October 2020

**Human Research Protections Program Training**

All persons involved in the conduct or oversight of research involving human subjects must demonstrate a minimum level of understanding of the ethical principles and relevant regulations. This requirement can be fulfilled by successfully completing a web-based tutorial sponsored by the University of Miami, which can be accessed at the following address: [citiprogram.org](http://citiprogram.org)

Investigators who have completed the CITI courses at another institution or taken formal courses in research ethics may be exempt from the Baptist IRB training requirements. Investigators who have registered and taken CITI courses with a different institution are encouraged to affiliate with Baptist Memorial Health Care (TN, MS, AR). This will allow the Baptist-IRB staff to verify and keep up with CITI training that has been completed.

**INSTRUCTIONS: Select Register**

1. **Select Your Organizational Affiliation**
   * + Start to type in *Baptist Memorial Health Care (TN, MS, AR)* and a drop down list will appear. Be careful as there are several Baptist institutions on the list.
2. **Learner Registration**
   * + Enter first and last name. Select an e-mail address that you can access you can complete the registration process by verifying the email.
3. **Create your username and password** 
   * + Create your username and password
     + Select and answer a security question.
4. **Gender, Ethnicity and Race**
   * + Information is voluntary
     + Use the blue information question marks for more information on specific categories.
5. **Register your interest for CE credits**
   * + Can CITI Program contact you at a later date regarding participation in research surveys?
6. **Demographic Information**
   * Complete (\*) items – if you have any questions call the IRB office at 226-1677 or 226-1678.
7. **Complete Curriculum**

* Please complete all items in the checked category or categories on the next page.

1. **Training Completion**

* When all requirements have been completed, you’ll be able to download a Course Completion Report. This report will provide a detailed record of your accomplishments. A copy of this file will automatically be sent to the BMHCC-IRB office. The minimum level of 80% is considered a passing score.

**Required CITI Training Courses**

**Required Courses for Investigators and Clinical Staff Interested in Conducting Clinical Investigations:**

* Biomedical Research (Basic Course)
* Biomedical Responsible Conduct of Research
* Conflict of Interest
* Good Clinical Practice

**Required Courses for Investigators and Clinical Staff Interested in Conducting Social or Behavioral Research:**

* Social and Behavioral Research (Basic Course)
* Social and Behavioral Responsible Conduct of Research
* Conflict of Interest
* Good Clinical Practice

**Required Courses for Investigators and Study Personnel Interested in Conducting Medical Record Reviews:**

* Data or Specimens Only Research (Basic Course)
* Conflict of Interest
* Good Clinical Practice

**Required Courses for Investigators Interested in Humanitarian Use Device:**

* Humanitarian Use Device (Basic Course)
* Conflict of Interest
* Good Clinical Practice

**Required Courses for Study Personnel (Regulatory):**

* Regulatory Group Only

**Required Courses for Study Personnel (Data Managers):**

* Data Management Course Only

**Required Courses for Research Participant Advocate:**

* Research Subject Advocate
* IRB Members
* Conflict of Interest

**Required Courses for IRB Members:**

* IRB Members (Basic Course)

**Required Courses for Unit Nurses Who Assist Researchers in Identifying Potential Subjects and Obtaining Informed Consent:**

* Nursing Research (Basic Course)

**Recertification**

* Once every three years all research investigator and staff will be required to take a refresher course. You will be notified by CITI via email when this is due. The modules required at that time will be indicated on the CITI home page.

**Financial Conflict of Interest (FCOI)**

As required by policy S.AD.1006.03, all study investigators and research staff are obligated to complete a financial conflict of interest tutorial as well as a submit a financial disclosure form. The training opportunity is provided by the National Institute of Health (NIH) Office of Extramural Research. NIH has created an online FCOI tutorial for all Institutions that are applying for, or that receives PHS research funding via grant or cooperative agreement (see 42CFR50.602). This training is compliant with Federal Regulation 42CFR50 Subpart F. Each Investigator is required to complete FCOI training. In this instance, Investigator refers to project directors, principal investigators, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. Training must occur:

* At least every four years, and
* Immediately when any of the following circumstances apply:
  + - Institutions revises its policy in a manner that affects the Investigator;
    - When an investigator is new to the Institution; or
    - When the Institution finds an Investigator is not in compliance with the Institution’s policy or management plan.

**INSTRUCTIONS:**

1. The link below will direct you to the NIH tutorial.

[https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm](https://urldefense.proofpoint.com/v2/url?u=https-3A__grants.nih.gov_grants_policy_coi_tutorial2011_fcoi.htm&d=CwMFAg&c=NwimJEPcMuFfAJV6iz0C4Q&r=DQ0h78t6dWGV3P-5JUwOGz_VUH0Hnp184WvppZGrQ6A&m=l8p55PVOdmHuISw_IZ_9IKfMmFYWkvbIhiQKKHUmBY0&s=eu9hlThPUriqc14lTQ8xhRBgCrGl62HBTq0BU6CV03g&e=)

1. A certificate of completion must be kept on file with the IRB. Please email your certificate of completion to Baptist IRB at [Baptist.IRB@bmhcc.org](mailto:Baptist.IRB@bmhcc.org) .

In addition to completing the FCOI tutorial, please complete and submit the FCOI Disclosure Form online at:

<https://sites.bmhcc.org/clinicalresearch/>. A new FCOI Disclosure Form is to be submitted every year.

**Contact Us**

Need more information or if you have any questions, contact the Baptist IRB office at 901-226-1677 or 901-226-1678.



Patty Claiborne, PharmD

Baptsit-IRB Vice-Chair

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