June 2015

Human Subjects Protection Update
(Special Communication)

IRB (Institutional Review Board) *Boston Children's Hospital*

Change in Principal Investigator Eligibility for IRB Protocols

Effective June 29, 2015, the eligibility criteria for who can serve as a Principal Investigator (PI) for non-exempt, human subject research protocols submitted to the IRB will change. The new policy seeks to implement a mechanism of accountability and continuity for human subject protections and is not intended to restrict academic productivity or leadership. Trainees may no longer serve as a PI of a protocol submitted to the IRB. Individuals who do not meet the criteria to be a PI may still participate as a Co–Investigator and perform leadership roles in the conduct of the research.

Starting June 29, 2015 to serve as a PI an individual must be qualified under one of the following eligibility requirements:

a. Physicians, Dentists, and Psychologists that are credentialed through the hospital with the BCH medical staff registrar as an active medical staff member and have an appointment of Instructor or higher at Harvard Medical School *

   ** It is acknowledged that there may be BCH staff physicians with only clinical responsibilities and no Harvard appointment. The decision as to whether they can be a PI will be made on a case by case basis with the Department Chair/Division Chief*

b. PhDs with appropriate research appointments through the medical staff registrar at BCH

c. Other patient service professionals (registered nurses and clinicians with doctoral preparation, master's prepared clinical nurses, pharmacists, audiologists, respiratory therapists) and other employees of the hospital or foundations must meet all the following criteria for consideration to be a PI:
   - research is part of their scope of employment responsibility and not to meet a training or degree requirement
   - they have training and experience and confirmed clinical research competencies
   - they receive approval from the Vice President of Patient Services or designee

Individuals who are trainees, including Fellows, Residents, Masters or Doctoral Candidates, Postdoctoral Researchers or any other patient services professionals may not serve as the PI. Trainees may not serve as the PI for research conducted as part of their thesis or dissertation to support an academic degree. The restriction of trainees applies equally to physicians, dentists, PhDs and other patient services professionals. Trainees may serve as a Co-Investigator under the supervision of an individual qualified to serve as a PI. We recognize this is an additional responsibility for faculty and others who mentor residents, interns, fellows, post docs and other patient services professionals; however, appropriate oversight is required to assure human subject protections while enhancing the educational process and supervision of those learning to conduct clinical research. **Please review the following question and answer series for further information about this policy and its implementation.**

Who can be a PI?
Q&A

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1. **Why was this policy implemented?**

   All non-exempt, human subject research must have a principal investigator who is: 1) qualified by training and experience and 2) has sufficient authority and relevant scientific knowledge to personally carry out or supervise all aspects of the research. The PI is responsible for all aspects of the protocol as approved by the IRB. Trainees are often transient, unable to complete the research and provide the continued oversight necessary during the entire duration of the research. In addition, many trainees do not have the experience to serve this role. In our current regulatory environment and for the protection of research subjects, it is essential that senior faculty and staff serve this role. Benchmarking with many other institutions also helped us recognize the need to make this change.

2. **Does this policy also apply to medical record and specimen requests?**

   Yes, this policy applies to any non-exempt protocol submitted to the IRB.

3. **Can a fellow or resident still have a leadership role in the research project?**

   Yes, fellows, residents, interns and others who may not qualify to serve as the principal investigator may be listed as a Co-Investigator. There is nothing to limit a trainee from preparing the protocol, taking a leadership role in conducting the research, submitting a grant to obtain funds to cover the research or serving as a lead author on any publication. The intent of the revised policy is not to limit a trainee's ability to engage in clinical research as part of their education, but rather to assure that they are mentored appropriately and there is a senior person who takes ultimate responsibility for human subject protections.

4. **Can an individual still apply for funding if they are not listed as the PI on a protocol?**

   Yes, this policy has no impact on the ability to apply for funding and being listed as the principal investigator for a grant. Any request for funding will still need to meet institutional policies. If the grant requires a human subject certification, the IRB office will be able to provide a certification. The certification will list the name of the individual applying for funding even though it may be certified under an approved IRB protocol that lists another PI. This is already a common practice if the individual is listed as a Co-Investigator on the protocol.

5. **If I am not the PI on a protocol submitted to the IRB, can I still be first author on a paper about the research?**

   Yes, being listed as PI on an IRB protocol has no bearing on which authors are listed on publications or in which order. Authorship is a separate determination made by the principal investigator and any co-investigators. You should discuss authorship issues with the research team as you plan your research.

6. **How does this policy apply to other patient services professionals who want to conduct research?**

   Other patient service professionals (registered nurses and clinicians with doctoral preparation, master's prepared clinical nurses, pharmacists, audiologists, respiratory therapists) and other employees of the hospital or foundations must meet all of the following criteria to be considered as a PI:

   - research is part of their scope of employment responsibility and not to meet a training or degree requirement
   - the individual has training and experience and confirmed clinical research competencies
   - the individual receives approval from the Vice President of Patient Services or designee.

7. When does the policy become effective?

As of Monday June 29, 2015 any non-exempt protocol that is submitted to the IRB will need to meet this new requirement. We realize that some protocols may be entered in CHeRP before that time. A protocol in the system on June 29, 2015 that has completed scientific review will fall under the previous PI eligibility requirements. However if the protocol is in a draft state or scientific review has not yet been completed, the new PI eligibility requirements will apply. This means that it is possible a protocol was started in CHeRP with one PI, but will need to be revised before it can go forward for department review and then to the IRB.

8. Will CHeRP verify the PI eligibility requirements? If not, who will verify eligibility?

Currently CHeRP is unable to connect to other hospital databases and verify eligibility criteria; therefore, investigators need to self-verify appropriate credentials to be a PI on the CHeRP application. The CHeRP IRB form will be revised to ask that the PI select the category that describes his/her eligibility criteria. In addition it is the responsibility of the Department Chair/Division Chief or Department head to assure compliance with this policy. The Department/ Division signature for new submissions in CHeRP was revised to attest to the fact that the PI meets the eligibility requirements. The limited form for review of specimens and data does not get routed to the Department or Division for sign off, so it will be incumbent on the PI to appropriately characterize his/her eligibility on the form.

9. What happens to approved protocols where the PI does not meet the new eligibility criteria?

The IRB will not require that new PIs be selected for protocols that are in the IRB review process, if scientific review has occurred, or if the protocol is approved prior to June 29, 2015. In these situations the PI may remain for the life of the protocol. These individuals will be "grandfathered" for these specific, existing protocols only. However as of June 29, 2015, they will not be able to be PI on any new submission, unless their eligibility status has changed.

10. If a protocol is approved prior to June 29, 2015 and there is an amendment to change the PI on or after June 29th, will the new PI need to meet the new eligibility requirements?

Yes, after June 29, 2015, any changes in the PI for an on-going IRB protocol must meet the eligibility requirements.

11. If an individual is not listed as the PI of the protocol but is a Co-PI and taking a leadership role for the conduct of the research, will this individual still be able to receive the EQuIP new PI training?

Yes, the CHeRP forms are developed so if someone different from the PI is listed as the individual responsible for the conduct of the study, they will be required to take the New PI training if this is their first interventional trial. If this is also the first interventional protocol for the PI, both individuals will be required to attend this training before the protocol is approved.

12. What if I have questions?

IRB staff are ready to respond to any additional questions you may have. Please feel free to contact the IRB analyst assigned to your department. The list of analysts and the corresponding departments may be found at:

http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation/information-about-the-cci