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OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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SOP 20D- NIH FWA COVERAGE FOR NON-NIH EMPLOYEES WORKING ON NIH PROTOCOLS

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SOP 20D- NIH FWA COVERAGE FOR NON-NIH EMPLOYEES WORKING ON NIH PROTOCOLS

20D.1 PURPOSE

This Standard Operating Procedure (SOP) explains which non-employees are covered by the NIH Federalwide Assurance (FWA) and procedures required for FWA coverage for certain categories of personnel.

20D.2 POLICY

The NIH FWA covers both intramural and extramural NIH employees and certain other categories of personnel as set forth in this policy.

20D.3 DEFINITIONS

A. **Employee**: An individual who is engaged in the performance of a Federal function under authority of law or an Executive act and subject to the supervision of an individual named by paragraph (1) in 5 U.S.C. 2105 while engaged in the performance of the duties of his position. This includes Special Government Employees or Intergovernmental Personnel Act appointees for the purpose of this SOP.

B. **Federalwide Assurance (FWA):** A Federalwide Assurance is a written commitment by an institution to comply with the protection of human subjects regulations of 45 CFR 46. The FWA is filed with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

C. **Human Subjects Research:** In this SOP, this term refers to activities which: (1) meet the 45 CFR 46 definition of research (45 CFR 46 102(d)); (2) involve human subjects, according to the 45 CFR 46 102(f), and (3) are exempt from the provisions of 45 CFR 46 under 45 CFR 46.101(b). The term “Human Subjects Research” in this SOP always means non-exempt Human Subjects Research. (However, in 45 CFR 46, “human subjects research” includes also research that is exempt from the requirements of 45 CFR 46.)

D. **Individual or Institutional Investigator Agreement (IIA):** An agreement between an outside collaborator and NIH that extends the NIH FWA to either an individual investigator or institutional investigators who are not covered by an FWA (e.g. physicians in private practice or individuals who work at an institution that does not have an FWA)

E. **Performance Site (enrollment site):** A performance site, or an enrollment site, is a place where human subjects participate in research activities (e.g. often a clinic or hospital). The performance site's location may be different from the location where the IRB review occurs. Subjects are usually enrolled or followed at the performance sites.

F. **Special Volunteer:** A "special volunteer" is an individual who meets NIH requirements set forth in NIH Manual Chapter "2300-308-1 – Guest Researcher/Special Volunteer Programs" (see **References**) and has been designated as a Special Volunteer by the NIH. Special Volunteers (SV) are non-NIH employees who provide research services, direct patient care, clerical support, technical assistance, or any other necessary services for NIH using NIH facilities.

20D.4 NIH FWA COVERAGE

A Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by the DHHS OHRP. NIH has authority to determine which individuals are covered by the NIH FWA.

NIH employees (intramural and extramural) are covered by the NIH FWA. Additionally, certain non-employees may be covered as designated in this chapter or at the discretion of NIH, as outlined in **20D.5**.

OHSRP will assist NIH investigators in evaluating how to proceed and effectuate an appropriate agreement when collaborating with non-employees at sites that do not have an FWA.

20D.5 NON-EMPLOYEES COVERED BY THE NIH FWA

Non-employees can be covered by the NIH FWA in 3 different circumstances and may be subject to NIH approval:

A. A researcher[1] who is engaged in NIH human subjects research, working on an NIH protocol, at an NIH site with an NIH employee. These individuals must comply with NIH policy requirements, including, e.g., credentialing requirements, HRPP standard operating procedures and policies, HRPP training, applicable conflict of interest rules for individuals who are not employees, and NIH training on the Federal Privacy Act and computer security. These individuals are not required to sign any documents to show that they are covered by the NIH FWA. Their coverage is automatic, based on their responsibilities at the NIH, when working with an NIH employee at an NIH site.

B. Former employees (**20D.4)** or researchers (**20D.5.A**) (collectively "former NIH staff") at a non-NIH site and who want to remain on an NIH protocol performing only data analysis with identifiable data. (See criteria for FWA Coverage Agreement in **20D.6**) NIH approval and written documentation are required.

C. Non-employee collaborating investigator(s) (usually physicians) who provide NIH protocol interventions at non-NIH sites that do *not* hold a Federalwide Assurance (FWA) and will be engaged in human subjects research. If the non-NIH site does not have an FWA and does not opt to obtain an FWA, the NIH may enter into an agreement to extend NIH's FWA to these non-employee investigator(s) (see **20D.7** below). NIH approval and written documentation are required.

20D.6 FWA COVERAGE FOR FORMER NIH STAFF WHO LEAVE NIH BUT WANT TO REMAIN ON AN NIH PROTOCOL, PERFORMING IDENTIFIABLE DATA ANALYSIS ONLY

A. At its discretion, NIH may extend its FWA provided the following criteria are met:

1. The person was previously covered by the NIH FWA under **20D.4** or **20D.5.A**;

2. The person was a Principal Investigator (PI) or Associate Investigator (AI) on the NIH IRB approved protocol at issue while at the NIH;

3. The person's continued engagement in human subjects research will be limited to research with identifiable data from that same protocol.

[1] These researchers may include Guest Researchers, Special Volunteers, contractors (subject to terms of the contract), Intramural Research and Cancer Research Training Awardees and collaborators from academia and industry who are not Special Government Employees or Interpersonal Act appointees.

B. PIs must request the FWA coverage.

C. **PI requirements** that apply to FWA coverage of former NIH staff, who leave NIH but want to remain on an NIH protocol and do data analysis only:

The NIH PI will do the following:

1. Confirm that criteria above in **20D.6.A** are met;

2. Contact the OHSRP to determine if use of an FWA Coverage Agreement is appropriate;

3. Ensure that the protocol amendment and updated protocol state the name and the non-NIH affiliation, if any, of the former NIH staff member and that his/her role will be an AI and is limited to research with identifiable data. The PI should also indicate on the IRB amendment application that this former NIH staff person is covered by the FWA Coverage Agreement;

4. Ensure that the former NIH staff member complies with NIH IT security requirements for identifiable data. (For more information contact the IC Information System Security Officer (ISSO));

5. Ensure the Privacy Act requirements of sharing NIH data with the former NIH staff member are satisfied or establish Data Use Agreements if needed (For more information contact your IC Privacy Coordinator or Technology Transfer Center);

6. Ensure that a copy of SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations is provided to the former NIH staff investigator.

7. Obtain the former NIH staff member's signature on the NIH FWA Coverage Agreement **Appendix 3;**

8. Sign the agreement once the former NIH staff member's signature has been obtained;

9. Keep a copy of each FWA Coverage Agreement in his/her NIH study file; and

10. Forward a copy of the fully signed agreement to OHSRP (at ohsr_nih_ddir@od.nih.gov).

11. If NIH withdraws its FWA coverage of the AI who is a former NIH staff member, the NIH PI should promptly notify the AI of this action.

D. Responsibilities of the former NIH Staff member are set forth in the FWA Coverage Agreement

20D.7 EXTENSION OF FWA FOR COLLABORATING NON-EMPLOYEE INVESTIGATORS WHO ARE WORKING ON NIH PROTOCOLS BUT DO NOT MEET REQUIREMENTS IN 20D.5.A OR 20D.6

A. Process for extension

The DHHS Office of Human Research Protections permits an FWA-holding institution to extend the applicability of its FWA to cover two additional situations at non-NIH sites: 1) collaborating institutional non-employee investigator(s) and 2) collaborating individual non-employee investigators. NIH has developed template agreements for each of these situations (**Appendices 1** and **2**, respectively).

NIH investigators may desire to collaborate with a team of non-employee investigators who work at an institution that does not have an FWA. This group of non-employee investigators may be implementing an NIH protocol at a non-NIH site such as a clinic. An Institutional Investigator Agreement can be executed between NIH and that entity so that the NIH FWA is extended to cover these non-employee investigators (see **Appendix 1**).

Alternatively, individual non-employee investigators may be AIs on a protocol or provide the research intervention or follow-up care as dictated by the protocol. If these individuals are engaged in human subjects research, an Individual Investigator Agreement (**Appendix 2**) is required.

NIH has discretion about extending its FWA to cover such collaborators. In determining whether such an agreement is needed, NIH investigators and IRBs should consult the OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008) (see **References** and 20 - NIH HRPP Requirements for Collaborative Research.

B. The following conditions are required for NIH to enter an agreement to extend its FWA to a collaborating individual or institutional non-employee investigator(s):

1. The approval to extend coverage of the NIH FWA for a non-assured institution is made by the OHSRP Director or Deputy Director, who is responsible for signing these agreements. Copies of such agreements must be kept in the NIH IRB protocol file and by OHSRP and made available to OHRP upon request.

2. For collaborating institutional non-employee investigator(s), the appropriate authorities at the non-assured institution state in writing that the conduct of the research is permitted at their institution.

3. OHSRP approves the extension of the assurance through either an agreement to extend the FWA to collaborating institutional non-employee investigator(s) (see **Appendix 1**) or to collaborating individual non-employee investigators (see **Appendix 2**).

4. The NIH PI must give direction and provide any oversight as needed for all the collaborative research activities to be performed by the collaborating individual or institutional non-employee investigator(s) outside NIH.

5. The following documents are made available to the collaborating institutional or individual investigator(s): (a) A copy of the Belmont Report (see **References**); (b) A copy of 45 CFR 46; (c) FWA information (d) NIH HRPP SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations; (e) The NIH IRB approved protocol, together with a cover page including instructions regarding events that need to be reported as well as contact information for reporting.

6. The collaborating individual or institutional non-employee investigator(s) understands and accepts the responsibility for complying with the standards and requirements stipulated in the documents referenced in the preceding paragraph and for protecting the rights and welfare of human subjects involved in research conducted under the IIA or other written agreement used by the NIH.

7. The collaborating individual or institutional non-employee investigator(s) agrees to comply with all other applicable federal, international, state, and

local laws, regulations, and policies that may provide additional protections for human subjects participating in research conducted under the IIA.

8. The collaborating individual or institutional non-employee investigator(s) agrees to abide by all determinations of the NIH IRB.

9. The collaborating individual or institutional non-employee investigator(s) agrees to complete any appropriate training on human subjects research protections required by NIH prior to initiating research covered under the IIA.

10. The collaborating individual or institutional non-employee investigator(s) agrees to report promptly to the NIH PI and the NIH IRB any proposed changes in the research conducted under the IIA or other written agreement, and not to initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

11. The collaborating individual or institutional non-employee investigator(s) agrees to report immediately to the NIH PI who will inform the NIH IRB of any unanticipated problems involving risks to subjects or others as well as protocol deviations in research covered under the IIA.

12. If NIH withdraws the agreement to extend the FWA coverage to collaborating institutional non-employee investigator(s) or to collaborating individual non-employee investigators, the NIH PI should promptly notify the non-employee investigator(s) of this action.

20D. 8 CONFLICT OF INTEREST ASSESSMENT

Please refer to SOP 21 - Conflict of Interest Requirements for Researchers and Research Staff.

20D.9 TEMPLATES FOR AGREEMENTS TO EXTEND THE NIH FWA TO NON-EMPLOYEE INVESTIGATORS WORKING AT NON-NIH SITES

Three templates exist:

A. Institutional Investigator Agreements (**Appendix 1**), for a group of collaborating non-employee investigators who are part of an NIH protocol, but who are employed at an institution that does not have an FWA

B. Individual Investigator Agreements (**Appendix 2**), used to cover the activities of collaborating non-employee investigators who are independent health care professionals and who are not covered by an FWA

C. FWA Coverage Agreement, for former NIH staff who leave NIH but want to be AIs on an NIH protocol and who continue to work with identifiable data (**Appendix 3**)

REFERENCES

NIH HRPP Policy and Procedures: http://ohsr.od.nih.gov/OHSR/pnppublic.php

NIH Manual Chapter 2300-308-1 – Guest Researcher/Special Volunteer Programs: https://oma1.od.nih.gov/manualchapters/person/2300-308-1/

OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008): http://www.hhs.gov/ohrp/policy/engage08.html

Belmont Report: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

LIST OF APPENDICES

Appendix 1 - Institutional Investigator Agreement

Appendix 2 - Individual Investigator Agreement

Appendix 3 - NIH FWA Coverage Agreement

APPENDIX 1 - INSTITUTIONAL INVESTIGATOR AGREEMENT

NIH Institutional Investigator Agreement

Agreement between NIH and XXXXX, Inc. to extend the NIH FWA to collaborating non-employee investigators employed at an institution that does not have an FWA

Name of Institute with the Federal Wide Assurance (FWA): National Institutes of Health

Applicable FWA #: 00005897, expiration date _____

Name of the entity: XXXXX, and its employees who are involved in human subject research on this protocol.

Specify Research Covered by this Agreement:
XXXXXXXXXXXXXXXXXXXXXXXXX

XXXXX employees implement the study protocol by contacting potential research subjects and current subjects, examining, interviewing, and obtaining data requested in the protocol.

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1. XXXXX has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; 2) The U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) Terms of the FWA; 4) NIH HRPP SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations; 5) The NIH IRB approved protocol. 6) The relevant NIH policies and procedures for the protection of human subjects, (see **References**).

2. XXXXX understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

3. XXXXX will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

4. XXXXX will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

5. XXXXX will complete any educational training [specify] required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

6. XXXXX will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The Institute will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

7. XXXXX will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

8. XXXXX when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46, NIH policy, and stipulated by the IRB.

9. XXXXX acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. XXXXXX, Inc. will provide all information requested by the IRB in a timely fashion.

10. XXXXX will not enroll subjects in research under this Agreement prior to its review and approval by the IRB. [Specify if other requirements such as a site initiation visit]

11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

12. This Agreement does not preclude the XXXXX from taking part in research not covered by this Agreement.

13. XXXXX acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Signatory Officials

.

X_____
Senior Partner XXXXX

Name: _____
Title: _____
Address: _____
_____
_____
Phone: _____
E-mail: _____

Date: _____

X_____
National Institutes of Health

Charlotte Holden, JD
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10 Center Drive, Room 2C146
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Date: _____

APPENDIX 2 - INDIVIDUAL INVESTIGATOR AGREEMENT

Individual Investigator Agreement

Agreement between NIH and collaborating non-employee investigator(s) to extend the NIH FWA to the non-employee investigator(s) who are independent health care professionals and who are not covered by an FWA

National Institutes of Health_____

Federal Wide Assurance (FWA) #: 00005897, expiration date_____

Individual Investigator's Name: _____

Specify Research Covered by this Agreement: _____

(1) The above-named Individual Investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; 2) The U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) Terms of the FWA; and 4) NIH HRPP SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations; 5) The NIH IRB approved protocol; 6) The relevant institutional policies and procedures for the protection of human subjects, (see **References**).

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46, NIH policy, and stipulated by the IRB.

(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____

Name: _____ Degree(s): _____
(Last) (First) (Middle Initial)

Address: _____

_____
(City) (State/Province) (Zip/Country)

Phone #: _____

Email:

Date: _____

X_____
National Institutes of Health

Charlotte Holden, JD
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Date: _____

APPENDIX 3 - FWA COVERAGE AGREEMENT

National Institutes of Health
Federalwide Assurance Coverage Agreement

Name of researcher:

Research protocol covered by this agreement ("Research"):

By signing this certification, I am accepting the National Institutes of Health's (NIH) offer to be covered under its Federalwide Assurance (FWA). I further understand and acknowledge that:

- I am receiving no, and not entitled to, any other benefits or rights from NIH or HHS regarding my involvement in this Research;

- I am not an employee or agent of NIH;

- I will abide by the direction of the Principal Investigator of the Research;

- I will comply with the Research as approved by the Institutional Review Board of record (IRB) and will further comply with the determinations and directives of the IRB;

- My approved role in the Research is limited to data analysis;

- I am responsible for knowing and complying with all applicable federal, state, and local laws and regulations, including but not limited to the Privacy Act, 5 U.S.C. 552a, and the HHS Protection of Human Subjects regulations, 45 C.F.R. 46;

- I am responsible for knowing and complying with all applicable NIH policy related to my role in the Research (e.g., to immediately report unanticipated problems to the PI, and to satisfy human subjects research training and conflict of interest requirements);

- I will comply with my home institution's policies, as applicable;

- NIH may withdraw its FWA coverage at any time and without prior notice to me, and;

- If I am performing work on Research as part of my responsibilities for my home institution, that I have made my home institution aware of this agreement.

Name: _____

Signature: _____ Date: _____

Name of NIH PI: _____

Signature: _____ Date: _____

NIH Federal Wide Assurance (FWA) #: 00005897, expiration date_____