



## ADDITIONAL REQUIREMENTS FOR CLINICAL RESEARCH: ICH-GCP

### 1. Overview

Good Clinical Practice (GCP) guidance is an international “ethical and scientific quality standard” for designing, conducting, recording, and reporting clinical trials in human subjects that was developed by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). The GCP guidance developed by ICH is based on FDA regulations for the protection of human subjects and defines the roles and responsibilities of IRBs, investigators, monitors, and sponsors.

The purpose of this policy is to describe the requirements, in addition to DHHS and FDA regulations and HRPP policies, for clinical trials involving human subjects to be compliant with ICH-GCP guidance.

### 2. Definitions

**Clinical Trial:** Any investigation in human subjects intended to: discover or verify clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product; identify any adverse reactions to an investigational product; and/or study absorption, distribution, metabolism, and excretion of an investigational product to determine its safety and/or efficacy. *Note: Studies involving only behavioral interventions are not covered by this policy.*

**Good Clinical Practice (GCP):** Also: **ICH E6.** A standard established by the International Conference on Harmonisation for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. *Note: In the United States, the FDA has adopted GCP as guidance.*

**International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH):** Also: **International Conference on Harmonisation.** Voluntary, international initiative to increase coordination of the requirements for developing and marketing new drugs. The ICH includes representatives from the pharmaceutical industry and regulatory authorities from the United States, Japan, and the European Union.

### 3. General Information

- A. All clinical trials at Ohio State that follow ICH-GCP guidance must also comply with applicable [HRPP policies](#).
- B. For more detailed information on ICH-GCP, including a glossary of terms and the complete list of institutional, investigator, and sponsor responsibilities, see [ICH E6: Good Clinical Practice: Consolidated Guidance](#).



#### 4. Additional Institutional Responsibilities

- A. Clinical trials will be conducted in accordance with the ethical principles that have their origin in the Belmont Report and Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirements.
- B. To be approved, clinical trials must satisfy the requirements described in HRPP policy [[Review of Research by the Convened IRB](#)]. In addition, the IRB will determine that available information (nonclinical and clinical) on an investigational product is adequate to support a proposed clinical trial and that the study is scientifically sound and described in a clear, detailed protocol.
- C. For each research study, the IRB will determine that the resources necessary to protect subjects will be available, including adequate numbers of qualified research staff and adequate facilities. A qualified physician (or dentist, when appropriate) who is an investigator for the clinical trial is responsible for all clinical trial-related medical (or dental) decisions.
- D. IRB reviewers will be provided and review investigators' current curriculum vitae or other documentation evidencing qualifications.
- E. In addition to the required elements of consent disclosure described by HRPP policy [[Informed Consent Process and the Elements of Informed Consent](#)], informed consent disclosures will include the following:
- Important potential benefits and risks of alternative procedures or treatment that may be available
  - That by signing a written consent form, the subject or the subject's legally authorized representative is authorizing the monitor, auditor, IRB, and applicable regulatory authority direct access to the subject's original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations
  - That the clinical trial has been approved by the IRB.
- F. Additional protections for adults who are unable to provide consent are described by HRPP policy [[Vulnerable Populations: Students, Employees, and Adults Unable to Provide Consent](#)]. In addition, for clinical trials the IRB will determine:
- Whenever possible, non-therapeutic clinical trials (i.e., trials in which there is no anticipated direct clinical benefit to subjects) will be conducted with subjects who personally give consent and who sign and date the written consent document.
  - Non-therapeutic clinical trials may be conducted in subjects unable to provide informed consent with the consent of a legally authorized representative, provided the following conditions are fulfilled:
    - Clinical trial objectives cannot be met by a trial in subjects who can personally give consent
    - Foreseeable risks to subjects are low
    - Negative impact on subjects' wellbeing is minimized and low
    - Law does not prohibit conducting the clinical trial



- Inclusion of such subjects is specifically approved and documented by the IRB
  - Such trials, unless an exception is justified, will be conducted in patients having a disease or condition for which an investigational product is intended
  - Subjects in these trials will be closely monitored and will be withdrawn if they appear to be unduly distressed.
- G.** Some or all duties for investigational article accountability may be assigned to a pharmacist or another appropriate individual under the supervision of the principal investigator, as described by HRPP policy [[Research Involving Investigational Drugs](#)]. The investigator, pharmacist, or other designated individual will maintain records of the product's delivery to the trial site, product inventory and use by each subject, and return to the sponsor or alternative disposition of unused products. Records will document that subjects are provided the doses specified by the protocol and will reconcile all investigational products received from the sponsor. These records will include the following information:
- Dates
  - Quantities
  - Batch/serial numbers
  - Expiration dates (if applicable)
  - Unique code numbers assigned to the investigational products and trial subjects (if applicable).
- H.** Problems that must be reported to the IRB are described in HRPP policy [[Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems](#)], including the following:
- New information that may affect adversely the safety of subjects or the conduct of the clinical trial
  - Any changes significantly affecting the conduct of the clinical trial or increasing risk to subjects.

## 5. Additional Investigator Responsibilities

- A.** Investigators will provide evidence of their qualifications through current curriculum vitae or other relevant documentation requested by the sponsor, IRB, or applicable regulatory authority. Investigators will maintain lists of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.
- B.** During and following subjects' participation in a clinical trial, investigators will ensure that adequate medical care is provided to a subject for any adverse events related to the clinical trial, including clinically significant laboratory values. Investigators will inform subjects when medical care is needed for other illnesses about which an investigator becomes aware. An investigator will inform a subject's primary physician about the subject's participation in a clinical trial if the subject has a primary physician and the subject agrees to the primary physician's being informed.



- C. Investigators and research staff will provide the consent disclosures and follow the requirements pertaining to consent described by HRPP policy [[Informed Consent Process and the Elements of Informed Consent](#)] and ICH-GCP (see Section 4.E. above). Subjects or their legally authorized representatives will receive a copy of the signed and dated consent form and any other written information approved by the IRB to be provided to subjects.
- D. Although subjects are not obliged to give reasons for withdrawing prematurely from a clinical trial, investigators will make a “reasonable effort” to ascertain the reason(s) while fully respecting subjects’ rights.
- E. Investigators will be familiar with the appropriate use of an investigational product, as described in the protocol, current investigator brochure, product information, and in other information sources provided by the sponsor.
- F. Investigators will follow clinical trial randomization procedures, if any, and ensure that a code is broken only in accordance with the protocol. If a clinical trial is blinded, investigators will promptly document and explain to sponsors any premature unblinding.
- G. Investigators will follow HRPP policy [[Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems](#)] for reporting problems to the IRB. In addition, investigators will comply with the following GCP reporting requirements:
- All serious adverse events (SAEs) will be reported to sponsors, except for those SAEs that the protocol or other document (e.g., investigator’s brochure) identifies as not requiring immediate reporting
  - Adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations will be reported to sponsors according to the reporting requirements and within the time periods specified by the protocol
  - Any changes significantly affecting the conduct of a clinical trial or increasing risk to subjects will be reported to sponsors, the IRB, and, where applicable, the institution
  - Unexpected serious adverse drug reactions will be reported to regulatory authorities and the IRB
  - For reported deaths, investigators will supply sponsors and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
- H. Investigators will ensure the accuracy, completeness, legibility, and timeliness of data reported to sponsors. Investigators will follow GCP guidance and sponsor requirements for documentation and for changes and corrections to clinical trial documents. Investigators will permit monitoring and auditing by sponsors and inspection by appropriate regulatory authorities.
- I. Investigators will maintain clinical trial documents as specified in *Essential Documents for the Conduct of a Clinical Trial* ([GCP Guidance](#), Section 8) and as required by HRPP policy [[Privacy and Confidentiality](#)] and applicable regulatory requirements. Essential documents will be retained until at least two years after the last approval of a marketing



application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region, or at least two years have elapsed since the formal discontinuation of clinical development of an investigational product.

- J. If an investigator terminates or suspends a clinical trial without the sponsor's prior agreement, the principal investigator will inform the institution, sponsor, and IRB. If the IRB terminates or suspends approval of a clinical trial, the principal investigator will promptly notify the institution and sponsor.
- K. Upon completion of a clinical trial, the principal investigator will provide a summary of the trial's outcome to the institution and IRB and any required reports to applicable regulatory authorities.

## 6. Applicable Regulations/Guidance

AAHRPP "Tip Sheet 11: Following the Guidelines of the International Conference on Harmonization – Good Clinical Practice (E6)" (09/17/14); ICH "Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance" (04/96)

## 7. History

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