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1. PURPOSE

To describe the administrative process required to request the issuance of an Independent Researcher Agreement (IRA).

2. DEFINITIONS

- i. An *IRA* is the mechanism by which an individual who is not affiliated with CUNY and who is not acting as an employee or agent of another institution (the “Independent Researcher”) can become involved in research activities being conducted by CUNY. The IRA requires the completion of an Independent Researcher Agreement Application.
- ii. *Research* means: a systematic experiment, study, evaluation, demonstration or survey, in any academic field, designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, causes, functions or effects.

3. VOLUNTEER OR PAID RESEARCHER

- i. *Volunteers*. Most Independent Researchers will be unpaid. A CUNY Principal Investigator (PI) requesting involvement of a volunteer Independent Researcher is required to confirm that the volunteer is not displacing a regular, paid CUNY employee (see justification requirement in Independent Researcher Agreement Application) who would otherwise perform the work.
- ii. *Paid Researchers*. If the unaffiliated individual is to be paid and will perform work that is the same or largely the same as that of a paid CUNY or RF employee on the research team, then the individual should be hired as an employee and will not be an Independent Researcher covered by this Standard Operating Procedure.

If the Independent Researcher is to be paid as an independent contractor, the PI must confirm that the Independent Researcher will not perform work that is the same as or similar to work of a paid CUNY or RF employee on the research team, and: (a) contact his or her campus purchasing office for assistance with an independent contractor agreement if CUNY College/School funds (whether tax levy or non-tax levy) will be used; or (b) coordinate with his or her campus grants/sponsored program office and/or the RF as appropriate, if funds administered by the RF will be used. In both cases the Independent Researcher and the PI are still required to follow this Standard Operating Procedure regarding an IRA.

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4. THE IRA

The Independent Researcher Agreement Application is comprised of two (2) Parts: Request for Approval to Use Independent Researcher in CUNY Research (Part 1), and the Independent Researcher Agreement Application (Part 2). Both Parts must be completed and signed prior to the Independent Researcher's involvement in CUNY research:

i. **PART 1: Request for Approval to Use Independent Researcher in CUNY Research**

A CUNY PI can request approval to use an Independent Researcher in CUNY research by completing the Request for Approval (Part 1) of the Independent Researcher Agreement Application.

This Request for Approval must be completed in full and signed by the PI, and must be approved and signed by the Chair of the Department with which the PI has a primary affiliation and by the Provost or President (or designee) of the College/School where the PI is conducting research.

The Application requests the Independent Researcher's current citizenship and residency status as part of CUNY's due diligence with U.S. Export Control regulations; if the Independent Researcher indicates non-US Citizenship and/or country of residence, the PI must forward the Application to the College Export Control Administrator, or to the University Export Control Officer (UECO), for Export Control Review, prior to obtaining other institutional approvals.

ii. **PART 2: Independent Researcher Agreement Application**

The Independent Researcher must sign the Independent Researcher Agreement, as well as any applicable Appendices, prior to becoming involved in CUNY research. The Agreement addresses: (a) Conduct of Research, (b) Assumption of Risk, and (c) Waiver of Liability. The Agreement includes the following Appendices:

Appendix A – Human Subjects Research

This Appendix applies only to Human Subjects Research and addresses: (a) the Belmont Report, (b) U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, (c) CUNY FWA and applicable terms of the FWA, and (d) CUNY's institutional policies and procedures for the protection of human subjects.

Human subjects research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge, which involves a living individual about whom an investigator conducting research: (a) obtains information or biospecimens through

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intervention or interaction with the individual or (b) otherwise obtains, uses, studies, analyzes or generates identifiable private information or biospecimens. [45 CFR 46.102(e) & (l)] Department of Health and Human Services (DHHS)

Appendix A must be completed and signed when the Independent Researcher seeks to become engaged in CUNY's human subject research by:

1. Obtaining data about the subjects of the research through intervention or interaction with them; and/or
2. Obtaining, using, studying, analyzing or generating identifiable private information or biospecimens about the subjects of the research; and/or
3. Obtaining the informed consent of human subjects for the research.

Appendix B – Parent/Legal Guardian Consent

This Appendix is required to be completed by the Independent Researcher's parent or legal guardian if the Independent Researcher is under the age of 18.

5. AUTHORITIES

The President or Provost of the College or School where the PI is conducting research, or his/her designee, is the Institutional Authority for IRAs. Research team members (including the PI), or others at the CUNY Colleges or Schools do not have the authority to approve or sign IRAs on behalf of CUNY.

6. WORK INSTRUCTIONS

- i. To request an IRA, the PI or his/her designee shall complete and sign the Request for Approval of Use of Independent Researcher Part 1, and provide the Application to the College Export Control Administrator (ECA) or University Export Control Officer (UECO) for Export Control Review. The ECA or UECO will return the Application to the PI when the Export Control Review is complete.
- ii. When the Export Control Review is complete, the PI shall then provide the Application to the PI's Department Chair for review.
- iii. If the Department Chair approves the request and signs the Application, the PI shall then submit the Application to the President or Provost's Office of the College or School where the PI is conducting the research for review and either approval or denial by the President or Provost or his/her designee. Each CUNY College or School should develop and communicate an internal process for ensuring that IRA Applications are routed, reviewed, and signed appropriately.
- iv. If the Request is approved, the PI shall then obtain signatures on all relevant parts of the

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Independent Researcher Agreement. The Independent Researcher shall not begin involvement in the CUNY research until the Request for Approval is fully approved and signed, and the Independent Researcher has signed the Agreement and signed and/or obtained signature for any applicable Appendices.

- v. If the research involves human subjects research, animal research and/or hazardous biological materials, the PI shall submit the fully signed Request for Approval and Independent Researcher Agreement with all applicable Appendices to the relevant oversight body: the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and/or the Institutional Biosafety Committee (IBC).