PI Proxy for Electronic IRB submissions

The KUMC institutional review boards (IRBs) allow designated individuals to serve as "PI Proxy" for minor changes and updates to human subjects research that is managed through the electronic IRB system.

At any given time, one individual can be designated as the PI proxy.

Studies that are managed by the KUMC Research Institute or the University of Kansas Cancer Center may only have a proxy from those regulatory offices. For other studies, proxies must be a member of the study team, and the request must be submitted by the principal investigator.

If the principal investigator will be temporarily unavailable for an extended period, contact the IRB office about designating a sub-investigator as a proxy.

Proxy requests can be emailed to the IRB office at IRBhelp@kumc.edu

PI Proxy for Studies under the KUMC IRB

The Principal Investigator must submit the following items:

- Initial submissions
- Proviso responses when the proposal is deferred
- Changes to the protocol or consent form that are being made because of new safety concerns, changes to study design, aims or methods or because of new risks
- Request for a change of PI. *This request must be accompanied by a written acknowledgement by the new PI.*
- Continuing Reviews
- Study Closure requests

Additionally, principal investigators will be asked to acknowledge their awareness when a Report of New Information (RNI) is referred to the convened committee for review. Convened committee review is required when an RNI indicates a new safety concern or serious non-compliance.

A PI proxy may submit the following items:

- Minor consent form changes on approved studies if the changes do not involve increased risk or changes to study design (e.g., small increase in payment; minor clarifications or corrections; new contact information)
- Proviso responses when the study has been conditionally approved. If the proxy submits the proviso response, the study team is responsible for maintaining documentation that the principal investigator has reviewed and approved the submission.
- Administrative or other minor changes to the protocol (e.g., editorial corrections; new sponsor contacts; additional questions or new versions of a previously-approved survey)

- Signed conflict of interest management plans
- Updated Investigator's Brochures that do not necessitate protocol or consent form changes
- Recruitment/retention materials
- Personnel changes, other than a change to the principal investigator
- Enrollment closures (Submitting a notice of enrollment closure is voluntary, but some sponsors request an IRB submission.)

If the IRB office determines the changes are not minor, the submission will be returned for PI submission.

PI Proxy for Studies under an External IRB

The Principal Investigator must submit the following items:

- Initial submissions
- Request for a change of PI. *This request must be accompanied by a written acknowledgement by the new PI.*

A PI proxy may submit the following items:

- Personnel changes
- Signed conflict of interest management plans
- Consent form changes, when required. IRB submission is required only when the change impacts our local context review, such as changes to the HIPAA section, new COI disclosures, changes to radiation, changes to subject injury provisions.
- Reportable adverse events or non-compliance
- Notice of continuing review
- Study closure

For questions about the PI Proxy policy, please contact your IRB office at 913-588-1240 (Kansas City) or 316-293-2610 (Wichita).