# Regulatory File: Required Document List

Per DF/HCC Policy RCO-203, investigators or their designees are responsible for collecting and maintaining a regulatory file that will permit evaluation of the conduct of a study and the quality of the data produced. Store regulatory documents in a safe and secure location with access limited to research staff. Regulatory documents may be maintained in physical binders, or in a 21 CFR Part 11 compliance electronic file storage system per institutional policy. Sponsor may have additional document requirements above and beyond what DF/HCC requires.

## Document List and Requirements:

| Document Name and Requirements | Trial Master File[1] | Investigator File | Satellites Under the Main Site 1572 |
|---|---|---|---|
| **AGREEMENTS** | | | |
| Transfer of obligations *(if using a Clinical Research Organization (CRO))* | X | N/A | N/A |
| Signed and dated Investigator Agreement | Signed agreements for all sites | Agreements relevant to the site | N/A |
| **PROTOCOL** | | | |
| All IRB-approved versions of the protocol | X | X | X |
| **INFORMED CONSENT AND ASSENT FORMS** | | | |
| All IRB-approved versions of the consent/assent forms (blank copies) | X | X | X |
| **IRB/SCIENTIFIC REVIEW DOCUMENTATION** | | | |
| All SRC and IRB submissions, approvals, responses and related correspondence | All approved IRB submissions and notifications for all participating sites | All approved IRB submissions and notifications relevant to the site | Approvals, memos, and notifications relevant to the site. All submissions to local IRB (if applicable). |
| Approvals, notices and correspondence related to Activation | | | |
| Certificate(s) of Confidentiality (if applicable) | | | |
| **DEVIATIONS, VIOLATIONS, AND EXCEPTIONS** | | | |
| Ongoing documentation of all deviations, violations and exceptions | Documentation of events for all participating sites[2] | Deviations, violations and exceptions occurring at the site | Deviations, violations and exceptions occurring at the site |
| Copies of all protocol deviations, violations, or exceptions submitted to the sponsor and IRB and the IRB response/approvals | | | |

| Document Name and Requirements | Trial Master File[1] | Investigator File | Satellites Under the Main Site 1572 |
|---|---|---|---|
| **SAE REPORTS/UNANTICIPATED PROBLEMS** | | | |
| Ongoing documentation of all SAEs and unanticipated problems | Documentation of events for all participating sites[2] | Documentation of events occurring at the site | Documentation of events occurring at the site |
| SAE or unanticipated problems reports | | | |
| Correspondence, submissions, and notifications to/from the Sponsor, IRB, and PI | | | |
| **DATA AND SAFETY MONITORING** | | | |
| Data and Safety Monitoring Committee (DSMC) or Data and Safety Monitoring Board (DSMB) | All reports, summaries and communication for the protocol. | Any relevant communication from the sponsor-investigator pertaining to the site | Any relevant communication from the sponsor-investigator pertaining to the site |
| **MONITORING[3]** | | | |
| Log of all monitoring visits including dates and signatures of monitors | Log of visits occurring at all sites (collected at site closure) | Log of visits occurring at the site and reports related to visits occurring at the site | Log and reports related to visits occurring at the site |
| Monitoring reports | All monitoring reports for all participating sites | | |
| Master list of monitors | X | N/A | N/A |
| **DELEGATION OF AUTHORITY** | | | |
| A list of the appropriately qualified persons to whom significant trial-related duties have been delegated by the PI. | Copies of all logs for all participating sites (collected at site closure) | List of persons at the site, approved by the PI. | List of persons at the site, approved by the PI. |
| **STUDY PERSONNEL / FORM FDA 1572** | | | |
| Form FDA 1572 (listing all applicable personnel per RCO-203) | Initial and revised versions for all participating sites | Initial and all revised versions for the site | Per institutional requirements |
| CVs and documentation of medical license status as per RCO-203 | Cumulative for all personnel at all participating sites | File CVs, license verification, and training records for site personnel. | File CVs, license verification, and training records for site personnel. |
| Records of site initiation attendance and/or protocol-specific training (initial and ongoing) for all study team members. | | | |

| Document Name and Requirements | Trial Master File[1] | Investigator File | Satellites Under the Main Site 1572 |
|---|---|---|---|
| Financial disclosure information (as required by the sponsor), FDA 3455 (as applicable) | Cumulative for all personnel listed on each site's FDA Form 1572 when an IND/IDE is held by a DF/HCC investigator. | Only information specific to the site. | Only information specific to the site. |
| HSP and GCP training documentation and DF/HCC policy training records per EDU-100 requirements | Only for research staff at the individual site. May be filed centrally | | |
| **LABORATORY AND SAMPLE COLLECTION** | | | |
| Current and updated normal values/ranges for all medical, laboratory, technical procedures and/or tests included in the protocol | Cumulative for all personnel and facilities at all participating sites | Only information specific to the site. | Only information specific to the site. |
| Current and updated laboratory accreditation certificates (e.g., CLIA and/or CAP) all labs performing procedures and/or tests included in the protocol | | | |
| Lab Director's current CV (signed & dated on first page) for DF/HCC and DF/PCC facilities | | | |
| Tissue/sample collection logs, if applicable | | | |
| **SCREENING AND ENROLLMENT LOGS[4]** | | | |
| List of all potential subjects consented and screened, regardless of screening outcome | Relevant to the site. Collect from all participating sites *at study completion.* | Relevant to the site. | Relevant to the site. |
| List of all subjects enrolled in the study, regardless of changes in enrollment status | | | |
| **INVESTIGATIONAL PRODUCT/DEVICE[5]** | | | |
| Shipment and receipt records | Relevant to the site. Collect from all participating sites *at study completion.* | Relevant to the site. | Relevant to the site. |
| Accountability logs | | | |
| Dispensing Log | | | |
| Order forms | | | |
| Records of disposition, return, or destruction | | | |
| **INVESTIGATOR'S BROCHURE (IB) OR DEVICE MANUAL/PACKAGE INSERT** | | | |

| Document Name and Requirements | Trial Master File[1] | Investigator File | Satellites Under the Main Site 1572 |
|---|---|---|---|
| Original and each revised version of the Investigator's Brochure or Device Manual /Package Insert | X | X | X |
| **IND SAFETY REPORTS** | | | |
| Sponsor IND Safety Reports<br>Documentation of PI's determination as to whether IND Safety Reports require reporting to the IRB<br>Documentation of IND Safety Reports submitted to the IRB and the IRB response notices, if applicable | All reports received from the manufacturer(s) and documentation of distribution to participating sites when applicable | When required by RCO-204. | When required by RCO-204. |
| **GENERAL CORRESPONDENCE[6]** | | | |
| Records of relevant and significant communication that occurs during the conduct of the trial.<br>Include correspondence related to decisions made regarding the conduct of the trial or regulatory obligations. | Communication to/from all participating sites, regulatory authorities, manufacturers, study supporters, etc. | Relevant to the site. | Relevant to the site. |
| **OBA CORRESPONDENCE** | | | |
| For gene-transfer studies under an IND, correspondence will include the following:<br>• NIH/OBA letter summarizing RAC review/recommendations<br>• Copy of final IBC approval from clinical trial site<br>• Copy of all Safety Reports as submitted to NIH/OBA and local IBC<br>• Copy of all Annual Progress Reports as submitted to NIH/OBA<br>• Copy of the Final Report as submitted to NIH/OBA and local IBC | X | Only if relevant to the site. | Only if relevant to the site. |
| **DF/HCC MANUFACTURED/SHIPPED** | | | |

| Document Name and Requirements | Trial Master File[1] | Investigator File | Satellites Under the Main Site 1572 |
|---|---|---|---|
| For any study agent manufactured and/or shipped by DF/HCC institutions:<br>• Sample of labels(s) attached to the container(s)<br>• Certificate of Analysis for all batches | X | Only if relevant to the site. | Only if relevant to the site. |
| **FDA DOCUMENTATION[7]** | | | |
| Signed and dated original application and all subsequent submissions (e.g. amendments, AEs, annual progress and final report) to the FDA and the resulting notifications | X | N/A | N/A |
| Form FDA 3674 (Certification of Registration to ClinicalTrials.gov) | X | N/A | N/A |

[1] - *When a DF/HCC investigator is also the sponsor of the trial, there may be a combined Trial Master File and Investigator File.*
[2] – *Cumulative Log recommended*
[3] – *Do not file ODQ or FDA audit reports in the regulatory files. Core Site should collect copies of monitoring logs from all sites at study close out.*
[4] – *When subjects are registered in OnCore, OnCore can be used as a tool to maintain the screening and enrollment log electronically and a report can be produced for review as necessary.*
[5]- *Maintained per institutional practice, often in the Research Pharmacy during the study.*
[6]- *Examples include: Sponsor approvals of protocol deviations, study meeting minutes, requests for information (from sites/sponsors), newsletters, etc.*
[7] - *If research under an IND/IDE or otherwise applicable*