HRPP Toolkit Overview & Investigator Manual
Agenda

1. Introductions
2. Toolkit Overview
3. Investigator Manual
1

Introductions
Huron Team Introductions

Tom Bechert
Senior Director
tbechert@hcg.com

Christina Moord
Manager
cmoord@hcg.com

David Platz
Senior Associate
dplatz@hcg.com

Project Director
CNE Primary Contact
Brown Primary Contact
Session Goals

• Understand the purpose of the HRPP Toolkit and its methodology
• Review core toolkit documents relative to your role as a researcher
• Become familiar with the Investigator Manual
Toolkit Overview
HRPP Toolkit Overview

What is the HRPP Toolkit?

- The HRPP Toolkit is a comprehensive set of workflows, Standard Operating Procedures, Checklists, Worksheets, Templates and other documents developed and maintained by Huron’s experienced IRB professionals.
- These documents are intended to be accessible to IRB staff, IRB members, and investigators in order to foster transparency throughout the review process.
- Based in the regulations and industry best practices.
- Implemented by numerous HRPPs of all sizes – both biomedical and social-behavioral.
- Serves as a stand-alone application for AAHRPP accreditation.
HRPP Toolkit Overview

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
• Use of documents to support consistent IRB applications and reviews
• Documents support the application of ethical principles
HRPP Toolkit Overview

Toolkit - Goals

Objectives:

- Increase efficiency
- Ensure compliance
- Decrease unnecessary administrative burden
- Become AAHRPP accredited or re-accredited
- Execute a unification of your HRPPs
- Reduce IRB scope creep
- Reduce research team administrative work
HRPP Toolkit Components

**SOPs (44)**
Examples: Intake, Pre-Review, Non-Committee Review, IRB Meeting Conduct, Investigations

**Worksheets (37)**
Examples: Exempt determination, Criteria for Approval

**Checklists (15)**
Examples: Pre-Review, Non-Committee Review, Children, Waiver of Consent Process

**Process Maps**
Intake Flow Chart
Non-Committee Flow Chart
Convened IRB Flow Chart

**Templates (63)**
Examples: Consent document, Protocol, Minutes, Approval letters

**Other Resources**
Examples: Investigator Manual, HRPP Plan
HRPP Toolkit Components

Standard Operating Procedures (SOPs)

- Organized by business process (e.g., pre-review, review, post-review) rather than by topic (e.g., continuing review, management of protocol deviations)

- SOPs specific to researchers:
  - HRP-013 – LARs, Children and Guardians
  - HRP-090 – Informed Consent Process for Research
  - HRP-091 – Written Documentation of Consent
HRPP Toolkit Components

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 expedited review eligibility, exemption determinations, payments, advertisements, etc.
- Used primarily by IRB staff and IRB members, but is made accessible to investigators/study teams
HRPP Toolkit Components

Checklists

- Regulatory decision making that must be documented
- Need to be completed and retained in the submission file
- Includes checklists for topics such as research with children (Subpart D); pregnant women, fetuses and neonates (Subpart B); adults with impaired decision-making capacity; etc.
- Used primarily by IRB staff and IRB members, but is made accessible to investigators/study teams

CHECKLIST: Waiver or Alteration of Consent Process

The purpose of this checklist is to provide support for IRB members and the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. This checklist must be used for all reviews (initial, continuing, modifications, review by the convened IRB, and review using the expedited procedure).

- For initial review using the expected procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity, and retains this checklist in the protocol file.

Use a separate checklist for each waiver or alteration determination for a study.

Submission Information

<table>
<thead>
<tr>
<th>Basic Information</th>
<th>Submission Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Number</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Study Title</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Short Title</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Investigator</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Person Completing</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Checklist (Name)</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Date Completed</td>
<td>Click or tap here to enter text.</td>
</tr>
</tbody>
</table>

The research must meet one of the following four sets of criteria:

1. Waiver or Alteration of Consent Process (Check if "Yes," All must be checked)
   - [ ] The research is NOT FDA-regulated.
   - [ ] The research does NOT involve non-viable neonates.
   - [ ] The research involves no more than Minimal Risk to the subjects.

Page 1 of 5
HRPP Toolkit – Core Documents

HRP-101 – Human Research Protection Program Plan

- Program purpose and scope
- Key terms
- Ethical, legal and other requirements
- Responsible parties
- IRB authority and reliance
- Research community standards
- Reporting of concerns
- Monitoring and disciplinary actions
HRPP Toolkit – Core Documents

Protocol Templates

- HRP-503 – TEMPLATE PROTOCOL
- HRP-503a – TEMPLATE SBS PROTOCOL
- HRP-508 – TEMPLATE SITE SUPPLEMENT

- Completed by Investigator and submitted to the IRB
- Some sections are not applicable to certain types of research
- Instructions are provided for completing each section of the templates
HRPP Toolkit – Core Documents

Consent Templates

• HRP-502 – TEMPLATE CONSENT DOCUMENT
• HRP-506 – TEMPLATE CONSENT DOCUMENT – EXPANDED ACCESS
• HRP-507 – TEMPLATE CONSENT DOCUMENT – SHORT FORM

• Completed by Investigator and submitted to the IRB
• Incorporates required elements of consent
• Used for all human subject research studies that do not have a waiver of consent process or documentation

Permission to Take Part In a Human Research Study

[Insert title of research study here with protocol number, if applicable]

IRR Approval Date

Investigator: [Insert name of principal investigator]

Key Information: The following is a short summary of the study to help you decide whether or not to be a part of this study. More detailed information is listed below.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because

[Fill in the circumstances or condition that makes subjects eligible for the research]

What should I know about a research study?
• Someone will explain the research study to you.
• Whether or not you take part is up to you.
• You can choose not to take part.
• You can agree to take part and later change your mind.
• Your decision will not be held against you.
• You can ask all the questions you want before you decide.

Why is this research being done?
[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

How long will the research last and what will I need to do?
We expect that you will be in this research study for [hours/days/months/weeks/years, until a certain event].

You will be asked to [include a brief, clear summary of the procedures that will be done. For example, You will be given an investigational drug and asked to be seen to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]

More detailed information about the study procedures can be found under “What happens if I say yes, I want to be in this research?”

Is there any way being in this study could be bad for me?
[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social/behavioral research project or similar to the information that a physician might deliver in the clinical context of telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how these risks are changed by participating in the study]

More detailed information about the risks of this study can be found under “Is there any way being in this study could be bad for me? (Detailed Risks)”
HRPP Toolkit – Core Documents

HRP-103 – Investigator Manual

- A “How-To” manual for study teams
- Outlines researcher responsibilities for conducting research at Brown
- Identifies activities requiring IRB review

- Specifies qualification and training requirements
- Provides submission, protocol and consent guidance
- Identifies regulatory considerations: consent requirements, levels of review, criteria for approval
# HRPP Toolkit – Core Documents

## HRP-103 – Investigator Manual

### Table of Contents

Scope .................................................................................................................. 3
What is the purpose of this manual? ................................................................. 3
What is Human Research? ............................................................................ 3
What is the Human Research Protection Program? ...................................... 3
What training does my staff and I need to conduct Human Research? ......... 4
What financial interests do my staff and I need to disclose conduct Human Research? ................................................................. 4
How do I submit new Human Research to the IRB? ..................................... 5
How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use? ................................................................. 5
How do I request to rely on an external IRB? ................................................. 6
How do I request that this IRB serve as the IRB of record (sIRB) for my colla multisite research study? ......................................................... 6
How do I write an Investigator Protocol? ....................................................... 6
How do I create a consent document? ............................................................ 6
Do I need to obtain informed consent in order to screen, recruit, or determine prospective subjects? ............................................................ 6
What are the different regulatory classifications that research activities may fall into? .............................................................................. 7
What are the decisions the IRB can make when reviewing proposed research? .................................................................................. 7
How does the IRB decide whether to approve Human Research? .................. 8
What will happen after IRB review? ............................................................... 8
What are my obligations after IRB approval? ................................................ 8
What are my obligations as the overall study PI for an sIRB study? .............. 8
What are my obligations as investigator when relying on an external IRB? ... 9
How do I document consent? ...........
Next Steps

Researchers should now see all HRPP Toolkit documents in the IRB system.

Researchers are expected to begin using HRPP Toolkit documents this week. Effective July 1st, researchers must begin using the new protocol and consent templates.

Important Dates

- **Thursday, June 13th** – Protocol Templates and Vulnerable Populations
- **Monday, June 17th** – Protocol Templates and Vulnerable Populations
- **Thursday, June 27th** – Informed Consent
- **Monday, July 1st** – Reportable New Information
Questions?
Thank you!