## **GSU IRB Frequently Asked Questions**

- How do I contact the GSU IRB by email?
  - o <u>irb@govst.edu</u>
- Where can I find guidance for Human Subjects Research at GSU?
  - See the "Researcher's Guide to the IRB," under the "Guidance" tab on the GSU IRB webpage <u>www.govst.edu/irb</u>
- I want to do research with human subjects at GSU. What do I do with the IRB?
  - 1. Take the CITI Program training on Human Subjects Research
  - Apply for IRB approval of research: complete the proper Form(s), Attach appropriate documents, Attach CITI Program completion certificates, obtain proper Signatures, and Submit application through the Provost's Office
  - 3. Wait for approval to begin research
- Where do I get CITI training?
  - Training is online, link via the GSU IRB website under Human Subjects Research Information (top of right column), "Human Subjects Research CITI Training"
- Which CITI training should I do?
  - o <u>Social/Behavioral</u>: if you are doing social or behavioral research
  - BioMedical: if you are doing biomedical (e.g. interventions) research
  - Undergraduate: ONLY if you are a GSU undergrad
  - o IRB Board member: ONLY if you are a member of the Institutional Review Board
- What if I have questions about CITI training, including registration or the right course?
  - Contact Jennifer Morehead Farmer, Director of OSPR (<u>imorehead@govst.edu</u>)
- Where can I find forms to submit an application at GSU?
  - See the "New Protocols" section under the "Review Request Forms" tab on the GSU IRB webpage (<u>www.govst.edu/irb</u>). Forms can be downloaded from the website as fillable Word documents.
- Which application form should I use?
  - <u>Request for Exempt Status Form</u>: if your research involves:
    - no children, no prisoners, no risks to subjects, and qualifies within at least one of the conditional categories
  - o *Expedited and Full Review Form*: if your research involves:
    - children or prisoners, minimal or greater than minimal risks to subjects, externally funded studies
  - o <u>Classroom Exemption Review Form</u>: if you have consulted the IRB Chair, and:
    - the intent of the classroom assignment/project is to teach students about the ethics of working with participants and data collection
    - the assignment involves no or minimal risk to subjects
    - The findings will only be presented within the classroom or at GSU, but will NOT be presented or accessible outside of GSU.

- I have an approved protocol—can I make changes?
  - Yes, but you MUST obtain approval from the IRB first.
- How do I obtain IRB approval for changes to my approved protocol?
  - Submit an "<u>Amendment/Addendum Form</u>" found under the "Ongoing/Closing Protocols" section under the "Review Request Forms" tab on the GSU IRB webpage (<u>www.govst.edu/irb</u>). Forms can be downloaded from the website as fillable Word documents.
- What kinds of changes can I request?
  - As long as the project title, Project Director, and core research question(s) remain(s) the same, you may request to:
    - add researchers, add research sites, increase the number of subjects, change inclusion/exclusion criteria for subjects, change recruitment strategies, add new phases/surveys etc. to the project (within reason)
- I have an approved protocol with an expiration date. How can I keep doing research after this date?
  - The expiration date indicates that your protocol needs to be reviewed by the IRB every year.
  - You must complete and submit an "<u>Annual Continuing Review/Project Closure</u> <u>Form</u>" found under the "Ongoing/Closing Protocols" section under the "Review Request Forms" tab on the GSU IRB webpage (<u>www.govst.edu/irb</u>). Forms can be downloaded from the website as fillable Word documents.
  - o Please complete all sections and attach necessary documentation.
  - The IRB will review your submission and issue a decision. If approved, your protocol will be extended and expire after another year.
- I have an approved protocol but the project is completed. What do I do?
  - Please notify the IRB that you would like to close the project, even if Exempt.
    - The project can be closed if you are completely done with subject recruitment, data collection, data analysis and results dissemination, please notify the IRB that you are closing the project.
  - Please complete and submit an "<u>Annual Continuing Review/Project Closure</u> <u>Form</u>" found under the "Ongoing/Closing Protocols" section under the "Review Request Forms" tab on the GSU IRB webpage (<u>www.govst.edu/irb</u>). Forms can be downloaded from the website as fillable Word documents.
- How do I, my students, my division/department get more information and training about the GSU IRB process?
  - The IRB Chair, Dr. Renée Theiss, is happy to provide an informational session or workshop for students or faculty. Email <u>irb@govst.edu</u> to schedule a date/time.

## **GSU IRB Resource Links**

- Federal Regulations for Human Subjects Research (45 CFR 46)
  - o http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"
  - o http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
- US Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP)
  - o http://www.hhs.gov/ohrp/index.html
- GSU IRB Website
  - Research Guide, Forms, CITI training link, Full-board application submission dates, Full-board meeting dates
  - o http://www.govst.edu/irb
- CITI Program for Human Subjects Research ethics training
  - o https://www.citiprogram.org/index.cfm?pageID=88