**Investigators and their project team members must be familiar with each governing research contract, and understand when the contract calls for compliance with ICH-GCP and E6(R2) Good Clinical Practice Guidelines.**

**Please keep this on file with your regulatory documents and upload with submission.**

**PI Responsibilities**

**PI qualifications**

* The investigator provides evidence of his/her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the institution, the IRB, or the regulatory authority.
* The investigator is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

**Record retention**

* ICH requires the retention of “essential documents” for at least two years after the approval of a marketing application in an *ICH region* or until there is no pending or contemplated applications in an *ICH region* or development is formally discontinued.

**Informed consent documentation**

* ICH allows the delegation of the informed consent process to a designee.
* ICH requires the person conducting the informed consent process to sign and date the consent form.
* ICH requires that the subject receive a copy of the signed and dated written consent form and any other written information provided to the subjects.
* ICH requires inclusion of the following informed consent elements in addition to the essential elements required by regulations:
	+ - Discussion of trial treatments and probability of random assignment
		- Subject responsibilities
		- Anticipated payment, if any, to the subject
		- Important potential risks and benefits of alternative treatment
		- Authorization to access medical records by regulatory authorities (FDA and foreign)
		- Authorization for the monitor, the auditor, the IRB, and regulatory authority to access original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations

**Documentation when enrolling a subject who is unable to read**

* If a subject or legally authorized representative is unable to read, an impartial witness should be present during the entire informed consent discussion.
* By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject’s legally authorized representative, and that consent was freely given by the subject or the subject’s legally authorized representative.
* The witness should sign and personally date the consent document after:
* the written consent document and any other written information to be provided to the subject has been read and explained to the subject or their legally authorized representative, and
* after the subject or the subject’s legally authorized representative has orally consented to the subject’s participation in the trial, and
* if capable of doing so, the subject or legally authorized representative has signed and personally dated the consent document.

**Conduct of the project**

* The investigator is responsible for investigational product accountability at the trial site.
* This investigator may assign some, or all, of the duties for investigational product accountability at the trial site to an appropriate pharmacist, or other individual, who is under the supervision of the investigator (designee).
* The investigator, or designee should maintain records of the product’s delivery to the trial site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. The records should include dates, quantities, batch/serial numbers, expiration dates (if applicable) and the unique code numbers assigned to the investigational product and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.
* The investigator must maintain a list of appropriately qualified persons with the delegated significant clinical trial-related duties. (Does not apply if FDA regulations are followed).
* During and following a subject’s participation in a clinical trial, the investigator ensures that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the clinical trial.
* The investigator follows the clinical trial’s randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding.
* A qualified physician (or dentist, when appropriate), who is an investigator or co-investigator for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions. Investigators inform subjects when medical care is needed for other illnesses of which the investigators become aware.
* If the subject has a primary physician and agrees to it, the investigator informs the subject’s primary physician about the subject’s participation in the clinical trial.
* The investigator makes a respectful and reasonable effort to ascertain the reason for a subject’s withdrawal from the clinical trial, although a subject is not obliged to give the reason for withdrawal.
* The investigator maintains adequate and accurate source documents and trial records that include all pertinent observations on each of the site’s trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate and complete. Changes to the source data will be traceable, explained if necessary, and the original will not be obscured.
* The investigator reports all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g. investigator’s brochure) identifies as not needing immediate reporting.
* The investigator follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB.
* The investigator provides written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects.
* The investigator ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.
* The investigator permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.
* If the investigator terminates or suspends a clinical trial without prior agreement of the sponsor, the investigator informs the organization, sponsor, and the IRB.
* If the IRB terminates or suspends approval of the clinical trial, the investigator notifies the sponsor.
* The investigator maintains clinical trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by applicable regulatory requirements.
* Upon completion of the clinical trial, the investigator informs the organization, the IRB with a summary of the trial’s outcome using the Continuing Progress Report, and the regulatory authority with any reports required.
* In the event the clinical trial is Planned Emergency Research, the Investigator will inform the subject or the subject’s Legally Authorized Representative about the clinical trial as soon as possible and obtain informed consent if the subject or the subject’s Legally Authorized Representative wishes to continue participation in the clinical trial.

**Protocol & Investigator Brochure**

* ICH requires that the protocol identify any data to be recorded directly on the CRFs and to be considered source data (ICH 6.4.9)

**Essential documents**

* ICH requires the following documents:
	+ Subject Screening Log (to document subjects who enter trial screening)
	+ Subject Identification Code List (confidential list of subject names in case identity must be revealed for follow-up)
	+ Signature Sheet (to document signatures/initials of persons authorized to make CRF entries and corrections)
* ICH requires the following documents be filed at the site:
	+ Trial Initiation Monitoring Report (to document that trial procedures were reviewed with the Investigator and staff)
	+ Relevant Communications (letters, meeting notes, notes of telephone calls)
* ICH requires the investigator file a statement with the Sponsor that the local IRB is fulfilling ICH-GCP and applicable laws and regulations for this project.
* ICH requires the investigator to file documentation of IRB approval prior to receipt of shipped investigational product.

**ICH-GCP E6 Attestation**

Information

Description

**Investigator Statement**

* I have reviewed and confirmed these practices are in place at our site for XtrialX:
* I am responsible for supervising any individual or party who has been delegated trial related duties and functions at this site.
* The individuals who have been delegated trial related duties and functions at this site are qualified to perform those trial related duties and functions and will implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Name, Role, Signature

**Staff Statement**

* I have reviewed and confirmed these practices are in place at our site for XtrialX:
* I am responsible for Xdelegated trial related duties and functionsX at this site.
* I have been delegated trial related duties and functions at this site and am qualified to perform those trial related duties and functions and will implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Name, Role, Signature

**Staff Statement**

* I have reviewed and confirmed these practices are in place at our site for XtrialX:
* I am responsible for Xdelegated trial related duties and functionsX at this site.
* I have been delegated trial related duties and functions at this site and am qualified to perform those trial related duties and functions and will implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Name, Role, Signature

**Staff Statement**

* I have reviewed and confirmed these practices are in place at our site for XtrialX:
* I am responsible for Xdelegated trial related duties and functionsX at this site.
* I have been delegated trial related duties and functions at this site and am qualified to perform those trial related duties and functions and will implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Name, Role, Signature

**Staff Statement**

* I have reviewed and confirmed these practices are in place at our site for XtrialX:
* I am responsible for Xdelegated trial related duties and functionsX at this site.
* I have been delegated trial related duties and functions at this site and am qualified to perform those trial related duties and functions and will implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

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**ICH-GCP E6 Attestation**

Statement