**Guidelines for Faculty Research Mentors**

**Research Foundation for SUNY/Buffalo State**

**Institutional Review Board for Human Subjects Protection**

**Does my student’s project need to be reviewed by the IRB or its representative?**

If the project involves people, the answer is most likely yes. This includes projects involving a database of information that someone else collected. As long as the research involves living humans, your project requires some level of review. There are just a few exceptions: review is not required for program evaluation (unless you plan to disseminate the results of the program evaluation), journalism, and oral history projects.

**Why do we need to do this?**

Review of all research involving human participants is required by an agreement, called a Federal-wide Assurance (FWA), signed by Research Foundation for SUNY/Buffalo State and the federal Office of Human Research Protection. This assurance is designed to protect the rights of participants. By protecting the participants, this oversight also protects the researcher and the university**.** Failure to follow the federal regulations, including failing to submit a protocol for research, can have serious consequences for both the researcher and the university.

**How do I know what level of review my project requires?**

**Level 1: Department-Level Review**

Student projects that may be reviewed at the department level include laboratory projects, educational exercises and class projects, and action research within a classroom with performance or grades as the sole outcome measure. No studies completed outside of the United States may be reviewed at the department level. In order to qualify for department-level review, the research must be disseminated only within the campus. Each department has a representative who can review projects at this level.

**Level 2: Exempt or Limited Review**

The federal government uses the term “exempt” to indicate that a protocol is exempt from the higher levels of review because of its low risk for harm. This does not mean that the project is exempt from oversight and such projects still must be submitted for review. Projects that qualify for exempt or limited review include, but are not limited to, action research in the classroom with syllabus-related outcomes, including syllabus-related attitude questions, surveys on innocuous topics completed by adults, anonymous surveys (even on more controversial topics) completed by adults, and research using existing publicly available or de-identified databases. Limited review can occur for projects involving benign behavioral interventions, some studies involving deception, and projects completed by adults on more sensitive subjects, even if the data are not anonymous. Although the federal regulations distinguish between exempt and exempt with limited IRB Review, this really affects only the administrative side of things.

**Level 3: Expedited**

Projects that are more intrusive than exempt projects or that require the participation of children (aside from action research as noted in Levels 1 and 2), may qualify for expedited review. In this case, the protocol is similar to that of the full-board review, but the project is reviewed by one designated member of the IRB. The designee may approve the project, request additional information, or submit the proposal to the IRB for full-board review and approval. Some examples of expedited review projects include educational research that goes beyond syllabus-related outcomes, some research with vulnerable populations, and research that is not considered exempt.

**Level 4: Full-Board Review**

Full-board review is the highest level of review for human subjects protocols and is designed for projects that are sensitive in nature. The review is conducted at the next convened meeting of the IRB. Any research that might put participants at increased risk of harm must be reviewed at this level. The IRB meets regularly during the academic year.

**Do I need ethics training?**

All faculty members conducting human subjects research or supervising student research need to complete ethics training, as specified by the federal regulations. All students conducting human subjects research must also complete the training. Although researchers may complete other federally-approved training programs to satisfy this requirement, we encourage researchers to complete the CITI program, for which the university has a site license. To access this training, visit the CITI website <http://www.citiprogram.org>. You will find instructions for this on the Sponsored Programs website: <https://sponsoredprograms.buffalostate.edu/human-participants> Please be sure that your students know that they need to complete the social-behavioral program: a surprising number of students are confused about this.

**How do my students and I submit our project?**

Buffalo State uses an online protocol submission system, called SUNY PACS IRB. To access the system, click on the link on the Human Subjects page of the Sponsored Programs website. Faculty members can login with their Buffalo State username and password. Students will need to create a new account. Be sure that pop-ups are enabled in your browser. There are instruction sheets on the Human Subjects page to guide students and faculty through the process. A few notes on PACS:

* Once your student has created the study in PACS, he or she will need to add you as a study seam member. This is necessary so that you can see and approve your student’s work.
* There are templates for the protocol, informed consent and assent, etc., located both within PACS and on the Human Subjects page of the Sponsored Programs website. We recommend that you download and complete the templates before creating the study in PACS.
* On the Human Subjects page of the Sponsored Programs website, there are several instructional guides to walk you through the submission process, the process for submitting changes to a protocol, etc. These are field-tested and complete and can help you and your student avoid delays in the review process. Please use these sheets because, although the system is a good one, not everything is intuitive.

**Tips for Form Completion**

Review of protocols generally takes just a few weeks. After an initial review, we will contact the researcher with any questions or concerns. No further review will occur until the missing information has been submitted. This is the most frequent cause of delay in review. To prevent this, here are some tips:

* Purpose and background may be brief
	+ About a page is generally fine for straightforward projects
	+ Identify concisely what study will accomplish
* Characteristics of subject population
	+ Target of study may not be family members
	+ Estimate somewhat larger number than expected. This will prevent you from having to submit a request for changes to the study if you end up recruiting more participants.
* Be specific about how participants will be recruited
* Describe the study design in detail. For example...
	+ How many sessions will you complete?
	+ How long is each session?
	+ Over what period of time will sessions be conducted?
	+ What measures will be used? Attach all questionnaires.
	+ If this is in a school setting, are any of these measures part of regular instruction that all students will do regardless of the study? What will nonparticipating students do during the study? How will they not be singled out?
* Risks and benefits
	+ Remember that no study is “no risk”
	+ Minimal risk is defined as risk not greater than that encountered in everyday life
* Confidentiality
	+ Data are to be protected with “two locks.” This means that data must be both de-identified and securely stored in a locked cabinet or office.
	+ Any electronic data must be password protected
	+ Any electronic data that is unable to be de-identified (such as a video) must be password protected and encrypted
	+ Protocol must note that all data are to be retained for a minimum of three years in compliance with regulations
* Consent form
	+ All adults must consent to participate. If the study is Exempt, a consent statement at the start of the study is sufficient. If the study is Expedited or higher, written informed consent is required.
		- Consent forms must contain:
			* The purpose of the study (but not the hypothesis; Participants need to know enough about the study to make an informed choice to participate or not.)
			* What the participant will do in the study
			* A discussion of the risks, benefits, and compensation
			* A discussion of how confidentiality or anonymity will be maintained
			* Contact information for the researcher and the IRB
			* Effective 2019, consent forms must include a notice of whether or not the researcher anticipates using these data in some future study. Please see the revised consent form template on the Sponsored Programs website.
		- Consent forms should be written in the second person, as if students are talking to the participant and telling them about the study: “You are being asked…If you agree to participate, you will…”
	+ Parental consent is required for those under 18
	+ Parents will want to know
		- What their children will be doing
		- Is this a part of regular coursework?
		- Will their children be singled out?
		- Voluntariness
		- Confidentiality
		- Contact information for IRB and for researcher
	+ All children who are old enough to choose to participate must also give their assent to participate. This should be written at the child’s reading and comprehension level.
* If working with a school or other outside agency or group, the IRB must receive a letter indicating permission to collect data at the agency.

**What happens when the study is done?**

Faculty members must retain all of the informed consent forms for the period specified in the IRB protocol. Federal regulations specify a minimum of three years, but some individual fields may require longer retention of documents. Students are not to keep consent forms at their homes.

Full Board and some Expedited-level IRB review approvals are for a period not to exceed one year. One year after approval, your student will receive an automatic notice about the end of the project. If the project is complete, you and your student will need only to fill out a brief online form to note that. If the project is ongoing, you will be able to follow the necessary steps to apply for a continuation at that time. Exempt protocols and some Expedited-level protocols do not have a termination date. However, if there are modifications to the protocol, the researcher must submit a request for modification in the PACS system.

**Where can I get more information?**

Researchers should refer to the Research Compliance section of the Sponsored Programs website at <https://sponsoredprograms.buffalostate.edu>. The *Investigator’s Guide to Research with Human Participants*, the forms for human subjects applications, and other useful handouts and tools can be downloaded from that site.

Researchers may also contact Gina Game, Institutional Review Board Administrator, via e-mail at gameg@buffalostate.edu or by phone at 716-878-5723.