| **Required for both observational and interventional**  **clinical research studies** |
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Protocol and Amendments

This section should include a copy of each:

* IRB-approved protocol
* Signed PI protocol signature page
* IRB-approved protocol amendment
* Signed PI protocol amendment signature page

If a protocol was not submitted or approved by the IRB, a memo to file needs to be generated to explain the surrounding circumstances and the PI needs to sign and date the document.

Link to NIDCR Protocol Template Tools:

[http://www.nidcr.nih.gov/research/toolkit](http://www.nidcr.nih.gov/research/toolkit/)

| **Required for both observational and interventional**  **clinical research studies** |
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IRB-Approved Consent Documents

This section should include a copy of:

* All IRB-approved /stamped consent documents

A version number and date should be on each consent document.

An expiration date of the consent document on the actual document is preferable, but cross-reference to the IRB approval letter of the protocol may be required.

If applicable, the section should also include a copy of:

* All IRB-approved assent forms
* All IRB-approved short form consents for non-English languages\*

\*The short form consent for non-English languages should be used for a single subject who may be illiterate, blind, or otherwise unable to read the consent document. This should be used when the full consent document has to be read or translated for subject.

| **Required for both observational and interventional**  **clinical research studies** |
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IRB Documentation

This section should include:

* Federalwide Assurance (FWA) Number
* IRB Registration (optional)

Link to OHRP Database (FWA and IRB Registration):

<http://ohrp.cit.nih.gov/search/IrbDtl.aspx>

| **Required for both observational and interventional**  **clinical research studies** |
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IRB Approvals and Correspondence

This section should include a copy of:

* Approval letters (e.g., protocol, protocol amendment(s), consent documents, continuing review, etc.)
* Correspondence related to contingent approvals or stipulations
* Original IRB application/submission
* IRB correspondence
* Progress reports

If applicable, the section should also include a copy of:

* Approval letters for approved assent form
* Approval letters for short form consent for non-English languages\*
* Submission/acknowledgement of Investigator’s Brochure
* Approval letter/approved advertisement or recruitment materials
* Approval letter/approved written educational or other materials provided to study subjects

\*The short form consent for non-English languages should be used for a single subject who may be illiterate, blind, or otherwise unable to read the consent document. This should be used when the full consent document has to be read or translated for subject.

Link to Informed Consent Checklist:

<http://www.hhs.gov/ohrp/policy/consentckls.html>

| **Required for both observational and interventional**  **clinical research studies** |
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Investigator Qualification Documentation

This section should include:

* Current Curriculum Vitae (CV) and/or other relevant dated documentation (e.g., biosketch) for all investigators
* A clinical (dental, medical, etc.) license for the Principal Investigator and each sub-investigator, if licensed

CVs may be updated if an investigator’s qualifications increase or change during the course of the study.

Do not remove expired CVs as they demonstrate qualification for the entire duration of the study.

Licenses should be filed behind the corresponding investigator’s CV. Do not remove expired licenses.

The investigators must be actively licensed in the state in which the study is conducted.

The name on the license must correspond to the name on the investigator’s CV and the 1572, if applicable.

| **Required for interventional clinical studies using a drug,**  **biologic, or device** |
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Investigator’s Brochure

(For any drug/product under investigation)

For studies that involve administration of investigational drugs/products, this section should include:

* Investigator’s Brochure(s) (IB), or equivalent

**Or**

* Package Insert. Include labeling for approved medications.

The purpose of this document is to provide information on the mechanism of action, possible risks and adverse reactions, and the “expected” adverse reactions associated with the previous use of the drug/product.

If the package insert or the Investigator’s Brochure is amended during the trial or is updated, it should be included here.

| **Required for clinical studies regulated by FDA under IND** |
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FDA Form 1572 and 1571

FDA Form 1572 for IND studies when:

* A study involves an investigational drug

OR

* The study sponsor requests it

FDA Form 1571 for investigator initiated INDs:

* Document required when an investigator is applying for an IND; part of the submission packet to the FDA

| *Instructions for Forms 1571 and 1572:*  <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm>  *Forms 1571 and 1572 can be downloaded from*:  [http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ default.htm](http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm) |
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| **Required for clinical studies regulated by FDA under IND or IDE** |
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Financial Disclosure Forms

This section should include:

* Signed Financial Disclosure Forms (FDF) for the Principal Investigator and sub-investigator(s) listed on the 1572

The names of the Principal Investigator and sub-investigator(s) should match the names listed on the 1572. The protocol title and number should match the title and number listed on the 1572.

If any of the five financial interest questions are checked “Yes,” a statement addressing the nature and amount of the interest, arrangement, or payment must be attached to the FDF. Appropriate identifiers, i.e., protocol number and investigator name, must be included on each document included in the submission.

This FDA form is required for any clinical study submitted in a marketing application that the applicant or FDA relies on to establish that the product is effective, and any study in which a single investigator makes a significant contribution to the demonstration of safety.

Link for additional information:

<http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf>

| **Required for both observational and interventional**  **clinical research studies** |
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Study Communication

This section should include:

* A copy of all communication relative to the conduct of the protocol and agreements with other scientific collaborators, industry, and scientific directors, such as Material Transfer Agreement and Data Sharing Agreement. (Financial documents should not be included.)
* Important decisions regarding study conduct, such as Memos to File
* FDA Correspondence (see Regulatory Document History Log)

All printed communication (i.e., email) needs to be signed and dated by the individual printing and storing the document.

Communication about subject treatment/clinical care, protocol deviations, and study drug dosing should immediately be printed and stored in this tab.

* Email correspondence may be saved to a compact disc (CD) for electronic storage and noted in this section

Electronic media must be a permanent media, and must be appropriately secured and approved (i.e., password protected).

If saved to a CD or other electronic storage media, a memo to file needs to be generated describing the types of email on the electronic media, the start and stop dates of the email correspondence, and the signature and date of the individual creating the CD and writing the memo to file.

If a study team member receives a new computer or if a newer version of the email provider is used, it is highly recommended to create the CD and the memo to file at the time of the transfer to prevent any important study communication from being lost in the transition.

| **Required for both observational and interventional**  **clinical research studies** |
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Delegation of Responsibilities (DoR) Log

This section should include:

* An ongoing log that lists all study personnel and their specific responsibilities, signatures, initials, and obligation (start/stop) dates

Any changes in site study personnel require an update to the DoR.

| **Required for both observational and interventional**  **clinical research studies** |
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Clinical Research and Study Training

This section should include the following documents for all key personnel (investigators, coordinators):

* Educational completion certificates for Human Subjects Protection training
* Documentation of study related training

All key personnel working on NIH grants and contracts involving human research participants are required to complete training in Human Subject Protections. NIH has a free web-based training that satisfies this requirement.

<http://phrp.nihtraining.com/users/login.php>

Other free, optional web-based trainings that are recommended include:

Good Clinical Practices:

<http://gcplearningcenter.niaid.nih.gov/>

<https://crt.nihtraining.com/login.php>

If a certificate is not available at the end of a required training module, enter the appropriate documentation in the site Training Log.

Site-specific training: Consult your IRB or institution for training requirements.

Consider use of a central training binder to store non-study-specific training documentation for all study team members. If this strategy is used, file a signed and dated memo to file explaining where these training documents are stored.

| **Required for both observational and interventional**  **clinical research studies** |
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Screening/Enrollment Log

This section should include:

* A log without identifying information that lists subjects who were screened (including screen failures) and enrolled in the study

Subjects may be tracked separately on logs, such as a coded list with a key.

Note: If screening and enrollment information is entered into an electronic data capture (EDC) system, please include a memo explaining this process.

| **Required for both observational and interventional**  **clinical research studies** |
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Signed Consent Documents

This section should include:

* All original signed consent documents

**OR**, if signed consent documents are kept in a separate binder or in the subject’s medical or dental record:

* A signed and dated memo to file explaining where signed consent documents are stored and the reason for separate storage

The signed consent document must be retained even if a subject withdraws consent or fails the screening process.

| **Required for interventional clinical studies using a study**  **product for research** |
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Study Product Records

This section should include:

* Documentation of study product (drug, biologic, vaccine) disposition and accountability, or memo as to where records are located (e.g., Research Pharmacy) and who is maintaining accountability logs

For masked clinical studies, it is recommended that study product accountability records be filed in the research pharmacy to maintain the masking.

| **Required for both observational and interventional studies**  **using clinical labs as a study procedure** |
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Local Clinical Lab Certificates/Reference Ranges

For studies that utilize clinical laboratories for specimen testing, this section should include:

* Lab reference ranges if the reference range is not included on the lab form
* A copy of certifications or accreditations (CAP, CLIA, or State certificate) or a memo indicating that the laboratory maintains CLIA certification

| **Required for both observational and interventional clinical studies collecting clinical samples** |
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Specimen Tracking Log

This section should include:

* A log of research samples, which can include the type of specimen, purpose of storage, location of storage (e.g., freezer #, shelf #, and location, box 3), and link to subject ID number.

If applicable, the log should be modified to track if consent for future use was obtained or withdrawn.

| **Required for both observational and interventional**  **clinical research studies** |
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Unanticipated Problems

This section should include a copy of each:

* Unanticipated problem report

| **Required for both observational and interventional clinical studies that are more than minimal risk** |
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Serious Adverse Events (SAEs)

This section should include a copy of each:

* Serious Adverse Event form or memo
* “Dear Doctor” letter and IND safety report

| **Required for both observational and interventional**  **clinical research studies** |
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Protocol Deviations

This section should include:

* A copy of each Protocol Deviation form or memo, or a memo to file indicating if/where they are maintained electronically (e.g., in the clinical database)
* Protocol Deviation Tracking Log

Requirements for reporting protocol deviations are specific to each local IRB; review the requirements to make sure that they are followed appropriately.

| **Required for both observational and interventional**  **clinical research studies** |
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Clinical Site Monitoring Visits

This section should include:

* A site visit log signed by the clinical site monitor(s) at each visit
* A copy of each visit’s correspondence, which can include the confirmation letter, agenda, follow-up letter, and all attachments

| **As needed for both observational and interventional**  **clinical research studies** |
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Other

This section should include:

* Other important study documents, such as Certificates of Confidentiality, literature or publications, Technology Transfer Agreement, submissions to Radiation Safety Committee, Radiation Safety Committee approvals, submissions to Office of Biotechnology Activities, etc.