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Subseries: Conferences

OA/ID Number: 52080
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Folder Title:
Researchers Meeting - Dec 20 '95

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MEMORANDUM

DATE: December 12, 1995

TO: TIRR Researchers and BCM Department of PM&R Researchers

FROM: Lex Frieden and Harvey Levin, Ph.D.

A joint meeting of the Baylor College of Medicine Department of PM&R researchers and other researchers active at The Institute for Rehabilitation and Research will be held on Wednesday, December 20 from 11:00 - 12:30 in Rooms 2D&E in the Will Clayton Conference Center on the second floor of the Edna B. Dunn Tower at TIRR. The purpose of this meeting will be to inform researchers about current activities and plans both for research at TIRR and in the Department of PM&R. Among the topics to be discussed are the following:

1) a review of the research policies at TIRR;

2) a review of current grant-funded activities at TIRR and elsewhere in the Department;

3) a discussion of potential areas for research development at TIRR and other affiliated institutions;

4) a discussion of resident training needs and opportunities;

5) a discussion of specific undeveloped interests of TIRR and Department of PM&R researchers;

6) a discussion of space and other support needs of researchers at TIRR and other institutions; and

7) a review of the grant climate in Washington, DC.

This meeting will be in lieu of the Baylor Department of PM&R Research Committee meeting which was originally scheduled on this date. We realize that the BCM Holiday Luncheon is also scheduled to occur on this date from 11-2 p.m. We trust that those affected can attend the holiday luncheon after this meeting. We look forward to seeing you all on December 20, 1995.

NASA IRB

MEMORANDUM

DATE: December 12, 1995

TO: TIRR Researchers and BCM Department of PM&R Researchers

FROM: Lex Frieden and Harvey Levin, Ph.D.

A joint meeting of BCM Department of PM&R researchers and other researchers active at The Institute for Rehabilitation and Research will be held on Wednesday, December 20 from 11:30 - 1:00 in Rooms 2D&E in the Will Clayton Conference Center on the second floor of the Edna B. Dunn Tower. The purpose of this meeting will be to inform researchers about current activities and plans both for research at TIRR and in the Department of PM&R at BCM. Among the topics to be discussed are the following:

1) a review of the research policies at TIRR;

2) a review of the grant climate in Washington;

3) a review of current grant-funded activities at TIRR ~~(and perhaps elsewhere in the Department)~~;

4) a discussion of potential areas for research development at TIRR (and perhaps at some affiliated institutions);

5) a discussion of specific undeveloped interests of TIRR researchers ~~(and perhaps those of non-TIRR researchers in the Department)~~; and

6) a discussion of support needs which researchers at TIRR have ~~(and perhaps those of non-TIRR researchers in the Department)~~.

This meeting will be in lieu of the Baylor Department of PM&R Research Committee meeting which was originally scheduled on this date.

We realize that the BCM Holiday Luncheon is also scheduled to occur on this date from 11-2 p.m. We trust that those affected can work their holiday luncheon schedule around this meeting. We look forward to seeing you all on December 20, 1995.

RESEARCH STRATEGIC PLAN

A. Mission Statement and Background

Since its establishment in 1959, TIRR has advanced knowledge about medical rehabilitation while applying it directly to patient care, and educating and sharing its research. Targeting research problems significant to society and to persons with disabilities continues to be a key part of our mission.

> *"Research at The Institute for Rehabilitation and Research (TIRR) is a necessary and integral component of TIRR's mission to promote the integration of people with physical and cognitive disabilities into all aspects of community living. TIRR research contributes to maximizing personal functioning after disability, effective treatment of disability, efficient utilization of resources, and national and local healthcare and rehabilitation policy. Research at TIRR blends with TIRR's clinical and educational activities to promote well-being and alleviate suffering. Such research is fundamental to TIRR's commitment to continue to provide national and international leadership in the field of rehabilitation."*

This statement reflects strong commitment to the kind of research program that is key to TIRR's emphasis on quality of service to individuals, to the field of rehabilitation research, and to healthcare issues on a national and policy level. Historically, TIRR has initiated and nurtured an exceptionally productive rehabilitation research program. Service improvements realized from research have made TIRR a nationally and internationally respected facility.

The recently published 35th Commemorative History of TIRR describes 38 milestones for the Institute from 1950 to 1994--33 of them directly related to research efforts. These include many innovative technologies and devices, operation of the longest continually funded Research and Training Center (RTC) in the nation as well as two other RTCs, the development of regional model programs in spinal cord injury and brain injury, and the establishment of the Independent Living Research Utilization (ILRU) Program to address research, training and technical assistance needs in the field of independent living.

TIRR's leadership in rehabilitation is in large part due to innovative and integrated efforts in medical, technical, educational, or direct service provision. The research plan for the future will ensure that this focus is maintained and strengthened while the continuum of care is expanded, new programs are developed, and links to the clinical and education programs are reinforced.

Commitment to rehabilitation services beyond the point of discharge and to an integrated team treatment approach have been the keys to TIRR's reputation for excellence as a national, freestanding comprehensive medical rehabilitation and research facility. The following specific points of achievement illustrate this historically significant focus.

a) Through a series of early clinical demonstrations, TIRR developed innovative approaches to the care and treatment of people with the most severe and complicated physical disabilities. These approaches included interdisciplinary, program-oriented treatment of spinal cord injuries, traumatic brain injuries, and amputations. TIRR originally pioneered its interdisciplinary team-oriented approach to rehabilitation in the treatment of people with polio who required the comprehensive services of a variety of specialists in order to most effectively treat the disease and cope with its effects. Approaches effectively applied to the post-polio population were later extended to treatment of people with spinal cord injuries and most recently those with traumatic brain injuries.

b) TIRR pioneered the use of many technological innovations in rehabilitation including computer-based scheduling, Harrington instrumentation, implanted battery-powered assistive breathing devices, and sophisticated gas-powered upper extremity orthotic devices.

c) TIRR considered research and education to be equivalent to service delivery in its three-pronged mission. TIRR's research program in particular has been among the most successful rehabilitation research programs in the world. This can be seen clearly in the number of grant-funded projects undertaken, and by the amount of funding which has been generated to sponsor research programs at TIRR.

d) TIRR has maintained a mutually beneficial affiliation with a renowned medical school, Baylor College of Medicine, and more recently, TIRR has consummated affiliation with another respected medical school, the University of Texas Health Science Center at Houston. TIRR professionals who are also members of medical school faculty have been recognized widely for their contributions to the literature, their outstanding presentations at scientific meetings, and voluntary activities with professional associations and societies.

e) TIRR clinical and research staffs have been awarded over 40 federal research grants during the period from 1988 to 1994, drawing in funds in excess of $20 million over that period. Within the Texas Medical Center, the M.D. Anderson Cancer Center was the only recipient of more federal funding dollars during this period, even though TIRR is the smallest freestanding treatment and research facility in the medical center and M.D. Anderson the largest.

B. Guiding Principles

The commitment to continuing an historically strong TIRR research program and insuring its appropriate integration with clinical service and educational outreach demands thoughtful planning. The ongoing research program at TIRR will be guided by the following general principles.

- Research at TIRR will contribute to TIRR's broader mission of patient care and education.

- Research activities at TIRR will be fully integrated with clinical programs and educational activities.

- Research at TIRR will be facilitated by excellent communication and collaboration among professionals who are primarily clinicians, professionals who are primarily researchers, and professionals who are primarily educators.

- Research at TIRR will be pursued with the intent of contributing to TIRR's goal to continue its national and international stature and to be the regional rehabilitation provider of choice.

- Research funds will be utilized in a manner that facilitates involvement of clinical staff in research activities.

- Clinical practice will be conducted in a manner that facilitates and contributes to the research process when this does not compromise efficient, effective provision of clinical service.

- Research at TIRR respects the contribution that TIRR patients make to the research process.

- Research at TIRR will span the full spectrum from basic science to applied clinical research.

- Research objectives are formulated by a process that includes input from persons with disabilities and contributes to improved clinical service and community integration for such persons.

- Research at TIRR is interdisciplinary in nature whenever possible.

- Whenever appropriate, research at TIRR aims to evaluate the effectiveness of rehabilitation interventions to facilitate improved patient care and efficient utilization of resources.

- Research projects at TIRR are developed with an aim to facilitating dissemination of new knowledge to persons with disabilities, the general public, and other rehabilitation providers.

C. Research Plan Summary

Several clear lines of development will characterize the TIRR research program over the next three years:

Maintain Program Focus

Research at TIRR will help maintain a program-focused orientation and further develop successful programs in the areas of spinal cord injury, brain injury, amputation, musculo-skeletal, orthopedic, and pediatric rehabilitation.

Expand the Continuum of Care

Research at TIRR will assist in determining the need and feasibility of community-based programs outside the hospital and will cooperate in developing and evaluating new programmatic approaches. These include outpatient, follow-up, home visit, transitional, independent living, personal assistance services, and other types of noninstitutional services.

Build New Programs

Research at TIRR will explore possibilities that may lead to the establishment of new programs targeted to patients in comparatively unserved diagnostic groups. Among programs which will potentially be investigated are those serving people with arthritis, stroke, and cancer.

Engage in Collaborative Basic Science Research

TIRR researchers will collaborate with colleagues at other Texas Medical Center institutions on basic research projects relevant to the physiology and neurology of spinal cord and brain injury. TIRR facilities may be used as a clinical setting for the eventual applications and products of this research.

D. Domains and Specific Research Objectives

Current domains of research at TIRR translate into study of issues within several categories:

- Direct Service to Patients--primary care, preventive medicine, wellness and secondary prevention, psychological response to disability, and independent living training;

- Special Service Needs of Differing Population Segments--issues concerning women or other minorities with disabilities, and the special needs of aging populations, especially those who have postpolio- or spinal cord-related injuries;

- Education--patient education, training of healthcare professionals at all levels, community education;

- Technology--physiological-type mechanisms adaptive to neurological dysfunction (e.g., prosthetics, orthotics, and robotics), innovative surgical and therapeutic technologies, studies designed to investigate tissue or neurobiological repair and prevention;

- Policy--both analyzing and seeking to have a positive influence impact on policy issues related to disability rights as well as technology (i.e., in intervention and rehabilitation), issues and economics related to community integration and home-based rehabilitation, the evolving national healthcare environment.

- Outcome Evaluation--assessment and evaluation of successful outcomes for users of medical technologies, therapeutic techniques, interventions, achievement of independent living goals, empowerment, full community integration, evaluation of the effectiveness of service delivery systems; and

- Advocacy and Empowerment--patient education (e.g., to self-advocate or otherwise achieve access to self-determined services), education to assure the surrounding community's accessibility to people with disabilities, and systems advocacy to effect lasting policy change at the local, national, and international levels.

E. Closing Remarks

Research has played a key role in helping TIRR to become and to remain a leader in the field of rehabilitation and to develop, test, and refine innovative approaches to addressing the spectrum of needs that accompany onset of disability, regardless of its cause. TIRR will continue to pursue research goals that are consistent with its mission of service to persons with disabilities locally, statewide, regionally, nationally, and internationally. In all of its research pursuits, TIRR will adhere to the highest ethical standards and will consider not simply the benefits that accrue to the institution and to those of us engaged in the important work of research, but also the effects of these efforts in terms of each individual who is asked to contribute to such endeavors through direct involvement or through the involvement of a family member.

Ultimately, good research is about making ethical and compassionate choices. In the words of William James, "An act has no ethical quality whatever unless it be chosen out of several all equally possible." TIRR's research program will represent an action agenda based on choices that take into account both the institution and the people it serves.

Rev. 9/25/95

1333 Moursund
Houston, Texas 77030-3405
In the Texas Medical Center
(713)799-5000

Official Procedure

SUBJECT: RESEARCH		PROCEDURE NO.: A-31
DISTRIBUTION: Program Physicians and Management Council	REVISED: Sept. 1995	REVISION NO.:
APPROVED: Louisa Stelling		PAGE 1 OF 2

Purpose

To insure effective coordination and appropriate management and support for all research endeavors at TIRR.

Rationale

In order to provide monitoring and assurances required by Federal Regulations, and to ensure protection of patient rights and appropriate care and use of institutional facilities, TIRR must have certain standards and policies for the conduct of research within the institution. Additionally, effective coordination and management of research will insure best use of institutional resources and synergistic linkages with clinical programs.

Definition

For the purpose of this policy, the term research shall be broadly defined to include all research, service demonstration, technical assistance, training, and related grant funded or externally sponsored activities at TIRR.

Policy Outline

1. All research concepts for which serious efforts are needed or for which serious planning is undertaken shall be filed in the form of a concept memo with the TIRR Office of Grants Administration.

2. The TIRR Office of Grants Administration will provide feedback on the research concept as it may relate to other research, educational, or clinical programs which may be in a conceptual stage or which may be underway. The Office of Grants Administration will also provide assistance in reviewing funding possibilities for the concept, and may recommend consultation pertaining to research design and methodology, if necessary.

3. At such time as one or more investigators decide to mount a formal proposal, the Office of Grants Administration should be notified to insure coordination with other TIRR groups which may be responding to the same concept or program solicitation to insure that all possible support resources are organized and made available.

4. All proposals for external funding shall be submitted for administrative review to the Office of Grants Administration prior to the date of submission to the granting agency. Such proposals also shall be submitted simultaneously to the TIRR Grant Accounting Office and to the institutional research offices of affiliated institutions, as appropriate. A routing sheet should be prepared for each proposal, and should be signed by the TIRR Office of Grants Administration, the TIRR Grant Accounting office, and the TIRR COO prior to final submission of the proposal.

5. A TIRR institutional review board for research will be maintained as required by Department of Health & Human Services regulations for the protection of human subjects under 45CFR46, as amended, and by other applicable federal and state policies and regulations. All research initiatives and proposals involving human subjects must be approved by the TIRR Institutional Review Board prior to the administrative review process. In certain circumstances, the IRB may provide a letter indicating that review is pending and will be completed prior to initiation of the proposed activity.

6. Copies of all official notices of grant or contract awards shall be filed in a timely manner with the Office of Grants Administration where they shall be maintained as an institutional record, along with copies of relevant grant proposals, budgets, and other documentation.

7. A TIRR Research Committee appointed by the Senior Vice President for Grants Administration shall: 1) advise the Senior Vice President for Grants Administration on research policy, programs, procedures and practices; 2) assist in the production and implementation of a strategic plan for the development of externally sponsored programs at TIRR; 3) engage in mentorship and training programs related to research for TIRR staff members; 4) develop policies and procedures relevant to the dissemination of research findings; and 5) assist with coordination of the TIRR institutional review board and other research related committees and subcommittees.

1333 Moursund
Houston, Texas 77030-3405
In the Texas Medical Center
(713)799-5000

Official Procedure

SUBJECT:		PROCEDURE NO.:
MISCONDUCT IN RESEARCH		**A-32**
DISTRIBUTION: **Program Physicians and Management Council**	REVISED: **Sept. 1995**	REVISION NO.:
APPROVED: Louisa Stelmack		PAGE **1** OF **2**

DEFINITION OF MISCONDUCT IN RESEARCH

"Misconduct in Research" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. (Source: U.S. Public Health Service Regulations).

POLICY

The Institute for Rehabilitation and Research (TIRR) expects all of its staff and collaborators in research to adhere to the highest standards of conduct in pursuing their research and other activities. Any form of misconduct, whether involving falsification of data, plagiarism, abuse of confidentiality, use of unacceptable clinical practices, violation of regulations or standards governing research or any other form of scientific fraud is contrary to the principles upon which TIRR was founded and adversely affects the reputation of TIRR and its programs and staff. Misconduct violates the trust of agencies, foundations, and other entities which sponsor research at TIRR, and it may also constitute a violation of law.

TIRR has adopted standing policies regarding misconduct in research that are consistent with those in use by academic and clinical research facilities nationally. These policies comply with regulations issued by the Public Health Service (Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, effective November 8, 1989). Following is a brief summary of the procedures by which allegations of Misconduct in Research are reported to and investigated by TIRR.

- Allegations of misconduct in research must be reported in writing and in confidence to the Senior Vice President ("Senior VP") for Grants Administration, TIRR, 1333 Moursund Avenue, Houston, Texas 77030.

- The Senior VP shall promptly refer the matter to the TIRR Research Committee (the "Committee"). The Committee shall undertake an inquiry into the allegations. The Committee

shall promptly submit a written report of its findings to the Senior VP within sixty (60) days of initiation.

- If the results of the inquiry indicate that there is a reasonable basis for more thorough study, within thirty (30) days the Committee will undertake a formal investigation of the allegations. The investigation must be completed and a report of the results of the investigation submitted to the Senior VP within one hundred twenty (120) days of initiation.

- A final finding of misconduct may be appealed to the Executive Vice President and Chief Operating Officer ("Executive VP/COO") of TIRR within five (5) days of receipt by a respondent of the report of the Committee. The Executive VP/COO may delegate the handling of the appeal to a person or persons whom she or he deems qualified.

- The Committee shall prepare and maintain records of its proceedings and documentation concerning its activities.

- The privacy of persons who in good faith provide information concerning misconduct in science will be protected to the maximum extent possible.

- Federal regulations and reporting requirements must be followed strictly.

- TIRR must impose appropriate sanctions on individuals when allegations have been substantiated.

The foregoing summary is qualified in its entirety by reference to relevant Federal and non-Federal regulations that apply to research carried out with sponsorship from other than TIRR sources.

NASA COOPERATIVE AGREEMENT
1996 PROCESS PAPER

Pursuant to Cooperative Agreement NCC 9-36 between Texas Medical Center and NASA, substantial NASA involvement can be expected in the participation and management of the Cooperative Agreement.

The Cooperative Agreement specifically provides as follows:

"NASA designated representatives will be invited to participate in the review of proposals under this agreement and their comments and recommendations will be noted. The Texas Medical Center reserves the right to select the proposals to be conducted under this Cooperative Agreement; however, should they directly involve NASA, NASA reserves the right under the Cooperative Agreement to accept or reject their participation in the proposed efforts. Under this arrangement, in order for a Texas Medical Center institution to proceed with work it has proposed that involves NASA directly, both the Texas Medical Center and NASA must approve the effort. This approval must be granted by both Texas Medical Center and NASA prior to or at the time the Texas Medical Center initiates the grant with the institution. These approvals must be in writing."

Since funded efforts under the Cooperative Agreement must occur in cooperation with and with the consent of NASA, the following process has been established for applications that will be submitted under the Cooperative Agreement.

Process.

1. Requests for Applications will be transmitted to the Texas Medical Center member institutions eligible for funding under the Cooperative Agreement. Eligible Texas Medical Center institutions are those institutions that have obtained a federal overhead rate and are as follows:

   - The University of Texas Houston Health Science Center;
   - The University of Texas M.D. Anderson Cancer Center;
   - Baylor College of Medicine;
   - Texas Woman's University;

- Texas A&M University - Albert B. Alkek Institute of Biosciences and Technology;
- The Institute of Rehabilitation and Research;
- The University of Houston College of Pharmacy;
- Prairie View A&M University School of Nursing; and
- Texas Heart Institute.

The Requests for Applications will be transferred to the research officers of each eligible Texas Medical Center institution designated to receive them. It will be the responsibility of each institution's research officer to distribute and coordinate the application process throughout their respective institution. All questions concerning the applications should be directed to the research coordinators and not to Texas Medical Center.

2. Applications will be due approximately six weeks after the Request for Applications. Applications should be turned into the research officers of each institution with nine (9) duplicate copies. The application will consist of a two-page proposal, a one-page resume, and be limited to two pages of diagrams (if applicable). Applications that exceed this page limit will be rejected.

3. Prior to submission of the application to the Texas Medical Center for consideration, each institution's research office will be responsible for verifying the following:

a) that the certification form attesting to the accuracy of the budget has been completed and signed by the appropriate individuals (this form shall be supplied by the Texas Medical Center);

b) that the application meets one of the specific criteria under the Cooperative Agreement and that the criterion is clearly identified. If an overlap between criteria exists, this overlap should be verified to and an explanation be attached;

c) that a certification is completed verifying that the application involves only Texas Medical Center institution personnel and no personnel outside Texas Medical Center institutions, other than those NASA personnel with which the application may be coordinated.

4. Once all applications have been turned into the Texas Medical Center, they will be transmitted to NASA personnel for NASA criteria review. NASA will review all applications to assure that only eligible applications are ultimately considered by the Texas Medical Center Merit Review Panel.

5. Following NASA criteria review and approval, only those proposals that have passed NASA's review will be submitted to a 16-person Texas Medical Center Merit Review Panel ("Review Panel") for ranking by merit.

6. The Review Panel will include representatives of the member institutions and one outside panelist from Rice University and will be comprised of individuals with

expertise in the nine (9) categories identified in the Cooperative Agreement as follows:

- Baylor College of Medicine - three (3) panelists;
- IBT- Texas A&M University - one (1) panelist;
- The Institute of Rehabilitation and Research - one (1) panelist;
- The University of Texas Houston Health Science Center - three (3) panelists;
- The University of Texas M.D. Anderson Cancer Center - three (3) panelists;
- Texas Woman's University - one (1) panelist;
- The University of Houston College of Pharmacy - one (1) panelist;
- Prairie View A&M University School of Nursing - one(1) panelist;
- Texas Heart Institute - one (1) panelist; and
- Rice University - one (1) panelist.

7. Procedures for the Texas Medical Center Merit Review Panel

a) Each panel member must sign a confidentiality agreement, prepared in conjunction with the Cooperative Agreement, in which the panel member agrees to keep the discussions, deliberations, and conclusions of the Review Panel confidential.

b) The rating system for each proposal shall range from 1-5, with one (1) being the highest score. All ratings must be submitted by each panel member in writing, without exception.

c) The Review Panel will be divided into two (2) groups for purposes of reviewing the applications, so that Review Panel members are not precluded from submitting a proposal themselves.

8. Once the recommendations of the Review Panel have been made, the Advisory Committee of the NASA Cooperative Agreement may provide additional guidance to the Principal Investigator concerning the rankings of applications prior to the award of subcontracts under the Cooperative Agreement.

9. NASA Grant Officer approval must be received prior to the award of any subcontract under the Cooperative Agreement.

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MEMORANDUM

DATE: September 1, 1995

TO: TIRR Researchers
TIRR Program Physicians
Executive Council

FROM: Lex Frieden
Senior Vice President, Grants Administration

Please find attached five important documents pertaining to research at TIRR. The first attached document is the strategic plan for research at TIRR which was developed over the past year by a committee of TIRR researchers led by Dr. Mark Sherer. While this document has received substantial input and review, any strategic plan should be considered dynamic. Therefore, we welcome all comments and suggestions. Feel free to forward your ideas either to Dr. Sherer or to me.

The second document is the TIRR Research Policy. In general, this policy establishes guidelines and procedures for the coordination and administration of research and other grant-funded or externally-sponsored activities at TIRR.

Third, a copy of the revised TIRR grant routing form is attached. As you can see, this document is substantially different from that which preceded it. It has been designed to be "user friendly." If you have suggestions about ways to improve this form or its usefulness, please feel free to forward them to me.

The fourth attachment includes the current Institutional Review Board (IRB) Protocol Review Application and a description of the Basic Elements of Informed Consent. The application for protocol review should be used according to the Research Policy and submitted according to the instructions on the form.

Finally, a copy of the current Policy on Rules of Research Misconduct are attached. These should be reviewed by every researcher at TIRR and understood. They should also be kept on file.

Thank you for your attention to these matters. Please feel free to call me if you have any questions or suggestions regarding these materials.

RESEARCH STRATEGIC PLAN

A. Mission Statement and Background

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- Special Service Needs of Differing Population Segments--issues concerning women or other minorities with disabilities, and the special needs of aging populations, especially those who have postpolio- or spinal cord-related injuries;

- Education--patient education, training of healthcare professionals at all levels, community education;

- Technology--physiological-type mechanisms adaptive to neurological dysfunction (e.g., prosthetics, orthotics, and robotics), innovative surgical and therapeutic technologies, studies designed to investigate tissue or neurobiological repair and prevention;

- Policy--both analyzing and seeking to have a positive influence impact on policy issues related to disability rights as well as technology (i.e., in intervention and rehabilitation), issues and economics related to community integration and home-based rehabilitation, the evolving national healthcare environment.

- Outcome Evaluation--assessment and evaluation of successful outcomes for users of medical technologies, therapeutic techniques, interventions, achievement of independent living goals, empowerment, full community integration, evaluation of the effectiveness of service delivery systems; and

- Advocacy and Empowerment--patient education (e.g., to self-advocate or otherwise achieve access to self-determined services), education to assure the surrounding community's accessibility to people with disabilities, and systems advocacy to effect lasting policy change at the local, national, and international levels.

E. Closing Remarks

Research has played a key role in helping TIRR to become and to remain a leader in the field of rehabilitation and to develop, test, and refine innovative approaches to addressing the spectrum of needs that accompany onset of disability, regardless of its cause. TIRR will continue to pursue research goals that are consistent with its mission of service to persons with disabilities locally, statewide, regionally, nationally, and internationally. In all of its research pursuits, TIRR will adhere to the highest ethical standards and will consider not simply the benefits that accrue to the institution and to those of us engaged in the important work of research, but also the effects of these efforts in terms of each individual who is asked to contribute to such endeavors through direct involvement or through the involvement of a family member.

Ultimately, good research is about making ethical and compassionate choices. In the words of William James, "An act has no ethical quality whatever unless it be chosen out of several all equally possible." TIRR's research program will represent an action agenda based on choices that take into account both the institution and the people it serves.

Rev. 9/25/95

1333 Moursund
Houston, Texas 77030-3405
In the Texas Medical Center
(713)799-5000

Official Procedure

SUBJECT: RESEARCH		PROCEDURE NO.: A-31
DISTRIBUTION: Program Physicians and Management Council	REVISED: Sept. 1995	REVISION NO.:
APPROVED: Louisa Stelling		PAGE 1 OF 2

Purpose

To insure effective coordination and appropriate management and support for all research endeavors at TIRR.

Rationale

In order to provide monitoring and assurances required by Federal Regulations, and to ensure protection of patient rights and appropriate care and use of institutional facilities, TIRR must have certain standards and policies for the conduct of research within the institution. Additionally, effective coordination and management of research will insure best use of institutional resources and synergistic linkages with clinical programs.

Definition

For the purpose of this policy, the term research shall be broadly defined to include all research, service demonstration, technical assistance, training, and related grant funded or externally sponsored activities at TIRR.

Policy Outline

1. All research concepts for which serious efforts are needed or for which serious planning is undertaken shall be filed in the form of a concept memo with the TIRR Office of Grants Administration.

2. The TIRR Office of Grants Administration will provide feedback on the research concept as it may relate to other research, educational, or clinical programs which may be in a conceptual stage or which may be underway. The Office of Grants Administration will also provide assistance in reviewing funding possibilities for the concept, and may recommend consultation pertaining to research design and methodology, if necessary.

3. At such time as one or more investigators decide to mount a formal proposal, the Office of Grants Administration should be notified to insure coordination with other TIRR groups which may be responding to the same concept or program solicitation to insure that all possible support resources are organized and made available.

4. All proposals for external funding shall be submitted for administrative review to the Office of Grants Administration prior to the date of submission to the granting agency. Such proposals also shall be submitted simultaneously to the TIRR Grant Accounting Office and to the institutional research offices of affiliated institutions, as appropriate. A routing sheet should be prepared for each proposal, and should be signed by the TIRR Office of Grants Administration, the TIRR Grant Accounting office, and the TIRR COO prior to final submission of the proposal.

5. A TIRR institutional review board for research will be maintained as required by Department of Health & Human Services regulations for the protection of human subjects under 45CFR46, as amended, and by other applicable federal and state policies and regulations. All research initiatives and proposals involving human subjects must be approved by the TIRR Institutional Review Board prior to the administrative review process. In certain circumstances, the IRB may provide a letter indicating that review is pending and will be completed prior to initiation of the proposed activity.

6. Copies of all official notices of grant or contract awards shall be filed in a timely manner with the Office of Grants Administration where they shall be maintained as an institutional record, along with copies of relevant grant proposals, budgets, and other documentation.

7. A TIRR Research Committee appointed by the Senior Vice President for Grants Administration shall: 1) advise the Senior Vice President for Grants Administration on research policy, programs, procedures and practices; 2) assist in the production and implementation of a strategic plan for the development of externally sponsored programs at TIRR; 3) engage in mentorship and training programs related to research for TIRR staff members; 4) develop policies and procedures relevant to the dissemination of research findings; and 5) assist with coordination of the TIRR institutional review board and other research related committees and subcommittees.

TIRR GRANT PROPOSAL ROUTING & APPROVAL FACE SHEET

This document must be completed and filed with the TIRR Office of Grants Administration prior to application for any grant, contract, or other externally-funded project which will be conducted on TIRR premises or for which TIRR will be the recipient of funds. All questions related to this form or relevant processes should be referred to the TIRR Office of Grants Administration 797-5284.

Principal Investigator/Project Director_____ Phone No. _____

Co-Principal Investigator/Co-Project Director _____ Phone No. _____

Title of Proposal _____

_____

Proposal Number (if applicable): _____ Due Date: _____

Source or Sponsor of Grant or Contract (agency name): _____

Type of Sponsor:_____
(Government, private foundation, etc.)

Purpose or Type of Grant: _____
(Research, training, dissemination, etc.)

Type of Submission: _____
(Original, continuation, etc.)

Grantee or Contracting Institution (TIRR, BCM, UT, other): _____

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Funds Requested:
Present Period: $_____ Total Period: $_____

Grant/Budget Period (dates):
Present Period: _____ Total Period: _____

Indirect Rate Used: _____% Match Required Yes ____ No ____

Explain Source of Matching Funds (if applicable), or other in-kind match: _____

_____

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Location of Activities: _____

Cooperating Institutions: _____

Additional Space Required: _____

Additional Personnel Required: _____

Additional Services Required: _____

Additional Equipment Required: _____

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APPROVALS AND SIGNATURES

Necessary approvals have been given for the following:

Use of Human Subjects; approved by: _____ Date: _____

Use of Animals; approved by: _____ Date: _____

Use of Biochemicals; approved by: _____ Date: _____

Use of Radioisotopes; approved by: _____ Date: _____

Use of DNA; approved by: _____ Date: _____

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I certify that:

__ All contracts or subcontracts conform to TIRR specifications and policies.

__ All salaries of new staff conform to TIRR salary structure and policies.

__ There are no conflicts of interest inherent in this project.

__ All patents or other proprietary products of this project will be licensed to TIRR.

_____ _____
Signature of Principal Investigator Date

==========

APPROVAL:

_____ _____
Department Manager Date

_____ _____
Grants Accounting (Shuh-Ming Hsu) Date

_____ _____
Grants Administration (Lex Frieden) Date

_____ _____
CEO/COO (Charles Beall, Jr./Louisa Adelung) Date

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APPLICATION FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW AND APPROVAL
THE INSTITUTE FOR REHABILITATION AND RESEARCH (TIRR) IRB COMMITTEE

Submit one copy of complete research proposal for our file. Submit 8 copies of the brief proposal as outlined below to the Office of Research, Room A-205 at TIRR. For additional information, please call, 799-7011.

1. Title of research proposal:

2. Principal investigator and associates:

3. Granting Agency:

4. Period of grant, giving dates:

5. Hospital or institution where research is to be done:

6. Outline of research proposal:

   A. A brief description of any background information necessary for the IRB Committee to thoroughly understand and review this research.

   B. A concise statement of the purpose and objectives of this research.

   C. A summary of the methods and procedures to be used, including the following:

   - A description of the requirements for the subject population. Justify the use of any subject whose ability to provide informed consent may be questionable (i.e., children, prisoners, mentally disturbed).
   - A description of, and potential for, any and all risks to the subjects, including physical, psychosocial or legal. What, if any, other methods could possibly be used, and why were those methods rejected?
   - A description of any pain or discomfort to the subject associated with this study.
   - A description of the consent procedures to be followed, including how and where informed consent will be obtained.
   - A description of the procedures to be used in protecting the subject against, or at least minimizing, any potential risks (including confidentiality safeguards) and an assessment of the expected effectiveness of these procedures.
   - An assessment of any potential benefits to the individual subject, and to society in general, which could result from the planned work. Include a risk-to-benefit ratio analysis.
   - Describe any cost to the patient and/or their insurance carrier, and indicate any possible reimbursements to the patient.
   - A justification of the number of subjects to be used .

   D. Attach questionnaires, interviews, or other data gathering tools not listed above.

   E. Copies of Informed Consent Forms. These forms should be written in terms understandable to the average subject.

I certify that this protocol conforms with the OSHA/HHS guidelines for HIV/HBV occupational safety.

_____ _____

Signature of Principal Investigator Date

BASIC ELEMENTS OF INFORMED CONSENT (revised 11-93)

A. A brief explanation in lay terminology of the purposes of the research, the procedures to be followed (including any treatments or procedures which are experimental), and the expected duration of the subject's participation;

B. A description of any reasonably foreseeable risks or discomforts to the subject (including likely results if any experimental treatment should prove ineffective);

C. Who should be contacted if there are questions, problems or if harm occurs;

D. Give the name and phone number of the Research Committee chairman (Dr. Don Lehmkuhl) stating that the subjects may contact him with questions regarding their rights as a subject;

E. A description of any benefits to the subject or to others which may reasonably be expected from the research;

F. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

G. A statement describing the extent to which confidentiality of records identifying the subject will be maintained (example: Procedures for minimizing risks will include identifying data by numerical designation rather than by the person's name. The registry linking the numerical designation with the person's name will be stored in a secure place in the investigator's office. Research data resulting from my participation in this study may be published but I will not be personally identifiable in any way in such a publication.)

H. Describe any cost to the patient and/or insurance carrier and indicate any possible compensation to the subjects.

I. An explanation as to whether compensation and medical treatment are available if injury occurs and, if so, what they consist of or where further information may be obtained. Whatever the case, include the following, verbatim: "In the event of injury resulting from this research, The Institute for Rehabilitation and Research (TIRR) and/or _____ are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities and emergency treatment and professional services will be available to research subjects, just as they are to the community generally. My signature below acknowledges my voluntary participation in this research project. Such participation does not release the investigators, institutions, (if applicable, and sponsor or granting agency) from their professional and ethical responsibility to me.

J. A statement that the participation is voluntary, refusal to participate or discontinuation of the participation will involve no penalty or loss of benefits to which the subject is otherwise entitled; and

K. Signature and date line for the subject or for his/or representative and witness.

1333 Moursund
Houston, Texas 77030-3405
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(713)799-5000

Official Procedure

SUBJECT:		PROCEDURE NO.:
MISCONDUCT IN RESEARCH		**A-32**
DISTRIBUTION: **Program Physicians and Management Council**	REVISED: **Sept. 1995**	REVISION NO.:
APPROVED:		PAGE **1** OF **2**

DEFINITION OF MISCONDUCT IN RESEARCH

"Misconduct in Research" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. (Source: U.S. Public Health Service Regulations).

POLICY

The Institute for Rehabilitation and Research (TIRR) expects all of its staff and collaborators in research to adhere to the highest standards of conduct in pursuing their research and other activities. Any form of misconduct, whether involving falsification of data, plagiarism, abuse of confidentiality, use of unacceptable clinical practices, violation of regulations or standards governing research or any other form of scientific fraud is contrary to the principles upon which TIRR was founded and adversely affects the reputation of TIRR and its programs and staff. Misconduct violates the trust of agencies, foundations, and other entities which sponsor research at TIRR, and it may also constitute a violation of law.

TIRR has adopted standing policies regarding misconduct in research that are consistent with those in use by academic and clinical research facilities nationally. These policies comply with regulations issued by the Public Health Service (Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, effective November 8, 1989). Following is a brief summary of the procedures by which allegations of Misconduct in Research are reported to and investigated by TIRR.

- Allegations of misconduct in research must be reported in writing and in confidence to the Senior Vice President ("Senior VP") for Grants Administration, TIRR, 1333 Moursund Avenue, Houston, Texas 77030.

- The Senior VP shall promptly refer the matter to the TIRR Research Committee (the "Committee"). The Committee shall undertake an inquiry into the allegations. The Committee

shall promptly submit a written report of its findings to the Senior VP within sixty (60) days of initiation.

- If the results of the inquiry indicate that there is a reasonable basis for more thorough study, within thirty (30) days the Committee will undertake a formal investigation of the allegations. The investigation must be completed and a report of the results of the investigation submitted to the Senior VP within one hundred twenty (120) days of initiation.

- A final finding of misconduct may be appealed to the Executive Vice President and Chief Operating Officer ("Executive VP/COO") of TIRR within five (5) days of receipt by a respondent of the report of the Committee. The Executive VP/COO may delegate the handling of the appeal to a person or persons whom she or he deems qualified.

- The Committee shall prepare and maintain records of its proceedings and documentation concerning its activities.

- The privacy of persons who in good faith provide information concerning misconduct in science will be protected to the maximum extent possible.

- Federal regulations and reporting requirements must be followed strictly.

- TIRR must impose appropriate sanctions on individuals when allegations have been substantiated.

The foregoing summary is qualified in its entirety by reference to relevant Federal and non-Federal regulations that apply to research carried out with sponsorship from other than TIRR sources.