

Investigator Qualification LOG INSTRUCTIONS

PURPOSE

This log assists with the tracking of study team qualification documentation including Curricula Vitae (CV), Medical Licenses, Financial Disclosures (FD) and Human Subject (HSP)/ Good Clinical Practice (GCP)/Responsible Conduct of Research training. It is used to record the dates the documents became active (using either signature dates or completion dates) so that qualification documentation attributed to specific staff members can be easily updated and verified.

HOW TO USE

- Complete the form header by adding the Short Study Title, and the Principal Investigator's name.
- List the names of study team members and add the dates of the documents as follows:
 - CV signature dates and their corresponding expiration date. CV's are valid for 2 years (current date + 2 years = expiration date).
 - Medical (or other) license expiration date. Please note that investigators must be licensed in the state in which the study is conducted. Be sure to replace these as they expire, keeping in mind that medical licenses are valid for one year but other licenses may vary.
 - Financial Disclosure for the study team is completed electronically by the PI on an annual basis. Consider including study personnel financial disclosure responses in this section.
 - CITI HSP training completion/expiration date. HSP training is required by the IRB before personnel can be added to a study, it expires after 3 years.
 - CITI GCP training completion/expiration date. GCP training is not required by the IRB however some sponsors require it and CCTS requires study teams receiving CCTS funding to complete GCP training. Unless the certificate states otherwise, GCP training expires after 3 years
 - CITI RCR training completion/expiration date. RCR training is mandated by the Office of the Vice President for Research (OVPR) and needs to be completed before submitting an IRB protocol application, it expires after 4 years.
- Update the log as needed following any change in site study personnel.
 - Once a study team member has been removed from the study, update the log to include their off study date (the date the individual completed their work on the study). Once personnel have been taken off the study there is no longer a need to maintain their qualification documentation.
 - Please keep in mind that study personnel listed on this log must be IRB approved to be on the study. As a study team member's role comes to a close and they are removed from the study they must also be removed from the IRB approved study personnel list.

GOOD PRACTICE RECOMMENDATIONS

- The name on the license must correspond to the name on the investigator's CV, Financial Disclosure and 1572 (if applicable).
- Review the log periodically, updating as needed to keep it current
- CV's may be updated if an investigator's qualifications increase or change during the course of the study.
- Do not remove expired CV's, Licenses, etc. They demonstrate qualification for the entire duration of the study.
- Be sure to customize the template to make it study specific.