



Name of the CRU: **Oncology Clinical Research Unit**

Date: November 29, 2017

CRU Director Signature: Karen Kharasch

Unit Head Signature: J. P. Abrego

1. Scope of Research within the Oncology CRU:

The Oncology CRU is composed of all investigators, clinical research teams and Clinical Trials Office (CTO) staff. Protocols can be developed and conducted by investigators in the following departments: medicine, gynecology, radiation therapy, surgery, and others as appropriate and approved by Oncology CRU leadership. These protocols will be conducted on both the outpatient and inpatient hospital units at Duke University Medical Center, as well as other Duke-affiliated and/or Duke-approved institutions. The protocols are largely cancer-focused, but some non-cancer-focused protocols fall within the scope of the Oncology CRU, depending on alignment with the goals of the Disease Groups specified below or the Duke Cancer Institute (DCI). The protocols encompass interventional and non-interventional studies, which span multiple disciplines and involve variable levels of complexity. Oncology CRU also partners with the Duke Cancer Network (DCN) to provide cutting-edge research programs to patients through their regional network of community cancer practices. Prospective clinical trials that involve research patient enrollment will be posted on the DCI website <http://www.dukecancerinstitute.org/research/clinical-trials/> in a manner that promotes easy access and accurate information to both community physicians and oncology patients and their families.

The Oncology CRU seeks to promote the following key elements of quality research:

- Respect for participants' dignity, rights and safety
- Respect for diversity within the society
- Personnel and scientific integrity
- Leadership
- Honesty
- Accountability
- Transparency of the research process
- Authentic, accurate and complete data collection
- Clear and supportive management
- Compliance with applicable federal, state, local, and institutional regulatory requirements

2. Key Personnel:

Oncology CRU:

Medical Director: James Abbruzzese, MD

Research Practice Manager (RPM): Bonnie Vernarelli, RN, MSN, MBA

Research Practice Manager (RPM): Wendy Bloomer, PhD, CCRP

Financial Practice Manager (FPM): Chris McIver

DCI Clinical Trials Office (CTO):

Director of Research Administration and Operations: Karen Kharasch, BS

Finance Director: Jane Gaskins, CPA

Manager, Cancer Protocol Committee (CPC): Patrick Barrera, BS

Manager, Clinical Research Informatics: Tim Steele, BS, MBA

Manager, Clinical Trials Operations: Vijaya Chadaram, RN, MSN, CCRP

3. Oncology CRU Disease Groups & Leadership

The Oncology CRU currently consists of 13 Disease Groups. Each Disease Group has a trio of leaders representing clinical care, clinical research, and basic research, who will work together to promote and advance the diagnosis, treatment, and continuing care of cancer patients. Disease Group research remains within the scope of the Oncology CRU oversight, policies and procedures. The Disease Groups are supported by a dedicated clinical research support team which includes an Assistant Research Practice Manager (ARPM), clinical nursing staff, regulatory and data personnel and Clinical Trials Office personnel.

	Disease-Site	Director	Assoc. Director Clinical Research	Assoc. Director Basic Science
1	Brain Tumor	Allan Friedman, MD	Henry Friedman, MD	Darell Bigner, MD, PhD
2	Breast Cancer	P. Kelly Marcom, MD	Neil Spector, MD	Donald McDonnell, PhD
3	Endocrine Cancer	Julie Sosa, MD		
4	Gastrointestinal Cancer	James Abbruzzese, MD & Brian Czito, MD	John Strickler, MD	Gerard Blobe, MD, PhD
5	Genitourinary Cancer	Daniel George, MD	Andrew Armstrong, MD	Donald McDonnell, PhD
6	Gynecologic Cancer	Andrew Berchuck, MD	Angeles Secord, MD	Donald McDonnell, PhD
7	Head and Neck Cancer	David Brizel, MD	Walter Lee, MD	
8	Hematologic Malignancies	Nelson Chao, MD	David Rizzieri, MD	Yiping Yang, MD, PhD
9	Melanoma	TBD	April Salama, MD	
10	Sarcoma	Brian Brigman, MD, PhD	Richard Riedel, MD	David Kirsch, MD, PhD
11	Thoracic Oncology	Thomas D'Amico, MD	Jeffrey Crawford, MD & Neal Ready, MD	TBD
12	Phase I	James Abbruzzese, MD		
13	Radiation Oncology	Christopher Willett, MD		

4. Faculty Advisory Board

Composition:

The DCI Steering Committee serves as the Advisory Board to the Oncology CRU. The Oncology

CRU medical director is also the associate director of clinical research within the DCI Steering Committee.

Protocols conducted in the Oncology CRU are not evaluated by the Faculty Advisory Board or the Steering Committee. The National Cancer Institute (NCI) approved Data and Safety Monitoring Plan (DSMP) ensures adequate oversight of cancer research in human subjects. Oversight begins with a rigorous review of the scientific merit and safety of each protocol, followed by a multifaceted approach to data and safety monitoring. Protocols are evaluated by individual Disease Groups and the Cancer Protocol Committee (CPC) of the DCI. Within Disease Groups, protocols are evaluated by key investigators and staff, and are subsequently assigned a priority score within the Disease Group portfolio. Protocols approved by the Disease Group leaders are submitted for review via eIRB, at which point CPC review occurs. Within the CPC, protocols are independently peer-reviewed for scientific merit, priority, and progress. Scientific merit is assessed by scientific impact, protocol objectives, and study design, among other considerations. Priority within the Oncology CRU and DCI portfolio is assigned based on Disease Group priority, financial/logistical feasibility, patient need, and other considerations. Progress is evaluated by the CPC at least yearly, primarily by monitoring accrual and successful completion of key protocol benchmarks. Only those studies that meet CPC standards for scientific merit and quality get approved. Studies that do not meet key accrual or scientific benchmarks during continuing review are disapproved by the CPC. The DCI Monitoring Team conducts monitoring visits as defined by CPC, on DUHS sponsor-investigator therapeutic intervention and prevention intervention studies that do not have an external monitoring plan to ensure subject safety. Annually, one industry sponsored clinical trial from each oncology disease based group will be randomly selected for monitoring by the DCI Monitoring Team. Additional monitoring of protocols in disease based groups may be prompted by findings from internal monitoring visits, sponsor monitoring findings, unexpected frequency of serious and/or unexpected toxicities, or other concerns and may be initiated upon request of DUHS and DCI leadership, the CPC, the Safety Oversight Committee (SOC), the sponsor, the Principal Investigator, or the IRB. The monitoring team ensures that the study is conducted, recorded and reported in accordance with the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirements. In addition, the oncology CRU also has a Safety Surveillance team to provide consistent, efficient, and well documented processes for collecting, evaluating, and reporting safety data and to ensure adherence with applicable regulations.

5. CRU Governance and Financial Plan:

The Oncology CRU reports to the CRU medical director, James Abbruzzese.

Financial Plan:

Most of the Oncology CRU protocols are housed under the auspices of the DCI; however, there are some that reside within other clinical departments. The bifurcation depends on the staffing assigned to support the protocol. The operating structure within the Oncology CRU (DCI) is delineated into divisions based on disease based tumor groups as listed in Section 3. In addition to the disease groups, the DCI structure also includes the central clinical trials office responsible for oversight and compliance of all Oncology CRU projects. Projects that sit within the DCI are backstopped by the disease based programs using reserves accumulated through study margins

or philanthropic sources assigned to the division. The Central structure is funded using budgeted subsidies earmarked for infrastructure support.

FUNDING SOURCES – CENTRAL CLINICAL TRIALS OFFICE: The central services offered by the DCI in support of Oncology trials includes, but is not limited to, CPC, SOC, Safety & Compliance, Biobanking, Biostatistics, Bioinformatics, Informatics, Research Lab Services, and Space Management. DCI allocates the following funding sources to support these services:

- Indirect Cost Recovery
- Cancer Center Support Grant (NCI P30)
- DUHS Margin Share

FUNDING SOURCES – DISEASE BASED GROUPS: 90% of the program portfolio housed within DCI is sponsored through Pharmaceutical contracts. The remaining 10% includes foundational grants. All residuals (shortfall/surplus) generated by these studies are maintained within the individual divisions. The central business office of the DCI reviews performance quarterly and advises leadership on potential financial risk. In aggregate, the programs generate a small margin annually (cash-basis) which flows into program reserve accounts. These reserves are used to support investigator initiated studies (unfunded/underfunded) and backstop program infrastructure costs; surplus funds accumulated through studies **do not** flow into discretionary sources under the current model.

6. CRU Stakeholders:

Research subjects are our premium stake holders. Other stakeholders include the Federal Government (e.g., Department of Health and Human Services, Food and Drug Administration, National Institute of Health, National Cancer Institute), Duke Cancer Institute, Duke University Health Systems, Duke University School of Medicine, all Duke Oncology investigators, oncology research professionals, sponsors, and both internal and external collaborators.

7. Communication Plan:

Open communication from the Oncology CRU Leadership is a guiding principle of our organization. In addition to DOCR and Duke IRB SOPs, Oncology CRU specific SOPs and guidelines are available on the DCI Intranet. An annual DCI retreat was started in May 2012 to discuss the direction of the Oncology CRU and to provide progress updates to the Duke oncology research community. All presentations from the retreats are available on the DCI Intranet. The Oncology CRU RPMs hold monthly ARPM meetings and regulatory coordinator meetings to discuss any significant issues and provide updates as needed.

The DCI hosts a monthly Lunch ‘n Learn seminar series focusing on important aspects of cancer protocol development, submission, review, and conduct. It also disseminates information via a subscriber email list and, on occasion, in the DOCR monthly Clinical Research Update.

The Oncology CRU also develops educational and informational modules as necessary to target specific clinical research needs as they arise.

In addition, all Oncology research personnel are encouraged to attend educational programs provided by DOCR and Duke IRB.

8. Oncology CRU Organization Chart:

Oncology Clinical Research Unit 2017

