SOP #: I-A-7

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

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**Standard Operating Procedure**

**Pre-Compliance Activity Interview**

**1. PURPOSE**

To define the procedures utilized to conduct a pre-compliance activity interview.

**2. SCOPE**

This procedure applies to RISE interviews, randomly selected audits, departmental QA and “for-cause” audits performed by the Education and Compliance Office for Human Subject Research (ECS-HSR) Divisoin.

**3. RESPONSIBILITIES**

The ECS-HSR Coordinators are responsible for preparing for and conducting an interview prior to the compliance activity.

**4. PROCEDURES**

4.1The interview will be held prior to the conduct of a compliance activity, if feasible, with a member or members of the respective research staff. This interview is performed to evaluate the plans to implement the conduct of the study and identify the individual(s) responsible for various protocol related activities, such as:

* + 1. Preparing IRB protocol submissions
    2. Training study staff
    3. Recruiting study participants
    4. Implementing and documenting the informed consent process
    5. Maintaining study documentation
    6. Monitoring data
    7. Reporting and logging of adverse events/Unanticipated Problems (UAPS)/Reportable New Information (RNI) and protocol deviations
    8. Collecting, preparing and storing biological samples
    9. Analyzing study data
  1. During the interview, information may also be obtained regarding:
     1. Number of subjects screened and enrolled into the study
     2. Number of sites involved, if the study is multi-center
     3. Review of reported adverse events/UAP/RNI – status and resolution
     4. Occurrence of site monitoring visit(s)
     5. Adherence to data and safety monitoring plans
     6. Difficulties in subject recruitment or in study conduct
     7. Maintenance and security of research data
  2. The pre-compliance activity interview is to be utilized as an opportunity to address questions surrounding protocol implementation and study conduct.

1. **REFERENCES/DOCUMENTATION**

Sample pre-compliance activity interview form.

Original: 8/1/01

Reviewed/Revised: 6/1/11

Reviewed: 10/5/12

Reviewed/Revised: 11/13/15

Reviewed/Revised: 10/16/19

Reviewed/Revised: 11/20/20

STUDY / RISE\_

STUDY / Mon\_xxx\_xxx RISE\_GCP Review Discussion Date:

Investigator: Mentor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Start date: \_\_\_\_\_\_\_\_\_\_ Number completed: \_\_\_\_\_\_\_\_\_\_

Number enrolled (signed consent): \_\_\_\_\_\_\_\_ Number screen fail/withdrawn: \_\_\_\_\_\_\_\_

IRB approved XX participants to undergo research procedures.

| **Procedure** | **Responsibility / Comment** |
| --- | --- |
| IRB Submissions | * Who prepares the IRB submissions? * Is there any collaboration with a mentor (if applicable) and/or other staff member(s)? |
| FDA Submissions | * Who prepares the FDA submission and submits to O3IS?   (If applicable) |
| Staff training | * Have all members of the research team completed the CITI GCP training? * What are the training requirements for this protocol? * Have all members of the study team been trained on the protocol (sub-I, research assistants, etc.)? * Where is documentation of this training maintained? * Have appropriate clearances been obtained by all persons who will have direct contact w/ minors? * Is any emergency training required for research team members, e.g. CPR, comprehensive crisis management (CCM) training? * Does the PI and research staff receive notifications from the IRB and ORP regarding research training opportunities?   Provide Delegation of Authority Log (DAL) template  REMINDERS   * Training documentation should be maintained with the regulatory records.   \* *Implementation meeting*: Protocol title, training date, trainer’s name, signature of attendees, content of training session  \* *Email slide presentation*: Email from each person confirming review of slides   * If new staff is added, there needs to be documentation that the new staff was trained prior to the performance of any study procedures. * Comprehensive Crisis Management (CCM) Training is required on an annual basis by the Department of Psychiatry for research staff working directly with behavioral health participants, as determined by PI. |
| Research Team Meetings | * Will there be regular meetings? * How/who will document the minutes of the meetings? * Where will the minutes be stored? |
| Data and Safety Monitoring Plan | Describe the data and safety monitoring plan associated with the study.   * How often will meetings occur? * Who will attend? * What will be discussed? * Who will record minutes?   (Provide template for DSMB meetings.) |
| **Subject Safety** | |
| Adverse Events | * What procedures do you have in place to evaluate and report Adverse Events? * Do you anticipate subjects experiencing adverse events in this study (provide template)? * Who will document adverse events? * Who will assess causality?   Provide Adverse Event Template.  Remind sponsor- investigators that this is a requirement. |
| Reportable Events | * What procedures do you have in place to evaluate and document protocol deviations and/or unanticipated problems? * Are you familiar with submitting reportable events in OSIRIS/PittPRO (IRB P&P, Chapter 17)?   <http://www.irb.pitt.edu/content/chapter-17-reportable-new-information>   * Who will be responsible for entering reportable events and/or reportable new information into OSIRIS/PittPRO? * What other entities (i.e. sponsor, DSMC, IRB) will be informed of reportable events?   Reminders-   * Noncompliance/ Deviation Logs are mandatory 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. * Noncompliance/ Deviation Logs are not required to be submitted at annual review but must be available upon request. * Noncompliance/ Deviation Logs are recommended but non-mandatory for all other studies. * Noncompliance/ Deviation Logs should be reviewed on an ongoing basis to determine if it is a pattern of noncompliance that requires a change in the protocol, a revised corrective action plan or continuing noncompliance reportable to the IRB. * Joe Madia (412-383-1529 or jvm15@pitt.edu) |
| Other Safety Issues | * What plans do you have in place to address incidental findings? * What procedures will you implement if you identify child abuse? * What plans do you have in place to address subjects who express suicidal/homicidal ideation or other concerning psychiatric symptoms?   Reminders:  Information about the ChildLine and Abuse Registry can be found [online](http://www.dhs.pa.gov/provider/childwelfareservices/childlineandabuseregistry/index.htm). The number for the ChildLine is 1-800-932-0313.  Those expressing suicidal or homicidal ideation should be referred to Psy ED (Psychiatric Emergency Department) |
| Subject Record Keeping | * How will/ are research findings documented?   Who maintains the paper research records (demographic info, survey, free lists, note cards)?   * Are there procedures in place to ensure the correct versions of data collection tools are utilized? * Where is the data stored? Is it secure? * Who has access to the data? * Who enters the data? * Who is authorized to make changes to the data? * Will subject records be labeled with a study ID # rather than names (check consent and IRB application)? * How long will the records be retained?   The Office of Academic Computing is available to those in the Department of Psychiatry to assist with database creation and management. |
| Regulatory Record Keeping | * Who maintains the regulatory documents (IRB approval letters, IRB approved consent forms, DSM minutes, DAL, training records, licenses, CVs etc.)? * Where? * Are they stored electronically or in paper format?   Provide sample regulatory records checklist |
| Data Security | * Can you confirm your intent to comply with the information described in the Electronic Data Management section of your protocol?   Reminders  Gmail accounts should not be used.  Communications with the subject by email or text messages must be outlined in the consent form and approved by the IRB.  Local departmental databases or spreadsheets containing SSNs that are available through local servers or PCs are not permitted.  Anyone using Social Media should consult with CTSI Social Media Manager  For additional information, please refer to Electronic Data Security Guidelines found on:  <http://www.hrpo.pitt.edu/guidance> |
| **Subject Recruitment** | |
| Phone or Medical Record Screening | Describe Methods for Subject Recruitment (Pitt + Me, Flyers, Other advertisements, Registry, Letters)  For phone screening prior to informed consent, ask:   * Who will administer the phone screen? * Will the approved phone screening script be used? * Will screening information be retained? If so what? * Are forms for ineligible subjects shredded? * Who will review the medical record?   (Above screening methods as applicable)  Ensure that the phone scripts are signed and dated by the individual who completes them.  If Screen failure scripts are to be discarded make sure there is no identifiable information retained.  Procedures should match IRB protocol. |

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| Informed Consent | * Who conducts the consent process? * How are staff trained to administer informed consent? * What is discussed during the consent process? * Does the study involve minors? If so, are one or both parents required to sign the consent document? * Is this a longitudinal study involving minors who may turn 18 during the course of the study? * How will you document the informed consent process (provide template)?   Informed Consent REMINDERS – all may not apply to this study   * An IRB approved consent document should not be altered from its approved state. * The consent document should be printed from PittPRO each time a subject is to be consented to ensure that the most recent IRB approved version is used to obtain written informed consent. * The consent document should be printed on department letterhead. * The consent document should be reviewed for completeness before engaging in study procedures (e.g., printed names, signatures, and correct dates and times). * All pages of the originally signed consent document should be maintained by the study team. * A copy of the consent document should be provided to the subject. * The research record should clearly indicate that a subject was consented prior to the performance of study procedures (e.g., consent is obtained on the same day study procedures start). * It is good clinical practice to document the consent process in the research record, which is a requirement for studies that fall under the jurisdiction of the FDA (template). * Any re-consent should follow the same process. |
| Screening procedures | * Where will the screening procedures be done? * Who will perform the screening procedures (list as outlined in the protocol and address responsible party for the various procedures)? * How will the information collected at the visit be documented? * Who will review results and how will the review be documented? * Will medically significant results be provided to the potential subjects?   If abnormal lab values are discovered will the subject be notified and will recommendation be made for them to follow-up with primary care physician?  Reminder:  If staff are performing urine drug screens or pregnancy tests, remind them to include lot #, expiration dates, results and the name of the person who administered the test. |
| Eligibility | * Will an eligibility checklist be used (provide template)? * Who will be responsible for developing the study specific eligibility checklist? * Does more than one person review eligibility? * Who will confirm subject eligibility? When?   *\*Sign and date checklist*   * The research record should contain documentation to substantiate each eligibility criterion. If the only method to verify a criterion is by questioning a subject, the research record should indicate that the criterion was verified by subject self-report. |
| Blood samples | (If applicable)   * Who will perform the blood draws? * Where will they be performed? * Who will evaluate results? * Will there be samples obtained for research purposes only?   (Reminder to note CS/NCS) |
| Randomization | (If applicable)   * How will randomization procedures be carried out? * What documentation will be available in the research chart? * Who has the unblinded information (for double blind medication studies) in case of emergency? |
| Study procedures | * Where will the study procedures be done? * Who will perform the study procedures (list as outlined in the protocol and address responsible party for various procedure)? * How will the procedures be documented? * Are there any measures in place to ensure procedures are done per current approved protocol? * Who will administer the study intervention? * Who will assess if the subject can receive the study intervention? * Who will review results of laboratory/physical assessments? * Will medically significant results be provided to the potential subjects? * How will the information collected at the visit be documented? (Medical history/physical exam) |
| Surveys / Assessments / Questionnaires | (If applicable)  List the instruments being used:  Ask the following questions as applicable:   * What plans/ procedures to you have in place to train staff on assessment administration? * What plans do you have in place to evaluate interrater reliability?     The following tips to maintain good research records involving the completion of surveys were provided:   * All surveys should be labeled with at least one unique identifier and include the date of completion. * Documentation should be present to indicate who completed the survey. * All questionnaires, interviews or survey instruments (except for SCID or KSADS) must be uploaded in OSIRIS 2.8 and approved by the IRB. * IRB approved questionnaires, interviews or survey instruments must not be altered from their approved state. * The instruments should be completed in their entirety unless approved otherwise by the IRB. |
| Study Product | (If applicable)  Will the study drug be stored and packaged by UPMC Investigational Drug Services?  Has a template order been developed for the study product?    Who will sign the physician order?  Drug will only be administered after an order has been sent to IDS. Once the drug is supplied to the study team by IDS, it will be provided to the subject.  How will study drug be dispensed to participants at multiple sites? eg –Study drug order should be personally signed and dated by the PI or sub-investigator.   * Drug compliance worksheet should provide name of person who collected the information.   Consider using a drug diary |
| Phone calls | (If applicable)   * Who will make the follow-up phone calls? * Document the phone calls in the research record. Document each attempt.   The phone call worksheet should provide the name of the staff person making the calls and if the attempts were successful or not. |
| Data Analysis | * Who will perform the data analysis? |

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| Clinicalttrials.gov | * Who will be responsible for updates to Clinicalttrials.gov? * Questions can be addressed to Patrick Fawcett, Information Disclosure Administrator, at [ctgov@pitt.edu](mailto:ctgov@pitt.edu) . |

Total Number to Undergo Research Procedures

* The IRB approve XXX subjects to be enrolled at the site. If additional subjects need to be enrolled, then a modification to increase enrollment will need to be submitted to the IRB.

Consent Document

* List any issues identified in the consent document.

OSIRIS/PittPRO Application

* List any issues/discrepancies identified in the OSIRIS/PittPRO application and/or attached protocol.

GCP Tips

* Use pen, not pencil.
* Draw a single line through an error (do not obliterate), correct the error, and initial/date the change. No white-out.
* All source documents should be labeled with at least one unique identifier.
* Maintain source documents, which are the original recordings of any observations made or data generated about a participant during his/her study participation. These documents serve to substantiate the integrity of the study data, confirm the recorded observations and confirm the existence of the participants.
* Document everything. If it was not documented, then it did not happen.