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INSTITUTIONAL REVIEW BOARD (IRB)
STATEMENT OF POLICIES AND PROCEDURES
(Revision 09/22/2015)

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NOTE: For questions or additional copies of this manual, please contact Dayana Bermudez, IRB Administrator, at (646) 619-6701 or IRBAdministrator@healthsolutions.org.

INSTITUTIONAL REVIEW BOARD (IRB)

STATEMENT OF POLICIES AND PROCEDURES

(Revision 07/02/13)

I. Introduction

A. Principles

The Public Health Solutions Institutional Review Board (IRB) is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report"). In addition, the IRB adheres to the requirements set forth in the Department of Health and Human Services (HHS) Policy for Protection of Human Research Subjects (45 C.F.R. Part 46) for all applicable research, regardless of funding source. Based on these principles and requirements, the IRB has adopted this Statement of Policies and Procedures (this Statement) for its review of research protocols.

B. Definitions

1. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. "Human subject" or "subject" means a living individual about whom a researcher conducting research obtains data through intervention or interaction with the individual or identifiable private information:
 - a) "Intervention or interaction" means physical procedures by which data are gathered, manipulations of the subject or the subject's environment performed for research purposes, communication or interpersonal contact between a researcher and a subject.
 - b) "Private information" means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. However, that private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.
3. "Unanticipated adverse event" means, at a minimum, any unanticipated emergent injury or harm suffered by a subject involved in an ongoing project or activity of Public Health Solutions, or any non-urgent problem that may alter established relationships with human subjects, whether either is thought to be a consequence of the research or not.
4. "Serious adverse events" mean untoward occurrences that result in death, a life-threatening condition, inpatient hospitalization, persistent or significant disability or incapacity, serious physical harm, or a congenital anomaly.

C. Applicability and Scope of this Statement

The goal of the IRB is to work with researchers to safeguard the rights and welfare of human subjects. All studies involving human subjects (e.g., surveys, interviews, focus groups, interventions) should be assumed to require IRB review until determined otherwise. Exemption determinations are to be made by the IRB and not the researchers.

This Statement is applicable to all research involving human subjects, and all other activities, which even in part, involve such research, if:

1. The research is sponsored by Public Health Solutions;
2. The research is conducted by or under the direction of any employee or agent of Public Health Solutions in connection with his or her institutional responsibilities;
3. The research is conducted by or under the direction of any employee or agent of Public Health Solutions using any property or facility of Public Health Solutions;
4. Public Health Solutions receives a grant or award to conduct research, even where all activities involving human subjects are carried out by a subcontractor or collaborator; or

5. The research involves the use of Public Health Solutions' nonpublic information to identify or contact human research subjects or prospective subjects.

II. Responsibilities of Public Health Solutions and Researchers

A. Institutional Responsibilities

1. Public Health Solutions will take all reasonable and necessary measures to protect the rights and welfare of human subjects of research covered by this Statement.
2. Public Health Solutions will consider the following before human subjects are involved in research covered by this Statement:
 - a) The risks to the subjects;
 - b) The anticipated benefits to the subjects and others;
 - c) The importance of the knowledge reasonably expected to be gained; and
 - d) The informed consent process to be employed.
3. Public Health Solutions acknowledges its responsibility for the performance of all research that it conducts involving human subjects covered by this Statement.
4. Public Health Solutions is responsible for complying with federal, state, or local laws as they may relate to research that it conducts covered by this Statement.
5. Public Health Solutions will facilitate and encourage constructive communication among research administrators, department heads, researchers, clinical care staff, human subjects, and Public Health Solutions officers so as to safeguard the rights and welfare of the subjects.
6. Public Health Solutions will exercise appropriate administrative oversight to ensure that its practices and procedures for the protection of human subjects are effectively applied. At least annually, the IRB Administrator shall prepare a written report for the Public Health Solutions President regarding IRB operations, and the President shall report to the Public Health Solutions Board of Directors regarding IRB operations.
7. Public Health Solutions will consider additional safeguards in research when that research involves prisoners, fetuses, pregnant women, children, individuals institutionalized as mentally disabled, other potentially vulnerable groups, and human in vitro fertilization, e.g. bringing in guest reviewers with particular expertise.
8. Public Health Solutions will provide each individual conducting or reviewing human subject research (e.g., researchers, department heads, research administrators, research reviewers) with a copy of this Statement.

B. Institutional Researcher Responsibilities

All researchers involved in Public Health Solutions research, by their participation in Public Health Solutions activities, fully acknowledge and accept the high, professional duty they have to protect the rights and welfare of human research subjects and to comply with this Statement and all applicable Public Health Solutions policies and applicable laws and professional ethical standards. This includes, among other things, the following:

1. Research investigators are responsible for obtaining IRB review and approval prior to initiation of any human subjects' research.
2. Research investigators are responsible for preparing and providing to the IRB Administrator all research protocols and related information required for IRB review pursuant to this Statement and as otherwise specified by the IRB Administrator.
3. Research investigators are responsible for promptly reporting proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazard to the subjects.
4. Researchers are responsible for complying with all IRB decisions, conditions and requirements. Research investigators are responsible for reporting the progress of the

research to the IRB as often as and in the manner prescribed by the IRB, but no less than once per year.

5. The researcher must ensure that there are sufficient privacy protections for human subjects in Public Health Solutions research projects. The IRB strongly supports researchers obtaining federal certificates of confidentiality from HHS for research involving the collection of sensitive information. Examples of sensitive information include: data relating to sexual attitudes, preferences, or practices; the use of alcohol, drugs, or addictive substances; information pertaining to illegal conduct; genetic information; information that could be damaging to an individual's financial standing, employability, social standing or reputation; information normally recorded in a patient's medical record or pertaining to an individual's psychological well being or mental health.
6. The researcher will never conduct unapproved research. Regardless of researcher intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the IRB and Public Health Solutions will act promptly to halt the research, to assure remedial action, and to address the question of the researcher's fitness to conduct human subject research.

C. Outside Organizations

Public Health Solutions may conduct IRB reviews as a courtesy to other organizations that do not have their own IRBs. These reviews will be conducted for a certain fee depending on the type of review. The terms and conditions of these IRB reviews and the responsibilities of outside organizations utilizing the services of the Public Health Solutions IRB are outlined in the model Letter of Agreement attached as Appendix VI.

D. Unaffiliated Researchers

1. Individual research investigators who are not employees or agents of Public Health Solutions, but who participate in Public Health Solutions research, must enter into written agreements of commitment to relevant human subject protection policies, educational standards, and IRB oversight. Copies of such agreements shall be provided to the IRB as part of its initial and continuing reviews of research involving such researchers.
2. Outside researchers wishing to do research with Public Health Solutions clients/patients or staff must also submit, with the other required IRB forms and materials, a letter of support from the appropriate Public Health Solutions vice president or program manager.

E. Student Researchers

Student research may be conducted at Public Health Solutions with IRB approval. The student must be enrolled in a Masters or Doctoral level program at an accredited institution, and must submit a letter of support from an academic advisor, the student's resume or curriculum vitae, and proof of sponsorship from the Public Health Solutions Research and Evaluation Unit.

III. Criteria and Procedures for IRB Review

A. Procedures for Initial Review

1. One copy of the complete protocol, with all required accompanying materials, must be submitted to the IRB Administrator at least two weeks before the scheduled IRB meeting at which it is to be considered. If requested, the researcher must provide the IRB Administrator with additional copies of the complete protocol for distribution to the full IRB.
2. Each research protocol submitted by researchers to the IRB must, as appropriate, contain:
 - a) A detailed description of the anticipated subjects, including, without limitation, (i) the subjects' anticipated gender and race, (ii) whether it is anticipated that the subjects will fall within a category of vulnerable persons (i.e., children, prisoners, pregnant women, decisionally impaired individuals, economically or educationally disadvantaged individuals) and (iii) the recruitment practices to be used and whether they will involve payments to subjects, advertisements (and if so, copies of those advertisements) and/or

- compensation to researchers, health care providers or others for identifying and/or enrolling subjects;
- b) Assurances that the research investigators: (i) have completed adequate training in human subjects research protections, (ii) are not and have not been excluded or disbarred from, or otherwise found to be ineligible to participate in, federal health care-related programs, or convicted of a criminal offense related to health care, (iii) have not submitted the protocol (or a substantially similar protocol) to another institutional review board, which disapproved the protocol and (iv) are duly trained and qualified to conduct the proposed research;
 - c) Samples of all materials used to obtain and document informed consent, in all languages that will be used; and
 - d) Any additional information that would necessary for the IRB to evaluate the protocol using the criteria and requirements within this Statement.
3. All protocols will undergo a pre-review by the IRB Administrator to determine that the above guidelines have been followed.

B. Exemption from IRB Review

1. Researchers may request that their protocol be exempted from the required IRB Review.
2. The criteria used to decide whether to allow the exemption of research from review are presented in Appendix I. The IRB Chair, in consultation with the IRB Administrator, shall determine whether the proposed protocol can be exempted from review.

C. Expedited Review

1. Researchers may request that their protocol be considered for an expedited review. Expedited reviews are performed by only a few IRB members.
2. Expedited review is appropriate for research which involves minimal risk to human subjects, as described in Appendix II. The IRB may also use the expedited review procedure to review minor changes to previously approved research. The administrator in consultation with the chair shall decide which protocols should receive expedited review.
3. The criteria for IRB approval are the same for both expedited and non-expedited reviews.
4. If the protocol is accepted for expedited review but is not approved, then the protocol must be resubmitted for a full review as normal.
5. For additional information on expedited reviews, see Part VI.C below.

D. General Criteria for IRB Review and Approval of Proposals

1. Risk to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk and, whenever appropriate, by using procedures already performed on the subjects.
2. Risks to subjects are reasonable in relation to the anticipated benefits of the research, if any, to the subjects and the importance of the knowledge that might reasonably result.
3. The selection of subjects is equitable in light of the purposes and location of the research, with particular consideration given to the special problems of research involving vulnerable populations.
4. Informed consent is obtained and documented (unless waived by the IRB) from each prospective subject or the subject's legally authorized representative, in accordance with law and this Statement.
5. Where appropriate, there are provisions for protecting subjects by monitoring the collected data, e.g., data safety monitoring boards.
6. There are appropriate provisions to protect subjects' privacy and to maintain the confidentiality of data and records.
7. There is compliance with any applicable federal, state or local laws that require additional subject protections.

8. There are additional and sufficient safeguards to protect vulnerable subjects, such as children, prisoners, economically or educationally disadvantaged persons, pregnant women, and decisionally impaired persons.
9. There are no financial relationships that constitute a financial conflict of interest that poses material risks to study subjects, or if any such financial conflict exists, the research contains explicit mechanisms for effectively managing the conflict of interest.
10. If the research will involve prisoners as subjects, it involves solely a category of research set forth in 45 C.F.R. § 46.306(a)(2), and meets the requirements set forth in 45 C.F.R. § 46.305(a)(2)-(7).
11. If the research will involve children as subjects that:
 - a) If the research will involve no greater than minimal risk to the subjects, adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians pursuant to 45 C.F.R. § 46.408;
 - b) If the research will involve greater than minimal risk to subjects but presents the prospect of direct benefit to the individual subjects, that the risk is justified by the anticipated benefit to the subjects, the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians pursuant to 45 C.F.R. § 46.408;
 - c) If the research will involve greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition, that (i) the risk represents a minor increase over minimal risk, (ii) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, (iii) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, and (iv) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians pursuant to 45 C.F.R. § 46.408;
 - d) If the research does not fit within the prior categories, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, that it satisfies the requirements of 45 C.F.R. § 46.407; and
 - e) If the research will involve wards of the state, that it satisfies the requirements of 45 C.F.R. § 46.409.
12. If the research involves pregnant women, that:
 - a) Adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the researcher for monitoring the actual informed consent process;
 - b) Appropriate studies on animals and non-pregnant individuals have been completed;
 - c) The purpose of the activity is to meet the health needs of the mother or fetus or else the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the research objectives;
 - d) The research protocol does not involve pregnancy termination, or else the criteria set forth in 45 C.F.R. § 46.206(3)-(4) have been satisfied;
 - e) The research is not directed toward pregnant women as subjects, or else the criteria set forth in 45 C.F.R. § 46.207 have been satisfied; and
 - f) The research is not directed toward fetuses as subjects, or else the applicable criteria set forth in 45 C.F.R. § 46.208-.209 have been satisfied.

13. There are appropriate safeguards to prevent coercion or undue influence of all individuals, especially those with physical or mental illness or who are educationally or economically disadvantaged.
14. The appropriateness of the scientific method used is not a criterion for IRB review.

IV. Informed Consent

A. Basic Required Elements for Informed Consent

No Public Health Solutions research may involve human subjects unless the researcher has obtained the prior, legally effective informed consent of the subject or the subject's legally authorized representative. In certain limited circumstances involving public program research or no more than minimal risk to human subjects, outlined in Part IV.C below, these requirements may be modified or waived. In determining whether informed consent requirements have been satisfied, IRB members must be assured of the following:

1. Consent is sought under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.
2. Information given to the subject or representative is in language understandable to the subject or the representative, and if translations of the consent form are necessary, those translations are validated as per Part IV.E below.
3. Where protocol or consent modifications are necessary for IRB approval, the IRB Chair and/or appropriate members will work with research investigators to develop adequate safeguards for subjects. Substantive clarifications, protocol modifications, or informed consent document revisions shall require additional review by the convened IRB of responsive material. However, if specified revisions by the IRB require only simple concurrence by the researcher, the convened IRB may approve the research protocol on condition that the modification is agreed to by the researcher, and if such modification is agreed to by the researcher, the modified research protocol may be finally approved using an expedited review procedure.
4. Information given to the subject or representative, whether in oral or written form, contains no exculpatory language through which the subject or representative is made to or appears to waive any of the subject's legal rights, or which releases or appears to release the researcher, the sponsor, Public Health Solutions (or its agents and employees) from liability for negligence.
5. Information given to the subject or representative states that the study involves research.
6. Information given to the subject or representative explains the purpose of the research.
7. Information given to the subject or representative states the expected duration of the subject's participation.
8. Information given to the subject or representative describes the procedures to be followed, and identifies any procedures that are experimental.
9. Information given to the subject or representative describes any reasonably foreseeable risks or discomforts to the subject.
10. Information given to the subject or representative describes any benefits to the subject or others which may reasonably result from the research.
11. Information given to the subject or representative discloses appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
12. Information given to the subject or representative describes the extent, if any, to which the confidentiality of records identifying the subject will be maintained.
13. For any research involving more than minimal risk, the information given to the subject or representative explains whether any compensation or medical treatments are available if injury occurs, and if so, what they consist of or whether further information may be obtained.

14. Information given to the subject or representative states who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury or other problem.
15. Information given to the subject or representative states that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

B. Other Required Elements for Informed Consent

In addition to the basic elements of informed consent described in Part IV above, as appropriate, the following additional elements will be required:

1. Information given to the subject or representative states that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Information given to the subject or representative describes anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent.
3. Information given to the subject or representative describes any additional costs to the subject that may result from participation in the research.
4. Information given to the subject or representative describes the consequences of voluntarily withdrawing from the research and procedures for orderly termination of participation by the subject.
5. Information given to the subject or representative states that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. Information given to the subject or representative describes the approximate number of subjects involved in the study, and how subjects are selected.

C. Waiver or Modification of the Required Elements of Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or which waives the requirement to obtain informed consent, only if the IRB finds and documents that the research at issue satisfies all of the criteria of at least one of the following:

1. Public Program Research
 - a) The research is to be conducted by or subject to the approval of state or local government officials;
 - b) Is designed to study, evaluate or otherwise examine: (i) public benefit of service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs;
 - c) Could not practicably be carried out without the waiver or alteration.
2. Research Involving No More than Minimal Risk.
 - a) The research involves no more than minimal risk to the subjects;
 - b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c) The research could not practicably be carried out without the waiver or alteration; and
 - d) Whenever appropriate, the subjects will be provided additional pertinent information after participation.

D. Informed Consent Forms

1. Unless informed consent is waived, informed consent must be documented by the use of a written consent form approved by the IRB, signed by the subject or the subject's legally

authorized representative, with a copy of the form provided to the person who signed the form.

2. The consent form must address all of the required elements of informed consent.
3. The IRB may waive some of the required elements of the informed consent document in certain specific circumstances.
4. The IRB may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if the IRB finds and documents that all of the criteria of at least one of the following categories has been satisfied:
 - a) Certain Confidentiality Risks: (i) the only record linking the subject and the research would be the consent document, (ii) the principal research risk would be potential harm resulting from a breach of confidentiality, and (iii) the IRB has considered whether to require providing subjects with a written statement regarding the research.
 - b) Certain Low Risk Research: (i) the research presents no more than minimal risk of harm to subjects, (ii) the research involves no procedures for which written consent is normally required outside of the research context and (iii) the IRB has considered whether to require providing subjects with a written statement regarding the research.
5. Any new consent forms must be reviewed by the IRB.

E. Translations

In the event that the study population targets a particular group that does not speak and/or read English, recruitment materials and informed consent documentation must be translated into the language understood by the targeted group.

1. The translated consent form, as well as any other important study materials that may significantly affect the subject's wellbeing or ability to give informed consent, should ideally be prepared by a qualified translator.
2. Federal regulations require that an interpreter be present to facilitate the informed consent discussion for non-English speaking subjects, even if a translated consent form is used.
3. A "short form" consent document may be used as an alternative method for obtaining and documenting informed consent from occasional and unanticipated non-English speaking subjects, when no translated consent form is available. In this method, an interpreter's oral explanation of the un-translated consent form or other IRB-approved research summary is used along with a generic short form document that summarizes the basic elements of informed consent in the subject's own language and has been filled in with the appropriate contact information. The short form consent document should be signed by the subject as well as an impartial witness.
4. An impartial witness is required when either a short form document or a translated consent form is used. This witness must be proficient in the language of the researcher and the subject, and must be present during the entire consent process to confirm the adequacy of the informed consent process as well as the participant's voluntary consent. A qualified interpreter may also serve as the witness, but this should be clarified beforehand.
5. The following documents must be submitted to the IRB:
 - a) English and non-English versions of the documents.
 - b) Signed statements from all persons providing translation or interpretation services describing their qualifications, what materials were translated, which version of the source materials were used, and any conflicts of interest present.
 - c) Signed statements from the impartial witnesses, including the witness' qualifications and confirming that no conflicts of interest exist.

V. Other Requirements and Criteria for Review

A. Qualifications of Researchers

The qualifications of researchers will be considered when reviewing proposals, and researchers' professional development taken into account and related to the degree of protocol complexity and risk to human subjects. Accordingly, the IRB may require less experienced research investigators to be sponsored by seasoned researchers, and all researchers must fully cooperate with any such requirements. Proposals that require skills or experience beyond those held by the principal researcher may be modified to meet the researcher's experience, have additional qualified personnel added, or else be disapproved.

B. IRB Assurance of Compliance by Researchers

No research protocol will be approved unless it contains clear procedures for ensuring, at a minimum, prompt reporting to the IRB, appropriate Public Health Solutions officials, and appropriate government officials of all of the following:

1. Any unanticipated adverse event involving risks to subjects or others;
2. Any serious or continuing noncompliance with applicable human subjects regulations or the requirements or determinations of the IRB; and
3. Any suspension or termination of IRB approval.

C. Adverse Event Reporting

The following requirements for reporting adverse events, as defined in Part I.B above, must be followed by researchers as well as Public Health Solutions and its IRB.

1. All adverse events, particularly unanticipated adverse events as defined in Part I.B.3 above, must be reported to the IRB Administrator within two (2) weeks of occurrence.
2. Serious adverse events must be reported to the IRB Administrator within 24 hours of occurrence, regardless of whether they were anticipated, thought to be a consequence of the research, or not. As defined in Part I.B.4, serious adverse events mean untoward occurrences that result in death, are life-threatening, require inpatient hospitalization, result in persistent or significant disability, serious physical harm, or a congenital anomaly.
3. All adverse events must be reported in writing and again in the continuing review written progress report.
4. Any serious adverse event report must be reviewed immediately upon receipt by the IRB Administrator in consultation with the Chair and the Vice President of Research and Evaluation and an immediate assessment made as to appropriate intervention(s) on behalf of the rights and safety of the human subject(s) involved.
5. All other adverse event reports will be promptly reviewed and an assessment made as to appropriate interventions. Should the IRB Administrator determine that the research exposes human subjects to an unforeseen and unacceptable degree of risk, Public Health Solutions, as well as the researchers, shall act promptly to halt the research.

D. Mandatory Education and Training

Human subjects researchers shall complete appropriate human subjects research protection education, as specified by the IRB Chair. This education shall be required before any such persons review or conduct human subject research, and also on a regular, ongoing basis. Researchers must provide records demonstrating that this mandatory education requirement has been satisfied, e.g., certificates of training.

E. Research Collaborations

All institutions and researchers that collaborate in human subjects research must operate under an active Federal Assurance of Protection for Human Subjects, and all institutions engaged in such research (including subcontractors and sub-grantees) must hold their own such Assurances. Evidence of such Assurance shall be provided to the IRB as part of its initial and continuing reviews of such research.

VI. IRB Operating Procedures

A. General Procedures

1. Each research protocol must be approved by the Vice President of Research and Evaluation before it may be submitted to the IRB.
2. The IRB shall review research protocols presented to it by the IRB Chair, and shall have authority to approve, require modifications to (to secure approval), or disapprove such proposed research. This shall include, without limitation, that with respect to any Public Health Solutions research, the IRB shall have authority to observe or have a third party observe the consent process and the research. The IRB also has the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
3. Except for research protocols subject to expedited IRB review, all initial IRB reviews must take place at convened IRB meetings and all continuing reviews of these protocols must be discussed at convened IRB meetings.
4. Where protocols or consent modifications are necessary for IRB approval, the IRB Chair, IRB Administrator, and/or appropriate members will work with research investigators to develop adequate safeguards for subjects. Substantive clarifications, protocol modifications, or informed consent document revisions may be approved by the IRB Chair, the IRB Administrator, or by appropriate members.

B. Regular Review Procedures

1. All proposals, for both initial reviews and continuing reviews, must be considered at convened IRB meetings at which no less than six members are present, including at least one member whose primary concerns are in a non-scientific area. In the absence of six full members, alternates may take their place.
2. The IRB may approve, disapprove, or require modifications in all research protocols.
3. A proposal must be approved by a majority of members present at the meeting.

C. Expedited Review

1. Expedited review is appropriate for research which involves minimal risk to human subjects, as described in Appendix II. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. The administrator in consultation with the chair will decide which protocols should receive expedited review.
2. Expedited reviews are conducted by the IRB Chair, the IRB Administrator, or one or more experienced IRB members designated by the Chair.
3. The criteria for IRB approval is the same for both expedited and non-expedited reviews.
4. In reviewing the research, the reviewers may exercise all of the authorities of the IRB, including approving the research, except that they cannot disapprove the research. A research activity may be disapproved only after review in accordance with the regular procedure.
5. The IRB Administrator must notify the full IRB when a project has been approved by expedited procedure. This should be done at the next scheduled meeting.

D. Continuing Review

The IRB will conduct continuing review of all approved research at intervals appropriate to the degree of risk, but not less than once per year.

1. The IRB will determine that date by which the research must be reviewed. The researcher will be notified of the date at the time that the proposal is approved. The date also will be noted on the IRB's official calendar. It is the responsibility of both the IRB and the researcher to ensure that the review is conducted at the appropriate interval.

2. The researcher must submit a progress report two weeks prior to the assigned date. The report should confirm that there have been no changes and specify any problems which have interfered with the rights and safety of the subjects involved.
3. A researcher must notify the IRB promptly of any proposed changes in a study that would affect human subjects. Changes may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject.
4. A researcher must report promptly to the IRB any unanticipated problems involving risks to subjects and others.
5. The IRB may observe or have a third party observe the consent process and research.
6. The IRB may be called into an interim review session by the Chair at the request of any member, a Public Health Solutions official, or the project director to consider any matter concerning the rights and welfare of any subject.
7. If the risk involved in the research is more than minimal, the IRB must determine whether verification sources other than the researchers are necessary.
8. The IRB will notify the HHS Secretary whenever any unanticipated research problems arise in HHS-funded research or whenever the Board has suspended or terminated its approval of a research project.

E. Study Closure

1. Once all research activities are complete and all data analysis is either complete, or the only remaining analysis involves data where; (i) all identifiers have been destroyed, or (ii) the investigator no longer has access to codes, links, or keys to identifiers, then the study is eligible for closure (meaning the end of IRB oversight of the study).
2. If this is the case, the Investigator must submit the Study Closure Form and submit all appropriate information and documentation listed on the form including the Principal Investigator's Assurances. Please see Appendix III for the list of data points which must be removed from the dataset in order to meet these conditions.
3. Study Closure may also be appropriate if the jurisdiction of IRB review has been transferred to another institution. Transfer of jurisdiction occurs when an Investigator leaves Public Health Solutions for another institution and will be conducting his or her research at that institution, or when his or her grant is administered through or transferred to another institution and no research activities are (or are no longer) taking place at Public Health Solutions and Public Health Solutions' and its programs' clients are not the prime participants in the research study.

F. Complaints or Questions

1. The IRB shall consider any complaints or questions referred to it by research staff, subjects or other sources and pertaining to the use of human subjects in a research project or activity of Public Health Solutions.
2. The IRB may be called into an interim review session by the IRB Chair at the request of any IRB member, Public Health Solutions officer, or researcher or subject to consider any matter concerning the rights and welfare of any subject.
3. The IRB Chair shall inform the President of Public Health Solutions when the IRB is asked to consider any complaint concerning the rights and welfare of any research subject.

G. Meetings

1. All IRB initial reviews and continuing reviews shall be conducted at convened meetings held at least quarterly or more frequently as workload dictates, by notice from the IRB Chair or the IRB Administrator.
2. Public Health Solutions will recognize as “convened” those IRB meetings conducted via telephone conference call, provided that each participating IRB member (a) has received all pertinent material prior to the meeting, and (b) can actively and equally participate in the discussion of all protocols. The minutes of such meetings must document that these two conditions have been satisfied.
3. The researcher may be asked to attend the meeting of the IRB and should be available to answer any questions.

H. Notification of Approval/Disapproval

1. The researcher will be notified in writing regarding the approval, disapproval, or requested modification of the research proposal.
2. If a proposal is disapproved, the IRB must specify the reason for the rejection. The researcher may then reply either in person or in writing.

I. Minutes

Detailed minutes shall be kept of all IRB meetings that describe and record IRB considerations, and must include, without limitation, the following:

1. Attendance information, (including those voting members present and excused, the attendance of a Non-Scientist, and the attendance of IRB staff, guests and/or consultants);
2. Actions taken by the IRB and the votes on those actions (including the number of IRB members voting for, against, and abstaining);
3. The presence or absence of a quorum during the course of the convened meeting;
4. The basis for requiring changes in or disapproving research;
5. A written summary of the discussion of controverted issues regarding research protocols and their resolution;
6. Any IRB member conflicts of interest regarding research protocols under consideration;
7. Any exempt or expedited protocols identified during the period after the prior IRB meeting and before the current meeting noting the basis for these decisions,
8. The research protocols that are subject to an initial review;
9. The research protocols that are subject to a continuing review; and
10. The dates by which approved protocols must again be reviewed by the IRB to assure compliance with continuing review obligations.

J. IRB Records

The records required by this Statement shall be retained for at least three (3) years, and records relating to research which is conducted shall be retained for at least three (3) years after

completion of the research. All records shall be accessible for inspection and copying by authorized governmental officials at reasonable times and in a reasonable manner.

The IRB Administrator shall ensure that Public Health Solutions maintains adequate documentation regarding IRB activities, in a private and secure environment that protects the confidentiality of subjects, including, without limitation, the following:

1. Copies of all research proposals reviewed, scientific evaluations (if any) that accompany the proposals, unaffiliated researcher agreements and evidence of federal assurances for research collaborators (if any), approved sample consent documents, progress reports submitted by researchers and reports of injuries to subjects;
2. Minutes from past IRB meetings;
3. Records of all continuing review and oversight activities, including, without limitation, (a) records of all IRB reports of IRB findings to Public Health Solutions and to researchers; (b) documentation evidencing when and why IRB determinations have been made that particular research projects require continuing review more often than annually, and or require verification from sources other than the researchers that no material changes have occurred since previous IRB review;
4. Records of all material complaints or grievances regarding Public Health Solutions research (including, for example, those raised by research subjects), and records of the responses and resolution of such complaints or grievances;
5. Copies of all correspondence between the IRB and researchers;
6. A current list of IRB members, including documentation evidencing their qualifications; and
7. Statements of significant new findings provided to subjects.

VII. IRB Structure

A. Number and Qualifications of IRB Members

1. The IRB will be comprised of at least six (6) members and at most ten (10), including the IRB Chair, who: (a) are duly qualified through experience and expertise, and with varying backgrounds (including nondiscriminatory considerations of race, gender and cultural backgrounds), in order to promote complete and adequate review of research activities commonly conducted by Public Health Solutions, (b) have appropriate knowledge of the local context in which Public Health Solutions research is conducted; and (c) are of such character and competence as to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
2. Up to two (2) IRB alternate members may be appointed. These alternate members should be available to attend all IRB meetings. They are subject to the same qualifications and educational standards as regular members. Alternate members may substitute for regular members when regular members are unable to vote or attend an IRB meeting.
3. IRB members and alternates are appointed by the President of Public Health Solutions upon nomination by the IRB Chair, and shall serve until their resignation or until their removal by the President of Public Health Solutions.
4. The IRB shall include at least one member whose primary concerns are in scientific areas.
5. The IRB must include at least one member whose primary concerns are in nonscientific areas (a "Non-Scientist").
6. The IRB must include at least one member who is not otherwise affiliated with Public Health Solutions or part of the immediate family of a person affiliated with Public Health Solutions.
7. The IRB shall not consist entirely of men or entirely of women.
8. The IRB must not consist entirely of persons of one profession.
9. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, economically or educationally disadvantaged persons, pregnant women, handicapped or mentally disabled persons, consideration shall be given to the inclusion of

one or more individuals who are knowledgeable about and experienced in working with these subjects.

10. If any research under review will involve prisoners as subjects, the majority of the IRB, exclusive of any prisoner members, shall have no association with the prison(s) involved and at least one member of the IRB shall be a prisoner or a qualified prisoner representative.
11. The IRB Chair shall maintain current, complete records of IRB members, sufficient to demonstrate each member's qualifications and characteristics and the IRB's compliance with these diversity requirements. These records shall include, without limitation, earned degrees, representative capacity, indications of experience (such as board certifications, licenses), and employment or other relationship between the member and Public Health Solutions.
12. The IRB Chair shall report to the appropriate federal agency any changes in IRB membership.

B. IRB Chair

The IRB Chair shall be appointed by the Public Health Solutions President, with the confirmation of the Public Health Solutions Board of Directors. The IRB Chair shall be a member of the IRB and serve until his or her resignation or until removal by the President. He or she will be responsible for managing the IRB, and shall be a highly respected individual from within or outside Public Health Solutions, fully capable of managing the IRB and the matters brought before it with fairness, expertise and impartiality.

The IRB Chair's responsibilities, with the assistance of the IRB Administrator, shall include the following:

1. Identifying those research protocols that require IRB review at a convened meeting and ensuring those protocols are presented to the IRB;
2. Identifying those research protocols that are exempt from IRB review;
3. Providing IRB members with all necessary information sufficient to permit full and complete IRB initial and continuing research reviews;
4. Identifying and managing those research protocols that should be reviewed in accordance with primary and secondary review procedures;
5. Convening and chairing IRB meetings;
6. Ensuring the presence of a quorum at convened IRB meetings, defined as at least six voting members or alternates;
7. Ensuring that researchers receive, in writing, the results of IRB reviews of their research protocols and, if disapproved, a statement of the reasons for this decision as well as an opportunity for the researchers to respond;
8. Analyzing IRB operations on an ongoing basis, and reporting to the President of Public Health Solutions any additional resource requirements as well as appropriate performance metrics;
9. Approving the appointment of the IRB Administrator who is selected by the President from Public Health Solutions staff;
10. Ensuring that if research involving prisoners as subjects is approved, the appropriate certifications are made as required by 45 C.F.R. § 46.305;
11. Appropriately addressing concerns or grievances regarding IRB operations or Public Health Solutions research, including, without limitation, those made by subjects, and ensuring that necessary reports regarding adverse events in Public Health Solutions research are promptly made to appropriate governmental officials and others; and
12. Ensuring that Public Health Solutions maintains its Federalwide Assurance of Protection for Human Subjects.

C. IRB Administrator

The IRB Administrator will be a researcher in the Research and Evaluation unit employed by Public Health Solutions and will be responsible for day to day IRB operations. The IRB Administrator is staff to the IRB and may be an IRB member. The IRB Administrator's responsibilities shall include the following:

1. Ensuring that all exempted research protocols are reported to the IRB at the next convened IRB meeting;
2. Ensuring that researchers are informed about periodicity of continuing review and are reminded with sufficient time to comply;
3. Ensuring appropriate initial and continuing training and education in human subjects' protections and requirements for IRB members, IRB staff and Public Health Solutions research investigators;
4. Identifying and managing financial and non-financial conflicts of interest related to Public Health Solutions' human subjects research;
5. Ensuring that institutions and researchers that collaborate in Public Health Solutions research operate under an active Federalwide Assurance of Protection for Human Subjects, and ensuring that unaffiliated researchers enter into written agreements with Public Health Solutions assuring their commitment to human research protections and compliance with IRB oversight and this Statement

D. Temporary Replacement of the IRB Administrator

In the event that the IRB Administrator is the lead researcher for a protocol submitted to the IRB, responsibilities of the Administrator will be handled by the Public Health Solutions Vice President for Research and Evaluation. These responsibilities vary by the type of review that the protocol receives.

1. For exempt reviews, the Vice President will receive the Initial Review materials, review them with the IRB Chair, and notify the researcher that the protocol is exempt.
2. For expedited reviews, the Vice President will receive the Initial/Continuing Review materials and review them with the IRB Chair and one other IRB member. The three reviewers will vote on the protocol. The Vice President will notify the researcher of the results of the vote and any reviewers' comments.
3. For full IRB reviews, the Vice President will receive the Initial/Continuing Review materials and send them out to the IRB. He/she will be present at the IRB meeting to be part of and to record the discussion about the protocol, and will vote on the review. The Vice President will notify the researcher of the result of the vote and any reviewer's comments.

E. Conflicts of Interest and IRB Members

1. No IRB member may participate in the review of any research in which that member has a conflicting interest, unless the member is providing information requested by the IRB.
2. Examples of potential conflicts of interest include:
 - **Material Financial Interest** — An IRB member or member of his or her family* with a significant financial interest related to a specific study or its sponsor must disclose this interest. Significant financial interests include anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); and service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.

* Your family includes your spouse or domestic partner; your dependent children; your grown children, grandchildren, parents and grandparents (but only for those financial interests that are known to you); and any trust, organization or enterprise over

which you, alone or together with your family, exercise a controlling or significant interest.

- Personal or Professional Relationships—You must disclose whether you or your family hold any directorship, management role, or other special relationship with an outside entity, including not-for-profit as well as for-profit entities, having the potential for material gain, if the role appears related to your research responsibilities. You should also disclose any significant personal or professional relationship with someone involved in the research such as investigators who are collaborators, immediate supervisors or subordinates, or family members. Also of interest are relationships such as investigators from the same department, competitive relationships, or personal conflicts.
 - Significant Involvement in Research—IRB members or members of their family who are significantly involved in research as an investigator, consultant, study coordinator, or in some other significant capacity in the research must disclose this.
 - Other – You must disclose any other financial interests, such as reimbursed or sponsored travel expenses above \$5000 or royalty payments, that reasonably appear to be related to your responsibilities as a board member.
3. IRB Members who believe that they have or may have a conflicting interest in research to be reviewed by the IRB are required to disclose such actual or potential conflict on their Annual Conflict of Interest Disclosure Form. If an actual or potential conflict arises after the Member signs the form, s/he must inform the IRB Chair within 30 days of a material change to the member's disclosure status or prior to a convened IRB meeting involving consideration of research where the Member may have a potential conflicting interest, whichever is sooner. The Chair will make a determination whether a conflict of interest exists.
 4. If the Chair determines that there is reason to believe a conflicting interest exists, the Chair shall notify the IRB Member and the IRB, and the Member shall not vote with respect to such research, and shall not be counted as part of the IRB quorum with respect to such research. In addition, the IRB Member shall absent himself or herself from the meeting room prior to the vote, and such absence shall be recorded in the minutes.

F. Compensation and Indemnification

1. The IRB Chair and IRB members shall serve without compensation in their capacity as such.
2. Public Health Solutions shall indemnify each IRB member (“indemnitee”) who was or is a party, or is threatened to be made a party, to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such indemnitee was or is an IRB member, to the fullest extent permitted by law.

G. Advisors or Consultants

The IRB is free to seek specialized advice or consultation from outside sources it deems appropriate. Such advisors may not vote with the IRB.

H. Mandatory Education and Training

1. The IRB Chair, IRB members, and IRB staff shall complete appropriate human subjects research protection education, as specified by the IRB Chair. This education shall be required before any such persons review human subject research, and also on a regular, ongoing basis. The IRB Administrator shall maintain written records demonstrating that this mandatory education requirement has been satisfied; e.g. certificates of training.
2. All IRB members will be provided with a general orientation to the fundamental principles and the historical evolution of research ethics. This orientation shall be initiated by the IRB Chair in individual dialogue with each potential IRB member during the interview/screening process for IRB appointment. This shall include, without limitation that all IRB members will be provided with written copies of the Belmont Report, applicable federal regulations (45 C.F.R. Part 46) and this Statement.
3. IRB members will be kept abreast of new federal, state, and institutional regulations, proposed changes in regulations, relevant news items and topics of research controversy via regularly posted reports from the IRB Administrator. Additional educational items, internet-based training opportunities or informational articles will be regularly described or distributed at IRB meetings.

INSTITUTIONAL REVIEW BOARD (IRB)

STATEMENT OF POLICIES AND PROCEDURES

(Revision 07/02/13)

Appendix I:

Categories Exempted from IRB Review

Research can be exempted from IRB review if the only involvement of human subjects will be in one or more of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as:
 - a. Research on regular and special education strategies.
 - b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures, except where all of the following conditions exist:
 - a. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
 - b. The subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employ ability.
 - c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
4. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
5. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist:
 - a. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
 - b. The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.
 - c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
6. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
7. Certain research projects, which are subject to the approval of HHS and are designed to study, evaluate or otherwise examine public benefit or service programs, if the projects meet the criteria specified within 45 CFR § 46. 101(b)(6)

Appendix II:

Research Activities Which May Be Reviewed Through Expedited Review Procedures

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in 45 CFR § 46.110.

1. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purpose such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the researcher does not manipulate subjects' behavior and the research will not involve stress to subjects.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Appendix III

Study Closure and the Continued Use of De-Identified Data

A study may be closed from continuing IRB oversight if data collection has finished and individuals can no longer be identified through the dataset. To meet this condition, all of the following identifiers must be removed before the study can be closed:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
 1. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people, or
 2. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers (Fax).
6. Electronic mail addresses (E-mail).
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Appendix IV:

Public Health Solutions Conflict of Interest and Disclosure for IRB Members

Definition of Interests in Research

Significant Financial Interests in Research of the covered IRB member (and his or her family members[†]) include anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); and service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.

The term does not include:

1. Salary, royalties or other remuneration from Public Health Solutions or a government entity;
2. Other salary, royalties or other payments that when aggregated for the IRB Member and the Member's family members over the next twelve months, are not expected to exceed \$5,000;
3. Income from seminars, lectures or teaching engagements sponsored by government or nonprofit entities;
4. Income from service on advisory committees or review panels for government or nonprofit entities; and
5. An equity interest that (a) when aggregated for the IRB Member and the Member's family members does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a five percent ownership interest in any single entity *or* (b) is in a publicly traded, diversified mutual fund.

Personal/Professional Relationships include the following relationships of the IRB Member (and his or her family members):

1. Close relationships, such as close friendships, researchers who are collaborators or supervisor/supervisee.
2. Members of the same department, in a supervisory or subordinate role.

[†] Your family includes your spouse or domestic partner; dependent children; grown children, grandchildren, parents and grandparents (but only for those financial interests that are known to you); and any trust, organization or enterprise over which you, alone or together with your family, exercise a controlling or significant interest.

IRB Member Annual Conflict of Interest and Disclosure Statement:

To the best of your knowledge do you, or any members of your family:

1. Have a significant financial interest in any non-governmental entity providing financial support to, or receiving financial support from, research conducted by or through Public Health Solutions?

____ YES ____ NO

2. Have a significant financial interest in any non-governmental entity providing financial support to, or receiving financial support from, research outside of Public Health Solutions in which I or members of my family participate?

____ YES ____ NO

3. Hold an executive position, serve on the Board of Directors, or are a member of the advisory board of any non-governmental entity (other than Public Health Solutions) engaged in research likely to benefit Public Health Solutions?

____ YES ____ NO

4. Have a significant financial interest in any for-profit entity that has sponsored a research project likely to benefit Public Health Solutions where I or members of my family have assigned any student, postdoctoral fellow or other trainee, officer, support staff or other individual?

____ YES ____ NO

5. Have a significant financial interest in any non-governmental entity where I or members of my family have taken any action at Public Health Solutions likely to benefit that entity?

____ YES ____ NO

If you have answered in the affirmative to any of the above questions, please describe the circumstances below. If necessary, you may attach additional pages.

If I have answered affirmatively to any of the above questions, in accordance with Public Health Solutions IRB Policies, I understand that I may be determined to have a conflict with regard to certain matters coming before the IRB. I understand that no IRB member may participate in the review of any research in which that member has a conflicting interest, unless the member is providing information requested by the IRB. If the Chair determines that there is reason to believe a conflict of interest exists based on the answers I noted above, I understand the Chair will notify me and the IRB, I will not vote with respect to such research and will not be counted as part of the IRB quorum with respect to such research. In addition, I will absent myself from the meeting room prior to the vote, and such absence shall be recorded in the minutes.

I also understand that if I become aware of any situation that arises that in any way contradicts my answers above or that would cause a conflict interest, real or potential, as described in the IRB Statement of Policies and Procedures, I will immediately notify the IRB Chair and make full disclosure of any conflict, real or potential, and recuse myself as appropriate, including any real or potential conflicts that could arise as a result of a personal or professional relationship with a researcher involved in any project to be or being reviewed by the IRB. I understand that all such information will be held in confidence by the IRB unless required by law or regulations, or if the best interests of Public Health Solutions dictate otherwise.

Date

IRB Member

Signature

Appendix V:

Public Health Solutions Conflict of Interest and Disclosure for Researchers

Definition of Interests in Research

Significant Financial Interests in Research of the researcher (and his or her family members[‡]) include anything of monetary value related to the research project being reviewed by the IRB, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); and service as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service.

The term does not include:

1. Salary, royalties or other remuneration from the applicant institution or a government entity;
2. Other salary, royalties or other payments that when aggregated for the researcher and the researcher's family members over the next twelve months, are not expected to exceed \$5,000;
3. Income from seminars, lectures or teaching engagements sponsored by government or nonprofit entities;
4. Income from service on advisory committees or review panels for government or nonprofit entities; and
5. An equity interest that (a) when aggregated for the researcher and the researcher's family members does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a five percent ownership interest in any single entity *or* (b) is in a publicly traded, diversified mutual fund.

[‡] Your family includes your spouse or domestic partner; your dependent children; your grown children, grandchildren, parents and grandparents (but only for those financial interests that are known to you); and any trust, organization or enterprise over which you, alone or together with your family, exercise a controlling or significant interest.

Researcher Conflict of Interest Statement:

To the best of your knowledge:

1. Do you, or any members of your family have a significant financial interest in any non-governmental entity (other than Public Health Solutions) that may appear to affect or be affected by the conduct or outcome of the research project being reviewed by the IRB?

____ YES ____ NO

2. Do you, or any members of your family hold an outside position (i.e., an appointment to serve in a paid or unpaid position) as a member of the board of directors, trustee, executive, officer or employee or member of the advisory board of a non-governmental entity (other than Public Health Solutions) that may appear to affect or be affected by the conduct or outcome of, the research project being reviewed by the IRB?

____ YES ____ NO

3. Have you, or any members of your family, assigned any student, postdoctoral fellow or other trainee, officer, support staff or other individual to a project sponsored by the entity that is sponsoring the research project being reviewed by the IRB?

____ YES ____ NO

4. Have you, or any members of your family, received within the past calendar year, or do you, or any members of your family, expect to receive in this or the next calendar year, any consulting, royalty income or significant financial interest or paid or reimbursed travel, from the research sponsor or other entity that may appear to affect or be affected by the conduct or outcome of the research project being reviewed by the IRB?

____ YES ____ NO

5. Do you, or any members of your family, have any intellectual property rights related to or covering products or processes being used in the research project?

____ YES ____ NO

If you have answered in the affirmative to any of the above questions, please describe the circumstances below. If necessary, you may attach additional pages:

If I have answered affirmatively to any of the above questions, I understand that I may have a conflict of interest and, according to Public Health Solutions IRB Policies, the IRB may require additional protections for human subjects, more oversight, my participation in or disapprove the research under review.

I agree to answer any questions the IRB may have with respect to any actual or potential conflict of interest. I understand that all such information will be held in confidence by the IRB unless required by law or regulations, or if the best interests of Public Health Solutions dictate otherwise. I also understand that if I become aware of any situation that arises that in any way contradicts the above statements or that would cause a conflict interest, real or potential, as described in the IRB Statement of Policies and Procedures, I will immediately notify the IRB Chair and make full disclosure of any conflict, real or potential. I understand that all such information will be held in confidence by the IRB unless required by law or regulations, or if the best interests of Public Health Solutions dictate otherwise.

Date

Researcher Name

Signature

Appendix VI:

Model Letter of Agreement for Review of Protocols from an Outside Organization

Date
Name
Title
Address Line 1
Address Line 2

Re: Agreement for the Public Health Solutions IRB to Review Research Protocols for _____.

Dear _____:

This letter details the terms of the agreement by which the Public Health Solutions Institutional Review Board (IRB) will review research protocols for _____ (“Organization”).

1. This agreement is for one year from the date of this letter, and will automatically renew. After the initial one year period, either party may terminate upon 30 days’ notice.
2. Public Health Solutions requires advance notice of the number of protocols to be reviewed each year of this agreement, estimating the number of each type of review (i.e., the number of exempt, expedited, and full reviews). For the first year of this agreement, the estimated number of protocols must be provided within 7 days of the date on this letter and no less than 45 days prior to the requested date of review, unless an alternative timeframe has been agreed to by the IRB Administrator. For all subsequent years for which the agreement is renewed, the estimated number of protocols must be provided 45 days before the agreement renewal date. If Public Health Solutions does not receive an estimated number of protocols, Public Health Solutions may decide, at its discretion, not to renew the agreement. The Chair of the Public Health Solutions IRB will determine whether a protocol will be accepted for review based on the IRB’s current capacity and expertise.
3. For the first year of this agreement, Public Health Solutions has been informed that the estimates are as follows:
___ Exempt Review(s)
___ Expedited Review(s)
___ Full Review(s)
4. Protocols expecting exempt or expedited reviews may be submitted at any time.
5. Notice of protocols requiring full reviews should be given to the IRB Administrator five weeks prior to a scheduled IRB meeting. Protocols must be submitted at least two weeks prior to a scheduled IRB meeting.
6. Fees for various types of review and other services by the Public Health Solutions IRB are in the attached document “Public Health Solutions IRB Review Fees.”
7. Payment is to be made by check, payable to Public Health Solutions, immediately following notice of review completion.

All human subjects investigators must follow all requirements in the Public Health Solutions IRB Statement of Policies and Procedures, including mandatory training and education requirements and the submission of a conflict of interest statement. All approved protocols must adhere to the Public Health Solutions IRB schedule for continuing review in order to maintain study protocol approval. For further information, please contact the Public

Health Solutions IRB Administrator Dayana Bermudez (646)619-6701 or IRBAdministrator@healthsolutions.org. Public Health Solutions is not responsible for the performance of research approved by the IRB, conducted by the Organization. The Organization is solely responsible for ensuring compliance with the requirements and determinations of the IRB, as well as any federal, state, or local laws as they may relate to research approved by the IRB. Review and approval of a protocol by the Public Health Solutions IRB is not an endorsement of the research or the Organization by Public Health Solutions and Public Health Solutions' name/logo may not be used for any purposes by the Organization.

Agreed to and executed by:
Public Health Solutions

Signature

Print Name/Title

(Organization Name)

Signature

Print Name/Title

INSTITUTIONAL REVIEW BOARD (IRB)

STATEMENT OF POLICIES AND PROCEDURES

(Revision 07/02/13)

Appendix VII:

Administrative Process for Review, Investigation and Reporting of Scientific Misconduct in Research

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Appendix VII

Administrative Process for Review, Investigation and Reporting of Scientific Misconduct in Research

I. Introduction

A. Principles

Public Health Solutions fosters a research environment that actively discourages misconduct in all research and deals forthrightly with any possible misconduct associated with its research projects. Public Health Solutions' institutional process for handling reports of misconduct in research is based on the following guidelines.

1. The process used to resolve allegations of fraud should not damage science itself.
2. Public Health Solutions will provide vigorous leadership in the pursuit and resolution of all charges.
3. All parties will be treated with justice, fairness, and sensitivity to their reputations and vulnerabilities.
4. Procedures will preserve the highest possible degree of confidentiality compatible with an efficient and effective response to allegations.
5. The integrity of the process will be maintained by painstaking avoidance of real or apparent conflict of interest.
6. Procedures will be carried out expeditiously so as to lead to timely resolution of charges.
7. Pertinent facts and actions will be fully documented at each stage of the process.
8. Upon resolution of allegations, Public Health Solutions will discharge its internal responsibilities to all involved individuals and its external responsibilities to the public, research sponsors, and the scientific community to the extent that is appropriate and allowable.

B. Definitions

1. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - a) Fabrication is making up data or results and recording or reporting them.
 - b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 - d) Research misconduct does not include honest error or differences of opinion.
See 42 C.F.R. § 93.103.
2. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures listed below. See 42 C.F.R. § 93.212.
3. Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions. See 42 C.F.R. § 93.215.
4. "Records of research misconduct proceedings" includes:
 - a) The records that Public Health Solutions secures for research records, inquiries and investigations, except to the extent that it subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
 - b) The documentation of the determination of irrelevant or duplicate records;

- c) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate;
- d) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted; and
- e) The complete record of any appeal. See 42 C.F.R. § 93.317.

C. Responsibilities

1. Public Health Solutions seeks at all times to maintain an environment with a pervasive attitude of high ethical standards related to its research activities as well as to its service activities. The President of Public Health Solutions, in consultation with the Board of Directors, is responsible for ensuring proper practices for well-designed research protocols and for recording, retaining, and storing research data.
2. All authors named on a Public Health Solutions collaborative study will accept full responsibility for the work published or at least for that portion of the work for which they were directly responsible.
3. Professional relationships will be maintained among researchers to assure open discussion of data and research results and freedom of expression leading to enhancement of the climate of integrity, objectivity, avoidance of secrecy, and undue competition.

II. Procedures for Inquiries

A. Initiation of an Inquiry

1. The administration of Public Health Solutions is at all times alert to questionable conduct that might raise legitimate suspicion of fraudulent research. Any inquiry and investigation will be focused on substantive issues. Personal conflicts among colleagues will not be permitted to obscure facts.
2. Any allegations of misconduct in research will be reported to the President of Public Health Solutions or, if that would create a conflict of interest, to the Chair of the Board of Public Health Solutions. The President will counsel confidentially to any individual who presents an allegation of misconduct and will seek to assist in the resolution of the concern through appropriate procedures. If the President determines that the concern would properly be addressed through policies and procedures designed to deal with misconduct in research, the inquiry and investigation procedures will be discussed with the individual who presented the question of the integrity of a research project. If the individual chooses not to make a formal allegation but the President believes there is sufficient cause to warrant an inquiry, the matter will be pursued with no "complainant."
3. Even if the subject of an allegation was to leave Public Health Solutions before the case were resolved, the investigation would be pursued to a conclusion. Public Health Solutions will cooperate with the processes of any other involved institutions to resolve such questions.

B. Purpose

Whenever an allegation or complaint is made involving the possibility of scientific misconduct, the President will initiate an inquiry, which is the first step of the review process. Factual information will be gathered and reviewed to determine whether a full investigation is warranted.

C. Structure

The inquiry process will be conducted by a committee of individuals to be named by the Board of Directors. Committee members, who may be selected from within and/or outside Public Health Solutions, will collectively possess appropriate scientific expertise to assure a sound knowledge base from which to work. Any member of the committee who has a conflict of interest in a given case will not be involved in any aspect of the committee's work with that

case. The committee will consult with Public Health Solutions' legal counsel to minimize the risk of liability for actions taken in the conduct of any inquiry or investigation.

Throughout the process, the affected individual(s) will be afforded the maximum possible confidential treatment, a prompt and thorough investigation, and full opportunity to comment on allegations and findings.

D. Process

Upon initiation of an inquiry, the President will notify the respondent within a reasonable time, in writing, of the charges and the process that will follow and will convene a meeting of the committee. The President will be responsible for the timely conduct of all aspects of the inquiry process.

Whether a case can be reviewed effectively without the involvement of the complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit the complainant to remain anonymous. During the inquiry, confidentiality is desirable to protect the rights of all involved parties.

1. An inquiry will be completed within sixty calendar days of its initiation, unless circumstances clearly warrant a longer period, in which case those circumstances will be documented in the inquiry record.
2. The respondent will be reminded of the obligation to cooperate by providing material necessary to the inquiry. Lack of cooperation may result in an immediate full investigation and other institutional sanctions.
3. The privacy of the complainant and the respondent will be protected to the maximum possible extent.
4. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The report must also include:
 - a) The name and position of the respondent;
 - b) A description of the allegations of research misconduct;
 - c) A description of the support, if any, from Public Health Service funds, including grant numbers, grant applications, contracts, and publications listing this support;
 - d) The basis for recommending that the alleged actions warrant an investigation; and
 - e) Any comments on the report by the respondent or the complainant.
5. A copy of the report will be provided to the respondent and the respondent's comments will be included in the report.
6. If the research or research training involved in the inquiry is supported by Public Health Service funds, the Director of the HHS Office of Research Integrity (ORI) will be notified, in accordance with 42 C.F.R. § 93.309, when on the basis of the initial inquiry it is determined that an investigation is warranted.
7. The President must notify ORI immediately if it is ascertained at any stage of inquiry or investigation that any of the following conditions exists:
 - a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
 - b) HHS resources or interests are threatened.
 - c) Research activities should be suspended.
 - d) There is reasonable indication of possible violations of civil or criminal law. If there is a possible criminal violation, Public Health Solutions must notify ORI within 24 hours of obtaining the information.

- e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
 - f) The research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
 - g) The research community or public should be informed.
 - h) There is an immediate need to protect the interests of the person(s) making the allegation or of the individual(s) who is the subject of the allegation as well as his/her co-researchers and associates, if any.
8. Public Health Solutions will maintain detailed documentation of inquiries sufficient to permit later assessment by ORI of reasons for determining that an investigation was not warranted. This includes the inquiry report and final documents produced in the course of preparing that report, including the documentation of any decision not to investigate. These records will be securely retained for seven years following termination of the inquiry and will be made available to authorized HHS personnel upon request.

E. Findings

- 1. The completion of an inquiry is marked by a determination of whether or not a formal investigation is warranted. The President will inform the respondent and the complainant, when there is one, of the outcome of the inquiry. Allegations found to require investigation will be referred promptly to the appropriate committee. In keeping with federal regulations, the sponsoring agency of the research project will be notified at this point.
- 2. When an allegation is found to be unsupported but submitted in good faith, no further action will be taken beyond notification of the parties. Allegations not brought in good faith may lead to disciplinary action.
- 3. The proceedings of an inquiry, including the identity of the respondent, will be held in strict confidence to protect all parties. If confidentiality is breached, Public Health Solutions will take all reasonable steps to minimize the damage to reputations that could result.
- 4. Public Health Solutions will seek to protect a complainant against retaliation and will provide anonymity wherever possible. It is recognized that individuals early in their careers, with less authority, are particularly vulnerable. Individuals engaged in acts of retaliation will face disciplinary action.

III. Procedures for Investigations

A. Purpose

The purpose of a formal investigation is to explore further the allegations and determine whether misconduct has been committed. The respondent will be informed promptly should additional information emerge that justifies broadening the scope of the investigation beyond the initial allegations. A formal investigation will focus on accusations of misconduct and will examine factual materials of the case.

B. Structure of the Investigations Committee

The investigation process will be conducted by a committee of individuals to be named by the Board of Directors. Committee members may be selected from within and/or outside Public Health Solutions. The committee will possess appropriate scientific expertise to assure a sound knowledge base from which to work. Any member of the committee who has a conflict of interest in a given case will not be involved in any aspect of the committee's work with that case. The committee will consult with Public Health Solutions' legal counsel to minimize the risk of liability for actions taken in the conduct of any inquiry or investigation.

C. Process

Upon receipt of inquiry findings that an investigation is warranted, the President must notify the complainant and the respondent and convene a meeting of the Investigations Committee within 30 days. All involved parties are obligated to cooperate with the proceedings in

providing information relating to the case. All necessary information will be provided to the respondent in a timely manner to facilitate the preparation of a response. The respondent will have the opportunity to address the charges and evidence in detail.

1. The President must report Public Health Solutions' decision to initiate an investigation to ORI in writing on or before the date the investigation begins. This must include a full written report of the inquiry, as defined in the process section of the above procedures for inquiries.
2. It is expected that any investigation undertaken will be carried through to completion, but should Public Health Solutions elect to terminate an inquiry or investigation prior to completion, a report of such planned termination, including a description of the reasons for the termination, will be made to ORI, which will decide whether further investigation should be undertaken.
3. The investigation will include examination of all documentation, including but not limited to research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official in the course of the research misconduct proceeding.
4. To the extent it has not already occurred at the allegation or inquiry stages, all reasonable and practical steps must be taken during the investigation to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Whenever possible, must take custody of the records must be taken:
 - a) Before or at the time the institution notifies the respondent; and
 - b) Whenever additional items become known or relevant to the investigation
5. Interviews will be conducted with all possible individuals involved in making the allegation as well as those against whom the allegation was made, and other individuals who might have information regarding key aspects of the allegations. Complete recordings or transcripts of such interviews will be provided to the interviewees for comment or correction and will be included in the record of the investigation.
6. Documentation that substantiates the findings of the investigation will be prepared, maintained, and made available to the Director of the ORI, who will determine whether ORI will proceed with its own investigation or act on Public Health Solutions' findings.
7. At the discretion of the President, interim administrative actions may be taken to protect the integrity of the research project and the Federal funds supporting it.
8. The President will apprise ORI of any developments during the course of the investigation that disclose facts that may affect current or potential HHS funding for the respondent or that the Public Health Service needs to know to ensure appropriate use of Federal funds.
9. All aspects of the investigation must be completed within 120 days , including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI.
 - a) If unable to complete the investigation in 120 days, the institution must ask ORI for an extension in writing.
 - b) If ORI grants an extension, it may direct the institution to file periodic progress reports.
10. The respondent must be given a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. Any comments of The respondent may submit comments on the draft report within 30 days of the date on which s/he receives it.

11. The complainant may be provided a copy of the draft investigation report or relevant portions of that report. The complainant may submit comments, if any, within 30 days of the date on which the complainant received the draft report or relevant portions of it.
12. The President must notify ORI immediately if it is ascertained at any stage of inquiry or investigation that any of the following conditions exists:
 - a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
 - b) HHS resources or interests are threatened.
 - c) Research activities should be suspended.
 - d) There is reasonable indication of possible violations of civil or criminal law. If there is a possible criminal violation, Public Health Solutions must notify ORI within 24 hours of obtaining the information.
 - e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
 - f) The research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
 - g) The research community or public should be informed.
 - h) There is an immediate need to protect the interests of the person(s) making the allegation or of the individual(s) who is the subject of the allegation as well as his/her co-researchers and associates, if any.

D. Findings

1. The findings of the Investigations Committee will be submitted in writing to the President, who will convey the full report to the respondent, to the Board of Directors, and to all federal agencies, sponsors, or other entities initially informed of the investigation. The findings will be retained in a confidential and secure file at Public Health Solutions.
2. The final institutional investigation report must be in writing and include:
 - a) A list of allegations, describing the nature of the allegations of research misconduct.
 - b) Description and documentation of the Public Health Service support, including, for example, any grant numbers, grant applications, contracts, and publications listing Public Health Service support.
 - c) The institutional charges, describing the specific allegations of research misconduct for consideration in the investigation.
 - d) If not already provided to ORI with the inquiry report, a copy of these Policies and Procedures.
 - e) Research records and evidence documentation that will identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
 - f) A statement of findings, that will, for each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so:
 - (1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - (2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - (3) Identify the specific Public Health Service support;
 - (4) Identify whether any publications need correction or retraction;
 - (5) Identify the person(s) responsible for the misconduct; and

- (6) List any current support or known applications or proposals for support that the respondent has pending with non-Public Health Service Federal agencies.
 - g) Any comments made by the respondent and complainant on the draft investigation report.
 - h) Assurances and contact information to maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.
 3. Investigations into allegations of misconduct may result in various outcomes, including:
 - a) A finding of misconduct;
 - b) A finding that no culpable conduct was committed, but serious scientific errors were discovered; or
 - c) A finding that no fraud misconduct or serious scientific error was committed.
 4. An investigation of misconduct may disclose evidence that requires further action even in those cases in which no fraud or misconduct is found.
 - E. Responsibilities after Investigations
 1. Public Health Solutions will undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when those allegations are not confirmed, and similarly will seek to protect the positions and reputations of those persons who, in good faith, make allegations.
 2. Public Health Solutions will impose sanctions of individuals when allegations of misconduct are substantiated.
 3. The President will notify ORI of the final outcome of an investigation. This notification must include the following:
 - a) The final investigation report, including all attachments, and any appeals.
 - b) The final institutional action, stating whether the investigation found research misconduct, and if so, who committed the misconduct.
 - c) A statement of whether Public Health Solutions accepts the investigation's findings.
 - d) A description of any pending or completed administrative actions against the respondent.
 4. It is understood that, upon receipt of the final report of investigation and supported materials, ORI will review the information in order to determine whether the investigation was performed in a timely manner and with sufficient objectivity, thoroughness, and competence. ORI may then request clarification or additional information and, if necessary, perform its own investigation.
 5. It is further understood that, in addition to sanctions that Public Health Solutions may impose, HHS may impose sanctions of its own.
 - F. Appeal / Final Review
 1. A written appeal of the Investigation Committee's decision may be filed by the respondent with the Chair of the Board of Directors. An appeal should be restricted to the body of evidence already presented, and the grounds for appeal are limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision-making.
 2. New evidence may warrant a new investigation.
 3. Following an appeal, a final review by the Personnel Committee of the Board of Directors may be requested. The decision of that review would be final.
 4. If the appeal could result in a reversal or modification of the findings of research misconduct in the investigation report, then it must be completed within 120 days of the filing of the report with ORI. If unable to complete any appeals within 120 days, the institution must ask ORI for an extension in writing and provide an explanation for the

request. ORI may grant requests for extension for good cause. If ORI grants an extension, it may direct the institution to file periodic progress reports.

5. Appeals that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.

IV. Disposition

A. Disciplinary Action

The nature and severity of any disciplinary action will be determined by the Executive Committee of the Board of Directors. Examples of such action include:

1. Removal from a particular project
2. Letter of reprimand
3. Special monitoring of future work
4. Probation
5. Suspension
6. Salary reduction
7. Rank reduction
8. Termination of employment.

B. Notice to Other Concerned Parties

The Executive Committee will determine the need for notification of other concerned parties not previously notified as to the outcome of the case. These parties may include:

1. Sponsoring agencies, funds sources
2. Co-authors, co-researchers, collaborators
3. Editors of journals in which fraudulent research was published
4. State professional licensing boards or disciplinary board
5. Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated
6. Professional societies
7. Where appropriate, criminal authorities.