



Rancho Los Amigos National Rehabilitation Center PHYSICAL THERAPY DEPARTMENT POLICY AND PROCEDURE

RESEARCH GUIDELINES

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PURPOSE:

This document describes the organization, mechanisms, policies, and procedures for the conduct of research as a member of or through the auspices of the Physical Therapy (PT) Department at Rancho Los Amigos National Rehabilitation Center (RLANRC). These research guidelines are intended to ensure that components of the departmental mission remain complementary, that individual research projects are carried out effectively for maximum patient and staff benefit, and that research subjects are fully and ethically protected according to the letter and the spirit of medical center and federal guidelines regarding informed consent and the management of research risks and benefits

POLICY: This policy pertains to considerations for research involvement, procedures for obtaining necessary permission for research projects, and appropriate acknowledgment for research contributions. This policy is intended primarily for individual investigators who desire to conduct intramural (at RLANRC) or extramural (any academic, clinical, or setting other than RLANRC) research as members of the PT Department at RLANRC. This policy also applies to those investigators with primary affiliations from institutions other than RLANRC who wish to involve RLANRC PT Department staff or RLANRC inpatients or outpatients as research participants. Thus, this policy applies to, but is not limited to, the following individuals:

1. (Category 1): RLANRC PT personnel serving as principal investigators or co-investigators for research projects conducted at RLANRC that are not requirements for academic courses or degrees;
2. (Category 2): RLANRC PT personnel serving as principal investigators or co-investigators for research projects conducted at RLANRC that are part of academic program course or degree requirements;

3. (Category 3): RLANRC PT staff engaged in collaborative or independent research where data are collected at sites other than RLANRC when the listed affiliation of those RLANRC staff (in research materials, informed consents, professional presentations and publications, etc.) will or should include RLANRC;
4. (Category 4) RLANRC PT staff who serve as research committee members for students from PT or other academic programs when the research project data will be collected at RLANRC or with RLANRC staff or patients; and
5. (Category 5) Researchers from academic or other institutions who wish to incorporate RLANRC staff or patients as research personnel or subjects in their research studies.

I. CONSIDERATIONS FOR RESEARCH INVOLVEMENT

Primary considerations for individuals wishing to conduct research are the extent of time and effort required to adequately complete a research project and the availability of expertise and resources to accomplish the various tasks that constitute a successful research project. PT Department personnel should consult with their clinical managers, supervisor, or the PT Director to determine if short- and long-term commitments in investigator time or work assignments are feasible.

II. PROCEDURES FOR OBTAINING NECESSARY PERMISSION TO CONDUCT RESEARCH

Approval to conduct research must be obtained from several sources. Consultation with the organizational resources with research expertise [e.g., Rebecca Lewthwaite, Ph.D., (562) 385-6145, Sara Mulroy, Ph.D., PT, (562) 385-7177] is recommended before official approvals are sought. For RLANRC PT Department staff, management approval of time for preliminary project development should also be obtained well before approvals are pursued. Generally, a formal written application with accompanying research proposal and informed consent documents must be made to the Rancho Research Institute (RRI) Research Committee {formerly known of as Los Amigos Research and Education Institute, Inc. (LAREI)}. This committee serves as the Human Subjects Protection Committee or Institutional Review Board (IRB) of RLANRC. Forms required for Research Committee submission can be obtained directly from RRI (“Research Application Instructions, Forms and Information”) by calling (562) 385-8111.

Some studies will be exempted or receive expedited review from the Research Committee and a full application and proposal will not be required, but an

abstract with specific pieces of information must be submitted to RRI for approval prior to data collection; the IRB will determine whether a full application (application form, research proposal, informed consent forms, or other documents) or an abbreviated application is required. The Research Committee application form requires the signatures of relevant Department Heads, Service Chiefs, and the RLANRC Medical Director before the IRB will consider the proposal/abstract for approval. Potentially controversial or marginal approvals will be flagged for additional review by the Department of Health Services Research Oversight Board. Rancho's IRB meets once monthly to approve research projects and all materials are due to the committee several weeks before the scheduled meeting (telephone the RRI number above for a specific month's deadline).

Steps for Obtaining Project ApprovalRequired of Researcher Categories

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| 1. | Consult with RLANRC/PT Department research resources regarding significance, feasibility, and PT Department priority of the proposed project. | 1 through 4 |
| 2. | Consult with area or department management regarding <u>time/work assignment</u> support for preliminary project development/project. | 1 through 3 |
| 3. | Obtain Research Committee application materials from RRI | 1 through 5 |
| 4. | Prepare and submit draft(s) of Research Committee materials to RLANRC/PT Department research resource consultant for review/revisions and preliminary approval. | 1 through 4 |
| 5. | Obtain necessary approvals from Department Heads (except PT Director at this stage) and/or Service Chiefs. | 1 through 5 |
| 6. | Obtain PT Director's signature. | 1 through 5 |
| 7. | Obtain signature of RLANRC Medical Director | 1 through 5 |
| 8. | Obtain access to self-study modules from CITI through RRI related to "Foundations and Concepts of Research Involving Human Subjects" (Mandatory Research ethics training) and to HIPAA regulations relevant to researchers. Successfully pass investigator training questionnaires. These training modules must be completed specific to Rancho prior to project initiation and final IRB approval. | 1 through 5 |
| 9. | Submit complete application materials to the RRI Research Committee (outside RLANRC: Rancho Research Institute, Research Committee, Downey, CA, 90242; | 1 through 5 |

inside RLANRC: RRI Research Committee.

For individuals in Category 2: Approval from appropriate academic institution personnel, including academic/research advisor and academic institution's Institutional Review Board will be required in addition to approvals indicated above at RLANRC. Permission from the academic institution's IRB should be obtained prior to application to the Rancho Research Committee, if possible.

For individuals in Category 3, 4 and 5: IRB approval from any academic or clinical institution where data will be collected or where the principal investigator of the project has primary affiliation will be required in addition to RLANRC approvals. Permission from other relevant institutions' IRBs should be obtained prior to application to the Rancho Research Committee, if possible.

For project proposals involving the Pathokinesiology Laboratory of RLANRC: Arrangements that involve research or data collection at the Pathokinesiology Laboratory should be made directly with the staff of the Pathokinesiology Laboratory [(562) 385-7177]. For RLANRC PT staff in Categories 1, 2, or 3, where the investigator's staff time and PT Department support will be involved, Steps 1 and 2 above are required before seeking consultation with the Pathokinesiology Laboratory staff

III. PROCEDURES FOR OBTAINING APPROVAL TO PRESENT RLANRC DATA

Abstracts for presentation of research involving RLANRC data (Categories 1 through 4) must be approved by the PT Department Director prior to abstract submission

IV. ACKNOWLEDGMENT OF CONTRIBUTIONS TO RESEARCH

A. Authorship for Publications/Presentations

It is generally agreed among scientists and researchers that credit, in the form of authorship, will be given to those individuals who have substantially contributed to the conceptualization and completion of a research study. The notion of conceptual or intellectual contribution, rather than the contribution of mere time and effort to a project, is typically the key to determining whether authorship credit should be given to a member of the research team. Conceptual or intellectual contribution refers to contributions in the form of theoretical or content ideas (such as which variables to study, their hypothesized relationships, or the research questions to be addressed) and operationalizations (exactly how the research questions will be addressed, including the construction or selection of measures, the determination of appropriate research designs and protocols, and often data interpretation). Order of authorship (primary secondary, etc.) is customarily determined by the extent of conceptual/intellectual contribution, with those who propose, substantially determine the research question, and/or write

the substance of the paper for publication given priority over those who contribute operational details once the direction of the project has been largely determined.

The awarding of authorship to those whose contribution is more purely technical in nature, such as engineers who build a device necessary for a study to be accomplished or statisticians who offer advice on the appropriate research design or statistical analyses to address questions, or clinicians who “run” subjects through an established clinical protocol or treatment, constitutes a gray area in science. Often technical decisions made by these individuals contribute to the conceptualization of a study; thus authorship may be warranted on conceptual/intellectual grounds. One determinant of authorship, for some scientists or researchers, is whether technical personnel are paid for their services; if paid to participate and provide a specific service or product to the research team, they may be acknowledged in a footnote to the paper rather than receive authorship credit.

There are no hard and fast rules about who should receive authorship, and practices vary considerably across different fields and for individual scientists or researchers. Some individuals are very liberal in awarding authorship to anyone associated with a project, including those who support the project indirectly through securing laboratory funds or by performing statistical analysis. Others, however, are more conservative in allowing authorship only for those who contribute portions of the written research proposal or final manuscript for publication and/or have had substantial involvement in conceptualizing or operationalizing the particular study. The National Academy of Sciences has recently suggested that so-called “honorary authorships” (very indirect relationship to a particular study) should not be given and that those who allow their names to be used as authors of a study should be able to independently describe the substance and results of the study and should be held accountable for all procedures and conclusions in the event of a dispute. That is, a research team member should really know what went on from a first-hand perspective, why things were done as they were, and the nature and impact of her/his assumed intellectual contribution to the overall project, in order to support a claim to authorship. To avoid confusion at the end of a project as to who deserves authorship credit, the roles and responsibilities of each member as they relate to potential authorship should be discussed at the beginning of a project and adjusted as warranted by actual intellectual contributions. Individuals in doubt as to the legitimacy of authorship should seek advice and perspective from experienced scientists or others who are not involved in the project and who might offer an unbiased opinion. The RLANRC/PT Department research resource consultants may be appropriate to serve in this capacity.

B. Acknowledgments of Resource or Technical Support

Many individuals, including patients, staff members, administrators, technicians/statisticians and others, contribute to the completion and success of research studies through contributions of time, financial or material resources, or

particular technical expertise (e.g., editing, writing, statistical, clinical). Researchers are expected to acknowledge RLANRC via logos or wording on presentations and publications of work completed in association with RLANRC. Researchers should acknowledge individuals or organizations that have made important contributions to the work in footnotes or acknowledgment notes in presentations and publications. It is considered particularly important to acknowledge the sources of any financial assistance to projects where the supporting organization has a financial stake in the results of a study.



Director, Physical Therapy Department