A Practical Guide on Applying USF HRPP P&Ps in the Clinical Setting

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Learning Objectives

• Recognize the value of establishing SOPs in the clinical research setting
• Identify methods to apply your SOPs in the clinical research setting
• Apply SOPs and HRPP policies and procedures to support site processes and decision making by referencing them throughout monitoring visit activities
SOP Development

- ICH defines Standard Operating Procedures (SOPs) as “detailed, written instructions to achieve uniformity of the performance of a specific function” (ICH GCP 1.55)
Types of SOPs

- Administrative SOPs
  - Contracting, budgeting, institutional review and approvals

- Financial SOPs
  - Research billing, sponsor invoicing and payments, participant stipends

- Clinical SOPs
  - Site visits, clinical study operations, study supplies, investigational product management, informed consent, confidentiality, regulatory docs
Why SOPs Are Important

• Assure process consistency
• Provide a set of guidelines by which the research should be governed for that site
• Assure that the research at the site is carried out according to all federal regulations, ICH GCP requirements, and institutional policies
• Supports the protection of human research participants
SOPs are Meant to Multitask

- Identify the person responsible for completion of each step in the process – as delegated by the PI
- Describe the action to be taken at each step in the process
- Used to train new staff
- Can, and should, be used to monitor the performance of the site
When to Reference Your SOPs

• Before the trial
  – Site selection visit, study start up

• During the trial
  – IRB approvals, participant interactions, investigational product accountability, monitoring visits, reporting requirements

• After the trial
  – Audits, financial reconciliation of study account, storage and retention of study records
How to Use Your SOPs

• Readily available to all study staff
  – Electronic: secure website, shared drive
  – Hardcopy: binder in research clinic

• Should be provided to monitors, sponsors and CROs when requested

• As long as they are consistent with federal regulations and institutional policies you can, and should, stand by your SOPs
How to Use Your SOPs: The Persistent Monitor

• Sponsors and CROs also have SOPs
• Misalignment between site SOPs and Sponsor SOPs can occur – even when both entities’ SOPs are consistent with federal regulations
• Monitors are not always right!
• Do not hesitate to defend your actions if they are consistent with your SOPs and policies & procedures
SOPs that are Frequently Challenged

- Informed Consent Process and Procedures
- Reporting Adverse Events and Unanticipated Problems Involving Risk to Human Subjects and Others
- Deviations in Human Subjects Research
- Recruitment and Advertising in Human Subjects Research
- Legally Authorized Representative in Human Subjects Research
- Human Subjects Research Involving Children: Enrolling Wards of the State
Informed Consent Process and Procedures

- HRPP Policy No. 601
- Short Form
- IC Process
- Witness is required when subjects or LAR is illiterate
- Children (an individual under 18 years of age whose disabilities have not been removed by marriage or an act of the court)
  - Parental permission is required
  - Adolescents age 12-17 years – written assent is required
  - Children age 7-11 – verbal assent is required
  - Young children under 7 years if age – use a verbal script to provide explanation to match their level of understanding
- Use your SOP to document how IC process is conducted and documented at your site
Reporting Adverse Events and Unanticipated Problems Involving Risk to Human Subjects and Others

- HRPP Policy No. 212
- IRB accepts for review:
  - Internal, research related events or problems that are
    - Serious adverse events
    - Unanticipated/unexpected adverse events
    - Unanticipated problems
  - Internal or external events or problems that
    - Require changing the protocol
    - Require changing the IC document
    - Result in an administrative hold
- Use your SOP to document the process to report adverse or unanticipated events at your site
Deviations in Human Subjects Research

- HRPP Policy No. 713
- Protocol deviation: any departure or inadvertent act in study activity from the currently approved protocol
  - Serious deviations affect subject safety, rights, welfare and/or data integrity
  - Non-serious deviations do not affect subject safety, rights, welfare and/or data integrity
- Protocol violations: intentional acts in which the IRB approved protocol is not followed
  - All violations are processed as deviations
Deviations in Human Subjects Research

- HRPP Policy No. 713, continued
- Submit serious protocol deviations to the IRB within 5 working days of knowledge of the event
  - when the deviation results in or has the potential to increase risk to subjects or decrease benefit
  - or has the potential to recur
- Non-serious deviations should be recorded on a protocol deviation log and submitted to IRB at continuing review or final report
- Use your SOP to document how and when you report deviations at your site
Recruitment and Advertising in Human Subjects Research

- HRPP Policy No. 708

- 6.4 Advertisements of clinical trials on the web do not require prior approval by IRB if the information is limited to the following basic study details:
  - Title
  - Purpose of the study
  - Protocol summary
  - Basic eligibility criteria
  - Study site location
  - Contact information

- Use your SOP to document how advertising on websites such as ClinicalTrials.gov, Florida Cancer Trials, Florida Clinical Trials, and USF Health Clinical Studies Online Database are managed at your site.
Legally Authorized Representatives in Human Subjects Research

• HRPP Policy No. 812
• An individual or judicial or other body authorized under applicable law (FL law) to consent on behalf of a prospective participant to the individual’s participation in the procedure(s) involved in the research
• In FL, for purposes of consent to human subjects research, a LAR is considered a surrogate or proxy
• PI must obtain documentation from participants’ attending physician, clinician, therapist or counselor, or an impartial 3rd party, that the individual is not capable of giving informed consent
• Use your SOP to document the application of the proxy hierarchy at your site
Human Subjects Research Involving Children: Enrolling Wards of the State

- HRPP Policy No. 306
- FL law allows a state agency or institution to serve as guardian of a child and the child is considered a “ward of the state”. USF HRPP defines a ward as a person for whom a guardian has been appointed.
- Children who are wards of the state can be included in research only if such research is
  - Related to their status as wards; or
  - Conducted in settings in which the majority of the children involved as subjects are not wards
  - If research is approved as above, the IRB requires the appointment of an advocate for each child who is a ward
Human Subjects Research Involving Children: Enrolling Wards of the State

- HRPP Policy No. 306, continued
- A guardian does not have authority to consent to a child’s participation in research under FL law unless that guardian has been granted that authority by the court for participation in a specific research project. When a child has been appointed a temporary guardian there must be procedures to obtain parental permission for the child to participate in research.
- Use your SOP to document the management of children as wards of the state at your site.
QUESTIONS
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