Scope:
Accountable Care Organization, Administrative & Business Offices, Ambulatory, Behavioral Health, Breast Health Center, Center for Advanced Medicine B, Center for Advanced Medicine C, Foundation, Healthcare Center, Home Health, Hometown Health, Hospice, Hyperbaric, Laboratory, Medical Group, Monaco Ridge, Pregnancy Center, Regional Medical Center, Rehabilitation Hospital, Skilled Nursing, South Meadows Medical Center, Surgical Arts, Therapies, Urgent Care, Wound Care, X-ray & Imaging

Policy Statement:
Under the direction of the Renown Authorized Institutional Official (RENOwn.ORE.101), the Renown Research Office (RO) assures regulatory and financial compliance with applicable institutional, federal, state and local laws and supports researchers throughout Renown in the identification of research opportunities, the acquisition of funded research projects and the conduct of research and associated educational activities. The RO serves as the central research administrative office for Renown Health. However, each Renown Specialty Department or Program (Specialty Department) is responsible for study conduct activities as well as management of its research portfolio with the guidance and assistance of the Renown Research Office.

Purpose:
To outline the roles and responsibilities of the Renown Research Office and of the Specialty Departments or Programs (generally).

Definition of Terms:
N/A

These Policies and Procedures are guidance for the Organization. The Organization recognizes there may be specific facts and/or circumstances that warrant a departure from a specific policy provision. Nothing herein is intended to override an employee’s ability to use good judgment in such circumstances.
Procedure:

The RO operates in the following areas:

1. The general administrative management of research;
2. Support of the preparation of scientific proposals and the proposal budgets;
3. Review of and assistance in the preparation of protocols and study documents;
4. Negotiation and coordination of the research contracts and associated agreements and documents;
5. Support of the conduct of research studies;
6. Reporting, publishing and records management for research;
7. Project closeout;
8. Financial management of research activities; and
9. Compliance and internal controls.

**RESEARCH OFFICE ROLE**

**Policy and Procedure Development and Maintenance**

The RO is primarily responsible for drafting, and after approval by the Renown Executive Research Committee (ERC), maintaining Renown Research Policies. Policies in the Renown Research Policy series include:

1. Principal Investigator Eligibility;
2. Research Management;
3. Clinical Research Budget Development;
4. Research Conflict of Interest;
5. Scientific Misconduct;
6. Renown-wide costing issues with research projects; and,

The RO:

1. Coordinates with Principal Investigator, the UNR-IRB or alternative IRB, and the ERC to help ensure that clinical research and related activities are performed in accordance with
Federal regulations and Renown and sponsoring agency/company policies and procedures.

2. Assists the Specialty Department and the Principal Investigator (PI) in development of materials and tools necessary to appropriately train individuals involved in the conduct of the study around issues related to (but not limited to) protocol requirements, schedule of visits, execution of research plan.

3. Maintains documentation of training.

4. Assists the Specialty Department and the PI to assure that all key personnel or persons "engaged" in the research project have met training requirements in accordance with Federal regulations and Renown and sponsoring agency/company policies and procedures.

5. Cooperates with Renown compliance and monitoring efforts related to administration of the research program and reports instances of noncompliance to the appropriate compliance office.

6. Coordinates and facilitates monitoring and auditing visits. Notifies appropriate institutional officials of external audits by FDA and sponsors.

7. Collaborates with the Specialty Department, the PI and the ERC to respond to any audit findings and implement approved recommendations.

8. Cooperates with Renown and sponsoring agency compliance and monitoring efforts related to human research participant protection and reports instances of noncompliance to the appropriate compliance office.

**Preparation of Scientific Proposal**

1. The RO will assist the PI in study feasibility assessments as requested. However the primary responsibility to conduct feasibility assessments and the final authority to determine whether any activity is feasible rests with the Specialty Department and the PI and the PI's supervisor.

**Proposal Budget**

1. The RO will collaborate with the PI and Specialty Department to prepare a categorized budget and justification. The RO will work with appropriate Renown Departments to confirm accuracy and completeness of budgeted costs. However the primary responsibility to prepare the direct cost budget and the final authority to determine whether any activity is economically feasible rests with the Specialty Department and the PI and the PI's supervisor. The final determination of the appropriate Facilities and Administrative (F&A or "indirect") rate rests with the CFO.

**Protocol Preparation & Review**
1. The RO reviews and comprehends the protocol for purposes of assuring compliance with applicable laws regulations, policies and procedures; and to be able to assist the PI and the Specialty Department in their research activities. However the primary responsibility to review, comprehend and follow any protocol rests with the PI (particularly under 21 CFR § 312 and 21 CFR § 812). The PI is responsible for:

   a. Ensuring that a clinical investigation is conducted according to the signed investigator statement (or agreement for clinical investigations of medical devices), the investigational plan, and applicable regulations.

   b. Protecting the rights, safety, and welfare of subjects under the Investigator’s care.

   c. Controlling drugs, biological products, and devices under investigation (and the final authority to determine whether any activity is feasible rests with the Specialty Department and the PI and the PI’s supervisor).

The RO will:

1. Provide staff to attend investigator meetings as required or requested by the PI.

2. Collaborate with the PI to prepare IRB and any other regulatory submission documents as required by the protocol.

3. Assist with the preparation of other study materials as requested by the PI. These study materials include, but are not limited to, the informed consent document, case report forms (CRFs), enrollment logs, and drug/device accountability logs. However the primary responsibility to prepare or review, comprehend and properly use any informed consent document, CRFs, enrollment logs, and drug/device accountability logs rests with the PI, the PI’s supervisor, and the Specialty Department.

4. Work with the Specialty Department to establish and organize study files, including but not limited to, regulatory binders, study specific source documentation and other materials.

**Award, Negotiation, Acceptance, and Performance (Terms & Conditions)**

The RO is primarily responsible for the contractual underpinnings of any sponsored research. The RO will:

1. Work with the ERC to develop guidelines for acceptable contract or award terms and conditions in clinical and other research agreements.

2. Negotiate all non-scientific terms and conditions of all research-related agreements, working with General Counsel (and outside counsel if assigned by the Renown Office of General Counsel).

3. Approve all agreements (e.g., Nondisclosure Agreements or other agreements or documents subsidiary or ancillary to the research enterprise) which will be executed or
otherwise utilized by any Specialty Department or PI that will not be subject to individualized review and will establish such procedures for after-the-fact or other internal control and management of such agreements or documents.

4. Obtain appropriate signatures and dates for execution of contracts and other agreements.

5. Manage all contracts related to Renown research. This includes management of relationships with outside counsel, sponsoring agencies, development of contract templates, and collaboration with Office of General Counsel (OGC) on research-related legal matters.

6. Coordinate with the CFO, CIO, CAO, and other supporting organizations to obtain and manage the financial and accounting, information and security, facilities and property management related to any of the research contracts or other agreements.

While the RO is responsible for compliance with the contract terms and conditions, it is important to emphasize that investigators who conduct clinical investigations of drugs, including biological products, under 21 CFR §312, and investigators who conduct clinical investigations of medical devices, under 21 CFR §812, commit themselves to personally conduct or supervise the investigation. It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.

1. The RO, working with General Counsel (and any assigned outside counsel or technology transfer organization) manages any research intellectual property developed by a Renown inventor. This includes assisting the PI and OGC with filing of intellectual property protection with the U.S. government.

2. The RO works with the PI, Specialty Department, OGC and all affected Renown departments and personnel to assure that all studies and all study contracts are in compliance with all applicable institutional, federal, state and local laws, the terms and conditions of all contracts and agreements, and all policies and procedures governing research, including but not limited to those concerning education, IRB approval, conflict of interest disclosure, health and safety protections for participants and staff, environmental and other facilities and property requirements, and any financial terms or conditions.

Conduct of Research

The RO will:

1. Review and develop a familiarity with the protocol, e.g., study proceedings and timelines, inclusion and exclusion criteria, confidentiality, privacy protections.
2. Assist the PI in communication of study requirements to all individuals involved in the study.

3. Assist the PI and Specialty Department in providing appropriate training and tools for study team members. The PI and the Specialty Department are responsible for documenting date of training and signatures of study personnel trained on study specific training log, but the RO will provide appropriate internal controls to assure compliance with all contract and regulatory training commitments.

4. Assist the PI and the Specialty Department with collection of documents needed to initiate the study and submit to the sponsor (e.g., FDA Forms 1572, CVs, etc.).

5. Work with the PI and Specialty Department to develop and implement recruitment strategies in accordance with (IRB) requirements and approvals.

6. Assist the PI in the informed consent process, including interactions with the IRB.

7. Obtain appropriate signatures and dates on forms in appropriate places and assure that amended consent forms are appropriately implemented and signed.

8. Maintain effective and ongoing communication with sponsor, research participants, PI and Specialty Department and any sub-recipients during the course of the study.

9. Assist the PI in preparation of any modifications to the scientific protocol in accordance with Federal regulations and Renown and sponsoring agency policies and procedures.

10. Work with the PI to assure appropriate management of the day-to-day activities of the study including problem solving, communication and protocol management.

**Reporting**

The RO will:

1. Promote the ethical conduct of research by reporting good faith suspicions of misconduct in research as defined within Renown’s Research Integrity Policy and other misconduct as described in Renown’s Code of Conduct.

2. Assist the PI with scientific and compliance reporting requirements in accordance with Federal regulations and Renown and sponsoring agency policies and procedures.

3. Assist in the registration (if required) of the study at [ClinicalTrials.gov](http://ClinicalTrials.gov) and maintain current information on the site.

**Project Closeout**

The RO will:

1. Assist the PI in submission of accurate and timely closeout documents to applicable
Federal agencies, Renown entities, and the sponsoring agency in accordance with Federal regulations and Renown and sponsoring agency policies and procedures.

2. Arrange secure storage of study documents that will be maintained according to Renown policy or for the contracted length of time, whichever is longer.

**Financial Management Assistance**

The RO will:

1. Review and accept/correct the billing matrix to facilitate billing of study procedures to the appropriate research fund.

2. Review (for internal control/audit only) personnel activity reports if applicable.

**Conflicts of Interest (COI)**

The RO will:

1. Assist the PI and Specialty Department in taking appropriate steps to avoid conflicts of interest, or the appearance of conflicts of interest, between financial or other personal interests and the goals and policies of Renown.

2. Assist the General Counsel in preparation of research-related COI policies compliant with applicable sponsoring agency/company conflict of interest policies and procedures.

3. Work with General Counsel to disclose all financial conflicts of interest to the appropriate Renown officials, Agency or Sponsor.

4. Cooperate with Renown compliance and monitoring efforts related to conflicts of interest and reports instances of noncompliance to the appropriate compliance office.

**Human Research Participant Protection**

The RO will:

1. Assist the PI in protection of the rights and welfare of all human research participants involved in research in accordance with Federal regulations and Renown and sponsoring agency policies and procedures.

2. Assist the PI in assuring that all key personnel involved in human research have completed the required education for the protection of human research participants in accordance with Federal regulations and Renown and sponsoring agency policies and procedures.

3. Coordinate with the PI, Specialty Department, and the ERC to help ensure clinical research and related activities are performed in accordance with Federal regulations and
Renown and sponsoring agency policies and procedures.

4. Assist PI in development of materials and tools necessary to appropriately train individuals involved in the conduct of the study around issues related to (but not limited to) protocol requirements, schedule of visits, execution of research plan.

5. Cooperate with Renown compliance and monitoring efforts related to research and report instances of noncompliance to the appropriate compliance office.

6. Coordinate and facilitate monitoring and auditing visits; notify appropriate institutional officials of external audits by FDA and/or sponsors.

7. Collaborate with PI and institution to respond to any audit findings and implement approved recommendations.

**Protected Health Information (PHI)**

The RO will:

1. Work with the IHI to assure compliance with all Federal regulations and Renown policies and procedures instituted to safeguard PHI.

2. Work with the IHI and the Renown Privacy Officer (PO) to support the training requirements related to PHI and information security and work with the CIO and PO, the Specialty Department and the ERC to assure that all staff involved in research complete the appropriate level of training regarding the access, use, and disclosure of PHI in accordance with Federal regulations and Renown and sponsoring agency policies and procedures.

3. Cooperate with Renown compliance and monitoring efforts regarding the access, use, and disclosure of PHI and reports instances of noncompliance to the appropriate compliance office.

**Environmental Health and Safety/Facilities Use**

The RO will:

1. Assist the PI and Specialty Department in assuring that individuals handling hazardous or regulated materials are well trained in proper safety procedures and have completed required environmental health and safety training in accordance with Federal, State, and local regulations and Renown and sponsoring agency policies and procedures.

2. Work with the Environmental Health and Safety offices to ensure all facilities used are in compliance with all applicable regulations.

3. Maintain copies of any applicable records related to facilities use in connection with research agreements and equipment records related to sponsor-provided equipment
and to any applicable inspection/service reports.

**Human Gene Transfer**

1. The RO will assist the PI in protection of the rights and welfare of all human research participants involved in research in accordance with Nevada law, Federal regulations and Renown and sponsoring agency policies and procedures.

**RESPONSIBILITIES OF THE RENOWN RESEARCH SPECIALTY DEPARTMENT**

While the RO is the central administrative manager for research, each department or program that undertakes research is responsible for its own activities.

1. Initiation of a Research Program for a Department

   A. Each Specialty Department is responsible for:

   i. Developing its research business plan and goals;

   ii. Managing its research financial portfolio;

   iii. Managing daily study conduct;

   iv. Department or Program-specific orientation;

   v. Developing Department- or Program-specific research operating procedures;

   vi. Hiring of appropriately qualified research staff to meet department research needs;

   vii. Ensuring the research program meets RO policies and procedures as well as government regulatory requirements.

2. Study Management

   A. Each Specialty Department will:

   i. Select studies that would best fit the needs and goals of the Specialty Department and the Renown patient population. An Investigator who wishes to conduct a research trial utilizing resources within Renown will provide the study details to the research department or program leader. The research department or program leader will ascertain if the proposal meets criteria for FDA and DHHS regulations and is in line with the research program or departmental research portfolio goals.

   ii. Provide protocol-specific education to the clinical areas where research
activities will be conducted.

iii. Negotiate the direct costs for the study budget utilizing the RO budget template.

iv. Submit the study to the RO via email in accordance with RO 2.02.

B. The Specialty Department will be responsible for the conduct of the research study to include regulatory requirements, adhering to the IRB-approved protocol, subject enrollment and follow-up and financial responsibility.

C. The Specialty Department will conduct all studies following the regulations of the agency with oversight of the study (FDA, DHHS) and in adhering to the designated IRB policies.

References/Regulations:

- RENOWN.ORE.101; RENOWN.ORE.202; 21 CFR §§ 312 & 812; FDA Forms; Form 1572

Contributors/Reviewers:

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