TITLE OF POLICY: FACULTY RESEARCH PROPOSAL REVIEWS

DATE EFFECTIVE: February 11, 2014

LAST REVIEWED/REVISED: May 27, 2014

POLICY: All faculty research proposals planned for submission to any funding agency (internal or external) must receive both external scientific review and budget approval. Proposals that do not follow this policy are at risk of not being accepted by the University upon award. The purpose of this policy is to ensure the quality of research proposals submitted by faculty researchers from the School of Nursing. For external scientific review outside the University, the Office of Research Submission Form for the Evaluation of Research Confidentiality /Non-Disclosure Agreement (CDA/NDA) must be completed.

PROCEDURE:
Core elements of procedures for submitting grants are presented below.
1. The Principal Investigator (PI) meets with the department Vice Chair for Research (VCR) preferably at least 2-3 months prior to the SON Office of Grants Management submission deadline to discuss the proposal, departmental processes of submission, required documents, and development of the budget. The Grant Submission Timeline is given to the PI and reviewed with particular attention to the information needed to begin development of the budget. The department grants analyst is notified of the planned submission. If the application is for an educational training grant (HRSA, ACIE), the Associate Dean for Clinical Education is notified. Policy 408B should be followed.
2. The PI schedules an appointment with the department grants analyst to meet and discuss the submission process and begin development of the budget.
3. The PI and VCR will meet throughout the submission process.
4. The PI and VCR discuss the review process and the PI is responsible for identifying at least two external reviewers who are approved by the VCR. Once the PI emails the proposal to the VCR, the proposal and SON Scientific Review Form is emailed to reviewers who are asked to complete and return the review form and comments to the PI and VCR within an agreed upon timeframe.
5. The VCR will discuss reviews with the PI and will
   a. If minor or no revisions are suggested by reviewers: provide scientific approval or
   b. If major revisions are suggested by a reviewer: Inform the PI that the application may require substantial revision and re-review.
6. The department chair where the PI resides is responsible for providing written final approval of the budget and budget justification.
7. Grants analysts should be 1) notified in writing that scientific and budget approval have been granted, and 2) receive final proposal documents from the PI at least 10 business days prior to the funding agency deadline. Proposals that do not meet this deadline are at risk of not being submitted by the funding agency deadline.
8. For external scientific review outside the University, the Office Of Research Submission Form for the Evaluation of Research Confidentiality /Non-Disclosure Agreement (CDA/NDA) must be completed.

Reference: Policy 408B - Guidelines For Submitting Educational Proposals

Attachments: Review Form, Proposal Acceptability Form, Research Confidentiality /Non-Disclosure Agreement

Approved by Administration: 05/08, 02/14
Reviewed: 01/97, 03/99, 12/01; 03/04, 04/08, 02/14
Revised by Administration: 04/04; 11/04, 05/08, 02/14
SCHOOL OF NURSING SCIENTIFIC REVIEW FORM

Confidentiality and Conflict of Interest: Application and review materials are confidential. If you feel you have a conflict of interest or cannot review the proposal objectively, please inform the department Vice Chair of Research so that another reviewer may be assigned.

☐ Please check here if you wish to remain anonymous

Application Title _____________________________________________________________________________

Principal Investigator (s) ______________________________________________________________________

Funding Agency _____________________________Award Mechanism (if pertinent)_____________________

Date Sent to Reviewer_____________                      Review Due Date___________________

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1. Exceptional</td>
<td>Exceptionally strong</td>
<td>Essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2. Outstanding</td>
<td>Extremely strong</td>
<td>Negligible weaknesses</td>
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<td></td>
<td>3. Excellent</td>
<td>Very strong</td>
<td>Only some minor weaknesses</td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4. Very Good</td>
<td>Strong</td>
<td>Numerous minor weaknesses</td>
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<tr>
<td></td>
<td>5. Good</td>
<td>Strong</td>
<td>At least one moderate weakness</td>
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<tr>
<td></td>
<td>6. Satisfactory</td>
<td>Some strengths</td>
<td>Some moderate weaknesses</td>
</tr>
<tr>
<td>Low Impact</td>
<td>7. Fair</td>
<td>Some strengths</td>
<td>At least one major weakness</td>
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<td></td>
<td>8. Marginal</td>
<td>A few strengths</td>
<td>A few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9. Poor</td>
<td>Very few strengths</td>
<td>Numerous major weaknesses</td>
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Overall Impact: Provide an overall impact score to reflect your assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five core review criteria and the additional review criteria. Please pay particular attention to the specific aims and ensure that they mesh with the proposed work.

Overall Impact Score (circle)     1       2       3       4       5       6       7       8       9

Core Review Criteria (circle)

Significance  1        2        3        4        5        6        7        8        9

Investigators  1        2        3        4        5        6        7        8        9

Innovation    1        2        3        4        5        6        7        8        9

Approach      1        2        3        4        5        6        7        8        9

Environment   1        2        3        4        5        6        7        8        9

Additional Review Criteria (circle)

Statistical Analyses  1        2        3        4        5        6        7        8        9

Clarity and Organization  1        2        3        4        5        6        7        8        9

Human Subject Protection  1        2        3        4        5        6        7        8        9

(circle) Acceptable as is Acceptable with minor revisions Needs substantial revision and re-review

Please return review form and comments via email to department Vice Chair of Research and the PI
SCHOOL OF NURSING PROPOSAL ACCEPTABILITY FORM

Proposal Number:

PI:                                      _____________________________________

Title:  ______________________________________________________________________________________

This proposal has been reviewed by:

Reviewer 1:  ________________________________  _____  _____

Reviewer 2:  ________________________________       _____  _____

Department Vice Chair for Research:______________  _____  _____

This proposal is acceptable for submission:   _____  _____

This proposal is not acceptable for submission at this time   _____  _____

Department Vice Chair for Research ________________________  Date

Department Chair ________________________  Date

Reviewers: Name, University, School or Department

Reviewer 1:

Reviewer 2
**UNIVERSITY OF PITTSBURGH OFFICE OF RESEARCH (OR) SUBMISSION FORM FOR THE EVALUATION OF RESEARCH CONFIDENTIALITY /NON-DISCLOSURE AGREEMENTS (CDA/NDa)**

*FOR UNIVERSITY REVIEW AND SIGNATURE, SUBMIT THE FOLLOWING MATERIALS BY EMAIL: CLINICORF@PITT.EDU OR FAX (412/624-7414):**
**COMPLETED SUBMISSION FORM AND THE CDA ISSUED BY THE COMPANY/INSTITUTION (IF AVAILABLE).**

<table>
<thead>
<tr>
<th>1. University Principal Investigator (PI) Contact Information:</th>
<th>2. Company/Institution name providing or receiving information:</th>
</tr>
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<tbody>
<tr>
<td>Name:</td>
<td></td>
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<td>Title:</td>
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<td>Email:</td>
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<tr>
<th>3. PI's Departmental Administrative Contact for CDA/NDa Follow-up: (Not Office of Research Staff)</th>
<th>4. Company/Institution Legal Contact for any changes to CDA/NDa:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Name:</td>
</tr>
<tr>
<td>Phone/Email:</td>
<td>Email/Phone:</td>
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<tr>
<td>PI's Department:</td>
<td>PI's Dept ID:</td>
</tr>
</tbody>
</table>

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<tr>
<th>5. Are there any other parties to the CDA/NDa who are not under your supervision?</th>
<th>6. Company/Institution PI name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
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<tr>
<td>Yes</td>
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**General:**

7. Is this CDA/NDa to permit discussions solely regarding commercial licensing activity with the other party?

- No
- Yes- Please direct your request to the Office of Technology Management (OTM)

8. Is this CDA/NDa related to your potential private consulting activity with the other party?

- No
- Yes- The Office of Research cannot review this CDA/NDa. You should review any consulting arrangement with your Chair.

9. Pitt requires a specific purpose for each research CDA. What is the overall purpose of this CDA/NDa?

10. What information is the other party disclosing to you?

11. What non-public information are you disclosing to the other party?

12. If you are disclosing non-public information, did you develop this information or do you have the full rights to disclose this information?

- No, please explain.
- Yes

13. If you are disclosing non-public information, is it related to a potentially patentable invention or discovery?

- No
- Yes, Office of Technology Management staff name.

14. If this relates to any other agreement, please list all that apply, i.e., Sponsored Research Agreement, Government or Other Grant, CDA, License, MTA , Other Agreement

**FOR CDAs FOR CLINICAL TRIALS:**

15. Is the specific purpose of this CDA/NDa to discuss a clinical trial agreement/protocol?

- No- please skip the rest of this column.
- Yes Please check all that apply below.

- The study is investigator initiated. This means a Pitt faculty member has had substantive intellectual input into the protocol design; OR

- The trial is industry designed and sponsored but the experimental drug or device being evaluated in the trial:  
  - emits ionizing radiation; and/or
  - involves a gene transfer intervention; and/or
  - involves a transgenic xenotransplant; OR

- The study involves no use whatsoever of UPMC space, patients or records; OR

- The PI has a Pitt regular faculty appointment but lacks a UPMC/UPP appointment; OR

- The study is being financially supported by industry but has been designed by a collaborator at another non-profit institution.

- None of the above apply to this trial. Please contact: the UPMC OSPARS OFFICE 412-647-4481 for instructions on submission.

OSPARS handles confidentiality agreements for the review of industry-designed protocols to determine UPMC's interest in participating in the clinical trial. OSPARS also negotiates the clinical trial agreements for industry-designed and funded protocols most often involving an industry-held Investigational New Drug (IND) application or Investigational Device Exemption (IDE) for the material being evaluated in the clinical trial.

To the best of my knowledge, the answers to the questions are true, complete and accurate. I have read the referenced agreement and agree to comply with its terms and conditions. I am a University of Pittsburgh faculty member authorized to disclose or receive the information noted above.

**Principal Investigator:** ____________________________  **Date:** ____________________________

*Please note that a faculty and staff are not permitted to sign a University CDA or NDA as the sole endorsing signature, and that any such signature is not binding on the University of Pittsburgh unless an appropriately Authorized University Official, i.e. Director of the Office of Research or his designee, also signs.*

OR CDA Submission Form (07/2006, Revised 9/2012, 11/2013)