

# Academic Collaborations for DSMB Oversight of High Risk IITs

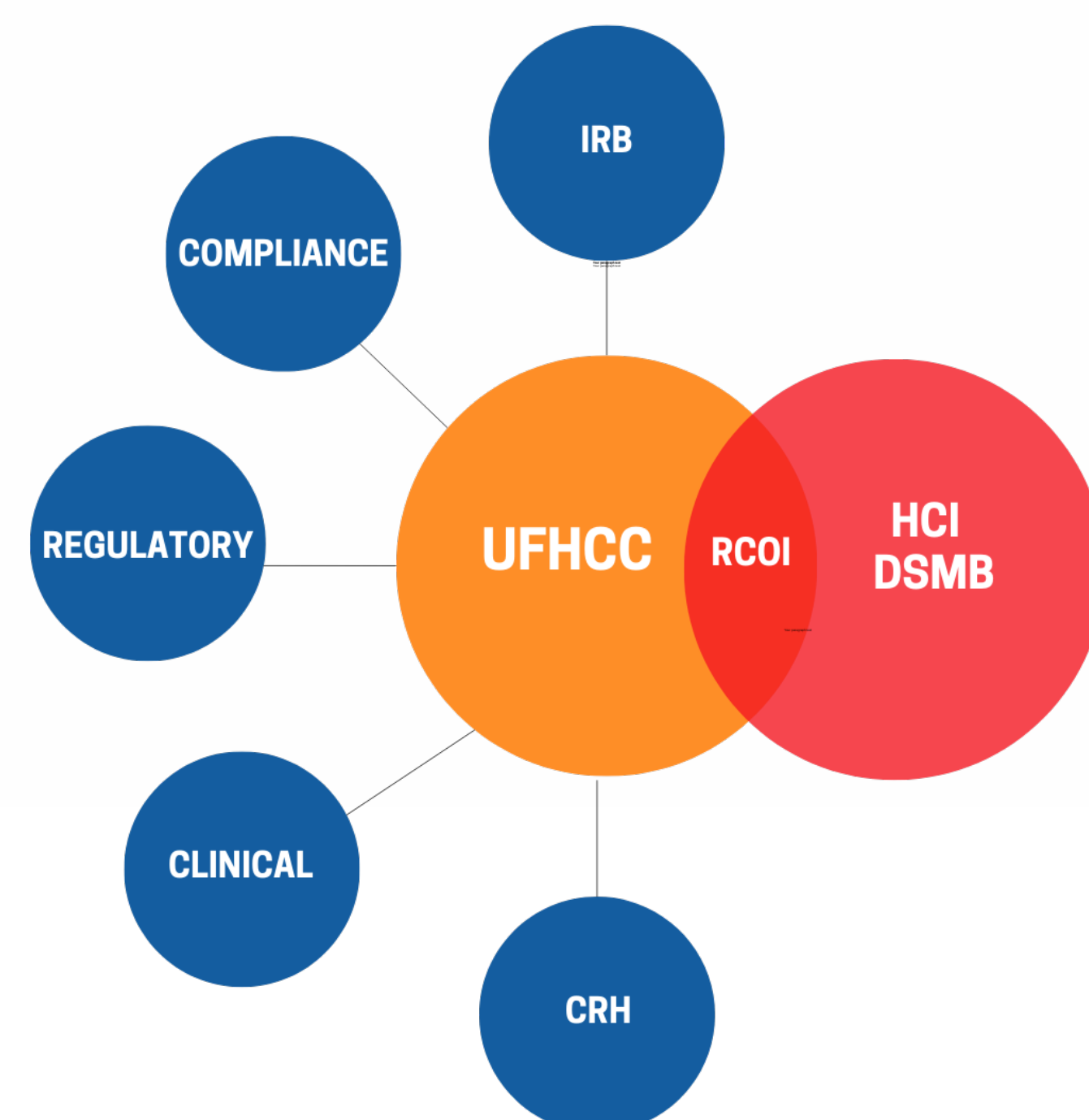
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## BACKGROUND

The University of Florida (UF) Research Conflict of Interest office (RCOI) exists to ensure regulatory and institutional compliance and promote the highest ethical standards in research. In 2024, risk mitigation plans were executed by RCOI for a portfolio of cancer-related Investigator Initiated trials (IITs) because of individual and institutional COI that could potentially bias the research. Individual COI was mitigated through restricted investigator access to study data. Institutional COI mitigation required data and safety assessments through an independent external Data Safety Monitoring Board (DSMB).

To support these IITs with limited budgets, University of Florida Health Cancer Center (UFHCC) sought collaboration with another academic cancer center to provide DSMB oversight for UF clinical trials governed by institutional risk mitigation plans.



## GOALS

- To advance translational science by effectively managing RCOI concerns, while maintaining patient safety and data integrity oversight
- Establish a relationship across National Cancer Institute (NCI)-designated centers that will set the stage for mutual trial operation support

## SOLUTIONS AND MEHTODS

UFHCC partnered with the NCI-designated Comprehensive Cancer Center Huntsman Cancer Institute at the University of Utah to provide external DSMB oversight. A statement of work (SOW) outlining roles and responsibilities, including budget, was negotiated and a contract was executed. The Huntsman Cancer Institute DSMB is responsible for reviewing Serious Adverse Events (SAEs) in real time, cumulative Adverse Events (AEs), deviations, cohort escalation/de-escalation decisions, and makes recommendations for study closure if concerns justify.

Study auditing is performed quarterly by the UFHCC Compliance office as outlined in the UFHCC NCI-approved Data Safety and Monitoring Plan (DSMP). Their findings are presented to the Huntsman Cancer Institute DSMB. The UFHCC auditor reviews 100 percent of study participants after their first visit, and at follow-up visits, 50 percent of participants since the previous review. Complete reports are compiled by the UFHCC team and provided to the Huntsman Cancer Institute DSMB prior to each meeting. The Principal Investigator and study team are responsible for attending Huntsman Cancer Institute DSMB meetings when their trials are due for review.

## OUTCOMES

- The Huntsman Cancer Institute DSMB oversees two UF IITs.
- Submission and review processes for DSMB evaluations were minimally disruptive, ensuring efficient workflow.
- Collaboration was characterized by professionalism and mutual respect.
- Strong communication channels established for prompt responses to queries or concerns.
- Leveraging another DSMB's expertise enhanced safety oversight quality and depth.
- Important translational science progressed under a stringent RCOI plan.

## LESSONS LEARNED AND NEXT STEPS

### Collaborating with an academic external DSMB to alleviate RCOI:

- Provides specialized expertise in cancer research.
- Enhances quality of safety oversight and mitigates institutional COI.
- Is a cost-effective solution compared to commercial alternatives, without compromising quality.
- Facilitates professional networking between cancer centers.
- Proved to be feasible and effective.
- Future opportunities to engage the Huntsman Cancer Institute DSMB for additional clinical trials and reciprocate the oversight.
- Cross-center collaborations should be highlighted in the CCSG application and review.

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