**IRB Member ICH-GCP.e6 Reviewer Checklist**

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| **IRB Meeting Date:**Click or tap to enter a date. | **eBridge #:** Click or tap here to enter text. |
| **Date of EXR Review:** Click or tap here to enter text. |
| **Principal Investigator:** Click or tap here to enter text. | |

**This checklist should be used with the New Protocol Reviewer Checklist for projects which must follow ICH-GCP E.6 requirements.**

**Independent scientific and qualification review has been completed**

* An independent body provides public assurance, among other things, by reviewing and approving / providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

**The application includes the following information**

* ICH requires IRB submission of:
  + Subject recruitment procedures
  + Written information provided to subjects
  + Information about subject compensation
  + Confirmation that clinical trials will be conducted in accordance with the ethical principles originating in the Declaration of Helsinki and the Belmont Report and that are consistent with good clinical practice and the applicable regulatory requirements
  + Investigator's current CV and/or other documents evidencing qualifications <http://fcd.mcw.edu/>

**The consent form includes these additional informed consent document requirements of ICH GCP**

* Outline of the subject's responsibilities;
* An explanation of the alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.
* A statement that the monitor, the auditor, the IRB and the regulatory authority will be granted direct access to the participant’s original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing a written consent form, the participant or participant’s legally authorized representative is authorizing such access
* The IRB application indicates that an impartial witness who is independent of the trial and who cannot be unfairly influenced by people involved in the trial will be present during the entire informed consent discussion if a subject or their legally authorized representative is unable to read. See *IRB SOP: Informed Consent Document for Human Subject Research* and *IRB SOP: Informed Consent Process for Human Subject Research*.

**The IRB application describes documentation of the consent process**

* The IRB application explains the role of the impartial witness and documentation of the consent process when the participant or their legally authorized representative is unable to read.

**For non-therapeutic clinical trials (in which there is no anticipated direct benefit to the subject), the IRB has made the following determinations**

* Subjects must personally give their consent and sign and date the written consent document, **OR**
* A Legally Authorized Representative may give consent for the subject provided the following conditions are met:
* The objectives of the clinical trial cannot be met by means of a trial in subjects who can personally consent
* The foreseeable risks to the subjects are low
* The negative impact on the subject’s wellbeing is minimized and low
* The clinical trial is not prohibited by law
* The opinion of the IRB is expressly sought on the inclusion of such subjects and the written opinion covers this aspect
* The trial, unless an exception is justified, will be conducted in patients having the disease or condition for which the investigational product is intended.
* Subjects will be closely monitored and will be withdrawn if they appear to be unduly distressed.

**Conduct of the study**

* Available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial
* For planned emergency research involving exception from informed consent, the IRB application indicates that the subject or subject’s legally authorized representative must be informed about the clinical trial as soon as possible and provides consent if the subject wishes to continue.

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| **Comments/Concerns/Missing Items which must be submitted before issuing Final Approval** |
| Click or tap here to enter text. |

Reviewer Name:Click or tap here to enter text. Date: Click or tap to enter a date.