

## Department of Radiation Oncology Clinical Research Accountability Unit (CRAU)

### General Summary

The Department of Radiation Oncology includes research faculty and staff who conduct human subjects research within UNC, UNC Health (UNCH), and UNC Rex (Rex). Research conducted at UNC and UNCH share resources, personnel, and common operating procedures. Research conducted at Rex by Radiation Oncology faculty investigators is largely managed by Rex staff and conducted under policies of the Office of Research Support and Compliance and Lineberger Comprehensive Cancer Center (LCCC). Studies led by Radiation Oncology faculty investigators often include collaboration with other departments and LCCC. The portfolio of clinical research studies within the department is largely investigator-initiated with internal funding, including both observational and interventional studies.

### CRAU Structure

The Radiation Oncology CRAU will conduct and manage the essential activities outlined below under the direction of the Faculty Director and Administrative Director.

#### **CRAU Faculty Director:**

- Colette Shen, MD, PhD, Director of Clinical Research

#### **CRAU Administrative Director:**

- Victoria Xu, Project Manager

### CRAU Essential Activities

The Radiation Oncology CRAU will maintain accountability for all studies led by Radiation Oncology faculty investigators. Studies conducted within the department that are led by non-Radiation Oncology faculty investigators will be accounted for by the study PI’s home department CRAU.

Administration	
Primary point of contact for CRSO and CRAU:	Victoria Xu
Primary point of contact for industry sponsors:	Victoria Xu
Monitor personnel and staffing:	Victoria Xu
Review study feasibility assessment outcomes:	
○ First-level review:	Victoria Xu Olivia Roberts
○ Second-level review:	Colette Shen
Review and verify administrative data about the CRAU:	Victoria Xu Olivia Roberts
Operations	
Point(s) of contact for OnCore utilization:	Victoria Xu

	Olivia Roberts
Pre-review of initial IRB submissions for quality and completeness:	PIs and/or their designees Point of Contact: Victoria Xu
Departmental IRB certification:	Colette Shen Lawrence Marks Ellen Jones Diane Powers (ORSC, Rex Studies)
Review aggregate audit and monitoring findings:	Victoria Xu Olivia Roberts
<b>Financial Management</b>	
Point(s) of contact for financial management best practices:	Victoria Xu Rhonda Haithcock