Institutional Review Board
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CITI Update

Creating a new account within Advocate for CITI training:

- The web site is www.citiprogram.org/
- On the home page there are three blue boxes on the right. The third one down is labeled "Create an account." Click on "Register"
- You will be asked to "Search for an organization." Type "Advocate"
- **Step One:** On the next page that pops up you will select from SIX Advocate sites.

  Please do not select "Advocate Health Care Network." That is outdated and we are asking CITI to remove it. You can select this site but you will then be taking more modules than are currently required.

  The sites that are listed were selected by CITI during the time we were negotiating our fee. If you do not find your site listed, please select the site geographically nearest to your location. Which site you select will have no bearing on you receiving full credit for completed modules:
  - Advocate BroMenn Hospital
  - Advocate Childrens' Hospital
  - Advocate Christ Medical Center
  - Advocate Illinois Masonic Medical Center
  - Advocate Lutheran General Hospital
- **Step Two:** Personal Information (fill it in and move to step 3)
- **Step Three:** Create Your Username and Password – Make sure you keep a record of this information for future use.
- **Step Four:** Learner Registration
- **Step Five:** Do you want to receive CEUs?

- **Step Six:** Learner Registration (asks for demographic info)

- **Step Seven:** Select Curriculum – You should select the choice that best fits the particular study and your role on the study team. The choices are:
  - Biomedical Researchers
  - Social-Behavioral Education Researchers
  - Biomedical Data or Specimen Only Research
  - IRB Members
  - Remedial

  The "Remedial" selection allows you to obtain training in some areas that are not covered by the other user groups. For example, Humanitarian Use Device (HUD) training (see #4 below) will be found under "Remedial."

  A curriculum of 13 modules titled Good Clinical Practice (GCP) is provided as a convenience because some commercial sponsors may require completion of this course set. GCP is **NOT** a substitute for any of the Advocate required modules listed above.

- **Last Step:** You will supply some final information to complete/finalize your registration. Once you are registered you can log on to CITI with just your username and password.

Advocate CITI Q & A

1. **Is CITI training mandatory for all research within Advocate?** IRB initial and continuing review applications will be considered incomplete if any member of the study team has not completed CITI training. This applies to all review levels (full, expedited, and exempt) as well as HUDs. Modifications and RNIs will not be processed unless the PI is current with his/her CITI training.

2. **Why do I need CITI training if the IRB determines that my research is exempt?** The category of "exempt" means that the project does meet the definition of human subject research, but it is conducted in such a way that ongoing IRB review is not required. Therefore, it remains important for research in this category to be conducted conscientiously. In some cases investigators may want to change the protocol that was reviewed by the IRB, in which case resubmission to the IRB is required and the changes may change the status of the study to "expedited", in which case having already obtained CITI training will be particularly important.

3. **Do I need CITI training if I am only requesting a determination about whether my project falls under the definition of "human subject research"?** No, CITI training is not required for that determination. If you are notified that your project does meet the definition of human subject research, then the study team members will need to obtain the training.

4. **Do I need CITI training if my IRB application is solely to use a device that is approved under a FDA Humanitarian Device Exemption (HDE)?** Yes, but since Humanitarian Use Devices are not considered human subject research even though they do require IRB review, a single CITI module is sufficient. The HUD course module can be found under the Remedial course options. All physicians and staff listed on a HUD protocol should complete that course.

5. **What should I do if my IRB application is complete except for members of the study team obtaining their CITI training?** Consider the role of such individuals on your team. If their role is key you should not submit the IRB application until their CITI training is complete. If they can be replaced by someone who has obtained CITI training consider that possibility and change study related documents accordingly (e.g., delegation of authority log). If the individual is considered key personnel at this time, consider removing him or her from your application, submit it to the IRB and then add the individual at a later time by submission of a Modification (HRP-213).

6. **Why aren't all Advocate sites listed on the CITI website?** CITI increased its fees in 2013. The cost would have been prohibitive had we agreed to a fee based on the number of research sites within Advocate. We were able to negotiate a reduced fee, after which CITI selected from among all our sites for purposes of administration. This selection was somewhat arbitrary and will have no bearing on individual users receiving full credit for any training they complete.

7. **I completed CITI training using the previously required Advocate modules on or after June 1, 2013 – OR - I completed CITI training at another institution within that time frame and it includes the modules currently required by Advocate. Do I need to complete training?** No. As long as your previous training includes the current Advocate requirements and it is within the 3 year period during which certificates are valid, you can submit that training with IRB applications. However, you should go to the CITI website and complete the process for affiliating your history with the current Advocate account. This is not difficult, but if you have any questions or problems call or email Terry Cole in the IRB office (teresa.cole@advocatehealth.com (55-6148 or 630-929-6148).

8. **Who has access to Advocate's CITI account for administrative purposes?** The primary administrator in the IRB office is Terry Cole. The IRB staff and AHC Research Directors can also verify most CITI records affiliated with an Advocate site (there are exceptions due to older certificates and/or some non-AHC institutions' relationship with CITI). Site users can always access their own credentials if they retain

their user ID and PW. IRB staff can assist if you've lost the ID or PW.

9. **Once my CITI training is complete how often will I need to renew it?** Individual training is good for 3 years. You will receive a reminder when it is time to update your certificate. Remember that the 3 years begins when you complete individual requirements. Therefore, if you complete training in one learner group (e.g., biomedical research) and the complete training in a different module (e.g., data and specimen collection) 6 months later, you will be reminded at different points in time about the need to renew each training curriculum. This reminder comes directly from CITI.

10. **What if my study includes a particular specialty or characteristic that is not covered in the general training?** As you are preparing your IRB application, please bear in mind that in individual cases the IRB will require more training than the general user groups require. For example, if your study entails work with stem cells you will need the single module training on that particular area of specialty. Likewise, if you conduct pediatric research you must complete the extra training on that topic. The most commonly required extra modules are shown in the table below.

If your research includes:	The study team will need to complete the following elective modules in addition to completing the required courses for your specific learner group:
Children (under 18 years of age)	Vulnerable Subjects - Research Involving Children (ID: 9)
Pregnant Women, Human Fetuses, and/or Neonates	Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)
Employees (i.e. nurses, residents, etc.)	Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)

11. **If I qualify for more than one learner group will identical individual courses for one learner group carry over to an additional learner group?** Yes. If, for example, you conduct chart reviews and biomedical research, the course you complete on "History and Ethical Principles" required for the Data and Specimen user group will be listed as complete when you are working through your module for Biomedical Research.

12. **What courses are required for each of the learner groups?** Refer to the chart below.

Advocate CITI Courses Required for User Groups: Refer to the chart below for required courses in each learner group. For each learner group below the entire module must be completed with a score of 75% or higher. Only the checked courses are required to complete a module. Additional individual courses may be required for a particular study (e.g., research involving minors). The Remedial Learner Group is not included here as its purpose is to provide access to all individual courses for additional training as particular circumstances dictate. Only the individual courses that are required to complete the required module for each learner group are included below; you can browse the website for additional courses.

	Biomedical Researchers	**Social-Behavioral Education Researchers**	**Biomedical Data or Specimen Only Research**	**IRB * Members** (see below)
"What Every New IRB Member Needs to Know"				1
Belmont Report and CITI Course Introduction	✓	✓	✓	1
History and Ethical Principles	✓	✓	✓	1
Basic IRB Regulations and Review Process	✓		✓	1
Informed Consent	✓	✓		1
Vulnerable Subjects: An Overview	✓		✓	1
Conflicts of Interest in Research Involving Human Subjects	✓	✓	✓	1
FDA-Regulated Research	✓			1
Unanticipated Problems and Reporting Requirements in Biomedical Research	✓			1
Research and HIPAA Privacy Protections	✓		✓	2
Records-Based Research			✓	2

Defining Research With Human Subjects		✓		2
The Regulations		✓		2
Assessing Risk		✓		2
Privacy and Confidentiality		✓		2
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research		✓		2
Vulnerable Subjects: Workers and Employees				2
Vulnerable Subjects: Pregnant Women, Fetus, Neonates				2
Vulnerable Subjects: Children				2
Cultural Competence in Research				2
Humanitarian Use Devices				2
Social and Behavioral Research for Biomed Researchers				2
Avoiding Group Harms: US Research Perspectives				2

*** IRB members should start with the block of modules numbered as 1.**