

KPGA Center for Research and Evaluation Procedure: Initiating Research Activities

Version 1.0

Overview

The Center for Research and Evaluation, on behalf of Kaiser Permanente Georgia, supports and has administrative responsibility for all research studies and clinical trials conducted in the region. This procedure outlines the steps required to initiate research activities.

Scope

This procedure applies to all Kaiser Permanente Georgia (KPGA) physicians and employees interested in pursuing research studies or clinical trials.

Responsibilities

- **Center for Research and Evaluation (CRE) Finance Team** – is responsible for assisting the Principal Investigator (PI) with the budget preparation, the KPGA CRE Proposal Approval form, and ensuring the proposal is properly formatted per agency requirements. In addition, they are responsible for submitting all documents to either Kaiser Foundation Research Institute or the funding agency.
- **Institutional Review Board (IRB)** – a board formally designated to protect the rights, safety and wellbeing of individuals involved in research projects and clinical trials. The purpose of the IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.
- **Kaiser Foundation Research Institute (KFRI)** – is responsible for reviewing and submitting all applications for federal research funds, negotiating and executing all contracts and subcontracts involving federal funds, and accepting all federally funded grant awards.
- **Principal Investigator (PI)** – is the primary individual responsible for the overall development and content of the proposal.
- **Project Manager Supervisor** – reviews research plan with PI and assigns a Project Manager to the proposed project.
- **Project Manager** – provides assistance to PI with the proposal submission process and may work on the study if funded.
- **Clinical Trials Manager** - provides assistance to PI in establishing, implementing, and conducting clinical trials.
- **Executive Director of Research** – as the supervisor of the PI, the Executive Director of Research is responsible for the scientific review of the research question and plan, and provides assistance and guidance as needed.

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- **Research Manager** – is responsible for conducting the feasibility review of the study to determine the staffing needs and availability of resources, and that adequate funds are being requested. The Research Manager supervises the CRE Finance team.
- **Research Review Committee (RC)** – is responsible for the scientific and ethical review of the study on behalf of KPGA. The committee is responsible for assessing the risk to the institution.

Procedures

Pre-Proposal

A pre-proposal (sometimes called a white paper, letter proposal, letter of intent, preliminary proposal, pre-application, or concept paper) is a short description of the proposed project. If the sponsor requires a pre-proposal the:

1. PI formulates research question and works with the Project Manager Supervisor to have a Project Manager assigned to the proposed project. The PI is strongly encouraged to consult with the Executive Director early in the process. The Project Manager will provide the PI with assistance on the pre-proposal submission process. If a preliminary budget is required, the PI and/or Project Manager will work with the CRE Finance team to establish a draft budget and budget justification.
2. If the sponsor asks the PI to submit a full proposal, follow the steps below for the applicable prime agency type.

For Federal/Sub-Federal Research Proposals:

1. PI formulates research question, creates a draft outline of the research plan, and works with the Project Manager Supervisor to have a Project Manager assigned to the proposed project. The Project Manager will provide the PI with assistance on the proposal submission process. The PI and/or Project Manager will work with the CRE Finance team to establish a draft budget and budget justification. If the budget contains a reduction of our fully negotiated F&A rate, the *KPGA CRE F&A Waiver Request Form* should be completed and routed for approval.
2. With the assistance from CRE Finance Team and Project Manager, the KPGA *CRE Proposal Approval Form* is completed. Attached to the *Proposal Approval Form*, is the abstract, proposal, protocol, budget, budget justification, and approved *F&A Waiver Request Form* if applicable. The CRE Finance Team will conduct a final review of the complete package to ensure accuracy of the information and then route it around for approvals. The CRE Proposal Approval Form must be fully completed 10 days prior to the agency due date.
3. Executive Director of Research conducts the initial scientific review of the research question and research plan and provides feedback to the PI. The PI is strongly encouraged to consult with the Executive Director early in the process.
4. The Research Manager conducts feasibility review

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5. Prior to submitting an application for PHS-funded research, investigators are required to complete the Investigator *Conflict of Interest Attestation* form.
6. Once all approvals have been obtained, the proposal can move forward in the submission process.
7. If any of the following changes occur after the *Proposal Approval Form* has been signed, the updated proposal packet will need to be submitted to the Executive Director of Research for re-approval prior to submission to the funding agency:
 - Addition or removal of personnel
 - More than 10% change in personnel effort
 - Change in F&A rate
 - Change in the Scope of Work
8. The CRE Finance Team will submit the final proposal documents to KFRI for their review, signature, and submission. KFRI requires 5 days prior to the due date for their review and submission.
9. The study can be submitted to the RC once the PI has received preliminary notification that their research proposal will be funded.
10. Once RC has approved the study, it can then be submitted to the IRB for their approval.
11. The CRE Finance Team will work with KFRI on the award acceptance.
12. Once the award has been received, the CRE Finance Team will enter the award into the system and generate a project ID.

For Non-Federal Research Proposals:

1. PI formulates research question, creates a draft outline of the research plan, and works with the Project Manager Supervisor to have a Project Manager assigned to the proposed project. The Project Manager will provide the PI with assistance on the proposal submission process. The PI and/or Project Manager will work with the CRE Finance team to establish a draft budget and budget justification. If the budget contains a reduction of our fully negotiated F&A rate, the KPGA CRE *F&A Waiver Request Form* will need to be completed and routed for approval.
2. With the assistance from CRE Finance Team and Project Manager, the KPGA *CRE Proposal Approval Form* is completed. Attached to the *Proposal Approval Form*, is the abstract, proposal, protocol, budget, and budget justification. The CRE Finance Team will conduct a final review of the complete package to ensure accuracy of the information and then route it around for approvals. The *CRE Proposal Approval Form* must be fully completed 10 days prior to the agency due date.

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3. Executive Director of Research conducts the initial scientific review of the research question and research plan and provides feedback to the PI. The PI is strongly encouraged to consult with the Executive Director early in the process.
4. The Research Manager conducts feasibility review.
5. Once all approvals have been obtained, the proposal can move forward in the submission process.
6. If any of the following changes occur after the *Proposal Approval Form* has been signed, the updated proposal packet will need to be submitted to the Executive Director of Research for re-approval prior to submission to the funding agency:
 - o Addition or removal of personnel
 - o More than 10% change in personnel effort
 - o Change in F&A rate
 - o Change in the Scope of Work
7. The CRE Finance Team will submit the final proposal documents to the funding agency.
8. The study can be submitted to the RC once the PI has received preliminary notification that their research proposal will be funded.
9. Once RC has approved the study, it can then be submitted to the IRB for their approval.
10. Prior to engaging in research activities, investigators are required to complete the Investigator *Conflict of Interest Attestation* form.
11. The CRE Finance Team will work with the funding agency on the award acceptance.
12. Once award has been received, the CRE Finance Team will enter the award into the system and generate a project ID.

For Clinical Trials:

1. The PI and/or Clinical Trial Manager obtains protocol and budget information for clinical trials.
2. The PI, along with the Clinical Trial Manager, will complete the *Clinical Trial Feasibility Assessment Checklist*, *Clinical Trial Budget Calculation* form, and the *Representation of Activities Preparatory to Research (RAPToR)* form.
3. The Clinical Trial Manager will conduct a final review of the PTR form to ensure accuracy of the information and then submit it to the Programmers for processing.
4. With the assistance of the Clinical Trial Manager, the KPGA *CRE Proposal Approval Form* is completed. Attached to the *Proposal Approval Form* is the

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Clinical Trial Feasibility Assessment Checklist, the *Clinical Trial Budget Calculation Form*, and the Protocol.

5. The Research Manager conducts feasibility review.
6. Executive Director of Research reviews and gives approval for the protocol to move forward in the approval process.
7. Once all regional approvals have been obtained, the CRE Finance Team will submit the contracting documents for the protocol to KFRI for their review, and contract negotiation.
8. The clinical trial is submitted to the RC.
9. Once RC has approved the clinical trial, it can then be submitted to the IRB for approval.
10. Prior to engaging in research activities, investigators are required to complete the Investigator *Conflict of Interest Attestation* form.
11. The CRE Finance Team will work with KFRI on the contract negotiation and award acceptance.
12. Once award has been received, the CRE Finance Team will enter the award into the system and generate a project ID.

KP Internally Supported Research:

1. PI formulates research question, creates a draft outline of the research plan, and works with the Project Manager Supervisor to have a Project Manager assigned to the proposed project. The Project Manager will provide the PI with assistance on the proposal process. The PI and/or Project Manager will work with the CRE Finance team to establish a draft budget if funding will be provided to support the research.
2. With the assistance from CRE Finance Team and Project Manager, the KPGA CRE *Proposal Approval Form* is completed. Attached to the Proposal Approval Form, is the abstract, proposal, protocol, budget, and budget justification. The CRE Finance Team will do a final review of the complete package to ensure accuracy of the information and then route it around for approvals. If applicable, the CRE *Proposal Approval Form* must be fully completed 10 days prior to the submission due date.
3. Executive Director of Research conducts the initial scientific review of the research question and research plan and provides feedback to the PI. The PI is strongly encouraged to consult with the Executive Director early in the process.
4. The Research Manager conducts feasibility review.
5. If any of the following changes occur after the *Proposal Approval Form* has been signed, the updated proposal packet will need to be submitted to the Executive Director of Research for re-approval prior to submission to the funding agency:

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- Addition or removal of personnel
 - More than 10% change in personnel effort
 - Change in F&A rate
 - Change in the Scope of Work
6. Once all regional approvals have been obtained, the PI and/or Project Manager can will submitted the final proposal documents to the funding unit.
 7. Once intent of funding has been obtained, the study can be submitted to the RC.
 8. Once RC has approved the study, it can then be submitted to the IRB for their approval.
 9. Upon IRB approval, the CRE Finance Team will enter the award into the system and generate a project ID.

Supporting Documents

- KPGA CRE Proposal Approval Form (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\FORMS)
- KPGA CRE F&A Waiver Request Form (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\FORMS)
- Investigator Conflicts of Interest Attestation Form (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\FORMS)
- KPGA CRE Clinical Trial Feasibility Check List (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\FORMS)
- KPGA CRE Clinical Trial Budget Calculation (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\FORMS)
- KFRI Proposal Submission Process (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\Policies Procedures\Budget and Finance User Guides\KFRI submission information)
- KFRI Financial Conflicts of Interest In Research NATL.KFRI.001 (I:\CHRSE\Proposal Award Finance\FORMS and Policies\Policies Procedures\National Policies)
- KPGA CRE Prep to Research Procedure (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\Policies Procedures\CCOR Specific Policies\Data)
- Representation of Activities Preparatory to Research Form (located I:\CHRSE\Proposal Award Finance\FORMS and Policies\FORMS)

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Document Approval, Ownership, & History

This document will be reviewed every two years for accuracy, relevance, and completeness.

Document owner: **Research Manager III**

Document approver: **Executive Director**

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