

FGCU Research Compliance and COVID-19

IRB/IACUC

We want to provide you with an update on how we can help you and your students through this tough time of social distancing due to the COVID 19 virus.

An amendment must be submitted when you change research procedures. This includes going from in-person interviews, surveys, etc. to on-line, e-mail or phone calls. This will not be possible for some studies. These studies may need to change their completion deadlines and could cause possible hardship on participants due to these changes.

Here are some things to do to stay compliant with regulations and ensure the safety of our study participants.

- New IRB/IACUC submissions should be able to be processed as usual, as long as we have access to go into the office. We are working from home and can do most things from there. We cannot copy and scan to approve and stamp consent forms or recruitment materials. If FGCU makes changes to not allow campus visits to perform these tasks, new IRB/IACUC applications will need to be emailed to [Sherry Alexander](#) for processing.
 - A new on-line IRB application will be released soon. Check the website before you begin a new study application for the latest form.
- Be sure to communicate. Communicate with the researchers on your team, communicate with your participants and communicate with the IRB/IACUC through [Sherry Alexander](#) with any changes or questions.
- Make amendments to your study as needed. If the study procedures are not affected and the risk/benefit are the same, you don't need to wait for a written approval, at this time. We will try to keep up by sending an e-mail that you can use for an approval and get the approval memo sent as soon as we can.
- Assess the risk to study participants due to any suspended deadlines you may have to make and report these. (This does not need an approval but send a continuation memo for record keeping purposes)
- Report any suspensions or changes that any cooperating or collaborating agencies may place on your study.

Let's work together to keep these studies moving forward. Start with the studies that have the most risk added to your participants. Take the least harmful path when you are making your adjustments. And, finally, be sure to communicate with our IRB/IACUC so we can help you successfully complete your study.

Export Controls

This is also an unprecedented time in the world of U.S. Export Controls. There are new concerns coming out every day and people are working to keep our country and our technology safe and secure during this time.

FGCU is committed to doing our part to stay within the limits of U.S. Export Controls.

Here are some helpful steps to keep in compliance with these laws and regulations.

- If students have to take lab equipment or supplies (FGCU laptops, biologicals, chemicals) out of the country for their class, please check with the Research

Compliance Coordinator, [Sherry Alexander](#), to see if there needs to be a license for that export or if it is even allowed.

- Remember to communicate with your Department Chair and Dean to let them know of anything that may be exported to another country.
- Keep the Research Compliance Coordinator updated on any physical item(s) that may be exported. Also, remember that the transfer of technology can be considered an export,
 - Technology is the dissemination of research data and information electronically through e-mail, phone, fax, cloud, and chat rooms or webinars.

Most of the research and class room work done at FGCU falls under license exemptions through Publicly Available, Fundamental Research, or Educational Information. There is the possibility that equipment, biologicals, chemicals or some technology need to be reviewed for licensing. If you are unsure, please contact the Research Compliance Coordinator, [Sherry Alexander](#) to work through the process of determining whether you need a license or it falls under one of these exemptions.