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:

The Renown Research Office (RO) functions to promote high quality, ethical research. The RO ensures regulatory and financial compliance with applicable institutional, federal, state and local laws. Though located on the Renown Regional campus, the RO supports researchers throughout Renown under the direction of the Renown Authorized Institutional Official. The Renown Research Office shall provide the policies and procedures governing research at Renown and contract with the designated Institutional Review Board and Human Research Protection Program, subject to the overall authority of the Renown Authorized Institutional Official in charge of research.

The Renown Research Office shall be advised by the Office of General Counsel and shall coordinate with the Chief Financial Officer, the Chief Medical Officer, the Chief Compliance Officer, the system Internal Audit office, and the Chief Information Officer.

Purpose:

To outline the functions and roles of the Renown Research Office.

Definition of Terms:

1. **Authorized Institutional Official (IO):** The executive appointed by Renown to accept authority, oversight and responsibility for the conduct of research within Renown Health. Per HHS Office of Human Research Protections (OHRP) guidance, this must be an
official of the institution who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. At Renown, the Authorized Institutional Official (IO) for Federal Awards and Federal-wide Assurances is designated by the CEO of Renown in accordance with RO 101. The IO designates a Patient Safety Officer who acts as research subject area expert.

2. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102 d) Note that the U.S. Food and Drug Administration (FDA) has defined "clinical investigation" to be synonymous with "research." "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA, or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. 21 CFR 56.102 and 50.3 Definitions.

Research governed by the RO includes both research related to human subjects and other research as defined above.

3. Human Subject:

A. Per 21 CFR 56.102 (e), "Human Subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

B. Per 45 CFR 46.102 (f), "Human Subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:

   i. Data through intervention or interaction with the individual, or

   ii. Identifiable private information.

4. Obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research. Obtaining identifiable private information or identifiable specimens includes, but is not limited to:

A. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source; and

B. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in the possession of the investigator. [http://www.hhs.gov/ohrp/policy/cdebiol.pdf](http://www.hhs.gov/ohrp/policy/cdebiol.pdf)

5. Cadaver Research: A cadaver is not considered to be a human subject. Therefore, research on specimens/data obtained from a cadaver would be considered a “non-
human subject.” Research involving cadavers may be submitted to the IRB for a determination of “non-human subject research” if such documentation is needed. Certain aspects of research involving cadavers or body parts obtained from cadavers may be regulated by Nevada law. Contact the Office of General Counsel with any questions.

6. “Health care records” is defined under Nevada Revised Statutes NRS 629.021 as “...any reports, notes, photographs, X rays or other recorded data or information whether maintained in written, electronic or other form which is received or produced by a provider of health care, or any person employed by a provider of health care, and contains information relating to the medical history, examination, diagnosis or treatment of the patient.”

7. “Human Research Protection Program” is a program with the responsibility to consider the rights and welfare of human subjects participating in research, including but not limited to ethical considerations, human subject protection and compliance with State and federal rules and regulations. The Human Research Protection Program (HRRP) designated by Renown Health is the University of Nevada Reno HRPP (UNR-HRPP).

8. “Intervention” includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a Health Care Record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

9. **Institutional Review Board (IRB):** The IRB is an administrative body that performs ethical review of proposed research and the designated IRB for Renown is the University of Nevada Reno IRB (UNR-IRB), unless otherwise designated by a Sponsor and agreed to by Renown. IRB review assures that all research activities conducted within Renown Health adequately protect the rights of human participants recruited to participate in research activities conducted under the auspices of the institutions and are scientifically sound as required under Public Law 93-348; 21 CFR 50, 56, 312, 812; DHHS 45 CFR 46; and ICH Guidelines. The IRB is responsible for the initial and continuing review of all research activities conducted at all Renown Health Institutions, following federal requirements set forth in the FDA Code of Federal Regulations 21 CFR 56, HHS 45 CFR 46 and ICH Guidelines E6. IRB refers to any and all of the Institutional Review Boards designated by Renown and serving under the Federal-wide Assurance of Renown Health.
10. **Principal Investigator (PI):** The key person in the research process is the Principal Investigator (PI). The various review mechanisms and institutional safeguards cannot adequately substitute for the intellectual commitment and drive that the individual Investigator brings to the research process. The PI is more than a titular head of the research project. She or he is the person who is ultimately accountable for the scientific integrity and productivity of the research study. When a person agrees to become a Principal Investigator, she or he has made a commitment that should not be taken lightly. The PI must be properly qualified in accordance with RO 3.01. The PI roles and responsibilities are further summarized in RO 3.07. Training for PIs is outlined in RO 303.

**Procedure:**

1. The overall responsibility for the conduct of research at Renown Health rests with the Authorized Institutional Official and the Renown Research Office (RO 1.01). The RO establishes and implements research policies and procedures in accordance with all federal regulations, Nevada and local law and regulation and Good Clinical Practices. However, while protecting the rights and welfare of human research subjects and ensuring the appropriate conduct of research is a responsibility that all institutional officials and Renown staff members share. The UNR-IRB is the contracted group that has been officially designated by Renown and RO to review and monitor biomedical research involving human subjects. In accordance with FDA and U.S. Department of Health and Human Services (HHS) regulations, the UNR-IRB or other designated IRB has the authority to approve, require modifications in (to secure approval), or disapprove research.

2. Structure: The Renown Research Office is located at Renown Regional Hospital. The Research Office has roles (RENOwn.ORE.101) in:

   (a) The general administrative management of research;
   (b) Support of the preparation of scientific proposals and the proposal budgets;
   (c) Review of and assistance in the preparation of protocols and study documents;
   (d) Negotiation and coordination of the research contracts and associated agreements and documents;
   (e) Support of the conduct of research studies;
   (f) Reporting, publishing and records management for research;
   (g) Project closeout;
   (h) Financial management of research activities; and
   (i) Compliance and internal controls.

3. Policy and Procedure Development

   (a) The principal responsibility for proposing new Research Policies, amendments or modifications of existing Policies and updating existing Policies rests with RO Director in coordination with the applicable organization functions relating to the policies. For
instance, Renown Research Policies relating to research, information technology and academic matters, including faculty matters, must be coordinated with Renown’s Chief Medical Officer, who consults with the outside organizations such as the University of Nevada, as appropriate. Renown Research Policies relating to budgetary, financial and accounting matters (including research accounting) must be coordinated with the Renown Chief Financial Officer. Renown Research Policies relating to facilities, human resources, security and other general areas of Renown Research administrative operations primarily reside with the Chief Executive Officer, or delegate. The RO Director is also responsible for keeping Renown Research Policies relating to their areas up-to-date.

(b) All RO policies will be developed, reviewed and revised consistent with the Renown Policy on Policies. (RENOWN.CCD.001).

4. RO Director. The responsible official for this policy is the Renown Research Office Director. Questions relating to the implementation of this policy should be directed to the RO Director, Office of the General Counsel or RO staff members for aspects of implementation for which they have delegated authority.

Additionally, the RO shall cooperate with development and maintenance of policies and procedures as set forth below:

(a) Human Subjects. The RO shall assure the protection of the rights and welfare of persons who participate in research programs conducted by Renown Medical Staff, employees, and researchers affiliated with Renown.

   i. Ascertain research projects meet criteria for Federal, state, local and international regulation, and whether any part of the research will take place in a Renown facility and thereby have oversight by the RO (and by an appropriate IRB).

   ii. Reviewing all research projects in determining the feasibility of the study, if the study and research team comply with Renown policies and procedures, including submission to the UNR-IRB or a designated alternate IRB with an existing Renown authorization agreement.

(b) Business Operations. The RO is responsible for:

   i. Billing compliance;

   ii. Financial management of studies;

   iii. Annual budget development.

(c) The Office General Counsel. The RO shall cooperate and coordinate with the Office of General Counsel in connection with:

   i. Contracts—management of 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 on research related legal matters.

ii. Intellectual Property - management of any research intellectual property developed by a Renown inventor. This includes filing of intellectual property protection with the U.S. Government.

iii. Policy Development.

(d) Information Management, Information Security, and Database Administration. The RO shall cooperate and coordinate with the CIO in connection with all matters relating to Information Management, including but not limited to HIPAA, Electronic Health Records (EHR), physical and data security, records management, internal contract/project management systems, and records disposition.

(e) Public Health/Environmental safety, Lab management, Epidemiology and Biostatistics. The RO shall cooperate and coordinate with the offices in charge of each of the above as necessary for matters of joint concern.

References/Regulations:

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<td>RENOWN.CCD.001; RENOWN.ORE.101; 45 CFR §46.102 (f) &amp; (d); 45 CFR §§46 &amp; 56.102 and 50.3; 21 CFR §§50, 56, 312, 812; Public Law 93-348; DHHS; and ICH Guidelines</td>
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