UMN HRPP Toolkit Overview

UMN is in the process of implementing Huron’s HRPP Toolkit to support its HRPP and IRB operations. The HRPP Toolkit is a set of documents for use and reference primarily by IRB staff, IRB committee members and investigator, and to a lesser extent, by other HRPP components.

The HRPP Toolkit was designed with the following concepts in mind:
- Maximum regulatory flexibility consistent with compliant procedures;
- Easy to follow, non-redundant procedures;
- Focus on business process and IRB workflow; and
- Use of documents to support consistent IRB applications and reviews.

The basic components of the HRPP Toolkit consist of:
- **HRPP Plan**
  - Overview of HRPP components, scope, etc.
- **Investigator Manual**
  - Researcher facing
  - Since the UMN Investigator Manual is in the process of being created, the revised/new documents, HRP-110 - Policy - Capacity to Consent, HRP-111 - Policy - Involuntary Hold and UMN Investigator Guidance Vulnerable Participants, were created to address the immediate need per the “Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program” Work Plan
  - Will eventually incorporate investigator guidance documents and policies
- **Standard Operating Procedures (SOPs)**
  - Include policy statements
  - Organized by business process (e.g., pre-review, review, post-review) rather than by topic (e.g., continuing review, drugs, and protocol deviations)
  - Cross-reference worksheets and checklists to be used; does not duplicate information
- **Worksheets**
  - Regulatory decision making that does not need to be documented
  - Used in review to support decision making but does not need to be completed and kept in the regulatory file
  - Includes worksheets for topics such as payments, advertisements, vulnerable populations, etc.
  - Used by IRB staff and committee reviewers; accessible to researchers for reference
- **Checklists**
  - Regulatory decision making that must be documented
  - Need to be completed and kept in the regulatory file
  - Includes checklists for topics such as research with children (Subpart D), prisoners (Subpart C), cognitively impaired adults, etc.
  - Used by IRB staff and committee reviewers; accessible to researchers for reference
- **Template protocols and informed consent forms**
  - Researcher facing
  - Provides guidance in the templates for researchers to provide information the IRB needs to evaluate criteria for approval
- **Template letters/reminders**
  - Most are focused on researcher correspondence (e.g. approval letters)