# ICH-GCP checklist for Study Teams

Please note: Emory’s Sponsored Programs practice is to remove contractual terms that require Emory’s adherence to ICH-GCP E6. If OSP/OTT should ever make an exception, they shall notify the IRB, and the following additional requirements should be in place prior to IRB approval of the research protocol.

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| **#** | **Item** | **Yes/ No** | **Notes** |
| 1 | Protocol includes a statement that clinical trials (CT) should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and the applicable regulatory requirements. |  |  |
| 2 | Protocol includes the evaluation of the available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial. |  |  |
| 3 | Protocol is detailed, clear detailing a scientifically sound clinical trial |  |  |
| 4 | PI assures (in protocol or separate signed statement) that he has the resources necessary to protect participants including adequate numbers of qualified staff and adequate facilities |  |  |
| 5 | The protocol explains that, where allowed or required, the PI has assigned some or all duties for investigational articles accountability at the trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the Researcher. |  |  |
| 6 | The protocol states that the investigator(s), pharmacist, or other designated individual will maintain records of the product’s delivery to the trial site, the inventory at the site, the use by each participant, and the return to the sponsor or alternative disposition of unused products. These records will include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial participants. Researchers should maintain records that document adequately that the participants are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor. |  |  |
| 7 | The protocol or signed statement indicates that the study PI has received and reviewed other investigator(s) current curriculum vitae or other documentation evidencing qualifications. |  |  |
| 8 | The protocol clearly states that new information that may affect adversely the safety of the participants or the conduct of the clinical trial and/or any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants will be promptly reported to the IRB. Promptly |  |  |

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|  | means in 5 business days. |  |  |
| 9 | The ICF discloses that alternative procedures or treatment that may be available to the participant, include their important potential benefits and risks |  |  |
| 10 | The ICF discloses that the monitor, the auditor, the IRB or EC, and the regulatory authority will be granted direct access to the participant’s original medical records for verification of CT procedures or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the participant or the participant’s legally acceptable representative is authorizing such access |  |  |
| 11 | The ICF discloses that the study has been approved by the IRB |  |  |
| 12 | Check that the study does not involve adults who are unable to consent if this CT is non-therapeutic (i.e. a trial in which there is no anticipated direct clinical benefit to the participant). If yes, skip checklist to # 20 |  |  |
| 13 | If this is a non-therapeutic CT enrolling adults who are unable to consent, the following has been followed and stated in the study protocol:  a) The objectives of the CT cannot be met by means of a trial in participants who can give consent personally. |  |  |
| 14 | b) The foreseeable risks to the participants are low |  |  |
| 15 | c) The negative impact on the participant’s wellbeing is minimized and low |  |  |
| 16 | d) The clinical trial is not prohibited by law |  |  |
| 17 | e) The opinion of the IRB or EC is expressly sought on the inclusion of such participants, and the written opinion covers this aspect |  |  |
| 18 | f) Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed. |  |  |
| 19 | g) The protocol states that the participant or the participant’s legally authorized representative is informed about the clinical trial as soon as possible and provides consent if the participant wishes to continue. |  |  |
| 20 | The protocol states that a qualified physician (or dentist, when appropriate), who is an Researcher or a Co- Researcher for the CT is responsible for all clinical trial- related medical (or dental) decisions. |  |  |
| 21 | The protocol states that during and following a participant’s participation in a clinical trial, the Researcher |  |  |

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|  | ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial |  |  |
| 22 | The protocol and ICF states that the PI and investigators will inform participants when medical care is needed for other illnesses of which the Researchers become aware |  |  |
| 23 | The protocol states that the PI 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 |  |  |
| 24 | The protocol and ICF state that the PI informs the participant’s primary physician about the participant’s participation in the clinical trial if the participant has a primary physician and if the participant agrees to the primary physician being informed |  |  |
| 25 | The protocol and ICF state that, although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the PI makes a reasonable effort to ascertain the reason, while fully respecting the participant’s rights |  |  |
| 26 | The protocol describes that the PI and other research staff provide all the disclosures and follow the requirements pertaining to consent covered by ICH-GCP. The IC process is documented in a separate document. |  |  |
| 27 | The protocol states that the PI will provide any requested documentation to show his/her qualifications to the sponsor, the IRB, or the regulatory authority. This documentation may include up-to-date curriculum vitae or other relevant documentation |  |  |
| 28 | The protocol or signed statement indicate that the PI is familiar with the appropriate use of the investigational product, as described in the protocol, in the current Researcher brochure, in the product information, and in other information sources provided by the Sponsor |  |  |
| 29 | The protocol or signed statement indicate that the PI will permit monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority |  |  |
| 30 | The protocol states that the PI will ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor |  |  |
| 31 | The protocol states that the PI will maintain the CT documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. |  |  |

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| 32 | The protocol states that essential documents are retained according to Emory Retention Policy. For more information, please access this link: [http://records.emory.edu/category/record-](http://records.emory.edu/category/record-category/university/research?page=1)  [category/university/research?page=1](http://records.emory.edu/category/record-category/university/research?page=1) |  |  |
| 33 | The protocol states that the PI maintains a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties |  |  |
| 34 | The protocol states that the PI will report all serious adverse events (SAEs) to the Sponsor except for those SAEs that the protocol or other document (e.g., Researcher’s brochure) identifies as not needing immediate reporting according to the Emory P&Ps. The Researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB per policy |  |  |
| 35 | The protocol states that the PI will report adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the Sponsor according to the reporting requirements and within the time periods specified by the Sponsor in the protocol. |  |  |
| 36 | The protocol states that the PI will supply the sponsor and IRB with any additional requested information in case of the death of a study participant. The documents may include autopsy or terminal medical reports. |  |  |
| 37 | The protocol states that the PI will provide written reports to the sponsor, the IRB, and, where applicable, the organization (e.g. OSP or OCR) on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants |  |  |
| 38 | The protocol states that, if the PI terminates or suspends a clinical trial without prior agreement of the sponsor, the PI will inform the organization (including OSP and OCR), sponsor, and the IRB |  |  |
| 39 | The protocol states that the PI will inform the sponsor if the IRB terminates or suspends approval of the clinical trial |  |  |
| 40 | The protocol states that, upon completion of the clinical trial, the PI will create a summary of the trial’s outcome. The PI will send the summary to the organization (OSP and OCR), the IRB, and the regulatory authority, in addition to any additional required reports. |  |  |
| 41 | The protocol states that GMP is being followed during the Manufacturing, handling, and storage of the investigational product |  |  |