

This document shows the responsibilities of a sponsor-investigator (IND/IDE holder) according to ICH GCP E6(R2), and gathers information relevant to the UMN Administrative Policy [University Sponsor and Sponsor-Investigator IND/IDE and FDA Pre-Submission Requirements](#). Any responsibilities delegated to other individuals who are not the sponsor-investigator must be documented, and the delegations communicated to the FDA.

Where support is available via UMN services, an endnote is provided to connect you if you would like assistance; if you do not reach out to these groups, they may not be aware of your study and thus unable to take on these responsibilities for you.

Where there is no institutional support available, sponsor-investigators are solely responsible for meeting or delegating the responsibilities listed in that row. Sponsor-investigators must always retain oversight of each responsibility, whether or not it has been delegated.

Part I: Basic Information

PI/Regulatory Sponsor Information

Principal Investigator (PI) basic information

Preferred First Name: _____

Last Name: _____

U of M Internet ID: _____

Phone Number: _____

Please attach the PI's Curriculum Vitae (CV).

If the Principal Investigator is not also the Regulatory Sponsor, provide information for the University of Minnesota faculty Regulatory Sponsor.

Not Applicable. The PI is also the regulatory sponsor.

Regulatory Sponsor basic information

Preferred First Name: _____

Last Name: _____

U of M Internet ID: _____

Phone Number: _____

Please attach the Sponsor's Curriculum Vitae (CV).

Alternate contact Information (optional, if you prefer another person to be your main point of contact, such as a coordinator):

Preferred First Name: _____

Last Name: _____

U of M Internet ID: _____

Phone Number: _____

Provide Project Identifiers

Current project descriptor:

- Drug
- Device
- Biologic
- Tobacco, GRAS* or food for therapeutic use
- Combination product
(<https://www.fda.gov/combination-products/about-combination-products/combination-product-definition-combination-product-types>)
- IDE/IND exemption or determination request
- NSR IDE Device
NOTE: NSR IDE Device studies fall into the category of an abbreviated Investigational Device Exemption (IDE) set forth in CFR 812.2 (b). A study that has been determined to be NSR must comply with the Abbreviated IDE Requirements at 21 CFR 812.2(b). An IDE is considered to be in effect and the IRB serves as the surrogate overseer.
- Other situations involving FDA correspondence; specify below

Specify _____

Have you done other work with this product?

- Yes, IRB Study Number(s): _____
- No

Is the investigational product provided by (check all that apply):

- Pharma or device manufacturer. If yes, name: _____
- Another academic or non-profit organization. If so, indicate the institution/organization: _____
- Manufactured, altered or stored at Molecular and Cellular Therapeutics (MCT)?
 - Yes
 - No
- Manufactured or altered at the University of Minnesota. If so, indicate the following Facility: _____
Do you plan to charge for the investigational product?
 - Yes. Note you must option prior written authorization from the FDA to so, and documentation of authorization must be submitted to the central file.
 - No

Does your study involve multiple sites?

- Yes. Ensure you have draft agreements with other study sites for multi-site investigations. "Site" refers to an institution conducting research, not the locations at which the research is being conducted. For example, the same study being conducted by investigators at the University of Minnesota, the Mayo Clinic and University of Wisconsin, Madison is an example of a multi-site study.
List sites: _____
- No

Who will monitor this study?

- CTSI
- Other: _____

Please note: Monitoring is required for all IND, IDE and NSR IDE studies. Monitoring information must match information indicated in the protocol. In addition, if CTSI is not tasked with monitoring this study, you must provide confirmation by CTSI for the non-CTSI monitoring service.

Provide Project and Sponsor Documentation

- I. Submit all relevant FDA correspondence to the [HRPP Central File Submission Portal](#).

*Generally Recognized as Safe by FDA

Part 2: Responsibilities of a sponsor-investigator
Checklist of responsibilities

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.10	<ul style="list-style-type: none"> Determine whether submission to FDA is required 		X ⁴	
5.10	<ul style="list-style-type: none"> Gather documents for FDA submission 	X ²		
5.21	<p>If the trial is terminated prematurely or suspended:</p> <ul style="list-style-type: none"> Inform investigators/institutions promptly, including the reason for termination or suspension 			X
5.21	<p>If the trial is terminated prematurely or suspended:</p> <ul style="list-style-type: none"> Inform regulatory authorities and the IRB, including the reason for termination or suspension 	X ^{2,3}		
5.22	<ul style="list-style-type: none"> Prepare trial/study reports and submit to regulatory agencies as required in regulations 	X ²		
5.22	<ul style="list-style-type: none"> Ensure reports in marketing applications meet ICH standards 			X
5.3	<ul style="list-style-type: none"> Designate appropriately qualified medical personnel who will be available to advise on trial-related medical questions or problems Outside consultants may be appointed for this purpose if necessary 			X
5.7	<ul style="list-style-type: none"> Define, establish, and allocate all trial-related duties and functions before the trial begins 			X
5.9	<ul style="list-style-type: none"> Document any financial aspects or agreements of the trials 			X
5.0.1	<ul style="list-style-type: none"> During protocol development, identify processes and data critical to ensure human subject protection and reliability of trial results 	X ¹		
5.0.2 5.0.3 5.0.4	<ul style="list-style-type: none"> Identify risks at the system level and clinical trial level Evaluate these risks and their potential impact on human subjects and the reliability of trial results Develop risk reduction strategies and incorporate these into the protocol (e.g. design, monitoring plans, training, etc.) Identify thresholds to trigger additional safety/ data reviews for issues that can impact subject safety or the reliability of trial results 	X ¹		

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.0.5	<ul style="list-style-type: none"> Document quality management activities and communicate these to the groups involved in these activities 			X
5.0.6	<ul style="list-style-type: none"> Periodically review risk control measures to determine they remain effective and relevant, based on emerging knowledge and experience 			X
5.0.7	<ul style="list-style-type: none"> Describe the quality management approach implemented in the trial Summarize deviations from predefined thresholds and remedial actions taken as a result 			X
5.1.1 5.1.3	<ul style="list-style-type: none"> Implement and maintain quality assurance and quality control systems via written SOPs to ensure the trial is conducted and data is generated, recorded, and reported in compliance with the protocol and regulatory requirements Apply quality control to each stage of data handling to ensure all data are reliable and have been processed correctly 			X
5.1.2	<ul style="list-style-type: none"> Secure agreement from involved parties to ensure access to trial sites, data, and reports for purposes of monitoring, auditing, and inspection 			X
5.1.4	<ul style="list-style-type: none"> Document agreements with institutions or any parties involved with the clinical trial in writing, either as part of the protocol or in a separate agreement 			X
5.11.1	<ul style="list-style-type: none"> Obtain statement from IRB that IRB operates according to GCP and applicable laws/regulations Document IRB approval, including approved documents 	X ³		
5.11.2	<ul style="list-style-type: none"> Document required changes requested by the IRB and the updated documents, along with IRB approval 	X ³		
5.11.3	<ul style="list-style-type: none"> Document IRB reapprovals or withdrawals/suspensions 	X ³		
5.12.1	<ul style="list-style-type: none"> Ensure sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure for the route/dosage/duration/population in the study 			X
5.12.2	<ul style="list-style-type: none"> Update the investigator's brochure as new information becomes available 			X

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.13.1	<ul style="list-style-type: none"> Ensure the investigational product(s), including placebo, are appropriate to the stage of development, manufactured according to GMP, and are coded/labeled to protect blinding and comply with regulatory requirements 			X
5.13.2	<ul style="list-style-type: none"> Determine acceptable storage temperatures, conditions and times, along with reconstitution fluids and devices for infusion when applicable Inform all involved parties, including pharmacists and other investigators, of these determinations 			X
5.13.3	<ul style="list-style-type: none"> Package the investigational product to prevent contamination or deterioration during transport and storage 			X
5.13.4	<p>For blinded trials:</p> <ul style="list-style-type: none"> Ensure the coding system allows for rapid identification of the product in the event of a medical emergency, but does not otherwise permit unblinding 			X
5.13.5	<p>If significant formulation changes are made during the trial:</p> <ul style="list-style-type: none"> Ensure the results of additional studies of the formulated product that would alter the PK profile of the product are available before the new formulation is used in trials 			X
5.14.1 5.14.2	<ul style="list-style-type: none"> Supply the investigational product to any co-/sub-/site-investigators and participating sites, when applicable, only after ensuring they have obtained IRB and other regulatory approvals 			X
5.14.3	<ul style="list-style-type: none"> Ensure co-/sub-/site-investigators and participating sites have written procedures for handling and storage of investigational product and documentation thereof, including receipt, handling, storage, dispensing, and return 			X

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.14.4	<ul style="list-style-type: none"> ● Ensure timely delivery of investigational product ● Maintain documentation of shipment, receipt, disposition, return, and destruction of the investigational product ● Maintain a system for retrieving investigational product (e.g. for recall, expired product, etc) and documentation thereof ● Maintain a system for disposition of unused investigational product and the documentation of this disposition 			X ⁵
5.14.5	<ul style="list-style-type: none"> ● Ensure the investigational product is stable over the period of use ● Maintain sufficient quantities of the investigational product to reconfirm specifications, if needed ● Maintain records of batch sample analyses and characteristics ● Retain samples until analysis of trial data is complete, or as required by regulations, to the extent stability permits 			X
5.15.1	<ul style="list-style-type: none"> ● Ensure protocol specifies the investigator(s)/institution(s) will provide direct access to source data/documents for monitoring, auditing, IRB review, and/or regulatory inspection 	X ¹		
5.15.2	<ul style="list-style-type: none"> ● Verify the consent form includes direct access to participant medical records for monitoring, auditing, IRB review, and/or regulatory inspection 	X ³		
5.16.1 5.16.2	<ul style="list-style-type: none"> ● Ensure ongoing safety evaluation of investigational product ● Notify all investigators/institutions of findings that could adversely affect subject safety, trial conduct, or alter IRB's approval to continue 			X
5.16.2	<ul style="list-style-type: none"> ● Notify regulatory authorities of findings that could adversely affect subject safety, trial conduct, or alter IRB's approval to continue 	X ^{2,3}		
5.17.1 5.17.2	<ul style="list-style-type: none"> ● Notify investigators/institutions of adverse drug reactions that are both serious and unexpected; reports must comply with regulatory requirements and ICH Guidance 			X

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.17.1 5.17.2 5.17.2	<ul style="list-style-type: none"> ● Notify the IRB and regulatory authorities of adverse drug reactions that are both serious and unexpected; reports must comply with regulatory requirements and ICH Guidance ● Submit safety updates and periodic reports to regulatory authorities, as required by regulations 	X ^{2,3}		
5.18.1 5.18.2	<ul style="list-style-type: none"> ● Ensure appointment of a monitor whose scope meets requirements in 5.18.1; is appropriately trained; and is familiar with the investigational product, protocol, consent form, SOPs, ICH GCP, and applicable regulatory requirements 	X ⁶		
5.18.3	<ul style="list-style-type: none"> ● Ensure trial is adequately monitored, based on the complexity and size of the trial, among other criteria ● Monitoring should occur before, during, and after trial conduct ● Develop a systematic, prioritized, risk-based approach to monitoring clinical trials 	X ⁶		
5.18.3	<ul style="list-style-type: none"> ● Ensure data monitoring includes examination of data outliers or trends ● Analyze site characteristics or performance metrics, when applicable, and select sites or processes for targeted onsite monitoring 			X

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.18.4	<p>Ensure data is available to a monitor so they may:</p> <ul style="list-style-type: none"> ● Verify investigator qualifications and resources ● Verify staff and facilities are adequate to safely and properly conduct the trial ● Verify storage of the investigational product is acceptable and sufficient ● Verify investigational product is only supplied to participants who are eligible to receive it, at the correct dose, and they are provided instructions on using, storing, and returning it ● Verify receipt, use, return, and disposition of investigational products is documented ● Verify the investigator follows the approved protocol and applicable amendments ● Verify written informed consent was obtained before each participant's participation in the trial ● Ensure the current investigator's brochure and supplies needed to conduct the trial and comply with regulations are available ● Ensure all trial staff are adequately informed about the trial, and performing trial functions only as delegated by the principal investigator and according to the protocol ● Verify only eligible participants are enrolled, and reporting the participant recruitment rate ● Verify source documents and other records are accurate, complete, updated, and maintained ● Verify all reports, notifications, applications, and submissions are provided, complete, accurate, and timely ● Verify accuracy and completeness of CRF entries and source data against each other, and informing the investigator of errors ● Determine whether adverse events were appropriately reported ● Determine whether the investigator is maintaining essential documents according to ICH E6(R2) 8 ● Communicate deviations to the investigator and take action to prevent recurrence 	X ⁶		
5.18.5	<ul style="list-style-type: none"> ● Ensure the monitor follows written SOPs for monitoring the trial 	X ⁶		

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.18.6	<ul style="list-style-type: none"> Ensure the monitor submits a written report to the investigator after each visit, including the date, site, monitor name, and investigator name, as well as what was reviewed and a list of findings or deficiencies, with actions to be taken to secure compliance 	X ⁶		
5.18.6	<ul style="list-style-type: none"> Review and follow-up on the monitoring report, and document any correspondence or actions taken 			X
5.18.7	<ul style="list-style-type: none"> Develop and follow a tailored monitoring plan 	X ⁶		
5.19.1 5.19.2	<ul style="list-style-type: none"> Appoint individuals, separate from monitoring or quality control, to conduct audits of trial conduct and compliance; auditors should have appropriate qualifications documented 			X
5.19.3	<ul style="list-style-type: none"> Ensure auditing of clinical trials and systems is conducted according to written SOPs, and is guided by complexity, size, risk, and importance of the trial Ensure observations and findings of the auditor are documented Provide an audit certificate when required 			X
5.2.1 5.2.2 5.2.3 5.2.4	<ul style="list-style-type: none"> Any or all sponsor-investigator responsibilities may be delegated to a Contract Research Organization (CRO) but the sponsor-investigator remains responsible for the quality and integrity of trial data The CRO should implement quality assurance and quality control Any trial-related duties or functions transferred to a CRO must be documented in writing. For these duties or functions, the CRO must follow ICH GCP guidance as if they are the sponsor. Any trial-related duties or functions not specifically transferred to a CRO are retained by the sponsor-investigator 			X
5.20.1	<ul style="list-style-type: none"> Take prompt action to secure compliance if/when noncompliance with the protocol, SOPs, GCP, or regulatory requirements is identified Perform a root cause analysis of noncompliance if it could impact human subject protection and/or trial results 			X

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.20.2	<ul style="list-style-type: none"> Terminate an investigator's/institution's participation in a trial if serious and/or persistent noncompliance is identified 			X
5.20.2	<ul style="list-style-type: none"> Notify regulatory authorities if an investigator or institution is terminated 	X ^{2,3}		
5.23.1 5.23.2 5.23.3 5.23.4 5.23.5	<p>For multicenter trials:</p> <ul style="list-style-type: none"> Ensure all investigators conduct the trial in compliance with the protocol and regulatory authorities, and have IRB approval Ensure CRFs are designed to capture required data at all trial sites Document the responsibilities of investigators prior to the start of the trial Provide instructions to investigators on following the protocol, complying with standards for clinical and laboratory findings, and completing CRFs Facilitate communication between investigators 			X
5.4.1 5.4.2	<ul style="list-style-type: none"> Utilize qualified individuals through all stages of the trial process, including trial design and planning through interim and final trial reports 			X
5.5.1	<ul style="list-style-type: none"> Utilize qualified individuals to supervise the conduct of the trial, to handle and verify the data, to conduct the statistical analysis, and to prepare trial reports 			X
5.5.10	<ul style="list-style-type: none"> Report any transfer of data ownership to appropriate regulatory authorities 	X ³		
5.5.11	<ul style="list-style-type: none"> Maintain essential documents for at least 2 years after last approval of a marketing application, or discontinuation (see 5.5.8), or longer if required by regulatory requirements or as needed 			X
5.5.2	<ul style="list-style-type: none"> Establish an independent data monitoring committee (IDMC) to assess trial progress and make recommendations on the continuation of the trial The IDMC should have written operating procedures and maintain written records of all meetings 			X

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.5.3	If using electronic data systems: <ul style="list-style-type: none"> ● Ensure and document that the systems conform to requirements for completeness, accurately, reliability, and validation ● Maintain SOPs for using these systems, including testing, maintenance, security, and recovery ● Ensure when system changes are implemented, there is no deletion of entered data ● Prevent unauthorized access to the data ● Maintain a list of individuals authorized to make data changes ● Maintain adequate backup of the data ● Safeguard any blinding during data entry and processing ● Ensure integrity of the data, especially during software upgrades or data migration 			X
5.5.4	<ul style="list-style-type: none"> ● If data are transformed during processing, ensure it is possible to compare the original data with the processed data 			X
5.5.5	<ul style="list-style-type: none"> ● Use an unambiguous subject identification code to allow for identification of all data reported for each subject 			X
5.5.6 5.5.7	<ul style="list-style-type: none"> ● Retain all essential documents pertaining to the trial according to ICH GCP E6(R2) Section 8 and applicable regulatory requirements 	X ³		
5.5.8	If the clinical development of the clinical product is discontinued: <ul style="list-style-type: none"> ● Maintain all essential documents for at least 2 years after formal discontinuation ● Notify trial investigators/institutions 			X
5.5.9	If the clinical development of the clinical product is discontinued: <ul style="list-style-type: none"> ● Notify appropriate regulatory authorities 	X ^{2,3}		

<u>ICH E6(R2)</u>	Responsibility	CTSI Services	HRPP Services	No institutional services available
5.6.1 5.6.2 5.6.3	<ul style="list-style-type: none"> ● Select co-/sub-/site-investigators (and institutions, when applicable) qualified by training and experience, with adequate resources to conduct the trial ● Before entering an agreement with co-/sub-/site-investigators (and institutions, when applicable), provide them with the protocol and investigator's brochure and allow them time to review ● Co-/sub-/site-investigators (and institutions, when applicable) must agree to conduct the trial in compliance with GCP, regulatory requirements, and the approved protocol; comply with procedures for data recording/reporting; to permit monitoring, auditing, or inspection; and to retain essential documents until no longer required by the sponsor-investigator <p>For multisite trials:</p> <ul style="list-style-type: none"> ● Organize/select a coordinating committee or coordinating investigator 			X
5.8.1 5.8.2 5.8.3	<ul style="list-style-type: none"> ● When required by regulations, ensure either insurance or indemnification for all investigators/sites against claims arising from the trial, excepting malpractice and/or negligence ● Establish policies and procedures to address the cost of treatment if trial-related injuries occur ● Ensure the method of compensating participants complies with regulatory requirements 			X

1. CTSI Research Prep Group: umncrsc@umn.edu
2. CTSI IND/IDE Support: umncrsc@umn.edu
3. CTSI Regulatory Specialist Team: <https://ctsi.umn.edu/services/regulatory-support#Specialists>
4. HRPP MedReg: medreg@umn.edu
5. Investigational Drug Services:
<https://www.fairview.org/for-medical-professionals/research/investigational-devices>
6. CTSI Monitors: <https://ctsi.umn.edu/services/regulatory-support#Monitoring>

Attestation

I confirm I have reviewed all pages of this document, and understand and agree to uphold my responsibilities as sponsor/sponsor-investigator of a clinical trial. Regardless of whether there is availability of U of MN support for certain components of the IND/IDE regulatory requirements, I acknowledge that it is my responsibility to obtain all support and resources for regulatory compliance needed for this activity. I am aware of university resources to assist where applicable, and that I must reach out to initiate this support if I choose to use it. I know that making a willfully false statement on this form may lead to consequences including limitations or conditions being placed on my privilege to serve as a sponsor or sponsor-investigator.

Printed Name of Sponsor/Sponsor-Investigator

Department/Division

Signature of Sponsor/Sponsor-Investigator

Date

Link to GCP Guidance and list of Regulations:

In addition to the requirements of 21 CFR 312 and 21 CFR 812, investigators who hold an IND or IDE must also meet all regulatory requirements pertaining to sponsors, appearing in other FDA parts, as applicable, as listed but may not be limited to:

For Drugs or Devices:

21 CFR 11 (Electronic records and electronic signature)

21 CFR 54 (Financial Disclosure by Clinical Investigators)

For Drugs and Biologics:

21 CFR 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General)

21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)

21 CFR 312 (Investigational New Drug Application)

21 CFR 314 (Drugs for Human Use)

21 CFR 320 (Bioavailability and Bioequivalence Requirements)

21 CFR 330 (Over-The-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective)

21 CFR 601 (Biologics Licensing)

For Devices:

21 CFR 807 (Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices)

21 CFR 812 (Investigational Device Exemptions)

21 CFR 814 (Premarket Approval of Medical Devices)

21 CFR 820 (Quality System Regulation)

21 CFR 860 (Medical Device Classification Procedures)