**Office of Human Research Protections Revised**

**the Regulations Governing Human Participant Research**

Following revisions by the federal government to the Common Rule governing human subjects research, the Institutional Review Board (IRB) at Buffalo State has made several changes to its review process. The revisions to the federal guidelines were designed to streamline the process for most researchers and we believe that these changes will improve the research approval process on our campus.

Changes that affect our campus include:

* **Continuing review:** The revised federal regulations no longer require continuing review for Exempt and some Expedited review studies. The revised federal regulations also no longer require continuing review for full-board studies for which data collection is complete and the only research activities are data analysis and write up. If this change applies to your study, there will simply be no ending date listed on your letter of approval. However, we would appreciate it if you would close your study in the online SUNY Pre-Award and Compliance System (SUNY PACS) IRB when it is completed so that we can know what research is ongoing on our campus.
* **Research in foreign countries:** The revised federal regulations now allow all research in foreign countries to be reviewed at the level at which it would be if conducted in the United States. Research in foreign countries may not be reviewed at the Department Level, but may be reviewed at the Exempt, Expedited, or Full-Board level, just as any other research would be.
* **Change in definition of research:** Oral histories and journalism are now specifically excluded from the definition of research, which means that these categories of work with human subjects no longer need to be submitted at all. Please note that participant observation still requires review.
* **Expanded exemption categories:** The revised federal regulations have significantly broadened the exemption categories. Specifically, research involving benign behavioral interventions and non-anonymous surveys for adults on sensitive topics may now be reviewed at the Exempt level. These new categories encompass a significant amount of the research at Buffalo State. However, there are no changes to levels of review for research with children in the revised regulations. Please remember that you must submit protocols for Exempt studies in order to obtain the Certificate of Exemption.
* **Change to consent forms:** **Secondary research:** There is a new required element for all consent forms. All research studies must now address whether the researcher anticipates using the data in future studies. Consent forms must now note if the data will or will not be used (or may be used) in the future and, if the data may be used, if it will be de-identified at that time. Please note that it is much simpler to request use of data in the future if the data will be de-identified.
	+ If the data will continue to be identifiable, the researcher may choose to seek approval of broad consent. There are some challenges with this—for example, researchers must keep track of who consents to broad consent and who does not and they need to have enough of an idea of what that future research might be to include in the consent form. Researchers must also address in the protocol why they need broad consent and not just the use of de-identified data in the future.
	+ Please see the revised consent form template and revised protocol templates for more information on this change.

Because of these changes, many templates and guides have been updated on the Sponsored Programs website. Please be sure to use these newest versions in any new submissions to the IRB. We will be forced to return any protocols using outdated forms.

Please see the Human Participants Research Compliance page for Buffalo State templates, policies, and procedures: <https://sponsoredprograms.buffalostate.edu/human-participants>.

For more information about the federal regulations themselves, please visit the Office of Human Research Protections website. The site has many links to videos and other educational resources: <https://www.hhs.gov/ohrp/education-and-outreach/index.html>.

If you have any questions about the implementation of these changes at Buffalo State, please contact IRB Administrator, Gina Game (gameg@buffalostate.edu) or IRB Chair, Jill Norvilitis (norviljm@buffalostate.edu).