**NIMH Regulatory Document Checklistfor Studies under an FDA IND or IDE**

***Purpose******:*** *This checklist may be used to record and track regulatory documents for studies under an FDA IND/IDE*

***Audience/User:*** *Principal Investigators and study team members who are delegated to manage regulatory documents for studies under an FDA IND/IDE*

**NIMH Regulatory Document Checklistfor a Study under an FDA IND or IDE**

Study teams are encouraged to use this checklist as a guide for creating a regulatory binder that compiles essential documents for the conduct of an NIMH-funded [NIH defined clinical trial](https://grants.nih.gov/policy/clinical-trials/definition.htm), or an NIMH-funded human subjects studies that do not meet the NIH definition of a clinical trial, with an investigational drug or device under an FDA Investigational New Drug (IND) application or Investigational Device Exemption (IDE). Principal Investigators (PIs) are responsible for following any institutional, state, or federal policies pertaining to regulatory documentation. A regulatory binder is a central organized file (can be paper or electronic or both) that houses documents pertaining to the conduct of the study (e.g., Institutional Review Board (IRB) approvals, CVs, licenses, meeting minutes, template case report forms, etc.) The following documents are recommended to be on file in the study regulatory binder. NIMH encourages study teams to verify what additional documents, or alternative formats of the documents in the checklists, their institution and IRB require.

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| **Document** | **Description** |
| **Essential regulatory documents described in International Council for Harmonisation (ICH) Good Clinical Practice (GCP) E6 (R2)** | The regulatory documents outlined in Section 8 of the ICH GCP document should be available in the study regulatory binder, as applicable: <https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf> |
| **Federalwide Assurance (FWA)** | Contains the institution’s FWA# and expiration date. These can be found online at: <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc> |
| **DSMB Charter\*** | Describes the member composition, role, obligations, meeting schedule/format, and study approval process for the Data and Safety Monitoring Board (DSMB).  |
| **DSMB reports, correspondence and approvals\*** | DSMB required documents should be submitted to the DSMB per the DSMB Charter.  |
| **Documentation of Human Subjects Protection Training** | Required for all study staff involved in the design and conduct of clinical research involving human subjects supported by NIH. |
| **Documentation of GCP training\*** | All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in GCP, consistent with principles of ICH E6 (R2). |
| **NIMH Progress report submissions and correspondence** | Submitted annually to NIMH Program Officer to outline study progress for a reporting period. |
| **Reportable Events Sent to NIMH** | Certain events related to a study require expedited reporting to NIMH. See: <https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy.shtml> |

\* Not required for NIMH-funded human subjects studies that do not meet the NIH definition of a clinical trial, with an investigational drug or device under an FDA IND or IDE.