**Good Clinical Practice Investigator Checklist**

(ICH Guidelines for Investigators – E6 (R2) dated 9 November 2016)

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| GCP 4.1 | Investigator’s Qualifications and Agreements | Yes | No | N/A |
| 4.1.1 | Investigator is qualified by education/training/experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulation(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authority(ies). |  |  |  |
| 4.1.2 | The Investigator is thoroughly familiar with the appropriate use of the IP as described in the protocol, in the current IB, in the product information, and in other sources provided by the sponsor. |  |  |  |
| 4.1.3 | The Investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements. |  |  |  |
| 4.1.4 | The Investigator/Institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities. |  |  |  |
| 4.1.5 | The Investigator should maintain a list of appropriately qualified person to whom the investigator has delegated significant trial-related duties. |  |  |  |
| **Suggestions to ensure compliance with this principle include**: maintain updated licenses/certifications; PI signs and dates the protocol and IB signature pages; certification of GCP course completion for **all** trial staff including the PI; maintain a delegation of duties/authority log as well as training logs; development of a written plan describing the PIs supervision and involvement during the course of the trial. | | | | |

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| GCP 4.2 | Adequate Resources | Yes | No | N/A |
| 4.2.1 | The Investigator should be able to demonstrate (e.g. based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. |  |  |  |
| 4.2.2 | The Investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period. |  |  |  |
| 4.2.3 | The Investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely. |  |  |  |
| 4.2.4 | The Investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the IP and their trial-related duties and functions. |  |  |  |
| 4.2.5 | The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site. |  |  |  |
| 4.2.6 | If the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated. |  |  |  |
| **Suggestions to ensure compliance with this principle include:** completion of site qualification questionnaire; regularly scheduled meetings between PI and trial staff inclusive of meeting minutes; develop and maintain training logs; see suggestion for 4.1 regarding development of PI supervisory plan; perform quality control review of the data. | | | | |

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| GCP 4.3 | Medical Care of Trial Subjects | Yes | No | N/A |
| 4.3.1 | A qualified physician (or dentist, when appropriate), who is an Investigator or a Subinvestigator for the trial, should be responsible for all trial-related medical (or dental) decisions. |  |  |  |
| 4.3.2 | During and following a subject’s participation in a trial, the Investigator/Institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The Investigator/Institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware. |  |  |  |
| 4.3.3 | It is recommended that the Investigator inform the subject’s primary physician about the subject’s participation in the trials if the subject has a primary physician and if the subject agrees to the primary physician being informed. |  |  |  |
| 4.3.4 | Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the Investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject’s rights. |  |  |  |
| **Suggestions to ensure compliance with this principle include:** the Investigator or Subinvestigator (physician or dentist where applicable) signs off on the enrollment criteria (e.g. Inclusion/Exclusion checklist); qualified investigator determines the clinical significance for results of abnormal test(s) or procedure(s) and advises on follow up needed (if applicable) in a timely manner – this information should be documented in trial records; documentation in the trial record communications with the trial subject when medical care is needed; documentation in the trial record of communications between trial staff and trial subject’s primary care provider if applicable; inclusion of language in the informed consent document indicating a copy of the IC document will be included in the subject’s medical record. In the event a subject withdraws from the trial; documentation of the reason why the subject withdrew, if subject agrees to provide, as well as documentation of attempts to contact subjects who may be lost to follow up. It is suggested the final attempt to contact the subject should be a certified, return receipt requested letter asking the subject to contact the trial staff. A copy of the letter and receipt should be included in the trial subject’s file. | | | | |

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| GCP 4.4 | Communication with the IRB | Yes | No | N/A |
| 4.4.1 | Before initiating a trial, the Investigator/Institution should have written and dated approval/favorable opinion from the IRB for the trial protocol, written informed consent, consent form updates, subject recruitment procedures (e.g. advertisements), and any other written information to be provided to subjects. |  |  |  |
| 4.4.2 | As part of the Investigator’s/Institution’s written application to the IRB, the Investigator/Institution should provide the IRB with a current copy of the Investigator’s Brochure. If the Investigator’s Brochure is updated during the trial, the Investigator/Institution should supply a copy of the updated Investigator’s Brochure to the IRB. |  |  |  |
| 4.4.3 | During the trial the Investigator/Institution should provide to the IRB all documents subject to review. |  |  |  |
| **Suggestions to ensure compliance with this principle include:** ensure all IRB correspondence and approval letters contain documents submitted; consent form updates should have a method of documenting versions; documentation of types of documents submitted to the IRB (protocol, amendments, IB, consent forms, recruitment material, etc). See OHRE SOPs 701, 1001 | | | | |

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| GCP 4.5 | Compliance with Protocol | Yes | No | N/A |
| 4.5.1 | The Investigator/Institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and which was given approval/favorable opinion by the IRB. The Investigator/Institution and the sponsor should sign the protocol, or an alternative contract, to confirm their agreement. |  |  |  |
| 4.5.2 | The Investigator should not implement any deviation from, or changes of, the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the changes(s) involves only logistical or administrative aspects of the trial (e.g. change of monitor(s), change of telephone number(s)). |  |  |  |
| 4.5.3 | The Investigator, or person designated by the Investigator, should document and explain any deviation from the approved protocol. |  |  |  |
| 4.5.4 | The Investigator may implement a deviation from, or a change in, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, an if appropriate, the proposed protocol amendment(s) should be submitted to: a) the IRB for review and approval/favorable opinion; b) the sponsor for agreement and, if required; c) the regulatory authority(ies). |  |  |  |
| **Suggestions to ensure compliance with this principle include:** documentation of the Investigator’s and sponsor’s signature on the protocol and subsequent amendments to the protocol signature pages; documentation of any deviations from the protocol to the sponsor and the IRB. See OHRE SOPs 1401 and 1402. | | | | |

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| GCP 4.6 | Investigational Product(s)  (IP) | Yes | No | N/A |
| 4.6.1 | Responsibility for IP(s) accountability at the trial site(s) rests with the Investigator/Institution. |  |  |  |
| 4.6.2 | Where allowed/required, the Investigator/Institution may/should assign some or all of the Investigator’s/Institution’s duties for IP(s) at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the Investigator/Institution. |  |  |  |
| 4.6.3 | The Investigator/Institution and/or a pharmacist or other appropriate individual, who is designated by the Investigator, should maintain records of the product’s delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the IP(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all IP(s) received by the sponsor. |  |  |  |
| 4.6.4 | The IP(s) should be stored as specified by the sponsor (see ICH GCP sections 5.13.2 and 5.14.3) and in accordance with the applicable regulatory requirement(s). |  |  |  |
| 4.6.5 | The Investigator should ensure that the IP(s) are used only in accordance with the approved protocol |  |  |  |
| 4.6.6 | The Investigator, or a person designated by the Investigator/Institution, should explain the correct use of the IP(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly. |  |  |  |
| **Suggestions to ensure compliance with this principle include:** a) for investigational drugs: submission of a request for services to Investigational Drug Services (IDS)and submission of the IDS approval with the IRB application. IDS will take delivery of the IP and will provide accountability logs for the receipt of and dispensing the IP to trial subjects and return to sponsor (if applicable) [for sites that are not on the main UNC Healthcare campus – arrangements should be made with IDS prior to dispensing IP]; IDS will develop an order set for IP based on the protocol for dispensing upon the authority of PI; b) for devices: an accountability log of the receipt and distribution to trial subjects and return (if applicable) to the sponsor. Additional suggestions include: obtaining IDS’s information on storage of IP; development of an SOP on transport of IP from IDS to a research site that is not located on the main campus of UNC Healthcare; development of an SOP on the storage and dispensing of IP (drug) if off campus; development of temperature logs to document required temperatures are maintained and SOPs to address temperature excursions; documentation in the trial record of discussions regarding the correct use of the IP with the trial subject. See OHRE SOPs 1301 and Pharmacy Policy - Investigational Drug Service: General Description PHARM 0619. | | | | |

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| GCP 4.7 | Randomization Procedures and Unblinding | Yes | No | N/A |
| The Investigator should follow the trial’s randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, **the Investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the IP(s).** | |  |  |  |

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| GCP 4.8 | Informed Consent of Trial Subjects | Yes | No | N/A |
| 4.8.1 | In obtaining and documenting informed consent, the Investigator should comply with the applicable regulatory requirement(s), and should adhere to CGP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the Investigator should have the IRB’s written approval/favorable opinion of the written informed consent form and any other written information to be provided to subjects. |  |  |  |
| 4.8.2 | The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject’s consent. Any revised written informed consent form, and written information should receive the IRB’s approval/favorable opinion in advance of use. The subject or the subject’s legally authorized representative should be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to continue participation in the trial. The communication of this information should be documented. |  |  |  |
| 4.8.3 | Neither the Investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial. |  |  |  |
| 4.8.4 | None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject’s legally acceptable representative to waive or to appear to waive any legal rights, or that releases the Investigator, the Institution, or the sponsor, or their agents from liability for negligence. |  |  |  |
| 4.8.5 | The Investigator, or person designated by the Investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject’s legally acceptable representative, of all pertinent aspects of the trial including the written information given approval/favorable opinion by the IRB. |  |  |  |
| 4.8.6 | The language used in the oral and written information about the trial, including the written informed consent form, should be as nontechnical as practical and should be understandable to the subject or the subject’s legally acceptable representative and the impartial witness, where applicable. |  |  |  |
| 4.8.7 | Before informed consent may be obtained, the Investigator, or a person designated by the Investigator, should provide the subject or the subject’s legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject’s legally acceptable representative. |  |  |  |
| 4.8.8 | Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative, and by the person who conducted the informed consent discussion. |  |  |  |
| 4.8.9 | If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects is read and explained to the subject or the subject’s legally acceptable representative, and after the subject or the subject’s legally acceptable representative has orally consented to the subject’s participation in the trial, and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject’s legally acceptable representative, and that informed consent was freely given by the subject or the subject’s legally acceptable representative. |  |  |  |
| 4.8.10 | Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following: a) that the trial involves research; b) the purpose of the trial; c) the trial treatments(s) and the probability for random assignment to each treatment; d) the trial procedures to be followed, including all invasive procedures; e) the subject’s responsibilities; f) those aspects of the trial that are experimental; g) the reasonably foreseeable risks or inconveniences to the subject and when applicable, to an embryo, fetus, or nursing infant; h) the reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this; i) the alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks; j) the compensation and/or treatment available to the subject in the event of trial-related injury; k) the anticipated prorated payment, if any, to the subject for participating in the trial; l) the anticipated expenses, if any to the subject for participating in the trial; m) that the subject’s participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled; n) that the monitor(s), the auditor(s), the IRB, and the regulatory authority(ies) will be granted direct access to the subject’s original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject’s legally acceptable representative is authorizing such access; o) that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws, and/or regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential; p) that the subject or the subject’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject’s willingness to continue participation in the trial; q) the person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury; r) the foreseeable circumstances and/or reasons under which the subject’s participation in the trial may be terminated; s) the expected duration of the subject’s participation in the trial; t) the approximate number of subjects involved in the trial. |  |  |  |
| 4.8.11 | Prior to participation in the trial, the subject or the subject’s legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject’s participation in the trial, the subject or the subject’s legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects. |  |  |  |
| 4.8.12 | When a clinical trial (therapeutic or nontherapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject’s legally acceptable representative (e.g., minors, or patients with severe dementia), the subjects should be informed about the trial to the extent compatible with the subject’s understanding and, if capable, the subject should assent, sign and personally date the written informed consent. |  |  |  |
| 4.8.13 | Except as described in 4.8.14, a nontherapeutic trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written informed consent form. |  |  |  |
| 4.8.14 | Nontherapeutic trials may be conducted in subjects with the consent of a legally acceptable representative provided the following conditions are fulfilled: a) the objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally; b) the foreseeable risks to the subjects are low; c) the negative impact on the subject’s well-being is minimized and low; d) the trial is not prohibited by law; e) the approval/favorable opinion of the IRB is expressly sought on the inclusion of such subjects, and the written approval/favorable opinion covers this aspect. |  |  |  |
| 4.8.15 | In emergency situations, when prior consent of the subject is not possible, the consent of the subject’s legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject’s legally acceptable representative is not available, enrollment of the subject should require measures described in the protocol and/or elsewhere, with the rights, safety, and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject’s legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see section 4.8.10) should be requested. |  |  |  |
| **Suggestions to ensure compliance with this principle include**: use of UNC OHRE approved template for the informed consent (the approved template includes all of the required elements listed in 45 CFR 46 and 21 CFR 56); if using an outside/central IRB, ensure all elements required in the consent document are included; documentation of the informed consent process used when obtaining consent to participate in the trial. See OHRE SOPs 1101, 1201, 1301, 4501, 4601 | | | | |

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| GCP 4.9 | Records and Reports | Yes | No | N/A |
| 4.9.0 | The investigator/institution should maintain 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 source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., *via* an audit trail). |  |  |  |
| 4.9.1 | The Investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports. |  |  |  |
| 4.9.2 | Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained. |  |  |  |
| 4.9.3 | Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trial should be maintained); this applies to both written and electronic changes or corrections (see section 5.18.4(n)). Sponsors should provide guidance to investigators and/or the Investigators’ designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor’s designated representatives are documented, are necessary, and are endorsed by the Investigator. The investigator should retain records of the changes and corrections. |  |  |  |
| 4.9.4 | The Investigator/Institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see section 8.) and as required by the applicable regulatory requirement(s). The Investigator/Institution should take measures to prevent accidental or premature destruction of these documents. |  |  |  |
| 4.9.5 | Essential documents should be retained until at least 2 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 2 years have elapsed since the formal discontinuation of clinical development of the IP. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the Investigator/Institution as to when these documents no longer need to be retained (see section 5.5.12). |  |  |  |
| 4.9.6 | The financial aspects of the trial should be documented in an agreement between the sponsor and the Investigator/Institution. |  |  |  |
| 4.9.7 | Upon request of the monitor, auditor, IRB, or regulatory authority, the Investigator/Institution should make available for direct access all requested trial-related records. |  |  |  |
| **Suggestions to ensure compliance with this principle include**: review/document data elements on the case report form with the sponsor; review Good Documentation Practices/ALCOA requirements (attributable, legible, contemporaneous, original, accurate); when a correction is made to a CFR, ensure the reason is either self-evident (e.g. BP in source document is 120/70; CRF is 130/70 – correction is self-evident to reflect source) **OR** there is documentation as to the reason for the correction; review ICH GCP E6 Section 8 for list of essential documents; at the trial close out visit, document who is the responsible party (name/contact information) for notification regarding trial records; maintain records of where trial documents are stored. | | | | |

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| GCP 4.10 | Progress Reports | Yes | No | N/A |
| 4.10.1 | Where required by the applicable regulatory requirements, the Investigator should submit written summaries of the trial’s status to the Institution. The Investigator/Institution should submit written summaries of the status of the trial to the IRB annually, or more frequently, if requested by the IRB. |  |  |  |
| 4.10.2 | The Investigator should promptly provide written reports to the sponsor, the IRB (see section 3.3.8), and where required by the applicable regulatory requirements, the Institution on any changes significantly affecting the conduct of the trial, and/or increasing risk to subjects. |  |  |  |
| **Suggestions to ensure compliance with this principle include**: submit and maintain any reports on the progress of the trial to the IRB and/or sponsor if applicable (e.g. DSMB/DMC reports, IND Safety Reports); establish a mechanism for documentation of PI review of said documents. | | | | |

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| GCP 4.11 | Safety Reporting | Yes | No | N/A |
| 4.11.1 | All serious adverse events (SAEs) should be reported immediately 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 immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects’ names, personal identification numbers, and/or addresses. The investigator should also comply with the with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB. |  |  |  |
| 4.11.2 | Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol. |  |  |  |
| 4.11.3 | For reported deaths, the Investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports. |  |  |  |
| **Suggestions to ensure compliance with this principle include**: review the protocol for sponsor SAE reporting requirements; review OHRE SOP 1401 for reporting requirements to the IRB. | | | | |

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| GCP 4.12 | Premature Termination or Suspension of a Trial | Yes | No | N/A |
| If the trial is terminated prematurely or suspended for any reason, the Investigator/Institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition: | | | | |
| 4.12.1 | If the Investigator terminates or suspends a trial without prior agreement of the sponsor, the Investigator should inform the Institution, where required by the applicable regulatory requirements, and the Investigator/Institution should promptly inform the sponsor and the IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension. |  |  |  |
| 4.12.2 | If the sponsor terminates or suspends a trial (see section 5.21), the Investigator should promptly inform the Institution, where required by the applicable regulatory requirements, and the Investigator/Institution should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension. |  |  |  |
| 4.12.3 | If the IRB terminates or suspends its approval/favorable opinion of a trial (see sections 3.1.2 and 3.3.9), the Investigator should inform the Institution, where required by the applicable regulatory requirements, and the Investigator/Institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension. |  |  |  |
| **Suggestions to ensure compliance with this principle include**: document notification of trial subjects regarding termination of the trial; document follow up with trial subjects to determine any appropriate therapy required for treatment if applicable; review OHRE SOP 401, 801, 1401, 1402, 1501, 2001, 2401 for reporting requirements to the IRB and other agencies. | | | | |

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| GCP 4.13 | Final Report(s) by Investigator/Institution | Yes | No | N/A |
| Upon completion of the trial, the Investigator should, where required by the applicable regulatory requirements, inform the Institution, and the Investigator/Institution should provide the sponsor with all required reports, the IRB with a summary of the trial’s outcome, and the regulatory authority(ies) with any report(s) they require of the Investigator/Institution. | |  |  |  |
| **Suggestions to ensure compliance with this principle include**: review OHRE SOP 701; provide sponsor with IRB termination notice if applicable. | | | | |