Office of Clinical Research

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Defining a Clinical Research Unit (CRU):

A UC San Diego Health Sciences CRU will have the infrastructure to support a strong foundation for the conduct of high-quality, ethical, and compliant clinical research. This infrastructure must include the following critical components**:**

1. Qualified Personnel:

- **Leadership:** The principal investigator (PI) should have demonstrated experience in clinical research, including expertise in the design, conduct, and analysis of clinical trials. The PI is responsible for the scientific direction and protocol oversight of studies.
- **Clinical Operations Management**: A CRU director or manager oversees daily operations, regulatory compliance, resource allocation, and coordination with investigators and institutional leadership. This role ensures smooth communication across departments and adherence to best practices.
- **Support Staff**: Include specialized administrative staff for managing regulatory documents, IRB coordination, financial management (e.g., grant administration, billing), and participant recruitment.
- **Organizational Structure**: Develop a clear organizational chart that defines roles for a faculty director, administrative director, regulatory team, study coordinators, project managers, and finance staff. This structure ensures transparency and accountability across all critical functions.
- **Training and Certification**: All personnel, including PIs and clinical staff, must maintain current certifications in Good Clinical Practice (GCP) and human subjects research ethics. Ongoing training specific to research protocols ensures adherence to study-specific procedures and the highest standards of participant care.

2. Infrastructure and Facilities:

- **Clinical Space**: Provide access to dedicated space for patient visits, research procedures, sample collection, and study monitoring. This includes exam rooms, infusion rooms, laboratory space, and secure storage for investigational products.
- **Medical and IT Equipment**: Ensure the availability of specialized medical equipment necessary for study-specific procedures and IT systems for secure data entry and storage. Include capabilities for remote monitoring and telehealth as needed.

  Annual Metrics (exceptions may occur – for example, studies involving rare diseases and studies conducted at the VA Medical Center, San Diego and Rady Children's Hospital, San Diego):

  - ≥10 faculty investigators with at least 5 serving as PI/PD on clinical research studies.
  - ≥50 new participants enrolled per year.
  - Sustainable revenue to support the organizational structure.

3. Participant Registration

- **Registration Requirement**: For studies involving a regulated investigational device, a therapeutic intervention subject to inspection by the Food and Drug Administration (FDA) under sections of the Code of Federal Regulations, or where a billable moment occurs, all research subjects must have a medical record created (UCSDHP 340.1). This process ensures proper documentation, patient safety, and accurate billing.
- **Record Maintenance**: These records should be maintained in accordance with institutional policies and federal regulations, ensuring all research-related activities are properly documented for compliance (including 21CFR part 11 compliance for research conducted under FDA oversight) and audit purposes.

4. Standard Operating Procedures (SOPs):

- Develop and implement standardized SOPs for key research activities, including participant registration, informed consent, IRB interactions, adverse event reporting, and data management. SOPs should align with institutional guidelines to ensure consistency and compliance.
- Regular updates to SOPs based on best clinical practices and regulatory changes.

5. Data Management and IT Systems:

- Maintain robust data management systems for accurate, secure, and compliant collection, storage, and analysis of clinical data. Systems must adhere to HIPAA and relevant data privacy regulations.
- **Data Monitoring**: Use tools for real-time monitoring and analysis to promptly identify trends, adverse events, or protocol deviations.
- **Data Backup and Recovery**: Have a comprehensive data backup and disaster recovery plan to safeguard sensitive information and ensure continuity of operations in case of system failures.

6. Quality Assurance and Monitoring:

- **Quality Management**: Develop internal and external quality assurance processes to verify data accuracy and ensure compliance with study protocols. Integrate sponsor or Contract Research Organization (CRO) monitoring visits as part of overall quality oversight.
- **Corrective Actions**: Establish procedures for addressing issues identified during quality assurance reviews, including a feedback loop for continuous improvement and protocol amendments.

7. Financial Management:

- **Comprehensive Budgeting**: Create detailed budgets that account for all study-related expenses, including staff salaries, participant stipends, and operational costs. Strategic allocation of resources should prioritize high-value studies and ensure the financial sustainability of the unit.
- **Grant Management**: Maintain transparency and compliance with funding requirements, ensuring proper allocation of resources and timely financial reporting to sponsors.

8. Patient Recruitment and Retention Strategies:

- Effective strategies for participant recruitment to meet enrollment targets, inclusive of diverse study populations.
- Measures to enhance participant retention throughout the duration of the study.
- Formal feasibility assessment (study patient population is accessible).
- Process for periodic review of accrual, with closure of poorly or non-accruing studies.

9. Continuous Education and Training:

- Ongoing education and training programs for research staff to stay current with evolving research methodologies.
- Training on new technologies and advancements in clinical research.

10. Publication and Dissemination:

- A commitment to disseminating research findings through publications and presentations.
- Ensure that all study results, including negative or null findings, are shared transparently in alignment with institutional and ethical guidelines.