1. **Scope of Research within the CRU:**
Duke University Health System Institutional Review Board (DUHS IRB) approval is required for all studies involving human subjects that utilize Duke University Health System (DUHS) patients, patient information, resources (equipment or personnel), or services that generate a Maestro Care charge. The operating business units responsible for the integrity, financial accountability, regulatory compliance, quality, and academic productivity of clinical research studies are the School of Medicine’s site-based Clinical Research Units and CRUs [per the Duke Office of Clinical Research (DOCR) policy: **Scope of Oversight and Responsibility of Clinical Research**].

The DPHS CRU is a collaboration between the Duke Office for Clinical Research (DOCR) and the Duke School of Medicine Department of Population Health Sciences (DPHS). All research involving human subjects being conducted by investigators with a primary appointment in the DPHS will receive support and operational oversight from DOCR and scientific oversight from a DPHS faculty review committee led by Dr. Kevin Weinfurt.

The Duke Department of Population Health Sciences engages in transdisciplinary research that integrates knowledge, theory, and tools from many scientific disciplines. The science of population health considers health outcomes, underlying determinants of poor health, and disease states in populations defined by factors such as geography, ethnicity, employment, and even health care systems. At Duke, our work in population health is bolstered by a strong connection to the health care system and the Durham community, allowing us to identify and implement changes to the health of the population.

This Oversight Plan outlines the steps necessary to allow for efficient protocol approval and start-up for studies submitted through the DUHS IRB that fall within the DOCR CRU portfolio, specific to DPHS studies. Certain functions (detailed below) will be the responsibility of the DPHS CRU, however, the primary responsibility for maintaining research integrity shall remain with the Investigator.

During proposal and protocol development, please feel free to contact the manager of the CRU (Alafia Hasan, alafia.hasan@duke.edu) and/or schedule a study-planning meeting with DOCR staff (email docr-studyplanning@dm.duke.edu).

2. **Key Personnel:**

   - CRU Director: Kevin Weinfurt, PhD
   - Research Practice Manager: DOCR
   - Financial Practice Manager: RASR & Population Health Administration

Clinical Research Unit Charter
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3. Advisory Council and Scientific Review process

Council Composition:

Director, Kevin Weinfurt, PhD
Managing Director, DPHS, Ashley Dunham, Ph.D.
Statistical Advisor
Research Practice Manager
Data Practice Manager
Financial Practice Manager

Function: The Advisory Council will meet quarterly with the responsibility of reviewing and providing recommendations regarding institutional standards and systems for the conduct of clinical research (including principal investigator and study coordinator training and certification, standard operating procedures, etc.) and providing guidance in the development and implementation of standardized tools and resources for clinical research (including budget templates, financial reports, project evaluation tools, study management tools, etc.)

The Scientific Review Committee will review the scientific integrity of newly proposed research projects ad hoc.

Scientific Review Process: New studies will be initially reviewed for operational feasibility and information security by the DOCR oversight manager. Operationally sound studies will be assigned to scientific review either within eIRB (data-only projects) or for discussion at a scientific review committee meeting (studies directly involving human participants). Projects funded under peer-review scrutiny (e.g., NIH grant-funded projects) will forgo departmental scientific review, but will undergo the same operational and feasibility review of other studies. Scientific reviewers will be assigned according to expertise with guidance from the Director.

Projects will be reviewed for:

- Scientific relevance
- Appropriate manpower
- Patient/participant base
- Facilities and resources
- Data protection and provenance
- Appropriate funding for successful completion

Operational feasibility and financial feasibility will be determined by collaborating managers within the CRU.
4. CRU Governance and Financial Plan:

Financial governance will be provided by the Department of Population Health Sciences Administration in collaboration with the Research Administration Support Resource (RASR) as defined in the RASR service level agreement. The Department of Population Health Sciences will provide backstop. SOM mandated management fee (minimum 10%) will be assessed on the residuals from all studies at closeout.

Deficits:
Deficits will be backstopped by the department.

5. Stakeholders:
- Department of Population Health Sciences
- School of Medicine
- Department of Community and Family Medicine
- School of Nursing
- Duke Campus Schools
- Social Sciences Research Institute
- Duke Clinical Research Institute
- Clinical and Translational Sciences Institute
- Community Partners

6. Communication Plan:
1. Faculty engagement: Introduction of the new CRU structure, processes, and contacts will be made with Population Health Faculty in the context of pre-existing departmental meetings or individual faculty meetings.
2. Research Staff engagement:
   a. CRU informational sessions/town halls to introduce the structure and the contacts, 1:1 discussions as needed.
   b. Regular staff meetings to disseminate new information (regulations, policies, new offices, new services, etc.) and to gather information and needs.
   c. Email and online communications.
   d. Policy, regulations, and training updates via the DOCR website.
Organizational Chart: