Participating Site and sIRB Tracking Log Toolkit

The Johns Hopkins School of Medicine, Office of Human Subjects Research Compliance Monitoring Program and the Reliance Program have created example guides to assist Principal Investigators and study teams in developing and implementing a system to assist with multisite study documentation practices.

Log templates:

1. Protocol Version/Date Log
2. Consent Version Log
3. Further Study Action Log

Note-to-File templates:

1. Consent Approval Timeline

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Protocol Version/Date Log | | | | | | | | | |
| Protocol version/date | Consent Changes Required (Y/N) | IRB of Record Approval Date | IRB of Record Release Date | Coordinating Center Posting Date | Psite Receipt Date | Local Approval Required (Y/N) | Local Approval Submission Date | Local Approval Release Date | Comments |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Consent Version Log | | | | | | | | |
| Consent Form Version date/Type\* | IRB of Record Approval Date | IRB of Record Release Date | Coordinating Center Posting Date | Psite Receipt Date | Local Approval Required (Y/N) | Local Approval Submission Date | Local Approval Release Date | Comments |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

\* Type (Main, Site, Arm, Assent, Language, etc.)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Further Study Action Log | | | | | | | | | |
| Date Sent to IRB | Type of Further Study Action\* | IRB of Record Approval Date | IRB of Record Release Date | Coordinating Center Posting Date | Psite Receipt Date | Local Approval Required (Y/N) | Local Approval Submission Date | Local Approval Release Date | Comments |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

\*Change in Research, Continuing Review, Progress Report, PER, etc.

Note To File Memo

Memorandum

*Note To File*

To: Regulatory Binder

RE: [IRB number, Study Title]

Date:

This study utilizes a sIRB, our site requires a local context review of consent changes after they have been approved by the IRB of record at Johns Hopkins School of Medicine. The local review process may result in a delay of time between approval of stamped documents, like the consent, and the availability of the document.

Please see the [protocol version, consent version] log for reference.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator (Signature) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (Signature) Date