Trainee Eligibility to Serve as the Principal Investigator of a Minimal Risk Human Research Protocol

What is a trainee?
An individual who is in a time-limited educational program leading to advanced qualifications or degrees, including but not limited to a medical student, nursing student, APN student, resident, or fellow.

What is a Principal Investigator (PI)?
The individual who is responsible and accountable for conducting the clinical trial. The PI assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.

The Peoria IRB policy allows trainees including students, residents and fellows to serve as the PI on a MINIMAL RISK research protocol if the department head is agreeable evidenced by his/her departmental signature in IRBNet prior to review by the IRB.

Common examples of minimal risk human research studies are: retrospective chart reviews, surveys, focus groups, noninvasive procedures and blood draw studies of a certain collected blood volume.
This Peoria IRB policy does NOT allow a trainee to serve as the PI for a \textbf{GREATER THAN MINIMAL RISK} research protocol. The trainee (student, resident or fellow) may still contribute substantively to the protocol and its performance in a role other than the PI.

\textit{In a GREATER THAN MINIMAL RISK protocol, the probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and/or where the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.}

\textbf{When is the effective date of this policy?}
January 1, 2019

\textbf{Is there an exception?}
YES! Exceptions to the ineligibility of a trainee to submit as the PI of a GREATER THAN MINIMAL RISK research protocol may be requested by the Department Head.

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\textbf{New Category of Reportable Unanticipated Problems: Frequent Deviations of the Same Nature} \\
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A protocol deviation is a departure from the approved protocol’s procedures made without prior IRB approval. By itself, a protocol deviation rarely increases the potential for risk to the subject or any damage to the integrity or completeness of the research data. Protocol deviations \textbf{DO} become reportable to the IRB as an unanticipated problem when an event of the same nature occurs frequently enough to suggest a pattern or a process problem.

Frequent deviations of the same nature may include but are not limited to:

1. More than 3 subjects signing an outdated or unstamped version of the consent form;
2. More than 3 subjects with missing protocol-required lab tests;
3. More than 3 subjects having “out-of-window” visits; and
4. More than 3 subjects deviating from specific protocol eligibility requirements (i.e. enrolling subjects with a blood pressure or a laboratory value slightly higher or lower than dictated by the protocol when all other criteria are met.)

Under the new policy, “frequent” is defined as occurring in more than 3 subjects in a single research study. Frequent deviations of the same nature are reportable to the IRB when the PI or a member of the research team becomes aware of the occurrences.

Through this new category of reportable unanticipated problems, the Peoria IRB hopes to assist investigators and research teams in identifying frequent deviations of the similar nature before they negatively affect the participant’s safety, rights, or welfare and/or the completeness, accuracy and integrity of the study data.

Frequent deviations of the same nature are unanticipated problems that must be reported to the IRB on the Unanticipated Problem Form (formerly the Unanticipated Problems Involving Research
Starting January 21, 2019, the research community will need to comply with the full set of Common Rule changes.

The new regulations DO NOT impact studies approved prior to January 21, 2019.

For New Studies, expect to see:

- IRB Project/Protocol Review Form changes
- Informed consent template revisions
- HSPP Policy & Procedure updates

Existing Studies - Open and existing PIRB studies (exempt, expedited and full board) will be “grandfathered,” meaning they will NOT be required to comply with the changes to the Final Rule. These studies will maintain the same consent form, the same expedited or exemption category determinations, and the same Continuing Review cycle.

Continuing Review - No longer required for NEW minimal risk research, including NEW studies that progress to the point of data analysis of identifiable data/biospecimens or obtaining only follow-up clinical data. Implementing a “Administrative Review” in place of Continuing Reviews for minimal risk studies.

Exemptions - New categories and clarification of existing categories. Some exemptions may require "limited IRB review" (similar to an expedited review process).

Informed Consent - A new "Key Elements" section and a rearrangement of content is designed to facilitate a potential subject's decision to participate or not.

Single IRB-of-Record (sIRB) - IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020.

OHRP has created a series of videos and other resources to help explain some of the new provisions and changes: https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html

Stay tuned for announcements!!
Did you know that the Investigator Conflict of Interest Disclosure Policy discusses a process for the immediate education of researchers and research staff when:

- A researcher and/or research staff is non-compliant with the financial conflict of interest disclosure policy for human subjects research or with the Peoria IRB-approved management plan?

Investigators found to be out of compliance with the Conflict of Interest Disclosure Policy or with their IRB-approved management plan will be required to complete the National Institutes of Health Financial Conflict of Interest web-based Tutorial. A certification of completion must be submitted to the IRB Office as evidence of COI re-training.

Conflicts of interest must be disclosed through the submission of the appropriate completed Conflict of Interest Disclosure Forms into IRBNet at:

1. Initial review whether the research is eligible for exempt, expedited, or full review;
2. If the Principal Investigator (PI) changes or authorized study personnel are added to a project via Change in Research;
3. At continuing review; or
4. Whenever a conflict changes, arises or is discovered (via Change in Research).

Principal Investigators and authorized study personnel must monitor whether new conflicts change or arise on a continuous basis until a final report is approved by the UICOM-P IRB.

**Upcoming PIRB Submission Deadlines & Meeting Dates**

Tuesday, November 27, 2018 for Thursday, December 13, 2018 Meeting  
Thursday, December 20, 2018 for Thursday, January 10, 2019 Meeting  
Thursday, January 31, 2019 for Thursday, February 14, 2019 Meeting  
Thursday, February 28, 2019 for Thursday, March 14, 2019 Meeting

*PLEASE NOTE: December and January meeting submission deadlines have been moved up due to holidays*

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