**The Catholic University of America**



 **Committee for the Protection of Human Subjects (CPHS)**

**General Note On Human Subjects Protection**

1. According to the Office of Human Research Protection (OHRP) “under Federal Policy (Revised Common Rule) at Section 101 awardees and their collaborating institutions are ‘engaged’ in human subject research whenever their employees or agents intervene or interact with living individuals for research purposes; or obtain, release, or access individually identifiable private information for research purposes.”
2. All CUA researchers and administrators who partake in human subjects are required to complete training in the protection of human subjects prior to obtaining institutional approval to begin a study. This free, web-based course presents information about the rights and welfare of human participants in research. The tutorial is designed for those involved in conducting research involving human participants. It satisfies the NIH human subjects training requirement for obtaining Federal Funds. You will have the option of printing a certificate of completion from your computer upon completing the course.

The primary training course is administered by CITI and offered free of charge to CUA users. You can access the course as follows:

* To logon to the CITI site for the first time:
* Go to [www.citiprogram.org](http://www.citiprogram.org) , click on "Create an account".
* Under "Select your institution or organization", select “The Catholic University of America” in the "Participating Institutions" drop down box.
* Next, proceed to create your own username and password and select the Learner group.
* For further instructions, you can click on the link "View The Catholic University of America Instructions Page"
* Print the test results and submit with your protocol.
1. All submissions to the IRB must be delivered in hard copy to the **Office of Sponsored Programs** or emailed as a single pdf file. They must include a cover page (found on the IRB web site) and human subjects research training certification along with the other documents described here depending on the action requested of the IRB.
2. Investigators who believe their research projects involving human subjects are exempt must complete and submit an ***“Exemption Certificate”*** and a ***“Justification for Exemption Form”*** to the IRB, through the **Office of Sponsored Programs**. The ***“Justification for Exemption Form”*** includes an area for researchers to provide a description of the protocol of their study and how the regulation applies.
3. If the research project is not exempt, the investigator must submit the Human Subjects Protocol application to the IRB, through the **Office of Sponsored Programs**, for expedited or full review.

Note that the exemption categories **DO NOT APPLY** when the research activities include:

* Prisoners, fetuses or pregnant women;
* The review of medical records if the information is recorded in such a way that subjects can be identified, directly or through identifiers linked to the subjects;
* Survey or interview techniques which include minors as subjects;
* Techniques which expose the subjects to discomfort or harassment beyond levels encountered in daily life;
* The deception of the subjects.

**For any questions please contact:**

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