Klein Family Parkinson's Rehabilitation Center
Clinical/Research Integration Award Proposal Form

KFPRC Application #:

Resubmission: ☐Yes* Previous Submission Date:
☐No
*If yes, please include a brief (1 page max) response to the prior reviews.

Title of Proposal:

Project Period:
Start: End:

APPLICANT INFORMATION

Principal Investigator/Project Leader:

Position Title:	**Degree(s):**
Department:	**Institution:**

Office Mailing Address:

Contact Information:
Phone: Email:

Department Administrator[1]:
Name: Phone: Email:

Other Key Personnel:

Name:	Department:	Role:	Clinical/Research:[2]

Human Subjects Research: ☐Yes ☐No
If yes, has an IRB protocol been submitted? ☐Yes ☐No Submission Date:
has IRB approval been granted? ☐Yes ☐No Approval Date:

Project Location(s): (Provide justification if any portion of this project will not be completed at TJU):

[1] Individual responsible for administrating the project budget and personnel time.
[2] State whether the individual is performing a clinical or research role (or both) on the current proposal.

Financial Support Requested: $

List additional sources from which funds for this project are being/have been sought:

List other current or prior projects (project title, project dates, brief description of project and degree of overlap) that relate to the proposed project. Note if any projects have received prior KFPRC support.

Signature of Applicant: Date:

Name of Department Chairperson:

I have reviewed this proposal in its entirety and find it to have scientific or clinical merit, be feasible to conduct and complete within the proposed time period, and has an appropriate budget. I have communicated any concerns to the contrary and suggested changes have been addressed by the Applicant. I agree to share oversight responsibility during the project.

Signature of Department Chairperson: Date:

Project Title:

Abstract

Project Title:

Project Objectives/Specific Aims

Project Title:

Proposed Budget

Personnel (list individual)	% Time/Hours[3]		Amount (in US dollars)
	Proposal	Other	
Benefits @22%, total			$ 0
Category Total			$ 0
Equipment (Itemize)			
Category Total			$ 0
Supplies (Group in major categories)			
Category Total			$ 0
Subject Reimbursement / Miscellaneous			
Category Total			$ 0
Income/Revenue			
Category Total			$ 0
Grand total (cannot exceed $20,000)			$ 0

[3] List personnel time as percent effort (except when per diem), where 100% reflects full time (40 hours/week). Specify percent effort for the time supported by this proposal (may be 0%), and time on this project supported by other funding sources. Only include effort supported by this proposal in the Amount column. If per diem, report the total project hours instead, appended by an "H" (e.g., 12H). Project roles and source(s) of alternative support should be explained in the budget justification.

Project Title:

Budget Justification Sheet

Briefly detail and justify all expenses and personnel listed in the Budget, including individuals who are involved but not supported by this project. For all personnel, note the individual (or TBD), title, role, and total percent effort or per diem hours on this project (explain if different from the amount supported under this award). All salary expenses must also include fringe benefits at a rate of 20%. The Budget is not to exceed $20,000 of KFPRC support, plus any expected revenue generated by the project itself. Use additional pages if necessary.

Project Title:

Certification for Protection of Human Subjects

Research involving human subjects

The applicant (principal investigator) is responsible for safeguarding the rights and welfare of human subjects involved in research activities supported by grants from the Klein Family Parkinson's Rehabilitation Center. In order to provide for the adequate discharge of this responsibility, no grant for an activity involving human subjects research shall be made unless the application for such support has been reviewed by an appropriate institutional committee (i.e., our Institutional Review Board, IRB). If uncertain whether the activities proposed under this award meet the designation of human subjects research, a determination should be requested from the IRB prior to submission of the proposal, and the determination letter included in the application materials.

Check one:

☐ This application does not propose any activities that would involve human beings as research subjects or their personal data.

☐ A determination has been made by the institutional committee that the activities under this project are not considered human subjects research.

☐ This is to certify that this application does propose research activities involving human subjects, and has or will be reviewed and approved by our Institutional Review Board (IRB) before the study begins in accordance with institutional policy.

If already approved, Date of approval:
IRB protocol number:

Name of Applicant/Principal Investigator:	
Signature of Applicant/Principal Investigator:	Date:

Required Application Forms Checklist:	**Yes**	**No**
Clinical/Research Integration Award Proposal Form	☐	☐
Abstract in layman's terms (250 words max)	☐	☐
Project Objectives/Specific Aims (1 page max)	☐	☐
Detailed Project Protocol (6 pages max)	☐	☐
References (no page limit)	☐	☐
Supplemental Project Details (4 pages max)	☐	☐
Proposed budget and budget justification form	☐	☐
Certification for Protection of Human Subjects form	☐	☐
For research proposals only: Signed Research Resources Utilization (RRU) form	☐	☐
For resubmissions only: Responses to Previous Reviews (1 page max)	☐	☐
Optional: Determination of Human Subjects Research	☐	☐

All sections should meet specified word/page limits noted above. Text should be in a sans serif font (Arial, Georgia, Helvetica, or Palatino Linotype), size 11, single-spaced, with a minimum of 0.5" margins. There should be no more than 6 lines of text per inch on the page. Page limits include all figures and citations. Although there are no length limit to the references or budget justification, these sections cannot be used to extend the length of the other sections.

The **Project Objectives/Specific Aims** should briefly summarize the main goals of the project. State what important question or problem the project is intended to address, the hypothesis or rationale for the project design, and what scientific and/or clinical aims the project will achieve.

The **Detailed Project Protocol** should include the following sections:

A. Project Title

B. Background/Significance/Rationale
   Explain the basis for the proposed project, including any previous evidence supporting the need and rationale for the proposed project. Describe the importance and expected impact of the project, and how it will improve scientific knowledge or clinical practice with regard to Parkinson's disease. Note any anticipated long-term impacts from this project or how it will guide/inform future clinical or research programs.

C. Innovation
   Explain the novelty of the project and how it is different from existing research or clinical programs. Describe the scope of the innovation; i.e., is it a broad innovation that affects the field, or just new to Einstein. Consider novelty of theory, methodology, and/or technology.

D. Clinical-Research Integration
   Explain how this project promotes clinical-research integration, both within the scope/duration of the project as well as any potential long-term impacts. Describe the composition of the team and the specific contributions of the clinical and research personnel to the project.

E. Procedure
   Describe the overall strategy, methodology, and any analyses/program evaluation used to accomplish the project objectives. Detail the specific project design and methods, being sure to address each stated objective. Explain who will be eligible to participate in the program, and how the number of people enrolled (e.g., sample size) is appropriate for the proposed project. Where possible/relevant, include a power analysis. Describe the means of data collection and analysis, or the method used to evaluate the success of the program, and how the data will provide evidence of the proposed objectives. Explain how project progress or outcomes will be evaluated (e.g., data analysis, monitoring of participant feedback), and steps to be taken if the data are not supportive or the project is found to not be progressing as intended.

F. References (not included in the maximum page count)

The **Supplemental Protocol Information** section is required for both research proposals and clinical program proposals, to provide additional detail about aspects of the project design. Some sections may be less relevant for clinical program proposals; where indicated, these sections may be removed. This section should not be treated as an extension of the Detailed Project Proposal, but should address only the specific points listed:

G. Resources Available to Conduct this Project
   Describe the setting in which the project will take place, noting any equipment, facilities, or other resources available to support this project. Demonstrate a potential for recruiting the desired number of participants within the project period. Describe the time that the applicant and other key personnel will devote to the project. Highlight any specific qualifications/prior experience of the staff in conducting this project.

H. Recruitment Plan

Describe how and from where potential participants will be recruited. If a chart review, describe how and which records will be accessed to collect data. Describe the methods to identify potential participants. Describe materials such as advertisements that will be used to recruit participants. Describe the expected level of involvement (e.g., number of hours/visits) each participant will be asked to complete. Describe the amount and timing of any payments to participants.

I. Eligibility Criteria (Inclusion/Exclusion)

Describe how participants will be screened for eligibility. Describe the criteria used to define who will be included or excluded from the project. If a chart review, include the criteria used to identify which charts will be analyzed, including the dates between which you will collect data.

Indicate specifically whether you will include or exclude each of the following special populations:

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

(You may not include members of the above populations as participant unless you indicate this in your inclusion criteria.)

J. Project Endpoints

Describe steps to monitor project feasibility and manage risk to participants. Note specific results/observations that represent primary and secondary study endpoints. Describe any primary or secondary safety endpoints.

K. Provisions to Monitor the Safety of Participants

*Delete this section if the project involves **no more than minimal risk** to participants. Describe the plans to periodically evaluate the data collected regarding both the harms and benefits to determine whether participants remain safe. Describe who will review the data. Describe which data are reviewed, including safety data, untoward events, and efficacy data. Describe when data are reviewed. This section is not required for clinical program proposals unless they involve more than minimal risk to participants.*

L. Withdrawal of Participants

Describe the anticipated circumstances under which participants will be withdrawn from the project without their consent. Describe any procedures for orderly termination. Describe procedures that will be followed if participants withdraw from the project or request that their data be withdrawn. If there is no possibility of withdrawal based on project design, state that in this section.

M. Risks to Human Participants

List the risks, discomforts, hazards, or inconveniences to the participant. For each, indicate the probability, magnitude, and duration. Consider physical, psychological, social, legal and economic risks. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant.

N. Medical Care and Compensation for Injury

*Delete this section if your project involves **no more than minimal risk** to participants. Describe the provisions for medical care and available compensation in the event of program-related injury. This section is not required for clinical program proposals unless they involve more than minimal risk to participants.*

O. Potential Benefits to Participants

Describe the benefits that individual participants may experience. For each indicate the probability, magnitude, and duration of the benefit. Indicate if there is no direct benefit.

P. Cost to Participants

Describe any costs that participants may incur through participation in the project.

Q. Consent Process

*Delete this section if your project is **not a research proposal**.*

Describe the setting of the consent process. Describe the role of the individuals involved in the consent process and the time that will be devoted to the consent discussion. Describe any waiting period

between informing the prospective participant and obtaining the consent. Describe any steps that will be taken to minimize the possibility of coercion or undue influence.

*If the project involves a **waiver or alteration of the consent process** (consent will not be obtained, required information will not be disclosed, or the research involves deception) describe. If the project has been determined to be non-human subjects research, explain.*

*If the project involves **children** describe how consent will be conducted. Describe whether parental permission will be obtained from either both parents or just one parent. Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.*

*If the research involves **adults who may be unable to consent**, describe the process to determine whether an individual is capable of consent. If permission of a Legally Authorized Representative (LAR) will be obtained list the individuals from whom permission will be obtained. Describe the process for assent of the participants. Indicate whether assent will be required of all, some, or none of the participants. If some, indicated which participants will be required to assent and which will not. If assent will not be obtained from some or all participants, explain why not. Describe whether assent of the participants will be documented and the process to document assent.*

R. Provisions to Protect the Privacy Interests of Participants

*Delete this section if your project is **not a research proposal**.*

Describe the steps that will be taken to protect participants' privacy interests. "Privacy interest" refers to a person's desire to control access of others to themselves. Describe what steps you will take to make the participants feel at ease with the project situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.

S. Data management plan

Describe the specific data to be collected. Describe who will be responsible for collection and transmission of that data. Describe the plan to manage these data, and any procedures for quality control of these data. If no data is being conducted (including for program evaluation), briefly explain why.

T. Provisions to Maintain the Confidentiality of Data

Describe the steps that will be taken to limit dissemination of identifiable data (including any program evaluation feedback provided by program participants). Describe where data will be stored, who will have access to the data, measures taken to secure the data, and how long data will be stored.

U. Vulnerable Populations

If the project involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare. Ensure that any vulnerable populations are listed in your inclusion criteria. If no vulnerable populations are included in this project, delete this section.

V. Sharing of Results

Discuss plans for sharing the results or outcomes of the project. Describe plans to share project results with participants, if any. If so, describe what results will be shared, how this information will be communicated to participants, and the circumstances when results will be shared. Describe plans to share results more broadly with the scientific or clinical communities.