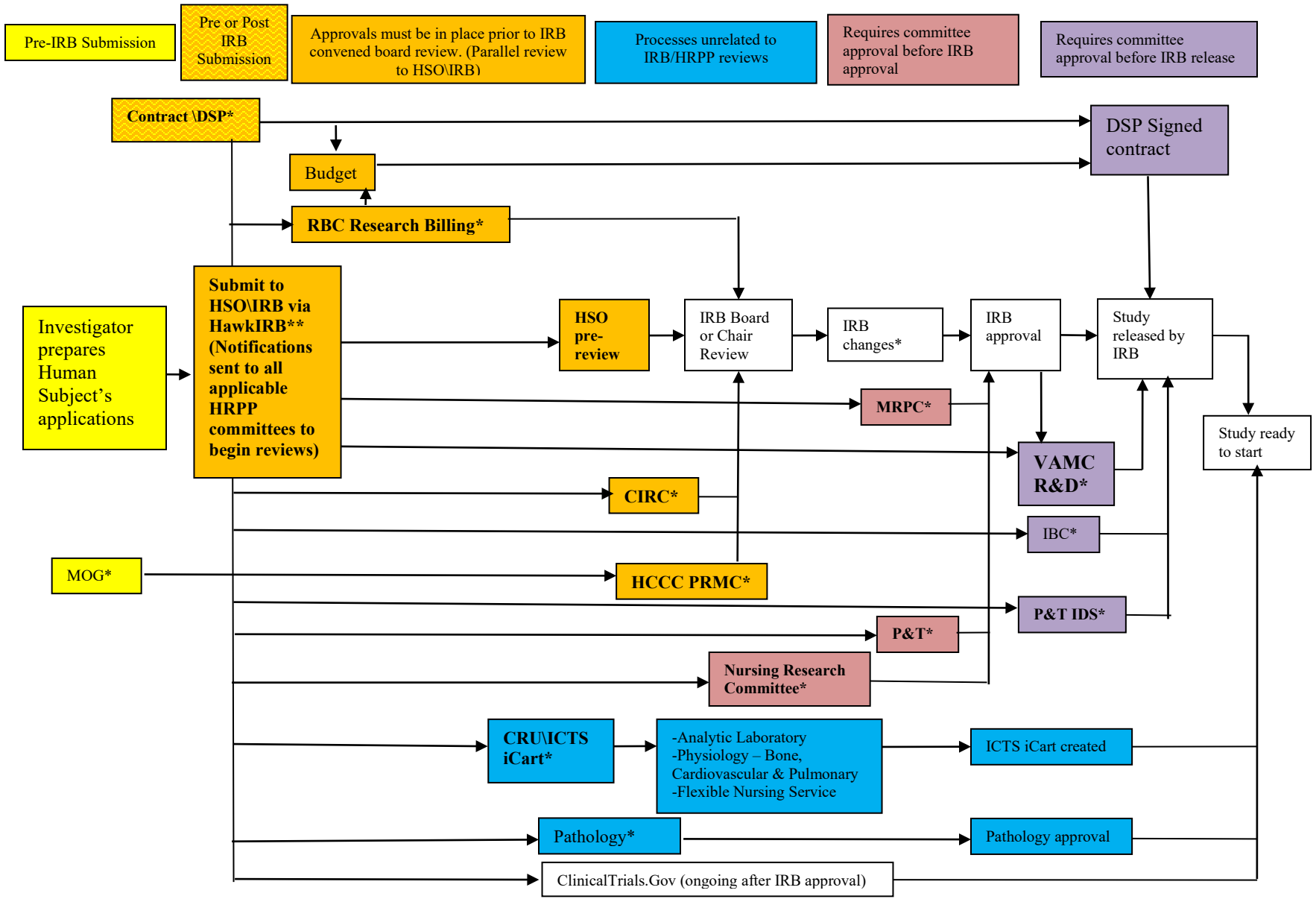
Human Subjects Research Review Process



* = these processes are only used if applicable to the specific study
** HawkIRB is the electronic research data source used either in full or in part by the above Human Research Protection Committees (denoted by **Bold** font).
***Original work revised and maintained with permission from Emily Avgenackis former ICTS Research Navigator and the ICTS

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RBC (Research Billing Compliance): HawkIRB sends automatic notices to the Research Billing Compliance office for studies involving any of the following activity at UI Health Care, *even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)*

- Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or
- Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)

RBC Billing uses the HawkIRB application, consent, and protocol as reference materials for their review. RBC Billing specific questions have been built into the HawkIRB application. RBC Billing approvals are uploaded and communicated from HawkIRB to the PI. Contact: Denise Krutzfeldt or (319) 384-9688.

DSP (Division of Sponsored Programs): If a study is supported by an external source, it must be reviewed by DSP. DSP requires a UI proposal routing form when a grant is submitted for government, foundation or voluntary health agency funding. DSP also negotiates contracts for industry-funded studies; to review industry-funded studies copies of the contract, protocol and budget, name, address and contact information for the corporate contact, and a UI proposal routing form are required. Contact information can be found here. HawkIRB sends automatic notices to DSP when a study has been submitted with either a federal or industry sponsored funding source. A signed contract must be executed before the IRB will release a study. The IRB does not require an approval from DSP for NIH funded studies. (Office for the Vice President of Research oversight) HawkIRB also generates Assurance documentation (via a 310 form) for all NIH funded projects. This documentation is sent from DSP to NIH and the PI.

IRB (Institutional Review Board): All research meeting the regulatory definition of human subjects research which is carried out by an individual with a University of Iowa faculty, staff, or student appointment must be reviewed by either one of the UI IRBs or any externally identified IRB. There are 3 internal UI IRB's: Biomedical (IRB 01), Social/Behavioral Science (IRB 02) and Veterans Affairs Medical Center (IRB 03). For studies reviewed by any IRB, fill out the HawkIRB application. Contact: irb@uiowa.edu or (319) 335-6564. (Office for the Vice President of Research oversight)

HSO (Human Subjects Office): The HSO is the administrative support office for the University of Iowa IRBs, externally identified IRBs, and the Human Research Protection Program. The HSO conducts pre review of all IRB applications to ensure they meet regulatory and institutional requirements in preparation for review by the Institutional Review Board &/or IRB Chairs. The HSO also completes all administrative reviews on external IRB requests, provides human subjects research related education, and conducts post approval compliance monitoring. Contact: irb@uiowa.edu or (319) 335-6564. (Office for the Vice President of Research oversight)

IBC (Institutional Biosafety Committee): HawkIRB sends automatic notices for all studies involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant(s). The IBC application (EHS rDNA Research Registration) must be filled out and submitted electronically through UIRIS. Contact: Nyree-Mortensen or (319) 353-5679. Approval from the IBC must be received by the Human Subjects Office (HSO)\IRB before the project can be released to the PI to begin the research. (Office for the Vice President of Research oversight)

MOG (Multidisciplinary Oncology Group): To ensure efficient use of Cancer Center resources for clinical trials, all protocols using any resources or patients from the Holden Comprehensive Cancer Center must be reviewed and approved by the appropriate MOG. Submit the MOG Clinical Trial Checklist to the

appropriate MOG leader or designee. Approval from the MOG must be received before final approval from the Protocol Review and Monitoring Committee can be granted. Contact: Cena Jones Bitterman or (319) 353-7846

HCCC PRMC (Holden Comprehensive Cancer Center Protocol Review and Monitoring Committee): HawkIRB sends automatic notices for all studies using any resources or patients from the HCCC. These studies require review and approval by the PRMC. Submit the PRMC Protocol Submission Packet by one of the methods outlined on page one of the packet. Approval from the PRMC must be received by the Human Subjects Office (HSO)\IRB before the project can be scheduled for review by the fully convened IRB. However, the HawkIRB application may be submitted before receiving approval from this committee. PRMC generally uses the HawkIRB application, consent, and protocol as reference materials for their review. Contact: Cena Jones Bitterman or (319) 353-7846

CIRC (Conflict of Interest in Research Committee): HawkIRB communicates directly with the eCOI system used by the Conflict of Interest in Research Office housed within the Human Subjects Office to determine if disclosed financial interests may be significant enough to affect conduct, design, reporting, or outcome of a human subjects research. Annual disclosure requirements are in place on an institutional level regardless of whether a financial conflict of interest exists. Approval from CIRC must be received by the Human Subjects Office (HSO) before the project can be scheduled for review by the fully convened IRB. However, the HawkIRB application may be submitted while the review from this committee is occurring so HSO pre-screen can be completed. Contact: Martha Hedberg or (319) 384-4256. (Office for the Vice President of Research oversight)

P&T (Pharmacy and Therapeutics Subcommittee): HawkIRB sends automatic notices for all studies involving approved or investigational drugs, and any other substance that is ingested, injected or applied to the body must be reviewed by the P&T Subcommittee. Necessary forms may include the Investigator-Dispensed Drug Study Form and the G12 Form. These forms can be included as part of the HawkIRB application in the P&T other committee review section. When a HawkIRB application is accepted into the pre-screen process, it automatically sends a notification to the P&T Subcommittee. Approval from this committee must be obtained before the IRB gives final approval. However, the HawkIRB application may be submitted to initiate this committee review, P&T IDS review, and allow HSO pre-screen to be completed. P&T uses the HawkIRB application, consent, and protocol as reference materials for their review. P&T specific questions have been built into the HawkIRB application. P&T Committee approvals are uploaded and communicated from HawkIRB to the PI. Contact: Ron Herman or (319) 356-1467.

IDS (Investigational Drug Service): In addition to the P&T review, HawkIRB sends automatic notices for all studies that involve inpatient medication or the use of investigational (i.e. not approved by the FDA) medications on outpatients. For activities occurring in UIHC, researchers must use the IDS to store, dispense, label, and distribute study medications. Necessary forms may include the Investigator-Dispensed Drug Study Form and the Investigational Drug Study Standard Charge Worksheet. P&T IDS uses the HawkIRB application, consent, and protocol as reference materials for their review. P&T IDS approvals are uploaded and communicated from HawkIRB to the PI. Approval must be received by the HSO\IRB before the project can be released to the PI to begin the research. Contacts: Kris Johnson or (319) 356-2577.

MRPC (Medical Radiation Protection Committee): HawkIRB sends automatic notices for all studies involving ionizing radiation, radioisotopes or lasers to alert MRPC their review is required. Before the MRPC can review a study the medical physicist dose consultant must be contacted to obtain dose calculations for the amount of radiation exposure each subject will get over the course of the study. Depending on the study, submit either the MRPC Short Form, MRPC Long Form – Diagnostic, MRPC Long Form – Therapeutic, or MRPC Laser Form; for more information on these forms go to the EHS Radiation Safety Forms or can be located on the MRPC Other Committee review page of HawkIRB. Approval from this committee must be obtained before the IRB gives final approval.

However, the HawkIRB application may be submitted to initiate this committee review and allow HSO pre-screen to be completed. MRPC uses the HawkIRB application, consent, and protocol as reference materials for their review. MRPC questions have been built directly into the HawkIRB application. MRPC approvals are uploaded and communicated from HawkIRB to the PI. Contacts: Gordon Axt or (319) 335-8501/Barbara Vitense or (319) 335-8501. (Office for the Vice President of Research oversight)

ICTS CRU and iCart (Institute for Clinical and Translational Science Clinical Research Unit): iCART is an service application to capture all CRU research services. Review by the ICTS CRU can be done concurrently with any process. It is outside the process of IRB/HRPP review, but approval must come from this committee before any of the ICTS CRU resources can be used in the study. Components of the ICTS CRU can be found here.

NRC (Nursing Research Committee): HawkIRB sends automatic notices for all studies using nursing, nursing resources or evaluates nursing practices. This includes studies that involve the participation of patients or nursing staff, procedures not normally part of the regular patient care or nursing activities of the unit or clinic and/or the development of instruments or procedures. The HawkIRB application prepopulates the Nursing Research Committee form. This form can be attached to the Nursing Research Committee section of the HawkIRB application. Approval from this committee must be obtained before the IRB gives final approval. However, the HawkIRB application may be submitted to initiate this committee review and allow HSO pre-screen can be completed. NRC uses the HawkIRB application, consent, and protocol as reference materials for their review. NRC questions have been built directly into the HawkIRB application. NRC approvals are uploaded and communicated from HawkIRB to the PI. Contact: Kirsten Hanrahan or (319) 384-7189.

VAMC (Veterans Affairs Medical Center): Research to be undertaken by or under the direction of the VAMC requires review and approval by both the IRB-03 and the VAMC Research and Development Committee. The IRB documents its approval on a VA form 10-1223 and sends it to the VA Research Office. The deliberations of the VAMC Research and Development (R&D) Committee are shared with the IRB in the form of a memo. If there are specific subject protection issues raised by the R&D Committee are addressed prior to IRB release. The VA uses the HawkIRB application, consent, and protocol as reference materials for their review. VA questions have been built directly into the HawkIRB application. VA approvals are uploaded and communicated from HawkIRB to the PI. Contact: Kari Points or (319) 335-0581 X7678

Department of Pathology: All studies involving testing utilizing the Department of Pathology services require prior approval by Pathology. Submit a Request for Research Testing form or the Research Application for Utilizing Pathology Services to the Pathology Research Coordinator or (319) 356-4149. Review of the Department of Pathology can be done concurrently with any process. It is outside the process of IRB/HRPP review, but approval must come from this committee before any Pathology resources can be used in the study.

Clinical Trials.gov registration requirements are handled by the Protocol Registration System (PRS) Administrator. The PRS Administrator assists researchers in ensuring they meet the regulatory requirements for registration of Clinical Trials. The HSO oversees this regulatory compliance aspect on behalf of the institution. Institutional review is concurrent with IRB review, however ongoing compliance interactions occur, post IRB approval. Contact: ct-gov@uiowa.edu or (319)335-6564 (Office for the Vice President of Research oversight)