UNIVERSITY OF PITTSBURGH **Policy No. 408C**
SCHOOL OF NURSING

ADMINISTRATIVE POLICIES AFFECTING THE SCHOOL OF NURSING

TITLE OF POLICY: **STUDENT AND POST-DOCTORAL FELLOW RESEARCH PROPOSAL REVIEWS**

DATE EFFECTIVE: 11/15/2016

LAST REVIEWED/REVISED: 11/15/2016

POLICY: All student and post-doctoral research proposals planned for submission to any funding agency (internal or external) must receive scientific review by the student's or post-doctoral fellow's mentoring or research team, faculty researchers outside the mentoring or research team, and budget approval by the relevant department chairs. 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 student and post-doctoral fellow 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 student and faculty advisor, or post-doctoral fellow principal investigator (PI) meets with the department Vice Chair for Research (VCR) of research mentor/faculty sponsor 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.
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 PI's research mentor/faculty sponsor will meet throughout the submission process.
4. The PI, PI's research mentor/faculty sponsor and VCR discuss the scientific review process and the PI and PI's research mentor/faculty sponsor are responsible for identifying at least two reviewers external to the PI's research team, or dissertation or DNP project or thesis committee who are approved by the VCR. Once the PI emails the proposal to the VCR, the proposal and scientific review form is emailed to the 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 PI's research mentor/faculty sponsor 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 and PI's research mentor/faculty sponsor that the application may require substantial revision and re-review.
    c. VCR will also prepare a letter for scientific approval for SON records.
6. The PI, PI's research mentor/faculty sponsor and departmental grants analyst finalize the budget. Once the PI emails the abstract, budget, and budget justification to the VCR, the VCR sends these documents to the department chair(s) who are responsible for any faculty or staff with effort on the grant application for written approval.
7. Grants analysts should be 1) notified by the VCR in writing that scientific and budget approval have been granted, and 2) receive final proposal documents from the PI at least 5 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. The VCR will also forward the approval letter to the staff administrator in the Center for Research and Evaluation for their records.
8. Once a research proposal has undergone budget and scientific review, components of the original approved proposal may be submitted to other funding sources without undergoing additional scientific and/or budget reviews at the discretion of the VCR.

Attachments: Research Confidentiality/Non-Disclosure Agreement

Approved by Dean's Council: 11/15/2016
Reviewed: 11/15/2016

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 (CLINCORP@PITT.EDU) OR FAX (412/624-7414):
***COMPLETED SUBMISSION FORM AND THE CDA ISSUED BY THE COMPANY/INSTITUTION (IF AVAILABLE).*

1. University Principal Investigator (PI) Contact Information: Name: Title: Email:	2. Company/Institution name providing or receiving information:
3. PI's Departmental Administrative Contact for CDA/NDA Follow-up: **(Not Office of Research Staff)** Name: Phone/Email: PI's Department: PI's Dept. ID:	4. Company/Institution Legal Contact for any changes to CDA/NDA: Name: Email/Phone:
5. Are there any other parties to the CDA/NDA who are not under your supervision? ☐ No ☐ Yes If yes, list all that apply:	6. Company/Institution PI name:

☐ Indicate here if Company/Institution does not have a preferred form of CDA and desires Pitt to generate the CDA.

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 412-647-4461 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)

From website: http://www.research.pitt.edu/ccc-confidential-disclosure-agreement-cdanon-disclosure-agreement-nda