



PHCIRB OPERATIONS AND POLICIES FREQUENTLY ASKED QUESTIONS (FAQs)

Q How frequently does the PHCIRB meet?

A Monthly. Every 3rd Friday. End of year dates are adjusted to accommodate holiday schedules. See the [2021 IRB Meeting Schedule](#).

Q What is the PHCIRB meeting set up?

A Meetings are conducted in person and via Cisco WebEx. Members are granted access to review materials in advance of the meeting via the protocol tracking database.

Q Is there a submission deadline?

A Yes and No.

Submissions for full committee review must be in the IRB inbox 3 weeks prior to the next meeting.

Submissions not requiring full committee review have no deadline and can be submitted at any time.

Q What are the composition, compliance, and registration details of the PHCIRB?

A Details [here](#).

Q How is member conflict and voting handled?

A See [PHCIRB policy #6404](#).

Q Has the PHCIRB ever been FDA audited and what were the results?

A FDA audits were conducted in 2007, 2015, and 2017. Neither audit resulted in a 483.

Q What are the investigator reporting responsibilities?

A See [PHCIRB policy # 6434](#).

Q What is the research education training requirement and to whom does it apply?

A See [PHCIRB policy # 6423](#).

Q Does the PHCIRB use a protocol tracking database?

A Yes, it is called IRBNet. The IRBNet system is fully compliant with the technology requirements for Electronic Records per 21 CFR Part II, Section 11.10 – Controls for Closed Systems, and the technology requirements for Electronic Signatures per 21 CFR 11 Subpart C – Electronic Signatures.

Q Do IRB fees apply?

A Yes. Please see our IRB [Fee Schedules](#) document. IRB fees are for review services and are not contingent upon approval of submissions.