IRB Application Process

Step 1: Determine if your project requires IRB review by completing the worksheet:

 $\underline{https://www.njcu.edu/about/office-research-grants-sponsored-programs/institutional-review-board}$

There are three categories:

- 1. **Exempt Review** for data obtained from databases, internet, and other publically available sources.
- 2. **Expedited Review** for low risk categories.
- 3. **Full Board Review** for research/projects that involve subjects listed in protected categories.

Step 2: Complete Required CITI Training - ALL principal investigators (PIs) and co-PIs involved in the project must complete CITI training in **human subjects research** PRIOR to submitting an IRB application. Unless you are conducting laboratory experiments, ALL PIs and co-PIs need to complete the Social and Behavioral Research Investigators course. The training/certification is available at https://www.citiprogram.org, where you can register through NJCU's membership and create your own username and password. Proof of CITI training is required for all researchers involved in IRB projects. Proof of Human Subject Certification is a Federally mandated requirement of IRB review.

Step 3: Start an IRB Application.

Step 4: Build a successful and complete IRB application packet (as follows):

- 1. View the IRB Checklist at https://www.njcu.edu/sites/default/files/pdfs/investigatorschecklist.pdf, which provides information about all of the required documentation.
- 2. Use the application forms at https://www.njcu.edu/sites/default/files/pdfs/njcu-irb-application2.pdf.

Email the complete application packet as one file to IRB@njcu.edu and cc kresch@njcu.edu.

**Students may not serve as PIs and may not submit IRB applications. All applications must be submitted by the NJCU faculty or staff member who is serving as the PI/faculty sponsor.

Review Period - Upon receipt, all applications are reviewed before being forwarded to the NJCU IRB. Satisfactory applications are acknowledged. Any incomplete applications or any about which there are questions, concerns, or issues requiring clarification, will be returned to the researcher(s) to address aforesaid issues. Once satisfactorily revised, the IRB application will be forwarded to the NJCU IRB. IRB applications are reviewed on a rolling basis. Applicants with exempt reviews will be notified within a working week. Expedited review and feedback normally takes 4-6 working weeks (exceptions during Summer/Winter Breaks).

Decisions - If an application is approved, an approval letter will be sent to the applicant and no further action from the investigator(s) is necessary prior to initiating the study.

- Should the research exceed the 12-month approval period, completion and submission of the renewal form is required. Additionally, **ALL** unanticipated problems involving risks to subjects must be reported to the IRB as soon as possible.
- In the event that the application is not approved pending receipt of additional information, clarifications, or modifications, the applicant may resubmit the modified application for the next IRB review cycle.
- Research that has **NOT** been approved by the IRB may not be initiated by the investigator. The reasons for the denial will be provided in writing. The investigator may respond in writing and this will be reviewed by the IRB Chair as soon as possible.