# Study Title: Sponsor Investigator: Principal Investigator:

# FDA website: [Information for Sponsor-Investigators Submitting Investigational New Drug Applications](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm)

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| **Task- Submission of Investigator Held IND (Investigational New Drug) Application**  *This checklist provides a list of items needed for an IND submission. The checklist includes links to various optional document templates and form links for your use in preparing an IND submission. The checklist is* ***not*** *part of the IND application submission to FDA.* | **Date completed and initials** | **Comments**  (Note if N/A) |
| Cover letter with contact information  (see [*template*](http://ora.emory.edu/research-compliance/oric/documents1/IND-application/IND_submission_cover_letter.docx)) |  |  |
| Cover sheet (signed “Investigational New Drug Application”)  Click on link to obtain FDA [Form 1571](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf) |  |  |
| Introductory statement & general investigational plan  (see [*outline*](http://ora.emory.edu/research-compliance/oric/documents1/IND-application/IND_application_intro_statement.doc); a [*sample*](http://ora.emory.edu/research-compliance/oric/documents1/IND-application/sample_introductory_statement_and_inv_plan.pdf) is available here) |  |  |
| Investigator data (“Statement of Investigator”)  Click on link to obtain FDA [Form 1572](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf) |  |  |
| Table of contents  (To be provided by S-I) |  |  |
| Investigator brochure (IB)  (If available from manufacturer; S-I is not required to create an IB for a single-site study) |  |  |
| Protocol (see [*outline*](http://ora.emory.edu/research-compliance/oric/documents1/IND-application/IND_app_protocol_outline.docx) ) |  |  |
| Chemistry, manufacturing & control information (CMC): if appropriate attach a cross-reference letter (see [*cross-reference information*](http://ora.emory.edu/research-compliance/oric/documents1/IND-cross_reference-BG.docx)) or package insert. Include a copy of all [labels](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.6&utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=312.6&utm_content=1) & claim for exclusion from environmental assessment (see [*template*](http://ora.emory.edu/research-compliance/oric/documents1/IND-exclusion_env_assessment%20BG.docx)) |  |  |
| Pharmacology & toxicology information: attach a copy of the current version of the manufacturer’s Investigator Brochure for the drug or/package insert and/or attach a cross-reference letter. (see [*cross-reference information*](http://ora.emory.edu/research-compliance/oric/documents1/IND-cross_reference-BG.docx)*)* |  |  |
| Previous human experience  (To be provided by S-I) |  |  |
| Additional information  Include “Certification of Compliance with ClinicalTrials.gov”  Click on link to obtain FDA  [Form 3674](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf)  If applicable, include cross-reference letter (see [*cross-reference information*](http://ora.emory.edu/research-compliance/oric/documents1/IND-cross_reference-BG.docx)*)* |  |  |
| Permanent file started for IND submission materials and all related FDA correspondence |  | File location (electronic &/or paper) |
| **Checklist for IND Application Submission Completed**  Retain checklist for your records; this is not part of submission to FDA. |  | **Print name** |

IND Submission Checklist

Form produced by Office of Research Integrity and Compliance

Version 8/30/21