



IRB Myths & Misconceptions: Myths Busted

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General

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Myth: The IRB asked me a question; there must be a right and wrong answer OR there must be something wrong.

Truth: Usually the IRB asks you questions simply to clarify. Clarifications can frequently impact the level of review required for your study.

Myth: The IRB charges review fees for all studies.

Truth: IRB review fees apply **ONLY** to industry-sponsored research.



Myth: I'm a student so I don't need to complete responsible conduct in research (RCR) or Conflict of Interest in Research (CoIR) disclosure.

Truth: Any person involved in the conduct of research must complete the compliance requirements.

Myth: Only patients are research subjects.

Truth: Your target population(s) is/are your research subjects (caregiver, parent/guardian, physician, etc.)

Board/Reviewers

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Myth: I have a similar study that was just approved and I used the approved consent form to draft the consent form for my new study submission so this will be approved with minor or no revisions.

Truth: A different set of eyes or expertise means a different review.

Myth: Once I submit my study, it will be assigned to the next available agenda.

Truth: Your study will be assigned to an agenda based on availability of appropriate expertise.



Myth: Studies can be assigned to a particular analyst.

Truth: Studies are assigned to analyst teams based on the day they are received in the pending docket.



IRB Approval

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Myth: I see the IRB chair/vice-chair has approved my study so I'm good to go.

Truth: Wait until you receive the automatic email notice from the eIRB system indicating your study was approved. The system sends the notice when the post-approval processing is complete.

Myth: I can send a recruitment email or letter to my patients about my study without obtaining IRB approval of that email or letter because they are my patients.

Truth: Recruitment is the first step in the consent process.

The IRB must review all recruitment materials and methods.





Myth: Reviewing clinic schedules for potential subjects is not a research activity.

Truth: This activity is preparatory to research and requires a prep to research request to meet HIPAA requirements.

Myth: IRB approval is not required if I am using my own data or specimens that already exist.

Does your study
require IRB review?

Truth: Human subjects research on any data or specimens requires IRB approval. If data or specimens contain no identifiers (18 HIPAA identifiers) it's likely not human subjects research but we recommend you get a determination letter from the IRB via the "Request a Determination" submission type.

Myth: My study is expedited, that means it will be approved quick.

Truth: In IRB world, expedited is not synonymous with fast. Research in this category is usually investigator-initiated which is the most likely to require lots of clarification.

Myth: My study falls under an exempt category, now I don't even need to finish the application and submit 'cause I'm exempt.

Truth: At OHSU, only the IRB can officially determine that your study is exempt FROM FURTHER IRB REVIEW. So finish the application and submit for review.

eIRB

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Myth: I can call ORIO and have them add me to my PI's study because he needs me to do a continuing review and I don't have access to the study.

Truth: The PI must review and approve personnel being added to their study so the IRB requires a modification request for study staff changes.

Myth: My PI is on vacation and a modification needs to be submitted while she is gone; I can call ORIO and have them temporarily switch the PI to one of the co-investigators so the project can be submitted.

Truth: The PI cannot be changed without documentation from the current PI relinquishing responsibilities for the study as well as documentation from the new PI accepting those responsibilities. The eIRB is accessible from any internet-capable computer, tablet, or smart phone – so there's no excuse.

Myth: My study is complete so I have no further IRB requirements.

Truth: When a study is complete a termination request must be submitted. If the PI is no longer at OHSU the responsibility falls to the department and if the study is not terminated by you, this may be administratively done by the IRB. If terminated by IRB, there may be a fee of \$550 charged to the PIs department.

Myth: All members of an advisory committee must be listed as co-investigators or study staff on the study.

Truth: Only those considered engaged in your research activities need to be listed as co-investigators or study staff.

Myth: My new research assistant has done all of their compliance requirements so I can add them to my study now.

Truth: Completing compliance requirements is great, you're even a few steps ahead of the game -- but the person cannot be added until they have registered for the eIRB system.



Myth: My analyst can see projects which have not been submitted by the PI.

Truth: The analysts can look up projects not submitted by the PI, but these do not appear in our inbox.

Forms

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Myth: All study staff must be listed on the first page of the consent form.

Truth: This can be a pretty extensive list and take up the entire first page of the consent form. The PI is required. We recommend that co-investigators who will consent subjects also be listed, but this is not required.

Myth: The IRB must review every document your sponsor sends you.



Truth: There are many documents the IRB does not need to review (CAP certificates, 1572 forms).

Myth: The HIPAA waiver of authorization for my study is only good for a year.

Truth: Once approved, the HIPAA waiver of authorization is good for the life of the study. Unless something changes that would affect the criteria for waiver approval or the scope of what the waiver covers.



Myth: PPQs are only for funded studies.

Truth: PPQs are required for all human subjects research. Yes, they must be fully signed. Yes, we do check for signatures. No, the analyst doesn't know who should sign for your division and/or department.

IRB Education

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Myth: You are on your own to figure out the confusing world of IRB.

Truth: In addition to this wonderful Brown Bag, the IRB offers standing Intro to IRB, eIRB Basics and eIRB Intermediate courses. Also, your amazingly helpful analysts are available to schedule one-on-one meetings with you.



Mark your calendars!

Next Brown Bag Session:

Repository Refresher

February 28th, 2013

11:30am – 12:30pm

UHS 8B60

Visit our website for more
information:
www.ohsu.edu/researchintegrity

