login form with the following fields: 'Institution ID' (with a dropdown arrow), 'Remember my Institution ID' (checkbox), 'User' (text input), and 'Password' (password input). A 'Login' button is located below the password field. A 'Forgot Password' link is also present. The left screenshot shows the form with empty fields, while the right screenshot shows the 'Institution ID' field populated with 'GRAMBLING'. The right screenshot also includes a 'TrustedSite' security badge in the bottom right corner.

Type in GRAMBLING as the Institution ID
Then click "Login".

HOW TO ACCESS SITERO MENTOR

- You're in and should see a page similar to this!



The screenshot displays the Axiom Mentor web application interface. At the top, a blue header bar contains the Grambling State University logo on the left and a user profile icon with the name 'CAROLYN JACKSON' on the right. Below the header, a left-hand navigation menu is visible, featuring a search bar with 'IRB' entered and a list of menu items including 'Info Page', 'Resources', 'My Protocols', 'Student Protocols', 'Reviewer (3)', 'CITI Certification', 'Meetings', 'IRB Members', 'IRB Admin', 'IRB Setup', and 'IRB User Management'. The main content area has a light blue background and contains a welcome message: 'WELCOME TO GSU-IRB'S NEW SUBMISSION PORTAL OPERATED BY SITERO/MENTOR!'. It also includes a 'Context Menu' icon and a list of instructions for navigating the system, such as 'When you see this icon: [icon] click it. We call this the "Context Menu" and when you click on it, you will get one or more options, depending on the context in which it is displayed:'. The menu options shown are 'Edit', 'Replace', 'Versions', and 'Delete'. Further instructions include a link to the Mentor User Guides and a contact email for Curt Naser (curtn@axiom-mentor.com). The page concludes with an introduction to the Grambling State University Institutional Review Board and its role in protecting human subjects, followed by a link to the documentation tab for more information on the protocol submission and review process.

IRB

IRB

Info Page

Resources

My Protocols

Student Protocols

Reviewer (3)

CITI Certification

Meetings

IRB Members

IRB Admin

IRB Setup

IRB User Management

Edit

WELCOME TO GSU-IRB'S NEW SUBMISSION PORTAL OPERATED BY SITERO/MENTOR!

Some notes for navigating the Axiom Mentor system:

When you see this icon: [icon] click it. We call this the "Context Menu" and when you click on it, you will get one or more options, depending on the context in which it is displayed:

[icon]

Edit

Replace

Versions

Delete

If you need additional information about the specific questions, hover over the [icon] button for more instruction.

To review the Mentor User Guides, [click here](#).

Axiom Mentor Contact: Curt Naser (curtn@axiom-mentor.com)

INTRODUCTION: The Grambling State University Institutional Review Board is charged by the Federal Government with protecting human subjects involved in research. The IRB performs prospective and continuing review of protocols, the informed consent process, and the procedures used to enroll subjects in order to ensure that the human subject research is conducted ethically and in compliance with the Belmont Report, and with applicable federal, state, local and institutional requirements.

If you have any questions about the process of IRB review, please contact Dr. Carolyn Marshall - Jackson, the IRB Chair, who will be happy to assist you. In addition, you can find a variety of documents related to the IRB process, including a link to the federal regulations and some founding documents on the ethics of research involving human subjects on the [Documentation](#) tab on the left navigation menu.

For complete information on the protocol submission and review process, please see our Standard Operating Procedures:
<<LINK TO FILE>>

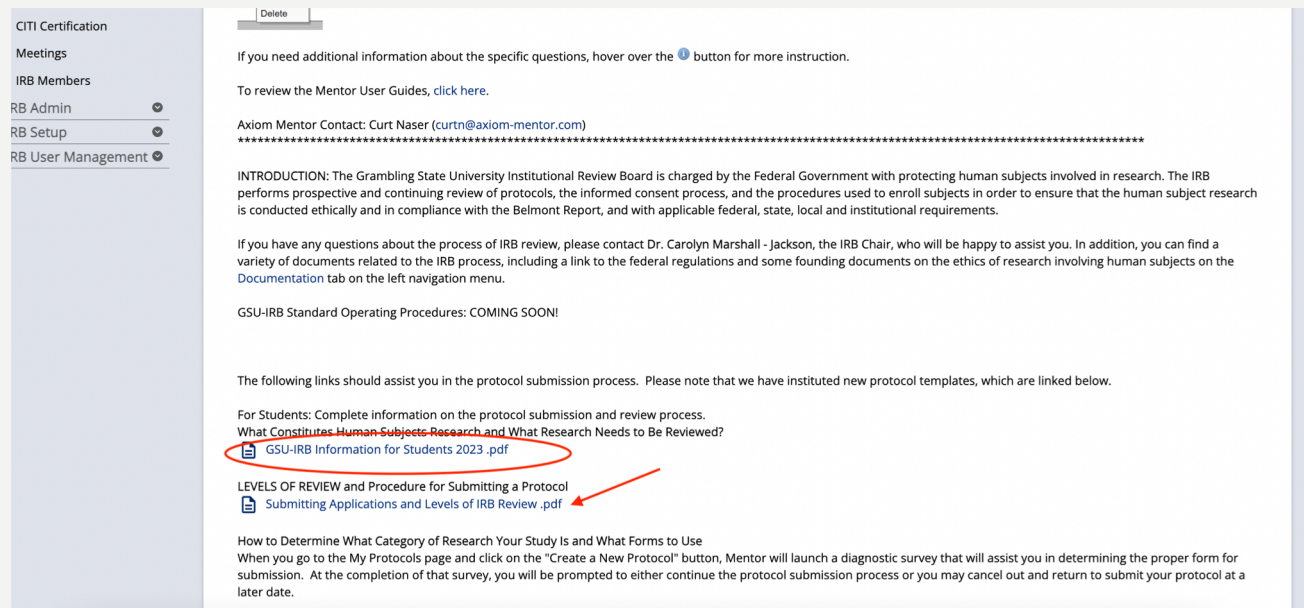
The following links should assist you in the protocol submission process. Please note that we have instituted new protocol templates, which are linked below.

What Constitutes Human Subjects Research and What Research Needs to Be Reviewed?
<<LINK TO FILE>>

How to Determine What Category of Research Your Study Is and What Forms to Use
When you go to the My Protocols page and click on the "Create a New Protocol" button, Mentor will launch a diagnostic survey that will assist you in determining the proper form for submission. At the completion of that survey, you will be prompted to either continue the protocol submission process or you may cancel out and return to submit your protocol at a later date.

Procedure for Submitting a Protocol

NOW LET'S WALK THROUGH SOME OF THE FEATURES...



The screenshot displays the Axiom Mentor web application interface. On the left is a vertical navigation menu with the following items: CITI Certification, Meetings, IRB Members, RB Admin (with a dropdown arrow), RB Setup (with a dropdown arrow), and RB User Management (with a dropdown arrow). The main content area on the right has a 'Delete' button at the top. Below it, there is a paragraph of introductory text, a link to 'Mentor User Guides', and contact information for Curt Naser. A section titled 'INTRODUCTION' describes the Grambling State University Institutional Review Board's role. Another paragraph provides contact information for Dr. Carolyn Marshall-Jackson, the IRB Chair. Below this is a 'COMING SOON!' notice for GSU-IRB Standard Operating Procedures. A section titled 'The following links should assist you in the protocol submission process' lists several resources. Two links are highlighted with red circles and arrows: 'GSU-IRB Information for Students 2023 .pdf' and 'Submitting Applications and Levels of IRB Review .pdf'. The final section, 'How to Determine What Category of Research Your Study Is and What Forms to Use', describes a diagnostic survey process.

CITI Certification
Meetings
IRB Members
RB Admin
RB Setup
RB User Management

Delete

If you need additional information about the specific questions, hover over the [?](#) button for more instruction.

To review the Mentor User Guides, [click here](#).

Axiom Mentor Contact: Curt Naser (curtn@axiom-mentor.com)

INTRODUCTION: The Grambling State University Institutional Review Board is charged by the Federal Government with protecting human subjects involved in research. The IRB performs prospective and continuing review of protocols, the informed consent process, and the procedures used to enroll subjects in order to ensure that the human subject research is conducted ethically and in compliance with the Belmont Report, and with applicable federal, state, local and institutional requirements.

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GSU-IRB Standard Operating Procedures: COMING SOON!

The following links should assist you in the protocol submission process. Please note that we have instituted new protocol templates, which are linked below.

For Students: Complete information on the protocol submission and review process.
[What Constitutes Human Subjects Research and What Research Needs to Be Reviewed?](#)
[GSU-IRB Information for Students 2023 .pdf](#)

LEVELS OF REVIEW and Procedure for Submitting a Protocol
[Submitting Applications and Levels of IRB Review .pdf](#)

How to Determine What Category of Research Your Study Is and What Forms to Use
When you go to the My Protocols page and click on the "Create a New Protocol" button, Mentor will launch a diagnostic survey that will assist you in determining the proper form for submission. At the completion of that survey, you will be prompted to either continue the protocol submission process or you may cancel out and return to submit your protocol at a later date.

Once logged in, you will find a variety of resources and IRB related information. You can click on the hyperlinked terms (see photo above) to access the information.

PREPARING AND SUBMITTING PROTOCOLS FOR REVIEW...

The screenshot shows the Grambling State University IRB submission portal. The header is blue with the Grambling State University logo on the left and a user profile icon with the name 'CAROLYN JACKSON' on the right. Below the header, there is a sidebar on the left with a dropdown menu set to 'IRB'. The sidebar contains a list of links: 'Info Page', 'Resources', 'My Protocols' (which is circled in red with an arrow pointing to it), 'Student Protocols', 'Reviewer (4)', 'CITI Certification', 'Meetings', and 'IRB Members'. The main content area on the right has a white background. It starts with an 'Edit' button and a welcome message: 'WELCOME TO GSU-IRB'S NEW SUBMISSION PORTAL OPERATED BY SITERO/MENTOR!'. Below this is a section titled 'Some notes for navigating the Axiom Mentor system:' followed by instructions on how to use the 'Context Menu' icon. An example of the context menu is shown, with options: 'Edit', 'Replace', 'Versions', and 'Delete'. At the bottom of the main content area, there is a note about hovering over a help icon for more instructions.

IRB

IRB

Info Page

Resources

My Protocols

Student Protocols

Reviewer (4)

CITI Certification


Meetings

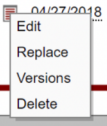
IRB Members


Edit

WELCOME TO GSU-IRB'S NEW SUBMISSION PORTAL OPERATED BY SITERO/MENTOR!

Some notes for navigating the Axiom Mentor system:

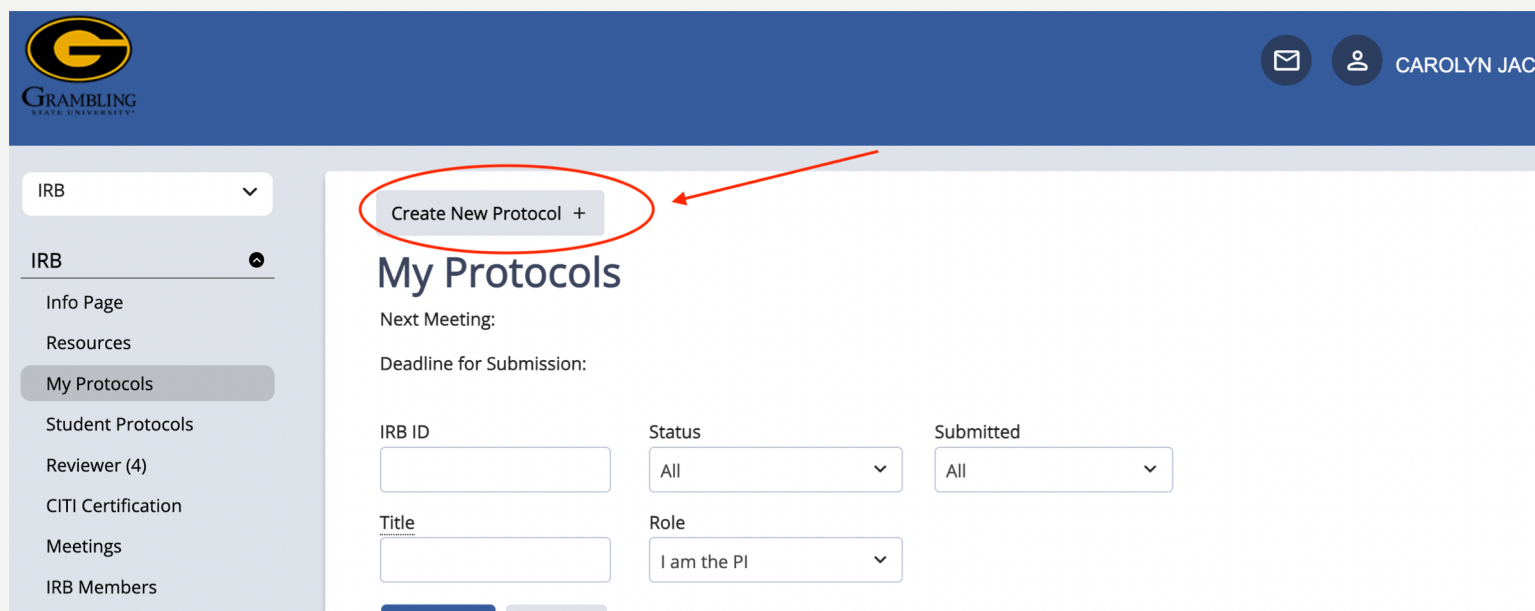
When you see this icon:  click it. We call this the "Context Menu" and when you click on it, you will get one or more options, depending on the context in which it is displayed:



If you need additional information about the specific questions, hover over the  button for more instruction.

To begin a new protocol, select **“My Protocols”** from the list on the left side of the screen.

PREPARING AND SUBMITTING PROTOCOLS FOR REVIEW...



The screenshot displays the Grambling State University IRB portal. The top navigation bar is blue with the university logo on the left and a user profile icon labeled 'CAROLYN JACK' on the right. A left sidebar contains a list of menu items: 'IRB', 'Info Page', 'Resources', 'My Protocols' (highlighted), 'Student Protocols', 'Reviewer (4)', 'CITI Certification', 'Meetings', and 'IRB Members'. The main content area is titled 'My Protocols' and includes a 'Create New Protocol +' button, which is circled in red with a red arrow pointing to it. Below this button, there are fields for 'Next Meeting:', 'Deadline for Submission:', 'IRB ID', 'Status' (dropdown menu), 'Submitted' (dropdown menu), 'Title', and 'Role' (dropdown menu).

On the next screen, select **"Create New Protocol"**.

PREPARING AND SUBMITTING PROTOCOLS FOR REVIEW...

Pre-Protocol Survey 2019

Cancel X

Is the study activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(l)]

- ☐ 1. Yes
☐ 2. No

Save Answers ✓

Cancel ⊗

Then follow on-screen instructions to complete the “**Pre-Protocol Survey 2019**”.*
Even if you get a message that your study IS NOT research with Human Subjects, you must still proceed to IRB review. The IRB Chair is the only entity who can make the final determination.

PREPARING AND SUBMITTING PROTOCOLS FOR REVIEW...

The screenshot shows the 'Create IRB Protocol' form. At the top right is a 'Cancel' button with a close icon. Below the title bar is a 'Grant Number' text input field. Underneath is a dropdown menu for 'Review Type', currently set to 'Expedited Review'. A red circle highlights the 'Review Type' label, and a red arrow points from it to the dropdown. The dropdown menu is open, showing a list of options: '-Select-', 'Exempt Review', 'Expedited Review' (highlighted with a red circle), 'Full Board Review', 'Quality Improvement', 'Reliance on an External IRB', 'Preliminary IRB Review (.118)', and 'Site Permission (external researchers only)'. To the right of the dropdown, there is a list of conditions for each review type, with red arrows pointing from the 'Expedited Review' option to the text: 'tick, heel stick, ear stick, or venipuncture as follows', 'cimens for research purposes by noninvasive means', 'procedures', 'uments, records, or specimens) that have been collected, or will be collected solely for nonresearch', and 'igital, or image recordings made for research purposes'. At the bottom of the dropdown list, there is a checkbox labeled '(f) Research on individual or group characteristics or behavior'.

Create IRB Protocol Cancel x

Grant Number

★ Review Type

Expedited Review

its your project:

-Select-

Exempt Review

Expedited Review

Full Board Review

Quality Improvement

Reliance on an External IRB

Preliminary IRB Review (.118)

Site Permission (external researchers only)

(f) Research on individual or group characteristics or behavior

tick, heel stick, ear stick, or venipuncture as follows

cimens for research purposes by noninvasive means

procedures

uments, records, or specimens) that have been collected, or will be collected solely for nonresearch

igital, or image recordings made for research purposes

Once done with the survey, you should proceed with protocol creation. Complete all items and under review type, select the appropriate type of review (see examples above). ***SELECT ONLY ONE REVIEW TYPE.** Once done with all items, Click **"SAVE"**.

PREPARING AND SUBMITTING PROTOCOLS FOR REVIEW...

IRB

- Info Page
- Resources
- My Protocols
- Student Protocols
- Reviewer (4)
- CITI Certification
- Meetings
- IRB Members
- IRB Admin
- IRB Setup
- IRB User Management

TEST #2

30

Please click the *Application Sections* link below and complete the forms you find there.

Required Questions Not Answered
1 Signature Missing

PI	Approval Status	Created	02/15/2024	Approved	Set Date
CAROLYN JACKSON	Expedited Review	Received			
Staff	Expedited Review Requested	Date of Completion	Set Date		
	(6) Collection of data from voice, video, digital, or image recordings made for research purposes				
	Withdraw Protocol from Review				

Application Sections Required Questions Unanswered: 39

Personnel

Add/Edit personnel

PI	Name	CITI Status	Signed Date	Date Added
	CAROLYN JACKSON	Docs ✓	Sign Electronically	02/15/2024

Protocol Fields

You should then be taken to the application where you will, designate your faculty advisor (if you are a student) and then you should follow instructions by answering questions and uploading the requested documents. You will upload your CITI certificates by selecting “**CITI CERTIFICATION**” on the left side of the screen.

REMEMBER...

- You must complete **all sections** of the application.
 - When all sections are completed, you will be able to “electronically” sign the application. If the sign/submit button is grayed out or missing, you have likely not completed all required items.
 - After signing, your application will be:
 - Sent to your faculty advisor for approval (ONLY if you are a student).
 - Submitted to the IRB for review (if you are faculty/staff OR if you are a student and your advisor has approved the protocol.)
- *You will receive updates from GSU-IRB/Sitero Mentor notifying you of protocol status.

IF YOU HAVE QUESTIONS OR CONCERNS...

- Schedule a meeting with Dr. Jackson by clicking the link below:
- [IRB](#) Info and Support

