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| Required Collaborative Institutional Training Institute (CITI) Training  | Completed  |
| **Minimum Required CITI Training** * Individuals involved in research are required to complete:
	+ Responsible Conduct of Research
	+ Conflict of Interest (required if externally funded or meet other criteria)
	+ Human Subject Protections
	+ Good Clinical Practice (required if engaged in the conduct, oversight, or management of clinical trials)
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders** * Completion of required CITI training is necessary to gain access to PittPRO.
* Additional research training requirements can be found at <https://www.orp.pitt.edu/training/training-table-list>.
* All investigators and research team members who are engaged in the conduct, oversight, or management of clinical trials (as defined by the NIH) are required to complete the CITI GCP training course, regardless of funding, before participating in any research activities.
	+ There are two GCP training courses available: GCP for Clinical Trials Involving FDA regulated research and GCP for Clinical Trials Involving Behavioral or non-FDA regulated research.
	+ Additional information on GCP training requirements (Human Research Protection (HRP) Policies and Procedures, Chapter 22) can be found at <https://www.irb.pitt.edu/policies-and-procedures/chapter-22-education-and-training>.
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| Approvals/Reviews/Acknowledgements  | Completed  |
| **IRB Approval** * Obtain IRB approval (i.e., protocol, consent document, etc.).
 | [ ] Yes [ ]  No  |
| **Helpful Tips and Reminders*** IRB approval must be obtained prior to the performance of research activities.
* PittPRO will automatically forward submissions to required ancillary reviews (i.e., scientific review, Radioactive Drug Research Committee/Human Use Subcommittee (RDRC/HUSC), Institutional Biosafety Committee (IBC), IND and IDS Support (IIS), Data Security).
	+ Additional information on required ancillary reviews can be found at <https://www.hrpo.pitt.edu/policies-and-procedures/required-ancillary-reviews>
* A modification to the PittPRO study application must receive prospective IRB approval prior to implementing the change(s) unless necessary to eliminate apparent immediate hazards to the subject. In this case, the changes may be implemented, and the modification submitted as soon as possible. A Reportable New Information (RNI) is also required.
* Submit continuing reviews to the IRB in a timely manner to ensure that there is no lapse in approval, as applicable.
* During a lapse of IRB approval, all activities must stop including data analysis.
* All questionnaires, interviews, and survey instruments (except for SCID or KSADS) must be uploaded in the PittPRO study application and approved by the IRB.
* When collecting information directly from a potential subject, prior to obtaining written informed consent, a screening script must be uploaded to the PittPRO study application (i.e., telephone screening script, screening questionnaire).
* Studies that are submitted by a student are required to have a designated faculty mentor who is responsible for providing oversight and guidance.
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| **Other Reviews/Approvals*** Obtain required agency approvals/acknowledgment requirements, as applicable (i.e., FDA, DoD, NIH, NIMH, etc.)
 | [ ] Yes [ ]  No [ ]  NA |
| ClinicalTrials.gov  | Completed  |
| **ClinicalTrials.gov Registration*** Register the study on ClinicalTrials.gov, if required.
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
* Questions regarding ClinicalTrials.gov should be directed to the Information Disclosure Administrator at CTgov@pitt.edu
* Registration, record maintenance and results submission requirements can be found at <https://www.ecshsr.pitt.edu/ct/registration>
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| Study-specific Training  | Completed  |
| **Study-specific Training*** Conduct study specific training for study team members (i.e., protocol, informed consent procedures, Adverse Event (AE), Serious Adverse Event (SAE) reporting procedures, case report forms (CRFs)/data entry, maintenance of source documents, laboratory processing/shipping, Standard Operating Procedures (SOP), etc.).
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** The Principal Investigator (PI) is responsible for ensuring that all members of the research team are appropriately trained prior to engaging in the performance of study procedures.
* If new research staff is added to the study, there should be documentation indicating that study-specific training was completed prior to engaging in the performance of study procedures.
* If there are significant changes made to the PittPRO study application, protocol or consent document, members of the study team should be notified of the changes and asked to confirm their review of updated documents. Written confirmation of review should be maintained with the regulatory documents.
* If a slide presentation is emailed to members of the research team for training purposes, an email from each person confirming review of slides should be maintained with the regulatory documents.
* Documentation of study-specific training should be maintained with the regulatory records.
* A training log template can be found at <https://www.ecshsr.pitt.edu/sites/default/files/training_log_11.12.20.docx>
* [Research Investigator Start-up Education (RISE)](https://www.ecshsr.pitt.edu/monitoring-compliance/rise-reviews) reviews can be requested by emailing ECS-HSR@pitt.edu
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| **Delegation of Study-specific Tasks** * Study-specific tasks can be delegated, by the PI, to qualified members of the study team. Although tasks may be delegated, the PI is ultimately responsible for the overall conduct of the study.
 | [ ] Yes [ ]  No [ ]  NA |
| **Emergency Training** * Verify research study staff have completed required emergency training, as applicable (e.g., CPR, crisis training).
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** A signature and delegation of authority log should be used to track study team members and the study-specific tasks that have been delegated to them by the PI (e.g., obtaining consent, assessing eligibility, assessing AEs, completing CRFs/data entry, etc.).
* A signature and delegation of authority log template can be found at <https://www.ecshsr.pitt.edu/sites/default/files/signatureanddelegationofauthoritylog_11.12.20.docx>
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| Child Clearances | Completed  |
| **Child Clearances*** Verify that research staff members, who have a significant likelihood of interaction with children, have obtained the necessary child clearances.
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** It is the responsibility of the PI to ensure that the research team, including faculty, have these clearances prior to any interaction with children.
* Interaction refers not only to face-to-face meetings, but also extends to communication via phone (including text messaging), social media or internet.
* The following three clearances are required by Pennsylvania law and/or UPMC and University of Pittsburgh policies:
	+ Pennsylvania Department of Public Welfare Child Abuse Clearance History
	+ Pennsylvania State Police Criminal Record Check
	+ FBI Criminal Background Check
* If interactions with children occur outside of the Commonwealth of Pennsylvania, it is the responsibility of the PI to obtain the appropriate clearances in compliance with requirements set by the host state or country.
* Additional information can be found at <https://www.hrpo.pitt.edu/child-clearances>
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| Regulatory Documents | Completed  |
| **Regulatory Documents*** Develop and maintain regulatory documents essential to the conduct of the study.
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** The following list has examples of regulatory documents that should be maintained, if applicable, in accordance with good clinical practice:
	+ IRB approved documents and correspondence,
	+ Signature and delegation of authority log,
	+ Research staff training records,
	+ Research staff qualifications (e.g., curriculum vitae, professional licenses),
	+ Data safety and monitoring meeting minutes/letters,
	+ Laboratory certification, permit, and normal ranges,
	+ Drug/device accountability record,
	+ Specimen tracking log,
	+ Screening, enrollment, and randomization logs, and
	+ Case report form templates.
* Regulatory documents may be maintained in electronic and/or hard copy format.
* For hard copy documents it is recommended that each section of the regulatory binder is labeled (e.g., IRB correspondence, protocol training, etc.) and that documents are stored in reverse chronological order, which means the newest document within a section is filed in the front of the section.
* For electronic regulatory documents, a memorandum with the document/folder name should be filed in the relevant section of the regulatory binder and should provide the location of the documents (i.e., electronic storage pathway).
* In lieu of maintaining a separate regulatory file for each study, the non-study specific portions of the regulatory file (e.g., curriculum vitae, professional licenses, laboratory certifications, etc.) may be kept in a central file to avoid duplication of effort. A memorandum should be placed in the regulatory binder identifying the location of these centrally filed documents.
* The University of Pittsburgh Guideline: Study Documentation for FDA Regulated Research and Clinical Trials and additional documentation templates can be found at <https://www.ecshsr.pitt.edu/monitoring-compliance/good-clinical-practice-gcp-toolbox>
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| Reporting Responsibilities/Reportable New Information  | Completed  |
| **IRB Reporting Requirements*** The University of Pittsburgh IRB reporting responsibilities of the Investigator should be reviewed: HRP Policy and Procedure on Reportable New Information (RNI), Chapter 17 <https://www.irb.pitt.edu/content/chapter-17-reportable-new-information>.
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** Allison Gerger, RN, MPH, CIP, Regulatory Affairs Specialist, is a resource for any reporting questions (412-383-1981 or amg131@pitt.edu).
* Investigators may have additional reporting obligations as specified by the study sponsor or oversight agency.
* Noncompliance/Deviation Log:
	+ The IRB requires that a noncompliance/deviation log be maintained for greater than minimal risk studies, studies that meet the federal definition of a “clinical trial”, and studies for which reporting is required by the funding agency. For all other studies, the IRB recommends maintaining a noncompliance/deviation log.
	+ Non-compliance/deviation logs are not required to be submitted to the IRB at the time of continuing review but must be available upon request.
	+ The noncompliance/deviation log should be reviewed regularly to determine whether there is a pattern of noncompliance requiring a protocol change, revised corrective action plan, or submission of an RNI for continuing noncompliance.
	+ A non-compliance/deviation log template can be found at <https://www.irb.pitt.edu/sites/default/files/deviationu_pitt_log_version_2_22_19_0.docx>
* Adverse Event Log:
	+ The IRB requires that sponsor-investigators of an IND or IDE maintain a log of adverse events.
	+ Maintenance of an adverse event log is a best research practice for all clinical investigators.
	+ A qualified investigator should assess each adverse event for severity and causality to study intervention and document this review by recording initials and date next to the entry.
	+ Adverse events should be assessed in a timely manner.
	+ The research record should include documentation of follow-up actions taken to address adverse events.
	+ An adverse event log template can be found at <https://www.ecshsr.pitt.edu/sites/default/files/aelog_11.12.20.docx>
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| Informed Consent Process/Documentation  | Completed  |
| **Informed Consent** * Review the Consent Process section of the PittPRO study application and develop methods to facilitate and document the informed consent process.
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders** * Informed consent must be obtained prior to the initiation of research procedures unless a waiver of consent is appropriately justified and approved by the IRB.
* The approved informed consent process as described in the PittPRO study application must be followed.
* For studies involving a drug, device or surgical procedure, state law requires the PI or a co-investigator, who is a licensed physician investigator, obtain informed consent, unless an IRB exception to this requirement has been granted.
* The HRP requirements for conducting the informed consent process and the final process of obtaining written informed consent can be found at <https://www.irb.pitt.edu/policies-and-procedures/obtaining-consent>.
* The IRB approved consent document cannot be altered from its approved state without submission and approval of a modification.
* The consent document should be reviewed for completeness before engaging in study procedures (e.g., printed names, signatures, correct dates, times).
* If study procedures are initiated on the same day that consent is obtained, the research record should demonstrate that consent was obtained prior to the initiation of study procedures.
* If the consent will be placed in the medical record, the time the consent was signed must be included on the document regardless of whether there is a space for that information.
* All pages of the original signed consent document should be maintained in a secure location.
* Printing the consent document from PittPRO at the time a participant is approached to provide informed consent ensures that the current IRB approved version will be utilized.
* A copy of the consent document should be provided to the participant.
* Documentation of the completion of the consent process is required for FDA-regulated research. For all other studies, it is recommended that a narrative note documenting the completion of the consent process be included in the research record.
* An informed consent process narrative note template can be found at <https://www.ecshsr.pitt.edu/sites/default/files/informedconsentprocessdocumentation_11.12.20.docx>
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| Source Documentation  | Completed  |
| **Source Documents*** Develop source documents
 | [ ] Yes [ ]  No [ ]  NA |
| Helpful Tips and Reminders* Source documents are the original recording of any observations made or data generated about a subject during participation in a clinical trial (e.g., UPMC or other hospital medical records, EKG tracing, biopsy report, laboratory report, etc.). These documents serve to substantiate the integrity of the study data, confirm the recorded observations, and confirm the existence of the subjects. Source documents should be maintained in the research record.
* The International Conference on Harmonisation (ICH), GCP defines a CRF as, “A printed, optical, or electronic document designed to record all of the protocol required information [e.g., study data] to be reported to the sponsor on each trial subject.” There must be source documentation to substantiate all data recorded on the CRFs.
* CRFs may be used as source documents if they represent data collected for the study and are where the data were initially recorded. An example of data initially recorded on the CRF may include verbal responses from the subject.
* Case report forms used as source documentation:
	+ CRFs should include a place to document the subject identifier, visit date and include a place for the individual(s) completing the form to record their signature and the date.
	+ Source documents cannot be discarded or shredded (even after data has been entered into a database).
* Computer records used as source documentation:
	+ When data is entered directly into a computer system, the electronic data in the computer system is the original source document (e.g., REDCap, Qualtrics, etc.). A printout or print screen of the electronic data is a copy, and not the original source document.
	+ Access to computer records should be limited to members of the study team.
	+ Data should be stored in a manner that is consistent with the PittPRO study application and the informed consent document (e.g., de-identified, etc.).
* Eligibility checklists should be developed to capture each criterion described in the protocol. Source documentation to substantiate the presence and absence of the protocol’s inclusion and exclusion criteria must be present in the research record.
* An eligibility checklist template can be found at <https://www.ecshsr.pitt.edu/sites/default/files/eligibilitychecklist_11.12.20.docx>
* Additional subject file documentation templates can be found at <https://www.ecshsr.pitt.edu/monitoring-compliance/good-clinical-practice-gcp-toolbox>
* The following documentation standards should be applied to the research records:
	+ Research records should be maintained for each subject.
	+ The records should include the signed consent document as well as information relevant to the subject’s condition during their study participation.
	+ Keep handwritten notes and signatures legible. If necessary, the individual’s name may be printed underneath the signature.
	+ Make error corrections by 1) drawing a single line through the incorrect information, 2) initialing, dating, and stating a reason for the change (if necessary), and 3) inserting the correction. If the change is obvious, i.e., a transcription error that can be verified with the original source, then a rationale for the change is not required. If the change is not obvious, i.e., a diagnosis or symptom that was deleted after initial entry, then there should be a rationale for the change.
	+ Entries that require correction should never be obliterated (e.g., white out should never be used).
	+ Entries should be made using dark ink (e.g., never use pencil).
	+ Never destroy original documents, even if they require error correction or if they are entered into an electronic database.
	+ Research records must be securely stored when not in use by the research staff, such as a locked file cabinet within a locked office, or locked office inside a clinic that is locked when not in use.
	+ All entries should be signed and dated in real time.
	+ A new entry should be added if additional information is required to clarify past-dated notes (e.g., do not alter past dated notes, chart notes/progress notes, etc.).
* The University of Pittsburgh Guideline: Study Documentation for FDA Regulated Research and Clinical Trials and additional documentation templates can be found at <https://www.ecshsr.pitt.edu/monitoring-compliance/good-clinical-practice-gcp-toolbox>
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| Data Security and Data Retention  | Completed  |
| **Data Security** * The Electronic Data Management section of the PittPRO study application should be reviewed to ensure that procedures are in place to comply with the information provided.
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** Communications with the participant by email or text message must be outlined in the consent document and in the Electronic Data Management section of the PittPRO study application.
* For additional information, please refer to Electronic Data Security Guidance at <http://www.hrpo.pitt.edu/electronic-data-security>
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| **Data Retention*** Review the University of Pittsburgh data retention guidelines, which can be found in Section 3, Item d of the Guidelines for the Responsible Conduct of Research. <http://rcco.pitt.edu/sites/default/files/Guidelines.ResponsibleConductOfResearch.pdf>
 | [ ] Yes [ ]  No [ ]  NA |
| **Helpful Tips and Reminders*** Data should be stored securely for at least seven years after completion of the project, submission of the final report to a sponsoring agency, or publication of the research, whichever comes last.
* Some agencies that sponsor research may specify a longer period for which data must be retained.
* Investigators leaving the University should consult with the relevant administrator(s) for their school and department to plan the relocation. Additional information can be found at <https://www.orp.pitt.edu/resources/checklist-investigators-leaving-university>
* There are additional requirements for maintenance of pediatric records.
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| Ancillary Accounts  | Completed  |
| **Establish Ancillary Accounts** * Establish ancillary accounts such as Investigational Service (IDS), CTSI/CTRC, Vincent for participant payment, REDCap, etc.
 | [ ] Yes [ ]  No [ ]  NA |