

Subject Study File and Source Documentation

Subject study files organize the records and case histories of human subject research participants. Accurate and complete subject study files allow for the reconstruction of any particular subject's study experience. They also show that the protocol was followed and that participants' rights, safety, and welfare were protected.

Subject study files will include study-specific forms, created and completed only for that particular research study, that support study data. Some studies, such as those involving investigational drugs and devices, may also have a medical record that backs up study data. For those studies, it's usually strongly recommended that the parts of the medical record that support study data be copied and added to the study file.

Initial Contact with the Subject and the Informed Consent Process

Potential subjects can be recruited in a variety of ways. They may respond to an IRB-approved advertisement or be identified from a clinic's patient population. The informed consent process begins once they've decided they want to learn more about the study. The documentation to add to the subject record for this study step would include the signed informed consent form, the completed informed consent process note, and any other documentation related to the initial subject contact. If subjects are first contacted by phone or mail, research staff may want to keep a single, centrally located log documenting all such contacts for all subjects. Also, if the study requires a HIPAA authorization form, the signed and dated form should also be kept in the subject record.

Study Activities

The first rule of study documentation is simple: If it's not written down, it didn't happen. Document everything, sign and date all records, and keep everything. Specific records to include are those documenting:

- The consideration of inclusion/exclusion criteria.
- All study-related visits and procedures, even those that are routine or standard of care. Note that research typically requires more documentation than routine clinical care. For example, for a research blood draw, it's strongly recommended that the blood draw location, volume of blood collected, and whether any complications were noted be specifically documented. That level of detail makes it easier to track exactly what happened to the subject and to follow up on any subsequent concerns related to the subject's participation.
- Any subject contact by phone or email.
- Lab, pathology, or other test results.
- The dispensing of any study-related drugs or devices.
- The completed Case Report Form (CRF), if the study is using one, along with medical and study records that support all data recorded on the CRF.
- Copies of reports related to any protocol deviations/violations or adverse events.
- Anything else related to a subject's participation.

Note that there is no regulation or policy describing how subject records must be organized. For example, some investigators keep all signed informed consent documents and HIPAAs in a single file, while others file each subject's forms with the individual subject record. Subject records can be organized in whatever manner works best for the study team. Just make sure they are all complete and accessible to the people who need to see them, and that they can be used to reconstruct the subjects' study experiences.

Reminders

- Make sure that all forms are signed and dated by the person completing them.
- Store all protected health information (PHI) securely so that access to it is limited, whether it is part of the medical record or collected solely for study purposes.
- Pencil fades, but pen lasts (more or less) forever. Use pen to fill out study records.

Questions? Call Trey Terry at the UAMS Research Compliance office at 686-5809.