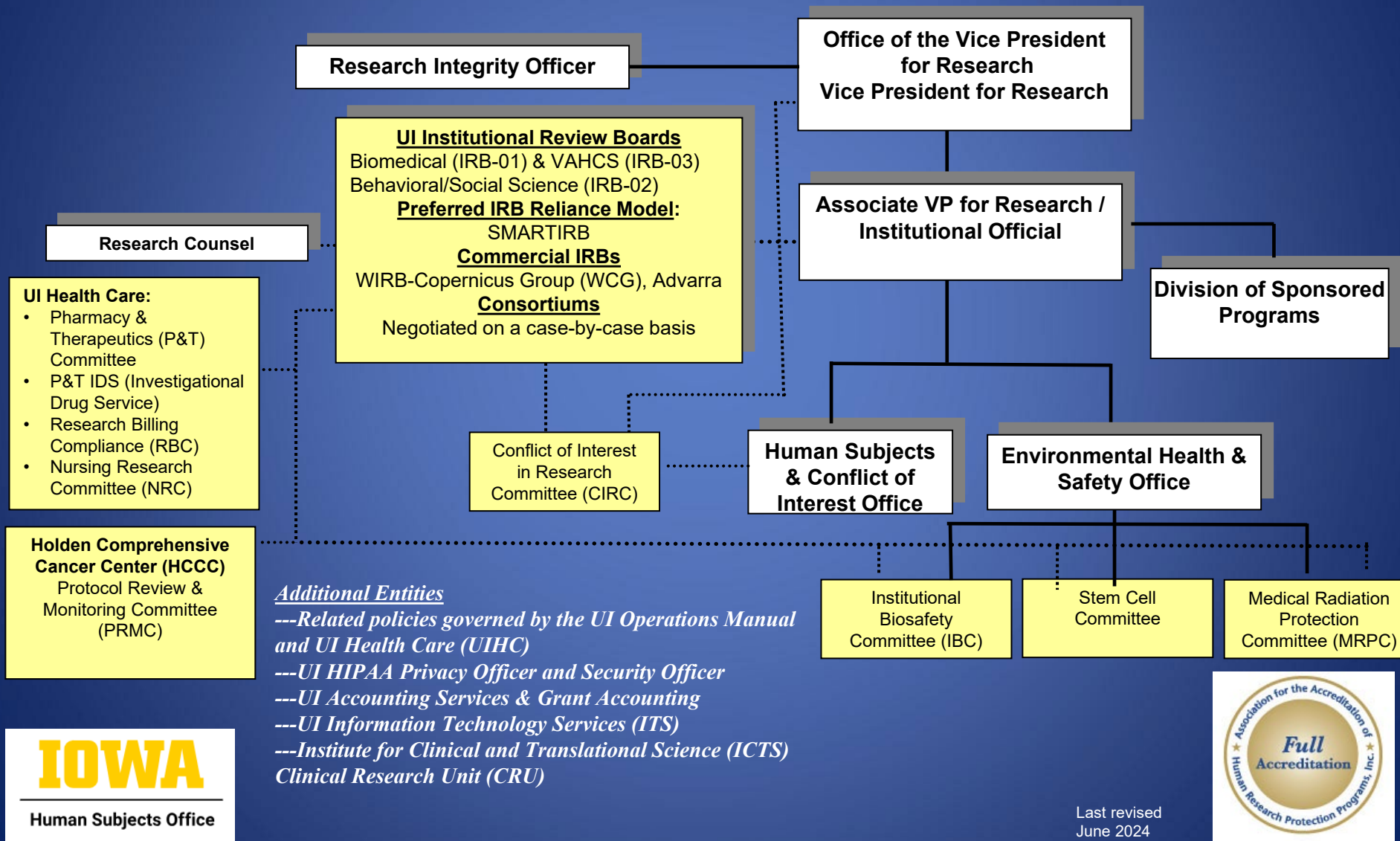


The University of Iowa Human Research Protection Program (HRPP)



Additional Entities
 ---Related policies governed by the UI Operations Manual and UI Health Care (UIHC)
 ---UI HIPAA Privacy Officer and Security Officer
 ---UI Accounting Services & Grant Accounting
 ---UI Information Technology Services (ITS)
 ---Institute for Clinical and Translational Science (ICTS)
 Clinical Research Unit (CRU)



Last revised
June 2024

OTHER APPROVAL REQUIREMENTS FOR HUMAN SUBJECTS RESEARCH

The University of Iowa IRB interacts with other committees in the Human Research Protection Program (HRPP) and other offices or entities that review research projects involving human subjects research. Many of them review information included in the HawkIRB application and attached documents. Others have a separate application form or process. **Use the dark boxes** in this chart to determine if you need approval from a particular committee, office or entity. **Click “Learn More”** to go to their web page. For most projects overseen by an external IRB, all approvals must be obtained from these other committees/entities prior to submission to the external IRB. Key to the color coding:

Concurrent with IRB review. Finalize before IRB releases application.	RBC, P&T, NRC, IBC, CT.gov, MRPC, P&T IDS, DSP
Review project <u>separately</u> from IRB review and approval process	CRU, Pathology
Review application <u>after</u> IRB approval	VAHCS

<p>Accounting Services</p> <p>Compensation for Subjects, Cash or Cash Equivalent</p> <p>Learn more</p>	<p>UIHC Research Billing Compliance (RBC)</p> <p>Research Involves Billable Services from UI Health Care</p> <p>Learn more</p>	<p>Pharmacy & Therapeutics Committee (P&T)</p> <p>Substance Injected, Ingested, or Applied</p> <p>Use of a Contrast Agent</p> <p>Learn more</p>	<p>Nursing Research Committee (NRC)</p> <p>Use of UI Health Care Nursing Resources</p> <p>Learn more</p>	<p>Institutional Biosafety Committee (IBC)</p> <p>Use of Recombinant DNA (rDNA)</p> <p>Learn more</p>	<p>Department of Pathology Services</p> <p>Using Pathology Services for Research Purposes</p> <p>Learn more</p>	<p>Clinical Research Unit (CRU)</p> <p>Using Clinical Research Unit Resources</p> <p>Learn more</p>
<p>Conflict of Interest in Research Committee (CIRC)</p> <p>PI or Team Member Has Financial Conflict of Interest</p> <p>Learn more</p>	<p>Protocol Review & Monitoring Committee (PRMC)</p> <p>Use of Patients or Resources from Holden Comprehensive Cancer Center</p> <p>Learn more</p>	<p>ClinicalTrials.gov (CT.gov)</p> <p>Meets Definition of Applicable Clinical Trial (ACT)</p> <p>Learn more</p>	<p>Medical Radiation Protection Committee (MRPC)</p> <p>Use of Diagnostic or Therapeutic Radiation</p> <p>Learn more</p>	<p>P&T Investigational Drug Service (P&T IDS)</p> <p>Use of Approved or Investigational Drugs</p> <p>Learn more</p>	<p>Division of Sponsored Programs (DSP)</p> <p>External Funding Source</p> <p>Research Related Agreements</p> <p>Learn more</p>	<p>Veterans Administration Health Care System (VAHCS)</p> <p>Use of Patients or Resources from VAHCS</p> <p>Learn more</p>

HRPP Committee Regulatory Mandates

CIRC: Conflict of Interest in Research Committee	• Public Health Service (PHS), Institutional Policy (Ch.18), & HRPP Accreditation
DSP: Division of Sponsored Programs	• Federal Acquisition Regulations, Department of Commerce, Federal Uniform Guidance, NIH, Institutional Policy (II-27, V-5, V.6,etc)
RBC: Research Billing Compliance	• The Centers for Medicare and Medicaid Services' Clinical Trial Policy
RBC/CMS: Research Billing Compliance for device trials only	• The Centers for Medicare and Medicaid Services' Clinical Trial Policy, Social Security Act (Section 1862(m)), HHS Regulations (42 CFR 405, Subpart B)
MRPC: Medical Radiation Protection Committee	• IDPH, Iowa Administrative Code, National Institute for Occupational Health & Safety, CDC, & UI\UIHC policies
PRMC: Holden Comprehensive Cancer Center Protocol Review and Monitoring Committee	• NCI (National Cancer Institute)
P&T: UIHC Pharmacy & Therapeutics	• Joint Commission, Medicare Pharmaceutical standards, & Iowa law on drug dispersing & storage
P&T IDS: Pharmacy & Therapeutics Investigational Drug Service	• Joint Commission, Medicare Pharmaceutical standards, & Iowa law on drug dispersing & storage
NRC: Nursing Research Committee	• UIHC Bylaws & American Nurses Magnet Accreditation
IBC: Institutional Biosafety Committee	• NIH, USDA, CDC, DHHS
VA Related Committees	• Veterans Health Administration