Marshfield Clinic

International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines and IRB Review

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. None

3. RESOURCE GUIDE BODY

This document highlights the IRB requirements that must be met for sponsored research projects that, by contract, will be conducted in accordance with ICH Guideline E6, Good Clinical Practice (GCP).

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States, as well as experts from the pharmaceutical industry in the three regions, to discuss scientific and technical aspects of product registration. The purpose of ICH is to recommend ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. "The objective of such harmonization is a more economical use of human, animal, and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines, whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health."

ICH's Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

3.1. ICH GCP Requirements

a. The IRB application will ask whether the study is subject to ICH GCP E6 Guidelines. When this question is answered affirmatively, IRB staff will ensure IRB members are aware of the additional requirements.

b. Researchers and IRB members should be aware that in order to fully comply with ICH GCP guidelines, the following modifications to existing IRB policies must be adopted:

- All written documents or information that will be provided to research subjects must be approved by the Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB), or the IRB designated by MCRF IRB for the study.
  - This includes materials that are distributed to all or most subjects due to their participation on a study. Examples of materials requiring review include patient education materials, newsletters, study-wide general

information letters, templated language for Thank you notes, birthday cards, appointment reminders and emails. It does not include individual correspondence regarding specific appointment dates/times, personal results, etc.

- These materials should be submitted to the IRB at the time of original review, or as they become available, using the Change or Update to Original Submission form.

- Investigators must report to MCRF Office of Research Integrity & Protections (ORIP) all adverse drug reactions that are both serious and unexpected. This supplements the IRB document, "Unanticipated Problems, IRB Reporting and Review of."

  - IND safety reports that are received by any member of the study team prior to initial, local IRB approval, such as those that are not included in the latest version of the investigator's brochure, are to be submitted using the "ICH GCP Adverse Event Report" form at the time of initial IRB submission. They will be reviewed as part of the IRB Application.

  - Adverse event reports that are submitted to meet ICH GCP requirements after IRB approval should also be reported on the form, "ICH GCP Adverse Event Report." These must be reported to ORIP within 30 days of a member of the study team becoming aware of them. The events will receive review by the IRB Chair or designee, and be recorded in the Research Studies Database. The form will be date stamped, "IRB- No Further Review Required," or if deemed appropriate, the IRB Chair or designee may request additional information from the reporting investigator. Upon completion of review, the stamped original reporting form will be returned to the investigator.

- Investigators must report to MCRF Office of Research Integrity & Protections (ORIP) all (1) changes increasing the risk to subjects and/or significantly affecting the conduct of the trial; and (2) new information that may adversely affect the safety of the subjects or the conduct of the trial.

  - These items must be reported to ORIP on a Change or Update to Original Submission Form within 5 days of a member of the study team becoming aware of them. The item will be processed via the review process defined in the IRB document, "Changes/Amendments to Approved Research."

- As part of the informed consent process, potential subjects must be informed of their rights and responsibilities. According to ICH GCP, this information must be conveyed in the consent document and verbally reviewed in detail with the subject.

  - If a study requires a subject to sign multiple consent documents, the rights and responsibilities statement need only be in the primary consent, unless the rights or responsibilities differ for the ancillary studies. In that circumstance, the relevant information must be provided in each consent document. This supplements the IRB document, "Informed Consent."

- ICH GCP requires that subjects be informed of alternative treatments or procedures that may be available to them, as well as the potential benefits and risks of each of those alternative therapies. This information must be included in the consent document, and should be carefully reviewed with the potential subject as part of the informed consent discussion. This supplements the document, "Informed Consent."
- Informed consent documents must tell subjects that study monitors, auditors, the IRB and regulatory authorities will be granted direct access to medical records for the verification of clinical trial procedures or data.

4. ADDITIONAL RESOURCES

4.1. References:
http://www.ich.org/products/guidelines.html

4.2. Supporting documents available:
- Changes/Amendments to Approved Research
- Informed Consent
- IRB Initial Review
- Unanticipated Problems, IRB Reporting and Review of

4.3. Forms
- (IRB) Changes or Update to Original Submission Form
- IRB ICH GCP Adverse Event Report

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control system transferred from Policy & Handbook Library - #2676.6. Updated IRB ARU form title to Change or Update Form.
2.0	Add hyperlink to IRB Forms and other applicable policies referenced in this document. 3.1(b) removed statement about non ICH study materials not routinely reviewed for better clarification. Reworded "written documents or Information" which requires IRB review in accordance with ICH GCP.

6. DOCUMENT PROPERTIES

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