**POST-IRB APPROVAL**

**FDA DRUG (IND) SPONSOR AND INVESTIGATOR RESPONSIBILITY (**[**21 CFR 312**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312)**)**

**Purpose:** Investigators who initiate and submit an IND application to the FDA assume the responsibilities of both the investigator and the sponsor. Under FDA regulations, a sponsor-investigator has the same obligations as a multi-national pharmaceutical manufacturer that sponsors or holds an IND. This form is for Sponsor-Investigators to conduct a self-assessment of their IRB approved studies to ensure that they are meeting their institutional and regulatory requirements. Onsite documents (listed in the middle column) correspond to the regulations written in [21 CFR 312](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312) (drugs, biologics) and institutional policy and can provide evidence that the Sponsor-Investigator has fulfilled their responsibilities. Depending on the specific study, additional documents may be needed.

The Office of Research Compliance Review (ORCR) recommends using this checklist during study initiation and as an ongoing internal review tool. For more information or questions, please contact: orcr-deptemail@umich.edu.

Additional information on sponsor-investigator responsibilities can be found on the following websites: [Operations Manual Part 8: Studies Regulated by FDA & Use of Investigational Articles](http://research-compliance.umich.edu/operations-manual-studies-regulated-fda-and-use-investigational-articles); [MIAP IND/IDE Consultation & Development](https://www.michr.umich.edu/rdc/2015/9/4/regulatory-support-for-fda-regulated-clinical-research); MICHR Study Monitoring

**Note:** Any U-M employee serving or seeking to serve as the sponsor or sponsor-investigator of an IND or IDE in conjunction with his or her University appointment must utilize MICHR MIAP services for document preparation assistance, application review, and maintenance of an active IND or IDE. In addition, when contacted by the FDA to schedule an inspection (or the FDA has arrived without advance notice), the PI or a member of the research team is expected to immediately contact the following offices: Office of Regulatory Affairs (UMMS-RegAffairs@med.umich.edu) and IRB of Record.

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| **STUDY INFORMATION** |
| HUM # | Click or tap here to enter text. |
| Study Title | Click or tap here to enter text. |
| PI Name | Click or tap here to enter text. |
| Date Self-Assessment Completed | Click or tap here to enter text. |
| Person Completing Self-Assessment | Click or tap here to enter text. |

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| **SPONSOR RESPONSIBILITIES** |
| **Requirement** | **Corresponding Documents** | **Response** |
| *TRAINING** Principal Investigator completed the required [MIAP IND/IDE Sponsor-Investigator Training](https://michr.umich.edu/rdc/2016/4/22/indide-sponsor-investigator-training)
 | * Documentation of completed MIAP training
 | [ ]  YesDate: Click or tap to enter a date. | [ ]  No | [ ]  N/A |
| *CLINICALTRIALS.GOV** Completed [registration](https://research-compliance.umich.edu/clinical-trials-registration-results-reporting) of the protocol on Clinicaltrials.gov.
* Registration date within 21 days of the first subject being enrolled.
* The consent form contains the mandatory language regarding registration and results reporting on ClinicalTrials.gov. See [IRBMED Standard Informed Consent Template](https://az.research.umich.edu/medschool/templates/standard-informed-consent-template)
 | * [Form 3674](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions) (Certificate of Compliance) submitted to FDA
* Registration within 21 days of first subject enrollment and assigned NCT #
* IRB approved consent form
 | [ ]  Yes | [ ]  No | [ ]  N/A |
| *AMENDMENTS*Once an IND is in effect:Protocol amendments are required for ([21 CFR 312.30](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.30)):* New protocol
* Changes to existing protocol
* New investigator

Information amendments ([21 CFR 312.31](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.31)):* Essential information not within the scope of a protocol amendment (e.g., new toxicology, chemistry, or technical information, discontinuation of clinical investigation)
 | * Original IND application (including 1571)
* FDA letter of no objection, if provided
* Amendments (with 1571)
* Other correspondence with FDA (e.g., response to a clinical hold, general correspondence)
 | [ ]  Yes | [ ]  No | [ ]  N/A |
|  **SPONSOR RESPONSIBILITIES**  |
| **Requirement** | **Corresponding Onsite Documents** | **Response**  |
| *IND SAFETY REPORTS (*[*21 CFR 312.32*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32)*)*For example:* Serious, related, and unexpected adverse reaction, or significant preclinical findings (written reports, e.g., MedWatch 3500A to FDA, and all participating investigators, if applicable (no later than 15 calendar days after the sponsor determines the information qualifies for reporting)
* Unexpected fatal or life-threatening reports (within 7 calendar days after sponsor's initial receipt of information)
* Follow-up information to a safety report (submitted as soon as available)
 | * IND safety reports (with 1571)
* Evidence of correspondence to other investigators, if applicable
 | [ ]  Yes | [ ]  No | [ ]  N/A |
| *ANNUAL REPORTS (*[*21 CFR 312.33*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.33)*)** Within 60 days of the anniversary date that the IND went into effect
 | * Annual report (with 1571)
 | [ ]  Yes | [ ]  No | [ ]  N/A |
| *INFORMING INVESTIGATORS (*[*21 CFR 312.55*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.55)*)** Provide all clinical investigators with Investigator’s Brochure (IB)
* Inform investigators of new observations discovered by or reported to the sponsor on the investigational product.
 | * Current Investigator’s Brochure or approved label

*For multi-site studies:* * Documentation that all sites have received the Investigator Brochure
* Documentation of communication with investigators regarding new observations and adverse events (AEs)
 | [ ]  Yes[ ]  Yes[ ]  Yes | [ ]  No [ ]  No [ ]  No  | [ ]  N/A[ ]  N/A[ ]  N/A |

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| **SPONSOR RESPONSIBILITIES**  |
| **Requirement**  | **Corresponding Onsite Documents** | **Response**  |
| *SELECT QUALIFIED INVESTIGATORS AND MONITORS (*[*21 CFR 312.53*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.53)*;* [*312.57(b)*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.57)*)** + Select PIs qualified by training and experience.
	+ Keep accurate records of financial disclosure according to [21 CFR 54](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=54).
	+ Ship investigational product only to those investigators participating in the trial.
	+ Select monitors qualified by training and experience.
 | * Signed [FDA Form 1572](https://www.fda.gov/media/71816/download)
* Current Investigator CV and license
* IRB approval letter
* Financial disclosure form, such as [FDA form 3455](https://www.fda.gov/media/69872/download) for PI and all Co-Investigators listed on 1572

*Multi-site studies (applies to training and shipping investigational product):** Investigator information is required for **each** site.
* FDA Form 1572 and PI CV is provided to FDA.

*For Monitoring of Study:** MICHR Monitoring Services
	+ Other (specify): Click or tap here to enter text.
* CV and training experience of monitor
* Ensure monitor is trained on protocol
 | [ ]  Yes [ ]  Yes [ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes | [ ]  No [ ]  No [ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |

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| **SPONSOR RESPONSIBILITIES**  |
| **Regulations** | **Corresponding Onsite Documents**  | **Response**  |
| *ENSURE ONGOING MONITORING (*[*21 CFR 312.56*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.56)*)** Monitor the progress of the clinical investigation.
* Ensure PI compliance or discontinue shipments of investigational drug and end the PI’s participation in the investigation.
* Review and evaluate drug safety and effectiveness.
* Discontinue investigation within 5 working days when unreasonable and significant risks to subject are identified.
 | Documentation of data and safety monitoring plan* Reports/meeting minutes from DSMB and/or medical monitor
* Documentation of data monitoring
* Research team has been trained on data collection sheets and/or CRFs
* Correspondence with monitor
* Documentation of monitoring
* Timely notifications to all investigators, IRB and FDA if investigation discontinued.
 | [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes  | [ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |

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| **SPONSOR RESPONSIBILITIES** |
| COMMENTS ON SPONSOR RESPONSIBILITIES: |

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| **INVESTIGATOR RESPONSIBILITIES**  |
| **Requirement**  | **Corresponding Onsite Documents**  | **Response**  |
| *IRB APPROVAL*Ensure IRB review and approval of any changes and prompt reporting of problems involving risk to subjects ([21 CFR 312.66](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66)) | * Initial IRB approval
* Scheduled continuing review (SCR)
* Amendments describing any study changes.
* Adverse event reports according to [IRBMED guidance](https://az.research.umich.edu/medschool/guidance/adverse-event-reporting) or study specific plan
* [Unanticipated problems](https://az.research.umich.edu/medschool/guidance/unanticipated-problems-involving-risks-subjects-or-others) (UaPs)
* Protocol deviations reported to the IRB ([ORIOs](https://az.research.umich.edu/medschool/guidance/other-reportable-information-or-occurrence-orio))
* Current Investigator’s Brochure
* Other IRB correspondence
 | [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes [ ]  Yes  | [ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |
| *CASE HISTORIES*Maintain adequate and accurate case histories on each subject’s participation in the trial ([21 CFR 312.62(b)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62)) | * Signed and dated consent forms for all subjects
* Supporting data (source documents)
* Case report forms (CRFs)
* Subject eligibility documentation
* Progress notes
* Concomitant medications recorded
 | [ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes | [ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |
| *INFORMED CONSENT** Obtain and document informed consent in accordance with provisions in [21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)
* Electronic signatures should be [21 CFR Part 11](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11) compliant
 | * IRB approved consent form that includes all required elements
* Use of 21 CFR Part 11 compliant [Sign Now](https://its.umich.edu/enterprise/administrative-systems/signnow/fda-regulated-documents) for electronic consent
 | [ ]  Yes[ ]  Yes | [ ]  No [ ]  No  | [ ]  N/A [ ]  N/A  |

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| **INVESTIGATOR RESPONSIBILITIES** |
| **Requirement** | **Corresponding Onsite Documents** | **Response** |
| *SUPERVISION*Supervise the conduct of the clinical investigation ([21 CFR 312.60](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60)) ensuring:* Appropriate delegation of tasks
* Adequate training to protocol
* Adequate supervision
 | * Delegation log
* Staff training log
* Minutes from research team meetings to review trial progress, AEs, protocol changes
* Notes from meetings with study monitor
* Written procedures for internal review of data
 | [ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes | [ ]  No[ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |
| *SUBJECT OVERSIGHT*Protect the rights, safety and welfare of study subjects ([21 CFR 312.60](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60)) | * Documentation of adherence to protocol
* Documentation of reasonable medical care for AEs
* Inform subject when medical care is needed for conditions unrelated to research
* Investigator is available to subjects during conduct of study
* Appropriate delegation to co-investigators if PI is not available
 | [ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes | [ ]  No [ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |

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| **INVESTIGATOR RESPONSIBILITIES** |
| COMMENTS ON INVESTIGATOR RESPONSIBILITIES: |

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| **DRUG ACCOUNTABILITY** |
| **Requirement** | **Corresponding Onsite Documents** | **Response** |
| *OVERSIGHT*Sponsor is responsible for record of drug receipt, dispensing, and disposition ([21 CFR 312.57](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.57), [312.59](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.59), [21 CFR 312.62](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62)):* Maintain adequate record of receipt and shipment of investigational drug.
* Ensure return of all unused investigational drug from individual investigators participating in the trial or authorize alternative disposition of unused product.
* Maintain written records of any disposition of drug
 | Drug accountability log includes:* Receipt date
* Quantity
* Lot #
* Return/disposition
* Method of disposal

If delegated to a drug depot (in multi-site study) outside U-M research pharmacy, ensure that they have:* Date
* Destination
* Who shipped
* Quantity
* Lot #
* Return/disposition
* Method of disposal

Drug dispensing record includes:* Date
* Lot #
* Quantity
* ID of subject administered
* Disposition/record of return
* ID of person dispensing

Return of drug:* Count: Click or tap here to enter text.
* Reason: Click or tap here to enter text.
 | [ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes[ ]  Yes | [ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No[ ]  No | [ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A[ ]  N/A |
| **DRUG ACCOUNTABILITY** |
| **Requirement** | **Corresponding Onsite Documents** | **Response** |
| Investigator is responsible to ensure control of investigational drug ([21 CFR 312.61](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61))* Drug will be administered only to those subjects enrolled in the clinical study and under investigator or designee’s supervision.
 | * Enrollment / randomization log
* Delegation log
 | [ ]  Yes[ ]  Yes | [ ]  No [ ]  No | [ ]  N/A[ ]  N/A |

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| **DRUG ACCOUNTABILITY** |
| COMMENTS ON DRUG ACCOUNTABILITY: |