



Department of Dermatology Clinical Research Accountability Unit (CRAU)

General Summary

Human subjects research (HSR) across the department is conducted among several high-functioning and relatively independent units. The department research portfolio includes basic science, translational science, and clinical trial studies.

The Dermatology Clinical Trials Unit (CTU) evaluates and monitors the safety and efficacy of new treatments for various dermatologic conditions in children and adults and conducts many industry-sponsored trials. The Observational Studies Unit (OSU) supports PI-initiated studies and other human subjects research studies that are generally internally funded. Additionally, the Laboratory/Pathology Unit (LPU) supports biospecimen studies with a focus on melanoma and non-melanoma skin cancers.

CRAU Structure

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

CRAU Faculty Director:

- Nancy Thomas, MD, PhD, Irene & Robert Alan Briggaman Distinguished Professor and Chair

CRAU Administrative Director:

- Sarah Shipp, Associate Chair for Administration

All research activities of the CRAU will be accounted for through the sub-CRAUs outlined below. The CRAU Faculty Director and Administrative Director will serve to promote alignment and collaboration across each of the sub-CRAUs. The Directors will also serve as the liaisons for the department to ensure research studies connect with the appropriate sub-CRAU.

Sub-CRAU	Faculty & Administrative Leads
Clinical Trials Unit (CTU)	Faculty Lead: Aida Lugo-Somolinos, MD
	Administrative Lead: Erika Hanami
Observational Studies Unit (OSU)	Faculty Lead: Chris Sayed, MD
Laboratory/Pathology Unit (LPU)	Faculty Lead: Nancy Thomas, MD, PhD
	Administrative Lead: Sharon Edmiston

CRAU Essential Activities

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

Administration	
Primary point of contact for CRSO and CRAU:	Erika Hanami
Primary point of contact for industry sponsors:	CTU: Erika Hanami LPU: Sharon Edmiston
Monitor personnel and staffing:	Sarah Shipp CTU: Erika Hanami OSU: Chris Sayed LPU: Sharon Edmiston
Review study feasibility assessment outcomes:	CTU: Erika Hanami Aida Lugo-Somolinos Donna Culton OSU: Chris Sayed LPU: Nancy Thomas
Review and verify administrative data about the CRAU:	Sarah Shipp CTU: Erika Hanami Aida Lugo-Somolinos Donna Culton OSU: Chris Sayed LPU: Sharon Edmiston
Operations	
Point of contact for OnCore utilization:	CTU: Erika Hanami LPU: Sharon Edmiston
Pre-review of initial IRB submissions for quality and completeness:	PIs and/or their designees Point of Contact: Sarah Shipp
Departmental IRB certification:	Sarah Shipp Kristin LeGrow
Review aggregate audit and monitoring findings:	Nancy Thomas Sarah Shipp
Financial Management	
Point of contact for financial management best practices:	Kristin LeGrow CTU: Erika Hanami LPU: Sharon Edmiston