Updates on Res Compliance (from Michale Brown, Assistant Director for Research Compliance)

March 5, 2020

Notice of Transition to New System for Issuing Certificates of Confidentiality for Non-NIH Funded Research

Key Changes

- NIH will no longer accept Certificate of Confidentiality requests through the current system as of March 11, 2020.
- Current users who need a copy of their Certificate or associated documentation should access the Certificate of Confidentiality system to download these files prior to March 13, 2020. Users will no longer have access to the current Certificate of Confidentiality system as of March 13, 2020.
- The new CoC system requires direct submission by the authorized institutional official, rather than by the researchers.

See official notice at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-075.html

International Compilation of Human Research Standards

The new <u>2020 edition of the International Compilation of Human Research Standards</u> is now available on-line. The Compilation is a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in 133 countries and from many international organizations. It includes information on:

- 1. General, i.e., applicable to most or all types of human subjects research
- 2. Drugs and Devices
- 3. Clinical Trial Registries
- 4. Research Injury
- 5. Social-Behavioral Research
- 6. Privacy/Data Protection
- 7. Human Biological Materials
- 8. Genetic
- 9. Embryos, Stem Cells, and Cloning

The Secretary's Advisory Committee on Human Research Protections (SACHRP) Webcast

SACHRP will meet March 11th and 12th. The agenda and webcast links can be viewed here: https://www.hhs.gov/ohrp/sachrp-committee/meetings/march11-12-2020/index.html. Discussion topics include the NIH draft Data Management and Sharing Policy, Deceased Donor

Intervention Research, End User Licensing Agreements, and a discussion of crafting "key information" sections of consent forms. Materials are made available upon request to SACHRP@hhs.gov.

From: Michael Brown

Sent: Wednesday, March 4, 2020 4:56 PM

Subject: Introduction and Conflict of Interest Information

Good Afternoon Deans and Department Chairs,

For those of you I haven't met, I'm Mike Brown, the new Assistant Director for Research Compliance. Part of my responsibilities in this position are acting as the College Conflicts Officer. As such, I'd like to remind our research community of two important CUNY Conflict of Interest policy requirements below. It would be most appreciated if you forward this information on to your faculty.

- 1. Per the <u>CUNY COI Policy and Procedures</u>, <u>all investigators</u> must complete the <u>CUNY Significant Financial Interest (SFI) Disclosure Forms for externally funded projects</u> and submit them to the Office of Research and Sponsored Programs. There are three scenarios in which SFI Disclosure Forms require submission:
 - 1. At the time of grant proposal or application;
 - 2. At the time the Principal Investigator submits an annual progress report;
 - Within 30 days of any material change in the previously disclosed SFI, discovery or acquisition of a new SFI, or when the investigator joins an ongoing sponsored project at CUNY.
- 2. The hiring, supervising, and contracting of family members* on research projects is prohibited unless a waiver of Section 3 (Nepotism in Hiring, Employment, Supervisory Responsibility, and Contracting) of the CUNY Conflicts Policy is obtained.

Procedures for requesting a Section 3 Waiver:

- 1. Prepare a Section 3 COI Policy Waiver Submission that includes:
 - 1. A justification for hiring family member and family member qualifications including a written request for the waiver, signed by the investigator;
 - A description of the roles of everyone involved supervising, hiring decisions, fiduciary decisions, overall project responsibility, and the role of the family member;
 - 3. A copy of the family member's CV.
- 2. Submit Section 3 Waiver Requests to Mike Brown at Michael.brown@qc.cuny.edu who

will submit to the Vice Chancellor for review.

I have also attached two guidance documents related to these two topics. See https://sites.google.com/qc.cuny.edu/research/resources 1?authuser=0

For more information on all CUNY COI Policy and Procedures, please visit: https://www.cuny.edu/research/research-compliance/conflict-of-interest/

Feel free to contact me if you have any questions or concerns, thank you!

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^{*}Family Member - Any person living in the same household as the Covered Individual, and any person related to the Covered Individual within the third degree of consanguinity or affinity. Such related persons include the Covered Individual's spouse and the parents, children, siblings, grandparents, grandchildren, aunts and uncles, nieces and nephews, cousins, great grandparents, and great grandchildren of the Covered Individual and his or her spouse, and the spouses of these relatives as well. (For purposes of this Policy, a "spouse" includes a domestic partner under applicable laws governing domestic partnerships and civil unions.) Please refer to Section 3.5. A Covered Individual should consult the University's Office of the General Counsel at ogc@cuny.edu if he or she has any questions about whether the provisions of Section 3 apply to his or her situation.