Introduction to the HRPP Toolkit

(August 2014)

YOUR BUSINESS | OUR SOLUTIONS

HRPP Toolkit Overview and Guiding Principles

- Fully compliant
- Minimal workload (e.g., documentation)
- No unnecessary extras
- Zero repetition
- Serve as a stand-alone AAMRRP application
- Business process oriented ("Joy of Cooling")
- Short and simple
- Usable by non
- Ready for automation

HRPP Toolkit

Changes for IRB
- Efficient workflow
- Quick turnaround time for review
- Application of the least restrictive level of review
- Investigator offered options to reduce review level
- More frequent use of waiver of documentation of consent
- Decisions are justified by regulatory criteria

Changes for Study Teams
- Simplified forms
- More flexibility in protocol description
- Relevant to all types of research (biomedical, clinical, translational, nursing)
- Investigator manual with concise complete description of investigator requirements
Revised, Investigator-Facing Documents

- Human Research Protection Program (HRPP) Plan
- Investigator Manual
- Application Forms
  - Initial
  - Continuing Review Progress Report
  - Modification
  - Reportable New Information Form
- Template Protocol
- Template Consent Document
- SOPs on consent process and documentation

Human Research Protection Program (HRPP) Plan

- High level policy regarding the conduct of human research at SUNY-B
- Describes the responsibilities of the components of the HRPP, including investigators, research staff, the IRB, and the Institutional Official

Investigator Manual

- Guides you through policies and procedures related to the conduct of Research that are specific to this organization
- General requirements for the conduct of research, such as:
  - Submission of a study
  - Writing protocol/consent documents
  - How to submit continuing review, modifications, other information
- Additional requirements for specific research:
Key Attributes of New Application Forms

- Designed with the input of investigators
- Clearly indicates what is needed
- Minimizes the information you have to enter:
  - Initial - 2 pages + 3 one page appendices when applicable
  - Continuing - 2 pages
  - Modification - 1 page
  - Reportable New Information - 1 page + list of reportable items
- Focus is on what the IRB must review to make a determination
- Most information is provided as uploaded documents

Reportable New Information Form

Use for reporting all new information
- Most important to report: New or changed risks
Page 2 lists everything that needs to be promptly reported
- If it is on the list, you have to report to the IRB in 5 days
- If it is not on the list, do not report
Requirements for adverse events greatly restricted to:
- Unexpected
- ARI
- Probably related
Post page 2 so all investigators and staff can reference.

Reportable New Information checklist: Information that needs to be reported within 5 days

1. Information that includes a new or increased risk, or a new safety issue
2. Harm experienced by a subject or other individual, which in the opinion of the investigator was unexpected and probably related to the research procedures
3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance
4. Failure to follow the protocol due to the action or inaction of the investigator or research staff
5. Incorrectly classified adverse event that was a prior event but was not reported to the IRB
6. Breach of confidentiality
7. Completion of a subject that cannot be rescheduled by the research team
8. Premature suspension or termination by the sponsor, investigator, or institution
9. Incarceration of a subject not in a study not approved by the IRB to involve prisoners
10. Audit, inspection, or inquiry by a Federal agency and any resulting reports (e.g., FDA Form 483)
11. Unanticipated adverse device effect
Template Protocol

- Guide to writing a protocol
- Asks for some information that may be in a sponsor protocol
  - Upload sponsor protocol and reference
  - Don’t copy and paste
- If something is not applicable, say so, skip, or delete
- Content is important, not format.
  - This is a guide that, if followed, reduces the likelihood of not submitting the right information.

Sample Language – Template Protocol

Template Consent

- Guide to writing a consent
- If something is not applicable, delete
- Content is important, not format.
  - This is a guide that, if followed, reduces the likelihood of not submitting the right information.
Sample Language – Template Consent

SOP on Consent Process

Questions/Concerns

- More information about the transition to the HRPP Toolkit will be communicated to you soon
- Please contact the IRB office with any questions or concerns.
Clients include:
- More than 95 of the top 100 research universities
- Nine of the top ten largest healthcare systems
  - ranked by Modern Healthcare
- Eight of the top ten largest Children's hospitals
- Many of the premier academic medical centers