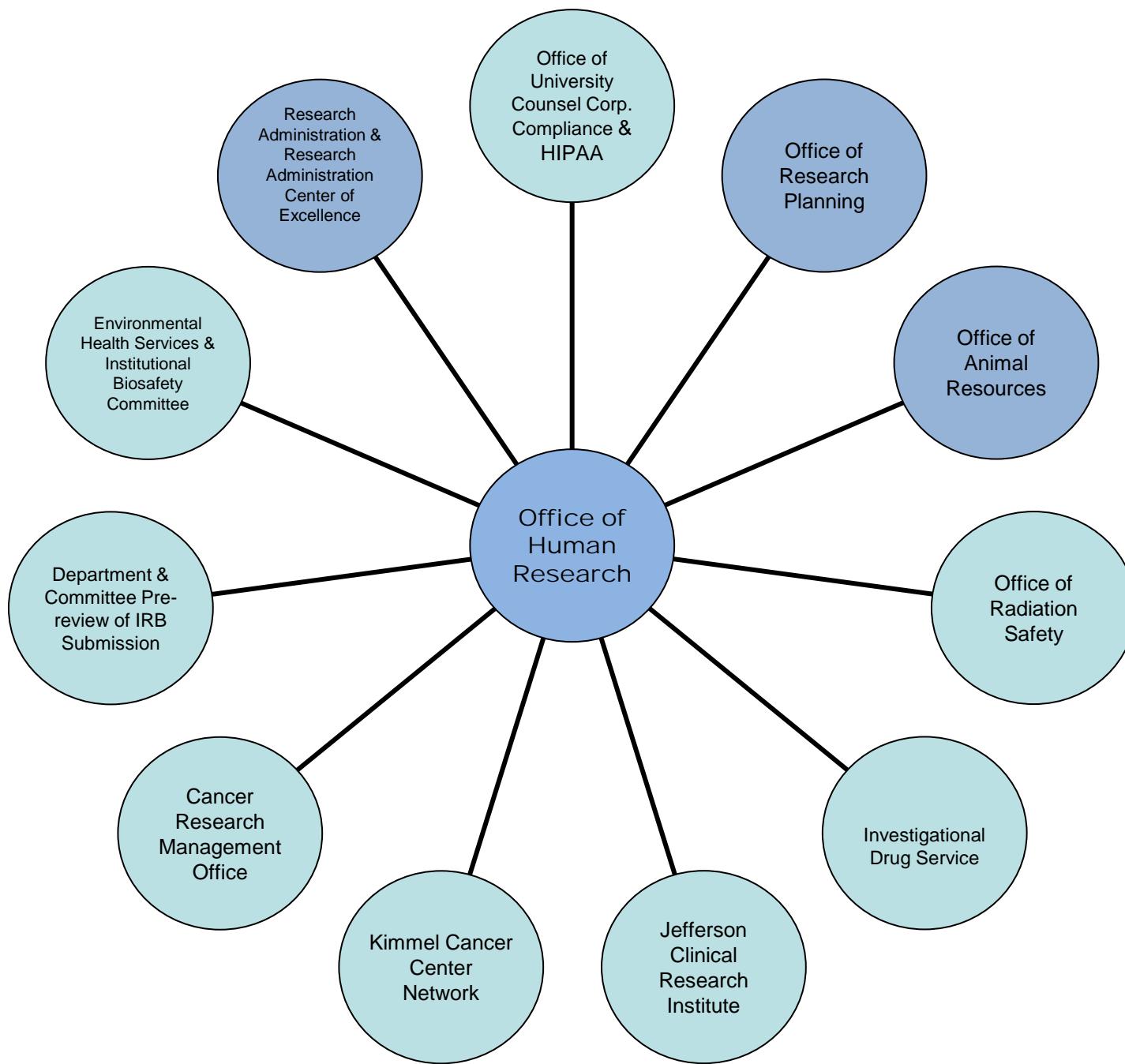


The TJU Human Research Protection Program (HRPP): Part I - Which Entities/Offices are Involved ?

J. Bruce Smith, MD, CIP



Reporting Hierarchy

Director, OHR



Associate Provost for Research Support
Services (Dr. Taraschi)



Provost (Dr. Tykocinski)

Office of University Counsel

- Conflict of Interest (COI) and the COI Committee
- Corporate Compliance
- IRB Noncompliance
- TJU Research Compliance Committee

ORA and RACE

- The Office of Research Administration
 - Budget review
 - Approval of grants for submission to the NIH and other publicly-supported agencies
 - Negotiation of contracts for commercially-sponsored clinical trials.
 - A representative from OHR regularly attends IRB meetings as a guest and may respond to questions regarding status or content of contracts.
 - may not participate in the decision-making process or vote on a protocol as it would represent a potential conflict.
- The Research Administration Center of Excellence:
 - Centralized pre- and post-award research administration to all departments.
 - Expertise in scientific writing and editing.

The Jefferson Sidney Kimmel Cancer Center (JSKCC) Clinical Research Management Office (CRMO)

- The CRMO is the shared resource of the NCI-designated JSKCC that supports physicians, scientists and other staff in the development, implementation, and conduct of clinical trials.
 - regulatory personnel are responsible for the preparation and submission of all regulatory reviews (e.g. new submissions, amendments, annual reports, safety information, etc. to the IRB and FDA).
 - personnel also serve as intermediaries between the Jefferson IRB, FDA or other regulatory bodies, and JSKCC investigators.

The Jefferson Sidney Kimmel Cancer Center Network (JSKCCN)

- JSKCCN is a partnership between the JSKCC and community cancer programs.
- Initiation of NCI cooperative group clinical research protocols in the network entities.
 - As of 2014, participation by hospitals, group and individual practices in the JSKCCN included 32 practices; 23 in Pennsylvania, 6 in New Jersey, 2 in Delaware, and 1 in New York State.
- JSKCCN sites perform only NCI Cooperative Group cancer trials.
- Jefferson participates with the NCI CIRB (independent review model) for regulatory oversight for the majority of these studies and for many cooperative group studies done on campus.

The Jefferson Clinical Research Institute (JCRI)

- Mission is to facilitate clinical research.
 - Faculty development
 - Standardization of training
 - Governance of OnCore®/Jefftrial (the university electronic clinical trial management system and the OHR Clinical Trials Repository)
 - Data monitoring services
 - Internal quality control audit
 - Coordinator staffing and regulatory support for investigators
 - Budget and contract services, invoicing, Medicare analysis, and the short or long term provision of coordinator staff for both sponsored and investigator initiated trials.

The Investigational Drug Service (IDS):

- Division of the Jefferson Hospital Pharmacy.
 - Dispense all research drugs/devices being used in clinical research conducted on in-patients and in some studies in the out-patient setting.
 - Review all inpatient investigational drug protocols and assist with patient enrollment, staff education and maintenance of study records, including protocol budgets.
 - Maintenance of investigational drug records in accordance with FDA regulations and the policies and procedures of the OHR/IRB and Thomas Jefferson University Hospital.
- A pharmacist from the IDS serves as a voting member on each of Jefferson's 3 IRBs

Other Offices

- Office of Radiation Safety: The Radiation Safety Committee (or a sub-committee depending on the nature of the research) reviews all human subjects research involving the use of radiation that exceeds that used in standard of care procedures.
- The Institutional Biosafety Committee (IBC) is administratively supported by the Department of Environmental Health and Safety. The IBC reviews all human subjects protocols that involve gene transfer or potential gene therapy.
 - Prior to either review by a convened IRB or IBC, an *ad hoc* committee comprised of several members of the IBC, and the IRB to which the study will ultimately be submitted, meet to review all documents related to assess overall safety and risk, and to make suggestions to the investigator for changes prior to formal submission for IRB and IBC review.
- The Office of Animal Resources (OAR) and the Institutional Animal Care and Use Committee (IACUC) interact with the OHR/IRB to insure that any human subjects protocol in which human tissue is injected or transplanted into laboratory animals is done under an IACUC approved protocol.