Office of Research Compliance
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RUSH UNIVERSITY MEDICAL CENTER

Research Compliance's "Frequently Asked Question" (FAQ) is a series of awareness tips sent to those involved in research activities. They are developed to enhance and build awareness around safeguards to protect the integrity of research and inform Rush's research community.

List of items to be included in Subject File

- Informed Consent Form (ICF)
  - Executed Original ICF by the subject
- Health Insurance Portability and Accountability Act (HIPAA)
  - Executed Original HIPAA Form by the subject
- Informed Consent Process Documentation
- Eligibility Checklist (Inclusion/Exclusion Criteria)- reviewed, signed, and dated by the Principal Investigator(PI) prior to subject's enrollment into the study.
- Eligibility Supporting Documents: any assessment (e.g., diagnostic test, lab results including the pregnancy test result for female subjects, operative procedure required to assess eligibility to enroll the subject into the study). All reviewed, signed, and dated by the PI
- Screening/Randomization/Study visit verification from IVRS- Source documentation from the Sponsor
- All study visits documentation – all assessments need to be reviewed, filed, signed and dated by the PI where required.
- Investigational Product (IP) – Labels of Device/Drug Dose administered to the subject
- Concomitant Medication Log- PI needs to sign and date at the completion of the study.
- Adverse Event (AE) and Serious Adverse Event (SAE): IRB submission and supporting documents. PI needs to review, sign and date in a timely fashion.
- End of Study Visit or Completion of the subject's participation in the study signed and dated by the PI
- Review of data collection tools/ procedures
- End of Study Visit or Completion of the subject's participation in the study signed and dated by the PI
- Lost to follow up – Documentation of the correspondence including the telephone calls between the site and Subject
- Documentation of terms of subject termination from the study
- Protocol deviations – Signed and dated by PI
- Study Visit Lab results - PI's review for clinical significance, signed and dated by the PI in a timely fashion.
- Subject Screen Fail reason/withdrawal from the study

Note to File:

Any missing documents, location of important documents not stored in the Master Regulatory File or Subject File should have a "Note to File" (NTF) filed in the appropriate section within the appropriate file to explain the reason(s) for missing document(s) and/or the alternate location of the information. Any missed visits, etc. that are related to the study should be explained in the appropriate section with a Note to File.

These may include site generated and/or sponsor generated notes to file. Sponsor generated NTF may be global or site specific.

If documents are maintained electronically, write a NTF indicating the location and who maintains them and include in the appropriate file location.

If documentation is filed separately, write a signed and dated NTF indicating the location and filed within the appropriate file location.

A NTF should:

- Be generated on a case-by-case basis.
- Include the subject and protocol it refers to
- Be signed and dated by the individual who is writing it
- Be legible if handwritten
- Explain clearly and specifically the reason for the error/omission/discrepancy or process /policy it aims to address
- Should include any corrective action or follow –up when applicable.
- Be filed or behind the study file or behind the subject file tab to which it applies.