Duke Department of Medicine
Duke University School of Medicine

TITLE: **POLICY: CRU Effort Level on Non-Industry Grant Proposals**
Number: **DOM CRU P001**
Effective Date: 10/4/2022

I. PURPOSE

The purpose of this policy is to define the appropriate level of effort for CRU staff on non-industry funding proposals within the Department of Medicine (DOM).

II. SCOPE

This Policy applies to all funding proposals of clinical research managed by the DOM CRU.

The ARPM is assigned to act as a first point of contact for PIs in coordination and conduct of research in the DOM CRU. ARPMs work with multiple user and resource groups across divisions / centers / institutes within or affiliated with DOM. ARPMs work closely with team leads to ensure shared standard of performance and common best practices. Currently the A/RPMs are funded through department, division and center allocation policies.

III. DEFINTIONS/ABBREVIATIONS

ARPM: Assistant Research Practice Manager
cGCA / GCA: clinical Grant & Contract Administrator / Grant & Contract Administrator
CRU: Clinical Research Unit
DOM: Department of Medicine
PI: Principal Investigator

IV. POLICY STATEMENT

The DOM expects ARPM effort to be included in all clinical research. By including ARPM effort in proposals, the division/center allocation is reduced. A signed acknowledgment form from the Division Chief/Center Director is needed for each grant proposal that does not contain ARPM effort.

V. PROCEDURE/GUIDANCE

The cGCA/GCA will work with the ARPM and PI to confirm appropriate level and duration of effort. The role of the ARPM in the SPS Personnel Tab should be recorded as "Clinical Research Manager".

The following template language is suggested for the budget justification.

"**[Full Name], (Assistant) Research Practice Manager (ARPM)** (calendar months)
The ARPM provides upper level management for Dr. [Full Name] study team in the Division of [XX]. The ARPM ensures Clinical Research Professionals and investigators are appropriately trained and are performing activities in accordance with good clinical practice, CRU standards, institutional policy, and regulatory requirements. The ARPM facilitates timely study conduct and milestone achievement. The

ARPM provides oversight of study personnel and assists with resolving recruitment challenges or other issues related to study conduct. The ARPM serves as a subject matter expert and resource to the PI and division staff.

Project complexity is rated based on the Clinical Quality Management Plan determination which uses the following criteria:

High	Prospective Phase I-III interventional procedure, device and/or drug studies (novel product or indication) and all studies under and IND or IDA with the FDA
Medium	Behavioral intervention, complex observational or sample collection studies that are more than minimal risk. This includes FDA approved drugs, devices or biologics used for their approved indication.
Low	Studies using procedures generally considered to be minimal or low-risk, such as blood sample collection, imaging (not using sedation or contract), questionnaires or behavioral surveys. This also includes retrospective studies, registries, repositories, and exempt research.

Recommended effort levels are assigned the percent of the ARPM salary for that division as listed below. If an ARPM is not assigned to that division, use the interim ARPM's salary. The salary information is populated in SPS when the ARPM name is entered into the system.

	Year 1	Subsequent Years
High	**5%**	**3%**
Medium/Low	**3%**	**2%**

VI. APPENDICES

1. Appendix A: Division / Center Acknowledgement Form

APPROVALS

Review and Approval	Dr. Laurie Snyder, Medical Director, Medicine CRU Denise Wynn, Director, Research Administration	October 2022
Revision History	Dr. Laurie Snyder and Erica Malkasian	July 2019