

Investigator & Study Team AAHRPP Summary Prep Sheet

Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.

Note: The documents referenced below may be found at <http://www.umassmed.edu/ccts/irb/investigator-guidance/> (for HRP 800-816) and at <http://www.umassmed.edu/ccts/irb/policiesops--checklistsworksheets/sop> (for other checklists and worksheets). You may wish to familiarize yourself with the locations of these documents to be able to find them during the site visit and for future reference.

Element III.1.A. Researchers and Research Staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.

What to know:

- Understand which activities are overseen by the HRPP or seek guidance.
- Understand the definitions of what constitutes research involving human participants according to legal and regulatory definitions and the Organization's policies and procedures.
- Know how the process/who to contact to get an opinion on whether an activity is research involving human participants from the HRPP.

Materials:

- Review/be aware of **“INVESTIGATOR GUIDANCE (HRP-800)”** which Informs investigators to contact the IRB for any questions about whether an activity is research involving human subjects
- Review/be aware of **“Human Research (HRP-421)”** the worksheet used by the IRB/available for use by investigators to determine whether a project constitutes research involving human subjects, and is available to investigators as a resource and tool.

Element III.1.B. Researchers and Research Staff identify and disclose financial interests according to UMMS policies and regulatory requirements and, with UMMS, manage, minimize, or eliminate financial conflicts of interest.

What to know:

- Understand UMMS's financial conflict of interest policy, including: a) which interests UMMS requires to be disclosed and b) how, when, and to whom to disclose financial interests.
- Understand how financial conflicts of interest can influence the protection of research participants.
- Understand the need for investigators to work with UMMS collaboratively in the management of financial conflicts of interest.

Materials:

- Review/be aware of: **“SOP: Management of Financial Interests (HRP-120)”** found at <http://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/> which directs investigators to the University of Massachusetts Medical School Policy for Promoting Objectivity in Biomedical Research
- Review/be aware of **University of Massachusetts Medical School Policy for Promoting Objectivity in Biomedical Research**, found at <http://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/>, and the associated Procedure, **Policy on Conflicts of Interest Human Subjects Research Guidelines & Procedures** found at <https://www.umassp.edu/bot/policies> which together define which interests must be disclosed, along with how and when and to whom financial interests must be disclosed.

Element III.1.C. Researchers employ sound study design in accordance with the standards of the discipline. Researchers design studies in a manner that minimizes risks to participants.

What to know:

- Understand the need to design research studies so that the research will most likely develop or contribute to generalizable knowledge in accordance with standards and ethical practices of the discipline; or, if Researcher did not design a research study, evaluate the research design to judge it to be sound enough to meet the study's objectives before agreeing to enroll participants.
- Understand the concept of minimizing risks: Consider study designs that minimize risks, describe the rationale for the chosen procedures and provide a risk/potential benefit analysis of the research. Incorporate plans to monitor the data for the safety of participants when appropriate (e.g. when the research involves more than minimal risk). Consider when/time points and who will conduct monitoring (e.g. sponsor, another researcher, other third party)

Materials:

- Review/be aware of “**INVESTIGATOR GUIDANCE (HRP-800)**” which Informs investigators about the obligation to employ sound study design in accordance with the standards of their discipline and design studies in a manner that minimizes risks to participants
- Review/be aware of “**Criteria for Approval (HRP-400)**,” the tool used by the IRB to guide review of the study, including sound study design, and is available to investigators as a resource and tool.

Element III.1.D. Researchers determine that the resources necessary to protect participants are present before conducting each research study.

What to know:

- Understand the importance of adequate resources to conduct research in a way that will protect the rights and welfare of participants and ensure the integrity of the research. This includes: personnel, time, and access to a study population.
- Understand that research should not be initiated without adequate resources to protect participants, and research should be stopped if adequate resources become unavailable.

Materials:

- Review/be aware of: “**INVESTIGATOR GUIDANCE (HRP-800)**” which informs investigators about their obligation to ensure that there are adequate resources to carry out the research safely.

Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.

What to Know:

- Know to use fair and equitable recruitment practices in research and avoid practices that place participants at risk for coercion or undue influence.

Materials:

- Review/be aware of: “**WORKSHEET: Criteria for Approval (HRP-400)**”, “**WORKSHEET:** which is used by the IRB to evaluate the recruitment practices description in the Investigator Study Plan, and is available to investigators as a resource and tool.
- “**WORKSHEET: Advertisements (HRP-402)**” and “**WORKSHEET: Payments (HRP-403)**”, which is used by the IRB to guide review of the recruitment plan as described in the investigator study plan to ensure fairness and equitability, and is available to investigators as a resource and tool.

Element III.1.F. Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

What to know:

- Understand the concept of respect for persons and the obligation to obtain the consent of participants or their legally authorized representatives.
- Understand that consent is a continual process, and conduct the consent process in a way that meets the criteria for legally effective consent.
- Understand the difference between the consent process and documentation of the consent process.
- Know how to document the consent of a participant or a legally authorized representative.

Materials:

- Review/be aware of “**INVESTIGATOR GUIDANCE: Informed Consent (HRP-802)**” which Outlines the default requirements for informed consent
- Review/be aware of “**INVESTIGATOR GUIDANCE: Documentation of Informed Consent (HRP-803)**” which Outlines the default requirements for written documentation of informed consent
- Be aware of “**WORKSHEET: Criteria for Approval (HRP-400)**” which is used by the IRB to evaluate informed consent process description and documentation in the Investigator Study Plan and is available to investigators as a resource and tool.

Element III.1.G. Researchers and Research Staff have a process to address participants’ concerns, complaints, or requests for information.

What to know:

- Be open to participants’ complaints or requests for information and know how to respond appropriately to such complaints or questions
- Know how explain to research participants how to contact the Research Staff to ask questions about the research or express concerns or complaints about the research—this is typically, but not exclusively, accomplished through language in the consent document.

Materials:

- Be aware of “**WORKSHEET: Criteria for Approval (HRP-400)**” which is used by the IRB to verify that study consent documents include information on how to contact the investigator for questions, concerns, or complaints and is available to investigators as a resource and tool.
- Be aware of the **human research concerns portal** available at <http://www.umassmed.edu/ccts/human-research/complaint-form/>

Standard III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the Organization’s policies and procedures for protecting research participants; and the IRB’s or EC’s determinations.

Element III.2.A. Researchers and Research Staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the Organization’s policies and procedures regarding the protection of research participants.

What to know:

- Understand that Researchers and Research Staff should be qualified by training and experience for their roles and responsibilities in conducting research so that they follow the protocol and abide by the UMMS policies and procedures.
- Understand that Researchers and Research Staff should have the knowledge to follow laws, regulations, codes, and guidance such as those concerning IRB review, consent requirements, reporting requirements, maintenance of records, retention of records, and supervision of research conduct.
- Understand and apply relevant professional standards that are applicable to their research, when appropriate.

Materials:

- Review/be aware of: “**INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)**, which describes the organization’s training requirements for investigators and study team members, and informs investigators of information on additional requirements found in:
 - “**INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)**”

Element III.2.B. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities and functions.

What to know:

- Be aware that the principal investigator is ultimately responsible for the conduct of research.
- Be aware that although investigators may delegate certain responsibilities and functions of the research, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.
- Ensure that Research Staff who are delegated responsibilities and functions are trained and able to perform the function and assume the responsibility for the delegated function.

Materials:

- Review/be aware of: “**INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)**, which also informs investigators of additional information and requirements found in
 - “**INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)**” and “**WORKSHEET: Additional Criteria DOJ (HRP-406)**”
 - “**INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)**.”

Element III.2.C. Researchers and Research Staff follow the requirements of the research protocol or plan and adhere to the policies and procedures of the Organization and to the requirements or determinations of the IRB or EC.

What to know:

- Be aware of and follow legal and regulatory requirements and UMMS policies and procedures that pertain to the research, including adherence to the determinations and requirements of the IRB.
- Once a research study is approved by the IRB, Researchers and Research Staff should follow the research plan or protocol as approved by the IRB, and not implement changes until they are approved by the IRB.

Materials:

- Review/be aware of: “**INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)**, which informs investigators of additional information and requirements found in
 - “**INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)**” and “**WORKSHEET: Additional Criteria DOE (HRP-409)**”
 - “**INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-813)**” and “**WORKSHEET: Additional Criteria ED (HRP-407)**”

Element III.2.D. Researchers and Research Staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the Organization’s policies and procedures; and the IRB’s or EC’s requirements.

What to know:

- Understand the Organization’s reporting requirements and know the type of events to report for events related to their research (at UMMS, this is called Reportable New Information or RNI).

Materials:

- Review/be aware of **INVESTIGATOR GUIDANCE: Prompt Reporting Requirements (HRP-801)**
- Be aware of “**FORM: Promptly Reportable Information (HRP-204)**,” which is in eIRB and used to report RNIs
- For additional reporting requirements, review/be aware of: “**INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)**, which informs investigators of additional information and requirements found in
 - “**INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)**” ,
 - “**INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)**”
 - “**INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)**” and “**WORKSHEET: Additional Criteria DOJ (HRP-406)**” and
 - “**INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)**”

For Investigators/Study Teams conducting research with Investigational Drugs or Devices:

For Investigational Drugs:

What to know:

- All investigational drugs, whether stored in Investigational Drug Service (IDS) or not, must be received by IDS. See <http://www.umassmed.edu/ccts/human-research/researcher-resources/investigational-drug-service/>

Materials:

- Be aware of: “**TEMPLATE Protocol (HRP-504)**,” which requires investigators to describe their process to control investigational drugs.

- Review/be aware of: **“INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800),”** which informs investigators of basic obligations and makes investigators aware of additional information and requirements found in:
 - **“INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)”** includes these requirements
- Be aware of: **“WORKSHEET: Drugs (HRP-425),”** which is used by the IRB to evaluate research using investigational drugs and is available to investigators as a resource and tool
- Review/be aware of **“SOP: Emergency and Compassionate Uses (HRP-180)”** which informs investigators of associated obligations, and
- Be aware of: **“WORKSHEET: Emergency Use Drugs and Biologics (HRP-451)”** which is used by the IRB to evaluate Emergency use of Drugs and Biologics and is available to investigators as a resource and tool

For Investigational Devices:

What to know:

- Devices must be properly stored and managed in accordance with sponsor, institutional and clinical system requirements, procedures and guidelines.

Materials Review/be aware of information contained on <http://www.umassmed.edu/ccts/human-research/researcher-resources/investigational-devices/>

- Be aware of: **“TEMPLATE Protocol (HRP-504),”** which requires investigators to describe their process to control investigational devices (in line with: **Standard Operating Procedure for Investigational Devices (HRP-913) 2014 Medical Device Management plan (HRP-914) and Medical device Electrical Inspection Procedure 2011 (CE001)** all found at the researcher resources weblink, above).
- Review/be aware of: **“INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800),”** which informs investigators of basic obligations and makes investigators aware of additional information and requirements found in:
 - **“INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)”** includes these requirements
 - **“INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)”**
- Review/be aware of **“WORKSHEET: Devices (HRP-426)”** which is used by the IRB to evaluate research using investigational devices and is available to investigators as a resource and tool
- Review/be aware of **“SOP: Emergency and Compassionate Uses (HRP-180)”** which informs investigators of associated obligations, and
- Review/be aware of **“WORKSHEET: Emergency Use Devices (HRP-452)”** which is used by the IRB to evaluate emergency use of Investigational devices and is available to investigators as a resource and tool.