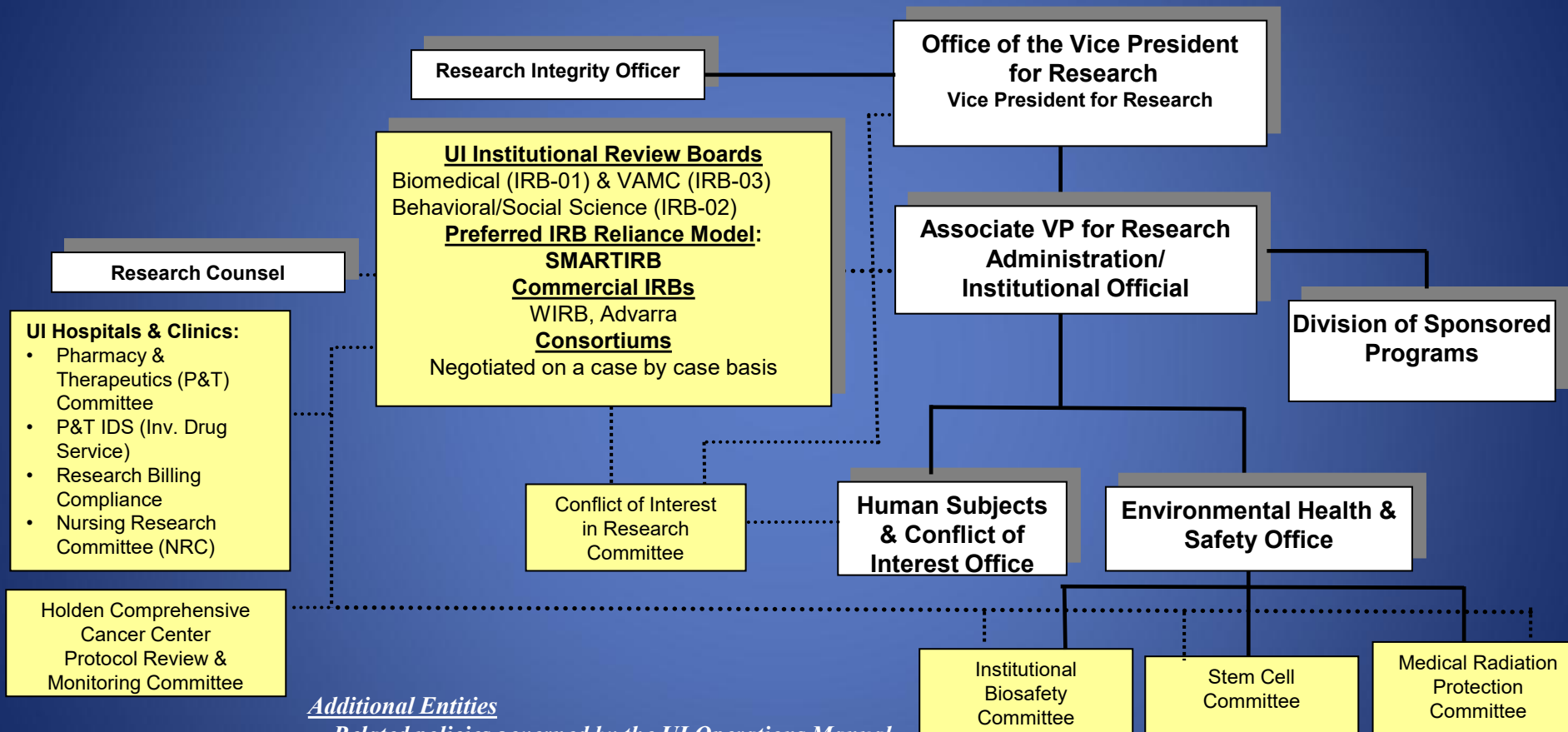


# The University of Iowa Human Research Protection Program (HRPP)



Additional Entities

---Related policies governed by the UI Operations Manual and UI Health Care

---UI HIPAA Privacy Officer and Security Officer

---UI Accounting Services & Grant Accounting

---UI Information Technology Services

---ICTS Clinical Research Unit



# 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 projects overseen by an external IRB, all approvals must be obtained from these other committees/entities prior to submission to the external IRB. Here is a key to the color coding:

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

<div style="background-color: #C8E6C9; padding: 10px; border-radius: 15px;"> <p>Accounting Services</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Compensation for Subjects, Cash or Cash Equivalent</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #C8E6C9; padding: 10px; border-radius: 15px;"> <p>UIHC Research Billing Compliance (RBC)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Research Involves Billable Services from UI Health Care</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>Pharmacy &amp; Therapeutics Committee (P&amp;T)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0; width: 80%;"> <p>Substance Injected, Ingested, or Applied</p> </div> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0; width: 80%;"> <p>Use of a Contrast Agent</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>Nursing Research Committee (NRC)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Use of UI Health Care Nursing Resources</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>Institutional Biosafety Committee (IBC)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Use of Recombinant DNA (rDNA)</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #F8BBD0; padding: 10px; border-radius: 15px;"> <p>Department of Pathology Services</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Using Pathology Services for Research Purposes</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #F8BBD0; padding: 10px; border-radius: 15px;"> <p>Clinical Research Unit (CRU)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Using Clinical Research Unit Resources</p> </div> <p><a href="#">Learn more</a></p> </div>
<div style="background-color: #C8E6C9; padding: 10px; border-radius: 15px;"> <p>Conflict of Interest in Research Committee (CIRC)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>PI or Team Member Has Financial Conflict of Interest</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #C8E6C9; padding: 10px; border-radius: 15px;"> <p>Protocol Review &amp; Monitoring Committee (PRMC)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Use of Patients or Resources from Holden Comprehensive Cancer Center (HCCC)</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>ClinicalTrials.gov (CT.gov)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Meets Definition of Applicable Clinical Trial (ACT)</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>Medical Radiation Protection Committee (MRPC)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Use of Diagnostic or Therapeutic Radiation</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>P&amp;T Investigational Drug Service (P&amp;T IDS)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Use of Approved or Investigational Drugs</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #E0F7FA; padding: 10px; border-radius: 15px;"> <p>Division of Sponsored Programs (DSP)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0; width: 80%;"> <p>External Funding Source</p> </div> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0; width: 80%;"> <p>Research Related Agreements</p> </div> <p><a href="#">Learn more</a></p> </div>	<div style="background-color: #B3E5FC; padding: 10px; border-radius: 15px;"> <p>Veterans Administration Health Care System (VAHCS)</p> <div style="background-color: #4F81BD; color: white; padding: 10px; border-radius: 15px; margin: 10px 0;"> <p>Use of Patients or Resources from VAHCS</p> </div> <p><a href="#">Learn more</a></p> </div>

# 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