Clinical Research Unit (CRU) Scope of Oversight and Responsibility of Clinical Research

Effective Date: November 1, 2012
Review/Revision: History: Version 1.4

Purpose: To define the scope of clinical research that is managed through clinical research units and the responsibilities each clinical research unit has for oversight of those projects.

The following entities are covered by this policy:
Duke Medicine

Policy:
Clinical research units (CRUs) are the organizational structure to provide oversight for all clinical research that does not meet the federal regulatory requirements for exemption from IRB review where:

- A Duke Medicine entity is the investigative site for the research OR
- A Duke faculty or staff member is responsible for clinical research.

The NIH definition for clinical research is (http://grants.nih.gov/grants/glossary.htm):

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes:
   - mechanisms of human disease
   - therapeutic interventions
   - clinical trials
   - development of new technologies
2. Epidemiological and behavioral studies.
3. Outcomes research and health services research.

Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

To ensure the integrity, financial accountability, regulatory compliance and quality of these clinical research studies, each study must have an CRU designated to provide oversight. If a CRU is not easily aligned, the Duke Office Of Clinical Research (DOCR) will assist in the alignment process in order to establish proper oversight.

Duke Medicine will rely on the CRU structure to ensure clinical research is:

- Scientifically aligned with the interests of the faculty and the academic mission of the Departments and Schools of Medicine and Nursing
- Compliant with applicable regulatory requirements and institutional standards for research
- Financially transparent and accountable
• Funded by an identified source that is sufficient to support the conduct of the study
• Conducted by individuals with the appropriate qualifications, training, and certification

CRUs are responsible to ensure for their clinical research portfolio that:
• Costs for clinical research activities are understood and covered
• Faculty and staff involved in clinical research are known
• Faculty and staff involved in clinical research have completed all applicable Duke Medicine training requirements
• Target enrollment on studies is understood and monitored
• Administrative costs of the CRU are properly allocated to the CRU Administrative Operations Hub Code, in accordance with the CRU Administrative Operations Hub Code Guidance Document.

In providing oversight the CRU is responsible for ensuring for each study:
• The safety and welfare of research participants
• Study feasibility (clinical, financial, etc.) and study selection
• Budget/grid preparation (a “grid” being the use of the protocol schedule of events to assign expenses to the study sponsor or the patient and their insurer)
• Coordination of contract negotiation
• Internal and external regulatory submissions
• Study-specific training
• Subject identification, screening, consent, enrollment, retention
• Data collection, integrity, security, transfer or receipt of data and retention
• Participation in and appropriate corrective action in follow up to audits and monitoring visits
• Study-specific expense and revenue tracking, billing compliance activities, sponsor invoicing and proper effort tracking of personnel
  1. Effort tracking is expected to follow the Effort Management in Clinical Research Guidance document
  2. Internally funded projects are expected to have identified fund codes in accordance with the Internally Funded Project Fund Code Guidance document
• Publication of results
  1. Ensure compliance with Federal requirements for CT.gov results entry for applicable studies in CRU

Each CRU Director will report directly to the functional unit head (Department Chair, Center/Institute Director or Dean of School). These unit heads have ultimate accountability for the oversight of all CRU activities, including both financial accountability for the margin or loss of the CRU and accountability for regulatory compliance of all human subject research conducted within the group.
**Procedure:**

1. CRU designation will occur prior to IRB review of the study. Refer to the CRU Review of New Clinical Research Proposals policy for details on selecting a CRU and CRU review.

2. Each CRU will have a written process for evaluation of submitted studies that is approved by DOCR and posted on the DOCR website.

**Clinical Research Unit Advisory Council**

The Clinical Research Unit Advisory Council is responsible for obtaining appropriate input from the research community regarding institutional standards and systems related to the conduct of clinical research. The Advisory Council is comprised of the Director, Research Practice Manager and Financial Practice Manager from each of the CRUs. The Advisory Council is co-chaired by the Vice Dean for Clinical Research and the Vice Chancellor for Clinical Research. The Advisory Council is charged with 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.)

On an annual basis, the Advisory Council will review and assess the overall performance of Duke clinical research activities, produce an annual report on clinical research and provide recommendations to the Chancellor and the Dean regarding institutional priorities and strategies. This assessment will include the academic output from clinical research, the aggregated results of compliance audits [i.e., audits conducted by the Clinical Trials Quality Assurance (CTQA) staff of the SOM Compliance Office as well as billing compliance audits] and the aggregated financial results. This assessment also will include an evaluation of the quality of support provided to clinical research by the institution and suggestions for its improvement.
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Clinical Research Structure and Organization

Effective Date: December 2, 2012
Review/Revision: History: Version 1.4

Purpose: To provide an overview for the structure and organization of clinical research for Duke Medicine (defined as the integration of Duke University Health System, Duke School of Medicine, and Duke School of Nursing, http://www.dukemedicine.org/). This includes both the actual conduct of clinical research (through the Clinical Research Units, CRUs) as well as the establishment of institutional standards (through the Duke Office of Clinical Research). Additional policies will describe the creation and dissolution of CRUs, along with their scope of responsibility and oversight.

The following entities are covered by this policy:
Duke Medicine

Policy:
Clinical Research Units (CRUs) are the organizational and functional structures that provide oversight for clinical research in which a Duke Medicine department, center/institute, Clinical Service Unit (CSU) or school serves as the investigative site for the research, or a Duke faculty or staff member is responsible for a research activity that involves intervention or interaction with Duke human subjects, use of biological specimens from Duke patients human subjects or access to confidential, private information from Duke human subjects. The CRU will be the operating and business unit responsible for the integrity, financial accountability, regulatory compliance, quality and academic productivity of clinical research studies.

Study selection decisions are made within the CRUs, as well as the coordination and allocation of resources, and the flow of funds associated with individual studies.

Because of the diverse needs of researchers, certain elements of the CRU structure will be required, but a variety of operating models will be allowed and encouraged. This document will define the basic expectations of every CRU and will comment on opportunities for alternative models.

Refer to the DOCR policy entitled, “Clinical Research Unit CRU) Scope of Oversight and Responsibility of Clinical Research” for details regarding the scope of research managed through CRUs and the related CRU responsibilities.

All CRUs will be expected to adhere to institution-wide policies established by the DOCR regarding the conduct of clinical research practice. Compliance with these policies as well as all applicable regulatory requirements will be audited on an ongoing basis by the Clinical Trials Quality Assurance (CTQA) staff of the School of Medicine Compliance Office.

CRU Components
Each CRU will consist of the following components/positions (position descriptions are detailed in Appendix 1):

- Group of faculty members in a particular therapeutic area who are involved in the enrollment of human subjects in clinical research studies
- Group of study coordinators and research staff (i.e., regulatory staff, clinical trial assistants, etc.) who are specifically aligned with a group of faculty
- Faculty Advisory Board
- Director
- Financial Practice Manager
- Research Practice Manager

All principal investigators and study coordinators involved in patient enrollment within Duke Medicine will work within a CRU. Because of the importance of disease-specific expertise, study coordinators will be aligned with a group of faculty in a particular therapeutic area.

**Responsibilities of the Principal Investigator**

The Principal Investigator (PI) is ultimately responsible for the conduct of their individual study and ensuring the rights and welfare of study subjects. The PI will identify and propose studies; participate in the development of the Schedule of Events, budget, and billing grid; participate in negotiation with sponsors; review and approve the proposed assignment of charges; and oversee and ensure proper conduct of the trial including study-related care of study subjects, communication with the IRB, informed consent, safety reporting, etc. The PI is responsible for compliance with regulatory requirements and institutional policies, including the charter and standard operating procedures of the CRU providing oversight for the study. The PI is also accountable for the academic productivity of research, adherence to clinicaltrials.gov requirements and assurance of adequate monitoring of studies for safety and early termination for efficacy.

All PIs will be required to maintain their credentials and training requirements. Additionally, successful audit performance and financial accountability will be required.

**Responsibilities of the Study Coordinator**

All clinical research within Duke Medicine will have an identified qualified study coordinator. This will ensure that human subject research activities are performed by individuals with appropriate training and qualifications. A qualified study coordinator is defined as an individual who:

- meets a set of minimum hiring requirements
- has attended a specified training program
- performs duties described in a standardized job description
- is evaluated according to a standardized set of performance factors
- works as part of a study team under the supervision of a CRU Research Practice Manager (RPM) (acceptable CRU management reporting relationships are outlined in Appendix 3)

There may be situations in which the duties normally performed by a study coordinator are performed by another staff member (such as the PI, a mid-level practitioner, staff nurse, or technician) either on a full-time or part-time basis. This is entirely acceptable provided that the
individual meets all of the requirements listed above and that the individual’s activities related to clinical research are supervised and evaluated by the CRU Research Practice Manager.

The clinical research staff will be employed by the CRU through the Schools of Medicine or Nursing.

**Procedure:**

1. Upon creation, leadership from each CRU is to draft a charter (template attached in Appendix 2 and available at http://docr.som.duke.edu/) with input from its constituency (principal investigators, study coordinators, research assistants, etc.).

2. The draft charter should be reviewed and signed off by the CRU Director and then forwarded to the Unit Head (Department Chair, Center/Institute/CSU Director or Dean of School) for approval.

3. Once the Unit Head has approved the charter, the DOCR will review and facilitate institutional endorsement through the Vice Dean for Clinical Research. Institutional endorsement is recognized by signature from the Vice Dean for Clinical Research. The final, endorsed charter will be posted on the DOCR website (http://docr.som.duke.edu/).

4. CRUs also are responsible for designating what percentage of effort CRU Leadership will spend in their roles of accountability to the unit and institution through their interactions with the DOCR.

5. Each member of CRU Leadership is expected to fulfill the responsibilities outlined by the attached position descriptions, including participation in leadership meetings and workgroups established by the DOCR. Tools for assisting in these responsibilities are found on the DOCR website (http://docr.som.duke.edu/).

6. The CRU will manage all financial aspects of studies performed by the group, including budgeting, financial reporting, invoicing, accounts receivables and tracking of revenues and expenses. CRUs will be required to use a common financial reporting approach that will enable project level accounting in order to determine the profit or loss of individual studies as well as the aggregation of project-specific financials to provide an overall view of financial performance of the CRU. This process will require the allocation of personnel effort to individual projects as well as various categories of administrative activities and training to allow the full cost of all activities to be determined. Faculty time will be appropriately allocated to studies to accurately reflect the time spent by faculty. Revenues and expenses will be reported consistent with standards and practices established and monitored by central research administration offices (such as the School of Medicine Finance Office and the DOCR).

7. A process should be in place so there are no hidden subsidies from the clinical and educational enterprises toward research costs, e.g., if the department wishes to subsidize clinical research, it can do so but the amount should be clear and should be determined in a prospective manner.

8. Each CRU must be backstopped by a designated entity or group of entities who have reached agreement on how to split the backstop (a department, center/institute, CSU, or school). In the event that the funds flow for an individual CRU spans multiple departments,
CSUs, or centers, a memorandum of understanding (MOU) will be created to specify how the CRU infrastructure will be supported and margins or losses will be assigned and distributed (detailed in Charter).

9. The CRU will be responsible and accountable for billing compliance in relation to the appropriate assignment of charges to grants, insurance or discretionary accounts.

10. Each CRU will prepare an annual summary that will include the number of studies, the number of subjects enrolled, the demographic profile of study subjects, studies reviewed through the QI program, updates on central reporting for research staff and a list of publications resulting from work within the CRU.
Appendix 1: CRU Personnel Roles and Responsibilities

Role and Responsibilities of the CRU Director
There will be a designated faculty leader, the CRU Director, for each CRU. In most, but not all cases, this will be an MD. This individual will have the following responsibilities:

- Ensure the financial integrity and solvency of the program, i.e., oversee the development of the CRU budget and fiscal operations during the annual budget cycle.
- Manage the protocol review, approval and prioritization process, i.e., provide oversight of protocol reviews that consider scientific and fiscal value.
- Oversee personnel in the organization that perform protocol development and implementation and study conduct activities; assure the quality of the faculty participation with regard to research conduct; and assure that all study team members, including faculty, have completed appropriate certification and training requirements.
- Manage conflicts of interest in conjunction with the chair or designee of the faculty member’s appointing unit (department, center/institute, CSU or school).
- Ensure the academic integrity and output of research related publications and presentations.
- Represent the CRU and its faculty to external sponsors and internal entities including functional units (departments, centers/institutes, CSUs, or schools) and central administrative and compliance offices.

The CRU Director’s effort in performing this role will be funded by the CRU.

The CRU Director will be accountable for performing activities in accordance with all institutional standards, including those relating to clinical research, and providing information to the DOCR as needed. The DOCR Director of Operations will have input into the selection of the CRU Director, as well as the annual performance review; however, the final supervisory authority belongs with the CRU Director and Department/CSU/Center/Institute/School. The DOCR will hold regular meetings and discussions with the CRU Leadership which CRU Directors will be expected to attend to maintain a sense of community, and to promulgate consistent practices across the institution.
CRU Finance Practice Manager -
SUMMARY

This job description is intended to describe the minimum set of responsibilities to be performed by the Financial Practices Manager (FPM). It is recognized that there may be different levels of financial manager or financial analyst positions depending on the size and configuration of the Site Based Research (CRU). The reporting structure will vary across the CRUs based on the volume and complexity of research conducted.

RESPONSIBILITIES

Oversight responsibilities:

The FPM is responsible to the CRU Director and department leadership in managing the finances of the CRU by performing and coordinating a variety of financial functions. The role of the FPM is to ensure that day to day activities are performed in accordance with CRU standards using Standard Operating Procedures (SOPs) that are in support of University policies.

Responsibilities include:

1. Collaborate with Study Team and Research Practice Managers (RPM) to prepare internal cost summaries and charge assignment grids (calendars) for each study. Share individual study financial summaries with PI’s at scheduled intervals.
2. Facilitate and supervise the negotiation of external study budgets and contracts.
3. Prepare the annual operating budget for the CRU portfolio.
4. Ensure proper recording of expenditures, specifically faculty and staff effort on studies and communicate regularly with study team regarding reconciliation of each CRU monitored WBS code per Duke General Accounting Principles.
5. Ensure proper recording of revenue associated with all studies; applying revenue management standards.
6. Generate and analyze financial reports reflecting the performance of studies as well as aggregated reports of the overall financial performance of the CRU, including infrastructure costs and study-specific expenses and revenue.
7. Maintain financial records for each CRU managed study per the institutional documents retention guidelines.

Responsibilities Shared by Research Practice Managers (RPM) and Financial Practice Manager (FPM)

Collaborate with RPM, CRC, and PI’s to prepare realistic internal cost summaries (ICS) for all new projects. ICS must be prepared from primary documents including the protocol, schedule of events, and include personnel and non-personnel expenses, patient care costs as well as startup and closeout costs. ICS should be prepared using an approved ICS template.

1. Review and evaluate the charge assignment grid based on the schedule of events and protocol.
2. Provide financial advice to PI’s and CRC’s in the negotiation of study budgets with sponsors.
3. Review of individual study finances on a regular basis (monthly or more often as needed) with the Research Practices Manager and as requested with the CRU director.
4. Facilitate efforts with Research Practices Manager to address budget-related issues with
the CRU Medical Director, PIs, and study coordinators as appropriate.

5. Coordinate with RPM that CTOV and grant billing reports received by study teams are reviewed on a weekly basis; ensure process is in place for ongoing update of recipients for these reports.

**DIRECT responsibilities:**

1. **Related to Contracts and Budgets**

   a. Review and route sponsored projects proposals through SPS to ORA, to ensure compliance with University procedures and institutional signature.

   b. Track the status of proposed projects related to budget and contract issues and provide updates to the CRU leadership, PIs and staff to support decision-making regarding new studies and resolve funding sources for underfunded projects.

   c. Confirm receipt of final contract or award; understand the terms and restrictions and deliverables of agreement.

2. **Post Award Accounting / Transaction Analysis**

   a. For industry funded projects, facilitate the Revenue Management process; Work with Study teams to track subject activity & milestones, match with contract payment terms and determine Earned Revenue for individual studies, determine monthly accrual amounts; Validate the information and submit entries for the General Ledger to SOM Finance.

   b. Monitor invoicing if invoicing occurs at the division/cluster level, and/or invoice sponsor as appropriate for negotiated fees and procedures, as dictated by contract. Monitor accounts receivable and follow up with sponsors as necessary.

   c. Collaborate with OSP for Federal and Foundation projects to ensure cash collection, particularly for Capitation or Invoice-required milestone agreements.

   d. Ensure process (SOP) is in place within the department and CRU for proper handling of sponsor checks for deposit and recording in the appropriate fund codes; in accordance with SOM check handling procedures.

   e. Monitor and communicate assignment of effort for Faculty and Staff to sponsored or internal funds, coordinate with RPM, CRU director and faculty/staff to align with work done; Work with other departmental staff/leadership as needed; Ensure compliance with federal requirements and institutional standards.

   f. Monitor compliance with institutional policies regarding the assignment, review, and validation of patient care expenses. Work with FPM, CRU director, research team, and PRMO to correct inappropriate charging of patient care expenses.

   g. Interpret departmental policies and procedures, making decisions on specific
operating problems and issuing instructions (i.e., patient billing issues, determining appropriateness of project expenditures based on budgeted expenses, etc.) on behalf of CRU and departmental leadership in accordance with precedents and policies.

h. Coordinate the close-out activity for completed projects and distribute margins in accordance with CRU procedures and institutional guidance; in cases of overdraft spending, follow CRU procedures for appropriate write offs.

3. Project / CRU Reporting and Analysis

a. Generate and analyze monthly financial reports of the CRU finances, showing the study revenue and costs associated. Share with CRU Leadership and PI’s on regular basis; to ensure an understanding of the current fiscal performance of the studies and identify areas of concern that may need resolution.

b. Provide guidance to the CRU leadership in terms of understanding the overall financial results of the CRU portfolio of studies. Any significant issues, transfers or outliers should be explained in detail.

c. Manage overdrafts in line with departmental procedures and SOM guidance.

4. CRU Operational Budgeting and Other Analysis

a. Prepare annual operating budget for CRU Central Operations (and clusters or divisions, as appropriate) and provide updates throughout the year regarding expense and revenue forecasts to CRU Leadership, Department Leadership and SOM Finance.

b. Assist CRU leadership and Department Business Managers with special financial related projects as needed.

c. Assist CRU and departmental leadership in determining appropriate procedures regarding the allocation of CRU overhead costs and distribution of margin;

Identify those studies with funding gaps and bring to the attention of the CRU Leadership Team/Faculty Advisory Council.

Engagement with Research Community & Central Administration

Participate in meetings of CRU Financial Practices Managers and CRU Advisory Council; provide input regarding institutional standards and systems; serve on sub committees as requested following the approval of the individual CRU director.

Represent the CRU and department head in meetings with PRMO, DOCR, SOM Finance and
other areas related to CRU and clinical research operations

Participate in audits conducted of CRU studies by both internal and external authorities, ensuring all appropriate financial records are available and accurate. Review and respond to all audit reports in collaboration with the RPM, PI and CRU Director. Assist in collaboration with the RPM, CAC and PIs in the development and implementation of all, corrective actions as they relate to finance practice management in a timely manner.

Obtain needed training in areas of clinical study conduct and regulations to strengthen knowledge of clinical research good clinical practices.

All other duties not specifically listed but required related to compliant financial management of CRU.

**REQUIREMENTS**

**Education/Training:**

Bachelor's degree in accounting/business field or related Duke financial experience.

Completion of Duke Research Costing Compliance certification within one year of appointment in role.

**Experience/Skills:**

Minimum of three years of experience in financial accounting to include preparing budgets, financial analysis & reconciliations, journal entries, and an understanding of financial statements.

Basic knowledge of, and experience with, accrual accounting concepts and research compliance fundamentals.

Strongly prefer previous experience in a clinical research setting and knowledge of both industry and government sponsored clinical research. Duke Research Cost Compliance certification is desirable.

Strong organizational, coordination, and prioritization skills.

Knowledge of Duke University information systems including SPS/IDX/SAP R3 & BW, e-Cert System is desirable. Strong knowledge of Microsoft Excel is necessary.

**REPORTING RELATIONSHIP**

The Finance Practice Manager will report to the CRU Director and/or Department/Center Business Manager.
CRU Research Practice Manager -
SUMMARY

Responsible to the CRU Director for the day-to-day operations of the CRU related to study conduct. Ensure that CRCs and designated research personnel are performing activities in accordance with good clinical practice, CRU standards, Institutional Policy and regulatory requirements using Standard Operating Procedures (SOPs) and periodic monitoring.

Accountable for performing activities in accordance with all institutional standards for study conduct, and more specifically those relating to clinical research, providing information to the DOCR as needed.

Manage the day-to-day operations of the CRU related to study conduct including IRB submissions and renewals; protocol initiation; participant recruitment, screening, consent and enrollment; safety reporting; and study close-out, record retention and audit ready files stored.

Monitor the status of timelines and key milestones for clinical research studies conducted within the CRU including contract execution, IRB approval, enrollment, etc.

Participate in audits conducted of CRU studies by both internal and external authorities. Review and respond to audit reports, and develop and implement corrective action in a timely manner when problems are identified.

Ensure that the CRU has up-to-date standard operating procedures, that staff are knowledgeable regarding SOPs, and that all activities are conducted in accordance with SOPs.

In centralized models where CRCs report directly to the RPM, recruit and hire CRCs with faculty input. Perform annual performance evaluations of CRCs in CRU’s where CRCs report directly to the RPM. Coordinate and assign CRCs and other research staff to specific studies and research related activities. Some CRUs may not be structured at this point to allow re-assignment of CRCs based on volume of activity. This role is advisory to the PI and the CRU director.

Because of the size of some CRUs, the central management model may not be practical in terms of numerous CRCs reporting to a single RPM. These CRUs may utilize a cluster management model approach where there is a “cluster lead” CRC to who the study conduct and regulatory compliance duties of all cluster CRCs report. The cluster lead is then accountable to the RPM.

Coordinate orientation and ongoing training for CRCs and other research staff. Ensure that current training records and required certifications are maintained and that all CRCs identified by the e-IRB system as responsible for a given protocol are qualified to serve in that role. Central administration will provide a report which identifies key personnel on each study on a quarterly or other acceptable basis.

Serve as an expert resource to PIs, CRCs, other research staff and outside agencies with regard to study-specific protocol requirements and problem-solving related to clinical, logistical, financial and regulatory issues.
Assist PIs, CRCs and research staff in the development of subject recruitment strategies, identification of barriers to enrollment, and implementation of appropriate interventions.

CRC activities supervised by the RPM include the following: Submit IRB protocols, amendments and renewals; Initiate studies; Recruit, screen, consent, enroll and follow-up with research participants; collect data and resolve queries; Supervise monitoring visits; Perform safety reporting; Ensure study drug compliance & drug accountability; Communicate research issues within and outside the department; Close out studies and ensure retention of records per Duke and sponsor policy; Ensure that research activities are performed in accordance with Good Clinical Practice standards, Duke policies and procedures, and applicable regulatory requirements; Enter subjects into eResearch in a timely and accurate manner; Monitor the progress of start-up timelines for new studies, including IRB approval, contract negotiations, budget & payment terms negotiation and development of the charge assignment grid, while providing regular updates to the CRU Director; Monitor the progress of ongoing studies including enrollment, data collection, and close-out, while providing regular updates to the CRU Director and other related research activities as determined by the RPM in day to day operations.

Conduct CRU QA audits.

Work with the CRU Financial Practice Manager (FPM) to: Evaluate the feasibility of new studies including staffing requirements, clinical and logistical considerations, and competing studies; provide input into financial feasibility of each new study by providing study plan details to FPM for the development of an internal cost summary; review and evaluate the charge assignment grid based on the schedule of events and protocol; provide training and consultative advice to PIs and CRCs in the negotiation of study budgets & payment terms with sponsors; regularly review study finances prepared by FPM; and facilitate efforts with FPM to address budget-related issues with the CRU Director, PIs, and CRCs as appropriate

Perform other related duties incidental to the work described herein. The above statements describe the general nature and level of work being performed by individuals assigned to this classification. This is not intended to be an exhaustive list of all responsibilities and duties required of personnel so classified.

**Education and Experience**

Allied Health degree or Associates degree in Clinical Trials Research and 8 years of related experience, with at least five years in a research setting. ACRP or SOCRA preferred.  
OR  
RN or Bachelor's degree and 6 years of related experience, with at least five years in a research setting. ACRP or SOCRA preferred.  
OR  
Master's degree and 4 years of related experience, with at least three years in a research setting. ACRP or SOCRA preferred.

**Knowledge, Skills and Abilities**

Basic Computer Proficiency required. Capable of working with email, databases and Microsoft Office.

Strongly prefer previous supervisory experience.
Strong knowledge of research operations, conduct (including GCP) and applicable regulatory requirements.

Strongly prefer national certification as a clinical research professional.

Strong interpersonal skills and ability to build credibility and positive relationships with principal investigators, CRCs and other research staff.
Clinical Research Unit Charter

Appendix 2: CRU Charter Template

Name of CRU:

Date:

CRU Director Signature: ___________________________

Unit Head Signature: ___________________________

NOTE: Example or explanatory text in italics may be deleted.

1. Scope of Research within the CRU:
   (Please list the division, department or sub-specialties/therapeutic areas of research that will be included in CRU. If applicable, address any common or frequent areas of overlap between the CRUs.)

2. Key Personnel:
   Director
   CRU Research Practice Manager
   CRU Financial Practice Manager
   Other

3. Define Clusters & Leadership within Clusters;
   May use text or attach and organization chart.

4. Faculty Advisory Board
   Composition: (List of membership, frequency of Board meetings, term of members, define how membership will be chosen or appointed)

   Function: (Please define how studies will be evaluated and how selection decisions will be made.)

5. CRU Governance and Financial Plan:
   Please describe who the CRU reports to (to whom the CRU is ultimately accountable) and which organization(s) provide the backstop for the CRU. [If more than one organization provides the backstop for the CRU, ensure that a memorandum of understanding (MOU) has been drafted.]

   Please describe sources of funding for CRU and method of allocation of CRU fixed costs to studies.

   What happens to Margins & Deficits?

6. CRU Stakeholders:
   Please list the CRU Stakeholders, which could include departments, centers, institutes, CSUs
7. **Communication Plan:**
*Please describe how information about the CRU will be actively communicated to CRU faculty and staff.*
Appendix 3: Acceptable CRU Management Reporting Responsibilities

Acceptable CRU Management Reporting Relationships

It is recognized that CRUs have different structures based on complexity, size and scope of research conducted. This document is intended to describe acceptable reporting relationships inside CRUs for RPMs, FPMs, CRCs and other research staff supporting the CRU. In all cases, the RPM reports to the CRU Director and the FPM reports in a dual manner to the CRU Director and to the Department Business Manager.

There are two basic options, which will have the appropriate oversight and accountability structure, depending on the size of the clinical research portfolio and faculty. Common to these two models are the following fundamental tenets:

1. The RPM is responsible and accountable (to the Director) for managing the study conduct and regulatory compliance duties of the Clinical Research Coordinators, which include the following. Careful management of these activities is considered essential to the CRC with regards to career ladder at Duke University. The CRCs and other research staff supporting the CRU are directly accountable to the RPM for these specific duty categories:
   a. appropriate training according to institutional standards
   b. good clinical practice (including IRB submissions and renewals; protocol initiation; patient recruitment, screening, consent and enrollment; drug accountability; safety reporting; and study close-out)
   c. minimum qualifications and experience for the CRC and other research staff roles
   d. adherence to CRU standard operating procedures, institutional HRPP and clinical trial billing policies, and all applicable regulatory requirements
   e. attendance at regular CRU meetings to debrief on CRU, institutional and departmental policies and procedures

2. The CRCs and other research staff remain accountable to the PI for all other activities, according to departmental practices including the scientific conduct of the study and other, non-research related activities, if applicable.

Note: further references in this document to CRCs will – in order to simplify the document – refer to CRCs and to and other research staff who serve in the same capacity.

CENTRAL Management Model:
Some CRUs may employ a centralized model where all CRCs have a direct reporting relationship to the RPM specifically for the study conduct and regulatory compliance duties noted above.

CLUSTER Management Model:
Because of the size of some CRUs, the central management model may not be practical in terms of numerous CRCs reporting to a single RPM. These CRUs may utilize a cluster
approach where there is a “cluster lead” CRC to who the study conduct and regulatory compliance duties of all cluster CRCs report. The cluster lead is then accountable to the RPM.
Internal Cost Assessment

Effective Date: June 30, 2013
Review/Revision History: Version 1.3

Purpose: To outline the process and requirements for developing an internal cost assessment (a determination of projected study costs) and what approvals will be required.

The following entities are covered by this policy:
Duke Medicine

Policy:
An internal cost assessment must be developed for all clinical research studies that require CRU oversight (refer to CRU Scope of Oversight and Responsibility of Clinical Research Policy). Regardless of whether the project is funded externally or internally, the CRU is required to determine projected costs before granting approval for the PI to proceed.

CRUs are required to use the approved Internal Cost Assessment (Attachment 1) or a CRU-specific template that includes all elements of the version provided. The template is posted on the Study Start-Up tab of the DOCR website. Foundation and Federally-funded studies require completion of an internal cost assessment, but use of the approved internal cost assessment template (or similar template) is not necessary.

CRU Leadership is responsible for review and approval of the Internal Cost Assessment as part of the initial CRU approval process (refer to CRU Scope of Oversight and Responsibility of Clinical Research Policy and CRU Structure and Organization Policy).

Procedure:

1. The CRU is required to implement a process for initial approval of proposed projects. Included in this process must be a review of the Internal Cost Assessment.

2. A study team wishing to initiate a study must submit, as part of the initial CRU approval process, the Internal Cost Assessment to CRU Leadership for review prior to or concurrently with IRB submission.

3. The CRU Financial Practice Manager (or designee) is responsible for review and approval of the Internal Cost Assessment. Denials and/or recommendations will be deferred to the CRU Director for review in accordance with the CRU procedures for initial approval.

4. Upon approval, the CRU should complete the study review process in accordance with the CRU’s documented procedures.
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<th>Duke Office of Clinical Research</th>
<th>Date:</th>
<th>4/3/13</th>
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<td>Date:</td>
<td>4/3/13</td>
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<td>Effective Date:</td>
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### Earned Revenue Calculation by Milestone

**Study Name:** Study to determine the efficacy of a drug on a disease  
**Sponsor:** Magic Drugs, Inc  
**PI:** Dr. Findacure  
**CRC:** Nancy Nurse  

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**Total Visit Earned Revenue:** $8,500

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**Total Invoiceable Earned Revenue:** $6,800

**Total Earned Revenue:** $13,300
**Cash Posted in R/3 SAP**

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$9,500 Total Cash Received

**Outstanding Revenue Calculation**

| Earned Revenue | $15,300 |
| Cash Received  | $9,500  |
| Amount Outstanding Revenue | $5,800 |
Actual cash received is on GL 324400.

The amount invoiced to the sponsor is on GL 324405 ($31,786).

To find the amount still owed by the sponsor, you must run a ZF109AR report.
The ITD Revenue is the amount of cash received ($281,314.08 on GL 324400) plus the amount invoiced to the sponsor ($31,786 on GL 324405) reflected on the ZFR1E report.

The amount still owed by the sponsor (accounts receivable) is $2,309.94, which is in the A/R column.
Handout 8
Page 1

ZFR1E
Reviewing A/R for Industry-Sponsored Clinical Research

Project/WEBs Element: [Redacted]
Person Responsible: [Redacted]
Project Period: 11/05/2009 - 06/30/2010
Project To Date thru Period 2 Fiscal Year 2014

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- Actual cash received is on GL 326600.
- The amount owed by the sponsor (accounts receivable) is on GL 326650. This is based on the accrued revenue listed on the trial tracker minus the amount of cash received by the sponsor.
- The total of the cash and accounts receivable equals the total earned revenue for this fund code.
- The true available funds on this project is the total of the Sponsored Programs Revenue cost element group minus the expenses.
The ITD Revenue is the cash received ($2,367,207.04 on GL 326600) plus the amount owed by the sponsor ($506,066.70 A/R on GL 326650) reflected on the ZFR1E report.

The true available funds on this project is the ITD Revenue minus the ITD Expenses, which is in the Rev vs Expense column.