On May 30, 2017, OSF Healthcare System announced a new online human subjects research training requirement for researchers with OSF-related activities. This requirement applies to individuals who are directly involved in conducting research with human subjects, or who are directly involved with the handling of identifiable private information related to those subjects, including protected health information, in the course of a research project in one or more of the following categories:

a. Research conducted by an OSF Healthcare employee.
b. Research performed on the premises of an OSF Healthcare facility, or using equipment belonging to OSF Healthcare.
c. Research involving OSF Healthcare patients, students, or staff as a cohort.

If you are not a researcher with OSF-related activities, you do not need to do anything different with CITI!

The four OSF-required CITI Program training courses for all personnel involved in conducting research at OSF Healthcare are:

- Conflicts of Interest (COI)
- Good Clinical Practice (GCP)
- Human Subjects Research (HSR)
- Responsible Conduct of Research (RCR)
**PLEASE NOTE:** If you have already completed the UICOMP Biomedical Basic Human Subjects or the Social/Behavioral Human Subjects Research Course with UICOMP, OSF will accept the UICOMP completion of this course until your expiration date (3 years after your completion date).

If you have completed the COI, GCP and RCR courses with UICOMP, your UICOMP completion of these courses will transfer to your OSF Healthcare System affiliation maintaining the UICOMP completion dates. When you encounter CITI Enrollment Question 3 “Human Subjects Research (HSR),” answer “Not at this time.”

Upon the expiration of the UICOMP CITI completion date, you will add the HSR course to your OSF Healthcare Systems registration by selecting “Add a course” and selecting your Role as Researcher & Staff for Question 3.

To affiliate with OSF, the link to CITI is [www.citiprogram.org](http://www.citiprogram.org)

You will begin by logging in and clicking on “Click here to affiliate with another institution.”

Search for Organization: OSF Healthcare System

Answer CITI Course Enrollment Questions

**Question 1:** Conflict of Interest: Yes – your UICOMP completion of this course will transfer to your OSF Healthcare System Affiliation maintaining the UICOMP completion date.

**Question 2:** Good Clinical Practice: I have never completed a GCP for Clinical Trials course.

**OR**

If you have completed the GCP course with UICOMP, (next two options), your UICOMP completion of this course will transfer to your OSF Healthcare System Affiliation maintaining the UICOMP completion date.

**Question 3:** Human Subjects Research (HSR): Answer “not at this time.”

**Question 4:** Responsible Conduct of Research (RCR): Select your Role as Researcher & Staff

If you have completed the RCR course with UICOMP, your UICOMP completion of this course will transfer to your OSF Healthcare System Affiliation maintaining the UICOMP completion date.

**Question 5:** Supplemental Courses: Mark nothing UNLESS interested in taking extra courses at this time.

Click SUBMIT

Please direct questions pertaining to the new OSF requirement to: Mike Bailey at 309-624-2618 or [Michael.W.Bailey@osfhealthcare.org](mailto:Michael.W.Bailey@osfhealthcare.org). For questions pertaining to UICOMP CITI requirements, please contact Wendy Bucklin at 309-680-8633 or [wbucklin@uic.edu](mailto:wbucklin@uic.edu).
In 2016, the National Institutes of Health (NIH) issued a policy on the use of a single Institutional Review Board (IRB) for multi-site research grant applications with due dates January 25, 2018 and beyond, and for contract solicitations published starting January 25, 2018. The compliance date for the policy is January 25, 2018. The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites.

Q: What studies must follow the NIH policy?

A: The NIH policy applies to all studies that are:

- Funded through grants, cooperative agreements, contracts, or the NIH Intramural Research Program, and
- Involve non-exempt human subjects research, and
- Involve multiple sites, all of which are conducting the same protocol.

Q: If an NIH awardee has an ongoing multi-site trial that is still recruiting, must a sIRB be selected and take over the review for all participating sites?

A: The NIH single IRB policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after the policy effective date. Ongoing, non-competing awards will not be expected to follow the policy until the grantee submits a competing renewal application after the policy is in effect. For contracts, the policy applies to all solicitations issued on or after the effective date.

Q: What happens on January 25, 2018?

A: All competing NIH grant applications (new, renewal, revision, or re-submission) with receipt dates on or after January 25, 2018 must include a plan describing the use of a sIRB for the study.

Q: Who will serve as the sIRB?

A: In most situations, the lead PI, in collaboration with the IRB office at the lead PI’s institution, will select the sIRB. The selected IRB must be willing to serve as the sIRB and all of the participating sites must agree to rely on the sIRB. Finally, NIH must concur with the selection.

For the practice of medicine, a doctor is allowed to use PHI as part of healthcare operations. HIPAA guidance suggests that additional protections come into play when looking at the same PHI but for research purposes. A treating physician/researcher should get a partial waiver of HIPAA Authorization for screening purposes approved by the IRB before looking at patient records for research eligibility.

A partial waiver of HIPAA Authorization for screening purposes should be requested if you do not yet know “who” your study population is. A partial waiver is to be used for screening and recruitment only. Once it is determined that a subject meets study criteria, a HIPAA Authorization must be obtained from an individual subject or a request for a waiver of HIPAA Authorization for the MAIN study must be granted by the Peoria IRB.

Requests for a partial waiver of HIPAA Authorization for Screening Purposes are commonly requested when a researcher will:
1. Access existing medical records or a database (paper or electronic) to obtain potential subjects’ PHI yourself;
2. Make a request to OSF Healthcare Analytics or UPH Data Warehouse to access existing medical records or a database to obtain potential subjects’ PHI;
3. Access patient schedules/logs (ex: clinic, surgery, admission) to obtain potential subjects’ PHI.

Example: A researcher wants to perform a retrospective chart review on patients

1) that were admitted
2) between January 1st and January 8th in the years of 2007-2017
3) and were adults

WHY: To see if there is an increase in documented adverse events during the first week of the year at a Level One Trauma Center.

In order to pare down the number of potential subjects to a manageable amount, the researcher should request a partial waiver of HIPAA Authorization to access the dates of admission to narrow the pool to January 1st-January 8th of the last 10 years, the age or DOB to determine if the subject is an adult, MRN and name and adverse event reports.
By applying the inclusion/exclusion criteria, the researcher has narrowed the potential subject pool to:

1) number of admissions per year (2,000)
2) number of admissions during one week over the last 10 years (384)
3) number of patients who were 18+ (230)
4) that had a documented adverse event (223)

Through this process, the researcher now has the names and MRNs of 223 patients that he/she can collect data on for his/her research project.

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**Fall Clean-Up: Shared Users in IRBNet**

Please take a moment to review and ensure that the “shared” users and permissions are current and accurate for your research project(s) to ensure unwarranted access by non-research team individuals in IRBNet. This step may be overlooked when a Change in Research is approved to remove Authorized Study Personnel.

PLEASE NOTE: A project should be shared “FULL ACCESS” with at least TWO (2) individuals to ensure access to IRBNet in the case of an unplanned leave or departure of one FULL ACCESS individual. Shared access for research team members can be changed at any time.

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**Hot...well Warm off the Presses...**

Quorum Review’s Knowledge Center featured an article on 02 August 2017 entitled “FDA Aligns Minimal Risk Consent Policies with the Common Rule.” The FDA has introduced one of the first, if not the first, tangible consequences of the 21st Century Cures Act that calls for harmonizing of human subject protection regulations between the FDA and the rest of the federal government.

Click [HERE](https://example.com) to read about the first movement towards harmonization.

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**The updated UICOMP Peoria IRB Website is currently under construction.**

Meeting Dates, Submission Deadlines, Fees for Sponsored Studies can be found at:

Public Responsibility in Medicine and Research (PRIM&R) Annual Ethics Conference:
November 5-8, 2017
San Antonio, TX

Additional information can be located at:
https://www.primr.org/aer17/

Office for Human Research Protections (OHRP) Educational Event:
“Change is Coming: Meeting Potential Challenges”
November 15, 2017
Governors State University
University Park, IL

Registration fee is $75.00 (deadline November 8th). Additional information can be located at:
http://www.govst.edu/professional-development-courses
(click on OHRP Educational Event)

Upcoming PIRB Meeting Dates

Thursday, September 14, 2017 – 12:30 PM
Thursday, October 12, 2017 – 12:30 PM
Thursday, November 9, 2017 – 12:30 PM

Thursday, December 14, 2017 – 12:30 PM (Submission Deadline 11/17/17)

Submission Deadlines are the end of business on the last Thursday of each month

Meetings are held in Room A100-2 at the University of Illinois College of Medicine Peoria.