District of Columbia Department of Health **Procedure Title: Institutional Review Board for Public Health Policies & Procedures**		**PROCEDURE 200.101** **Implementing Office:** CPPE **Training Required:** Yes **Originally Issued:** May 1, 2002 **Revised/Reviewed:** August 19, 2013
Approved by: Name, Agency Director	**Review by Legal Counsel:** Name, General Counsel	**Effective Date:** August 19, 2013 **Valid Through Date:** August 19, 2018

I. Authority	Reorganization Plan No. 4 of 1996; Mayor's Order 1997-42; Department of Health Organizational Order No. 27 (May 1, 2002), DHHS and FDA Regulations for the Protection of Human Subjects; 45 C.F.R. Part 46; National Research Act, Pub. L. No. 93-348.
II. Reason for the Policy	This policy establishes the function, organization, structure and jurisdiction of Department of Health Institutional Review Board for Public Health (IRBPH). This Policy also establishes Department policy and prescribes the procedures for the orderly submission, review, approval or disapproval, and monitoring of research.
III. Applicability	The guidelines stated in this policy apply to all research involving human subjects conducted by Department of Health (DOH) personnel, students, trainees, contractors, or others under the auspices or sponsorship of the DOH.
IV. Definitions & Acronyms	a. Research means a systematic investigation designed to develop or contribute to generalized knowledge. It includes any processes which seek ways to secure new information or organize pre-existing information in new ways, from or about human subjects or to introduce new untested procedures in the care, treatment, management or organization of human subjects which differ in any way from usual and customary medical, psychiatric, or other professional practice. b. Human Subject: an individual about whom an investigator conducting research, whether professional or student, obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes 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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for the obtaining of such information to constitute research involving human subjects.

c. Minimal risk: risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life of the subjects of the research or during the performance of routine physical or psychological examinations or tests.

d. Legally Authorized Representative: an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the procedure(s) involved in the research proposal. An official serving in an institutional capacity in the Department of Behavioral Health may not be considered a legally authorized representative for purposes of this policy.

e. Consent Auditor: a person appointed by the Institutional Review Board to ensure the adequacy of the consent process. This appointment will be made by the Chairperson of the IRBPH when the IRBPH finds that a specific project involves a substantial question about the ability of a subject(s) to consent when there is a significant degree of risk involved. The consent auditor will be responsible only to the IRBPH and will not be involved with the research. The consent auditor will be familiar with the physical, psychological and social needs, as well as legal status, of the class of prospective subjects.

f. Principal Investigator: a person who has primary overall responsibility for the development and submission of a research proposal for review. The principal investigator will have primary responsibility for the day-to-day conduct of a study and will be responsible for assuring that these activities are conducted in compliance with all current pertinent regulations and ethical and scientific standards.

g. Project Supervisor is the DOH representative of the appropriate discipline or training program to which a student trainee, visiting investigator or other non-staff person will be assigned when conducting an approved research project. The curriculum vitae of the project supervisor must be on file with the IRBPH.

h. Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be

	conducted. For purposes of most research the age of consent is 18. i. Assent means a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent. j. Employee for the purpose of IRBPH protocol review means any individual whose regular work station is in the DOH, whether paid wages or salaries including consultants on information technology (IT) assignment.
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VI. Procedures	**1. Functions** The IRBPH shall have the authority to: A. Review, approve, require modifications or additional information (to secure approval), disapprove, or waive any research activity covered by this policy; B. Require documentation of informed consent as specified in the regulations and the provision of any other additional information to subjects, if the Board determines that the additional information would meaningfully add to the protection of the rights and welfare of subjects; waive informed consent under the conditions specified in the regulations; C. Approve or disapprove requests to conduct research on human subjects; monitor and maintain required records for all approved projects; D. Ensure the protection of human subjects, their identities, and the records of research subjects in all public health programs that are directly, or indirectly funded by the Government of the District of

Columbia, and the U.S. Departments of Health and Human Services, Agriculture and Education; District of Columbia laws, regulations and guidelines governing privacy and confidentiality including the Health Insurance Portability and Accountability Act (HIPAA), Government Performance and Results Act (GPRA) will apply;

E. Ensure that any and all other functions required by District and Federal law and regulations are enforced; and

F. Ensure that the research contributes to the overall well-being of the community and improves the quality of services provided in the District of Columbia.

2. **Organization and Membership of the IRBPH**

A. The IRBPH is a permanent committee, which shall consist of no fewer than ten (10) persons, including the Chairperson, whose backgrounds and expertise qualify them to contribute significantly to a complete and adequate review of research activities conducted within the DOH. The chairperson will be selected by the Director, while other members of the IRBPH will be appointed by the Director or his/her representative in consultation with the Chairperson of the IRBPH based on the following criteria:

(i) Membership shall consist of both men and women, so long as no selection is made solely on the basis of gender or race/ethnicity;

(ii) Members of more than one profession or discipline is represented;

(iii) At least one (1) member whose primary expertise or area of training is in a scientific or health-related field;

(iv) At least one (1) member whose primary expertise or concern is in a nonscientific area; specifically law or ethics, including members of the clergy, teachers, other professionals who work with children/minors or concerned residents;

(v) The IRBPH shall include at least one member who is not otherwise affiliated with the Department and who is not part of the immediate family of a person who is affiliated with the Department;

(vi) No IRBPH member may participate in the IRBPH's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested

by the IRBPH;

(vii) Fifty percent of the IRBPH membership shall be comprised of District of Columbia residents;

(viii) One (1) member of the IRBPH should have been incarcerated or have had professional experience with incarcerated individuals;

(ix) The Director, in consultation with the respective Chairperson, shall review all appointments to the IRBPH at least every year. New members, however, may be designated in the interim; and

(x) Each member receives annual training and updates on research ethics and human subjects protections.

Alternate members may be nominated and appointed to act for regular members in their absence.

3. **IRBPH Review of Research**

The IRBPH shall review and have authority to approve, require modification or additional information, disapprove or waive all research activities in accordance with this Policy except as otherwise provided.

A. Research activities exempt from IRBPH review

Certain categories of research are generally exempt from review by the IRBPH. However, the principal investigator must file a written justification for the exemption with the Chairperson of the IRBPH who will evaluate the appropriateness of the claimed exemption. The written justification must include: the title of the project; the name of the principal investigator; brief summary of the project; proposed duration of the research, including expected dates of initiation and conclusion; and, where appropriate, an explanation of how the investigator will protect the privacy of subjects and maintain the confidentiality of data. The Chairperson of the IRBPH may require that specific activities, otherwise exempt comply with all or some of the procedure for IRBPH review of research protocols. Under an exempt review procedure, the review may be carried out by the IRBPH Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRBPH. The Chairperson of the IRBPH shall notify IRBPH members of the research proposals which have been approved under the expedited review procedure. The following categories are generally

	exempt from IRBPH review: (1) Research conducted in established or commonly accepted educational settings involving normal educational practices such as: (a) research on regular and special education instructional strategies, or (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 (a) information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (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 of 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; and (c) the research deals with sensitive aspects of the subject's own behavior or use of alcohol. This category is not exempt from IRBPH review if the research involves children. (4) 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 investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. All research involving the study of records of individual subjects receiving treatment through DOH is subject to additional confidentiality requirements of the District of Columbia Mental Health Information Act and the Federal Confidentiality of Alcohol and Drug Abuse Patient Record Regulations (when applicable). Questions concerning the confidentiality of records should be referred to DOH's Office of General Counsel.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. This type of research may only be conducted if it is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

B. Research activities subject to expedited review procedures

The IRBPH may review some or all of the research appearing on the following list through an expedited review procedure, if the research involves no more than minimal risk. The IRBPH may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRBPH Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRBPH. In reviewing the research, the reviewers may exercise all of the authorities of the IRBPH. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Section 6 below. The Chairperson of the IRBPH shall notify IRBPH members of the research proposals which have been approved under the expedited review procedure. The following categories are appropriate for expedited review:

(i) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) research on drugs for which an investigational

	new drug application (under 21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) research on medical devices for which an investigation device exemption application (under 21 CFR part 812) is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. (ii) Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth and permanent teeth if patient care indicates a need for extraction. (iii) 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. (iv) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied to either the surface of the body or at a distance and do not involve input or matter or significant amounts of energy into the subject or an invasion of 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). (v) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in a six-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. (vi) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling or the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(vii) Voice recording is made for research purposes such as investigations of speech defects.

(viii) Moderate exercise by healthy volunteers.

(ix) The study of existing data, documents, records, pathological specimens, or diagnostic specimens that does not include or become associated with personal health identifiers.

(x) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory or test development, where the investigator does not manipulate subject's behavior and the research will not involve stress to subjects.

(xi) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

(xii) Continuing review of research previously approved by the convened IRBPH as follows: where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

(xiii) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRBPH has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

C. Trainee and student proposals

Research protocols developed by students will be submitted to the IRBPH Chairperson. If approved, the Chairperson shall notify the Director of the IRBPH's decision and recommendation. Research protocols developed by students who are not employees of DOH will be submitted to the Chairperson of the IRBPH. Employees who are students shall submit proposals for review according to procedures outlined for general staff.

(i) Research protocols submitted by students (both employees and non-employees) must include

written assurances that proposals for master's and doctoral thesis conform to the requirements of the colleges or universities concerned.

(ii) Each student planning to carry out a research project in DOH must have a Department employee as a project supervisor. This supervisor will be appointed by the Chief of the professional branch in the Department most closely related to the student's academic discipline. The Project Supervisor will (a) confer with the student initially, usually before the submission of the proposal, to determine the feasibility of the project proposal; (b) guide and counsel the student during the course of an approved research project; (c) consult with the chiefs of the appropriate clinical services to secure approval for the student to work with patients/clients; (d) consult with other staff members as recommended by the Chairperson of the IRBPH; and (e) all other research activities shall be reviewed by the full IRBPH, if appropriate, in accordance with Section 6 below.

4. **Informed Consent**

A. General requirements for informed consent.

Except as provided elsewhere in this Policy, no investigator may involve a human being as a subject in research covered by this Policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or to the representative. The person consenting must be competent to consent. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or which releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. The person consenting must be so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. Therefore, the IRBPH should consider at least five possible sources of interference with the free power of choice:

(i) The language of disclosure of the information;

(ii) Relationship between the investigator or other persons and the subject;

(iii) Inducements or compensation;

(iv) The setting in which consent will be obtained; and

(v) The time when consent will be obtained.

Thus, consent is deemed voluntary when there are none of the identified unacceptable influences or interferences at work.

B. Basic Elements of Informed Consent

Except as provided in subsection "D" of this Section, in seeking informed consent, the investigator shall provide the following information to each subject:

(i) A statement that the study involves research, and explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(ii) A description of any reasonably foreseeable risk or discomforts to the subject;

(iii) A description of any benefits to the subject or others which may reasonably be expected from the research;

(iv) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(v) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(vi) For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(vii) An explanation of whom to contact for answers to pertinent questions about the research, and the research subject's rights, and whom to contact in the event of a research-related injury to the subject; and

(viii) A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

C. Additional elements of informed consent.

When appropriate, one or more of the following elements shall also be provided to each subject:

(i) A statement of the general purpose of the study;

(ii) An explanation of why the subject was selected for the invitation to participate;

(iii) A statement 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) which are currently unforeseeable;

(iv) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(v) Any additional costs to the subject that may result from participation in the research;

(vi) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(vii) A statement 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;

(viii) The approximate number of subjects involved in the study; and

(iv) A description of any compensation the subject will receive for participation.

D. Altered Consent Procedures

An IRBPH 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 waive the requirements to obtain informed consent provided the IRBPH finds and documents that:

(i) The research involves no more than minimal risk to the subjects;

(ii) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(iii) The research could not practically be carried out without the waiver or alteration; and

(iv) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. Documentation of informed consent.

Except as provided in subsection (ii) below, informed consent shall be documented by the use of a written consent form approved by the IRBPH, signed by the subject or the subject's legally authorized representative, and retained in the patient's clinical record. A copy shall be given to the person signing the form

(i) Except as provided in subsection (ii) of this Section, the consent form may be either of the following:

(a) A written consent document that embodies the elements of informed consent required by subsection 4(B). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(b) A "short form" written consent document stating that the elements of informed consent required by subsection 4(B) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRBPH shall approve a written summary of what is to be said to the subject or the

representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form".

(ii) The IRBPH may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(a) That the only record linking the subject and the research would be the consent document. The principal risk would be potential harm resulting from a breach of confidentiality.

Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes govern; or

(b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRBPH may require the investigator to provide subjects with a written statement regarding the research.

5. **Preparing and Submitting Proposals**

A. The principal investigator will first obtain approval from his/her immediate supervisor to conduct the proposed research. Sufficient information concerning the project (e.g., question(s) at issue; methodology; estimates of time required of DOH staff or other persons, including patients; and financial costs) shall be submitted to the supervisor to enable him or her to make an informed decision concerning the feasibility of the project. If the supervisor agrees the project should be conducted, a research protocol must be prepared by the investigator, which is responsive to the review criteria established in this Policy.

B. Review by the Administrator

Before submitting the proposal to the Chairperson of the IRBPH, the principal investigator shall submit it for the approval and signature of the administrator(s) responsible for any patients/participants involved in the research as well as the administrator to which the principal investigator is responsible. If the principal investigator is a student or trainee, the proposal, counter-signed by a DOH supervisor, is to be submitted for approval through the program director to the appropriate administrator(s) responsible. If the approval of the administrator(s) is not appropriate, the Chairperson of the IRBPH should be consulted to determine who should conduct DOH level review. The administrator(s) or other appropriate reviewing official(s) shall evaluate the proposal and determine:

(i) Whether the proposal is feasible from the standpoint of cost, personnel, equipment, and space;

(ii) Whether the results of the proposed research will likely be of sufficient importance to warrant the anticipated costs;

(iii) Whether the research will benefit DOH and the community;

(iv) Whether the research will have possible disruptive effects on DOH operations; and

(v) Whether the invitation of patients to participate in the research and the participation itself will interfere with the health care of any patients.

(vi) The administration is also responsible for:

(a) Informing and consulting with appropriate clinical staff about contemplated studies involving participation of their patients, and for monitoring research projects to ensure compliance with DOH Policies and Standards.

(a) Ensuring that, in any somatic intervention, there is liaison and supervision by the physician' responsible for the well-being of the patients.

C. Documents Required for Submission

Refer to the DOH IRBPH link below for submission procedures and required documents:

http://doh.dc.gov/service/institutional-review-board-public-health

6. **Evaluation of Proposals by the IRBPH**

A. Whenever a research proposal is submitted, the Chairperson will review the proposal culpable as to broad administrative acceptability and adequacy of format. After the completion of this initial review, the Chairperson will forward the proposal to the members of the IRBPH and /or others, if appropriate.

B. The IRBPH shall evaluate the proposal in terms of the scientific merit, the risks to the subjects involved, the adequacy of protection against these risks, the potential benefit of the proposed research to the subjects and others, the importance of the knowledge to be gained, and whether the research aligns with the principles of respects for person, beneficence and justice outlined in *The Belmont Report*. In order to approve the research proposal, the IRBPH shall determine that all of the following requirements are satisfied:

(i) The proposed research is consistent with the policy of DOH with regard to review and conduct of research;

(ii) The design and method of the proposal are scientifically sound and the research methods are appropriate to the objectives of the research and the field of study;

(iii) The proposal conforms to legal and medical requirements concerning the administration of pharmacological agents, psychological tests, etc.;

(iv) Selection of subjects is equitable. In making this assessment, the IRBPH should take into account the purposes of the research and the setting in which the research will be conducted;

(v) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by subsections 4(A)-4(E);

(vi) Informed consent will be appropriately documented in accordance with and to the extent required by subsection 7(A);

(vi) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

(viii) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(ix) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

(x) Risks to subjects are reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be obtained from the results. In evaluating risks and benefits, the IRBPH should consider the full range of risks and benefits that may result from the research.

C. If the Board concludes that there are subjects at risk, it must determine whether the following section from Title 45 Code of Federal Regulation Part 46 (45 CFR 46) are upheld:

(i) "The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks";

(ii) "The rights and welfare of any subjects will be adequately protected"; and

(iii) "Legally effective informed consent will be obtained by adequate appropriate means";

D. There must be informed consent by means of a witnessed signed consent form, which in addition to the usual required provisions of such a form, must contain the following statement:

In the event of any physical injury resulting from participating in the protocol, the DOH will provide emergency medical treatment. The pursuit of further treatment, if indicated, will be the employee's responsibility. Moreover, any resulting illness or disablement will not be considered work-related and thus the employee will be ineligible for workmen's compensation.

E. <u>Research involving investigational new devices</u>

The use of experimental drugs, drugs not yet approved by the Food and Drug Administration for general use, or established drugs which are to be administered by routes, in dosages, or for conditions not in accordance with approved FDA

requirements: The principal investigator must obtain approval for use of the drugs or device in compliance with FDA regulations. The investigator is required to provide the IRBPH with assurances that FDA approval is being sought.

F. Isotopes

The IRBPH shall ensure that any research proposal involving the use of isotopes has the approval of the Radiation Safety Committee prior to the use of isotopes.

G. The Principal Investigator will be required to present, in person, his/her research protocol before the IRBPH.

7. Considerations for Vulnerable Populations

The IRBPH must ensure that appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

A. Children or subjects under the age of 18

In addition to ensuring that the general requirements for informed consent are met, the IRBPH shall:

(i) Determine that adequate provisions are made for soliciting the assent of children, when, in the judgment of the IRBPH, the children are capable of providing assent. In determining whether the children are capable of assenting, the IRBPH shall take into account the ages, maturity, and psychological state of the children to be involved in research under a particular protocol, or for each child as the IRBPH deems appropriate. If the IRBPH determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research, but the consent of the parent/legal guardian is required. Even where the IRBPH determines that the subjects are capable of assenting, the IRBPH may still waive the assent requirement under circumstances in which consent may be waived in accord with subsection 4(E)(ii) above. In all other cases, assent shall be documented.

(ii) Determine that adequate provisions are made for soliciting the consent of each child's parent(s) or legal guardian(s). Where parental permission is to be obtained, the IRBPH may find that the consent of one parent is sufficient for research involving not greater than minimal risk or involving greater than minimal risk but presenting the prospect of direct benefit to the subjects. Where the research involves greater than minimal risk and no prospect of direct benefit to the children, appropriate consent must be obtained from both parents unless one is deceased, unknown, incompetent, not reasonably available, or not legally responsible for the care and custody of the child.

The IRBPH may waive the parental/legal guardian consent requirements of 7(A) above, if the IRBPH determines that the research involves conditions or subjects for which parental/guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children). An appropriate mechanism for protecting the subjects must be substituted which takes into account the nature of the research, the risks and benefits of the research and the age, maturity and status of the children.

B. Prisoners

The IRBPH may approve research involving prisoners only if it finds that:

(i) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(ii) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

(iii) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRBPH justification in writing for following some other procedures, control subjects must be selected randomly from the group of

available prisoners who meet the characteristics needed for that particular research project;

(iv) Adequate assurance exists on a consent form that the prisoner understands that their participation in research will have no bearing on their sentence or assist in the possibility in parole or probation.

(v) Where the IRBPH finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

C. Pregnant women, fetuses, and neonates

The IRBPH may approve research involving pregnant women, fetuses and neonates only if it finds that:

(i) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(ii) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(iii) Any risk is the least possible for achieving the objectives of the research;

(iv) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of 45 CFR 46 subpart A;

(v) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of 45 CFR 46 subpart A except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;

(vi) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(vii) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses

(viii) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(ix) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

8. **Employee Participation in Research**

A. An employee of the DOH may participate in a research protocol under the following conditions:

(i) They must not receive compensation for participating, unless they are randomly selected for research out of the general population.

(ii) They must either voluntarily request to participate or be recruited by one of the investigators of the protocol;

(iii) If the employee is recruited, the recruitment process must be free of any element whatsoever that may arguably be interpreted as undue influence or coercion through the supervisor for the employee; and

(iv) If the employee's participation will require him/her to be absent from the work station and/or impair him/her in performance of usual duties, the employee must obtain appropriate permission from his/her supervisor.

(v) If the employee is recruited for external research, no DOH resources or equipment may be used by the participating employee as part of their participation in the study.

9. **Cooperative Research**

When cooperating institutions conduct joint research, the institutions may use joint review, reliance upon the review of another qualified IRBPH or similar arrangements aimed at avoidance of duplication of effort. However, in research activities involving DOH patients as subjects or patients' records, the Department IRBPH (or Chairperson, if expedited or exempt review is appropriate) shall review the proposal to ensure that it adequately safeguards the rights and welfare (including privacy) of subject patients. The Chairperson of the IRBPH shall determine, in consultation with IRBPH members, whether review by another qualified IRBPH is sufficient to recommend approval of the research activity.

10. **Obtaining the IRBPH 's Approval**

A. After approval of the proposal by the IRBPH, the Chairperson will send a written decision and recommendation(s) to the Principal Investigator and a copy to the IRBPH Members and the Director. Any dissenting opinions or qualifications will be included in the written decision. All decisions concerning proposals are made by a majority vote of the IRBPH, except when proposals are suitable for expedited or exempt review, in which case, the Chairperson of the IRBPH or designee may make his/her written decision and recommendation(s) directly to the Principal Investigator and send a copy to the IRBPH Members and the Director.

B. The IRBPH Members will indicate their approval or disapproval to conduct the research on the voting sheet bearing his/her decision and recommendation(s). The signed

and dated voting/recommendation sheet with the decision of each IRBPH Member will be returned to the Chairperson.

11. **Notifying the Investigator**

The Chairperson will then notify the investigator who submitted the proposal, in writing, of the IRBPH's decision within 24 hours after review. The Chairperson will also inform the investigator in the same letter, of any administrative or legal requirements with which he or she must comply or of any modifications necessary to secure IRBPH approval or the research activity. If a research activity is disapproved, the letter shall include a statement of the reasons for disapproval and give the investigator an opportunity to respond in person or in writing.

12. **Amendments to Proposals**

Any substantive changes or modifications in the approved project must be submitted in writing to the Chairperson of the IRBPH. Amendments or revisions of a proposed project will be submitted in the same manner and numbered as the original proposal. The Principal Investigator will be required to submit written responses addressing these proposed changes or modification to the IRBPH. Two copies are required upon submission: (i) a copy reflecting red-line track changes and (2) a clean copy.

13. **Documentation of Patient's Personal Participation as an Active Subject in a Research Project**

The medical record shall contain documentation of the patient's personal participation as an active subject in research projects. This documentation shall include:

A. The name of and a brief statement describing the research project.

B. The name of the principal investigator who is responsible for selecting the patient and the data selected.

C. The date on which the subject became actively involved (subjected to medication, or any other physical, social, psychological procedure).

D. Any adverse reactions of the subject during the project as a result of the research; action taken and results.

E. Date of termination of the patient's participation and reason.

F. A copy of the written and signed informed consent form, if appropriate, must be in the patient's medical record, and a copy given to the patient and to the principal investigator.

NOTE: The primary clinician, the principal investigator or the investigator's designee as provided in the protocol, will enter this information into the record. The principal investigator will always be responsible to give needed information to the primary clinician and vice versa.14. **Monitoring Research and Progress Reports**

A. When a research project is approved, the IRBPH shall state in writing the frequency with which it wishes to review and monitor the project once it is operational. The IRBPH shall conduct continuing review by means of progress reports of research covered by this policy at intervals appropriate to the degree of risk, but not less than once a year (after date of initiation), and shall have the authority to observe the consent process and research. The Chairperson will exercise discretion, depending on the degree of risk of the research or other issues of concern about the research, as to whether such review requires a review by the full Board. For proposals involving children, review will be conducted at least every three months after initiation of the research.

B. Progress reports required by the IRBPH shall contain the following:

(i) Brief narratives describing the progress of the research including relevant dates of initiation of specific activities;

(ii) Any unforeseen difficulties encountered or unexpected result or research, or significant preliminary findings;

(iii) Number of subjects (or other samples, e.g., statistical records) involved to date;

(iv) Expected completion date of project (if the project will extend beyond the period approved by the IRBPH, an amendment must be proposed and IRBPH approval sought);

(v) Any changes in research activity not reviewed by the IRBPH which have been necessary to eliminate apparent immediate hazards to human subjects. (All other proposed substantive changes in the research activity or the occurrence of unanticipated problems involving risks to subjects must be promptly reported to the Chairperson of the IRBPH).

(vi) Any proposed amendments to the proposal requiring IRBPH review.

C. Copies of final report of the research activity will be forwarded to the Chairperson of the IRBPH for filing, and to the Director.

D. Upon completion of the research procedures, the principal investigator will attempt to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences that may have arisen with respect to the participants as a result of the procedures.

E. Upon completion of the research, the principal investigator, whether a member of the staff or an outside researcher, is responsible for communicating the purpose, nature, outcome, and possible practical or theoretical implications of the research to the staff of the program in a manner they can understand.

F. The IRBPH is responsible for reporting to the Director and Secretary of DHS or the Director of the FDA, any serious or continuing non-compliance by investigations with the requirements and determinations of the IRBPH.

15. **Suspension or Termination of IRBPH Approval of Research**

The IRBPH has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRBPH's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the Director HHS, Office of Human Research Protections (http://www.hhs.gov/ohrp/index.html) and the Food and Drug Administration (where appropriate).

16. **Operating Procedures of the IRB**

A. In its regularly scheduled meetings, the IRBPH shall conduct business in the following order:

(i) Review, discuss, and take necessary action regarding any reports of adverse events or harm coming to human subjects as a result of participation in any ongoing research. If a consent auditor has been appointed to oversee the consent process in any ongoing protocol, this person will be asked to report on his or her observations of the adequacy of the consent process being audited.

(ii) Except when an expedited or exempt review procedure is used (see subsection 3 (B)), the IRBPH shall review proposed research at convened meetings at which a quorum of the members of the IRBPH are present, including at least one member whose primary concerns are in nonscientific areas and an external member. A quorum shall consist of a majority (more than half) of the current IRBPH membership including the Chairperson.

(iii) Any member who has been involved in the approval process of a protocol under consideration or determined to have a conflict of interest, shall not be eligible to vote.

(iv) Proposed research may not be disapproved nor may adverse action be taken regarding any project unless the investigator(s) have been notified in writing of the cause for concern and have been given reasonable opportunity to respond to the full IRBPH. In cases where the Chairperson judges that immediate harm may come to any subject or research, he/she may order a suspension of the project without advance IRBPH approval. In such cases the Director, the investigator, and all members of the IRBPH shall be notified of the Chair's actions and the reasons therefore, in writing within 3 working days. If the investigator requests it, a meeting of the IRBPH shall be called within 10 working days to confirm, amend or revoke the action of the chair.

(v) Should the IRBPH desire to review an ongoing project/protocol for reasons other than stated in 15(a)(iv) above, the IRBPH, by majority vote, shall appoint a member or members to undertake such review. The appointed individual(s) shall provide a written report to the IRBPH.

B. The IRBPH may request further information in writing or by personal interview with the principal investigator or request modification of the proposal thereby deferring final action.

C. The proposal may be enhanced. If improvement in the research plan appears possible, the addition of changes considered appropriate by the reviewers will be presented to the investigator as recommendations which he or she should carefully consider.

17. **IRBPH Records**

The IRBPH shall prepare and maintain adequate documentation of IRBPH activities, including the following:

A. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposal, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects. Records shall also include copies of written justifications for claimed exempt research.

B. Minutes of IRBPH meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRBPH; the vote on these actions including the number or members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. The minutes shall identify members by name unless a majority of the members present vote to record in the minutes the discussion of a specific issue without identifying any individuals. In the case of such a vote for anonymity, the minutes shall record the vote and the reason(s) for the decision to invoke anonymity.

C. Records of continuing review activities.

D. Copies of all correspondence between the IRBPH and the investigators.

E. A list of IRBPH members and their qualifications and experience.

F. Statements of significant new findings provided to subjects as required by subsection 4(C)(vii).

G. The records required by this Policy shall be retained for at least three years after completion of the research and the records shall be accessible for inspection and copying by authorized representatives of DHHS at reasonable times and in a reasonable manner.

H. A file of approved research proposals for the use of those persons at the DOH having research interests. The file will allow those with common interests to exchange information, and to consider cooperative research activity. The file will also serve as an additional resource for ideas and techniques of potential research benefit.

	I. The IRBPH shall issue an annual report prepared by the Chairperson every February1st, which will include the following: number of projects; current members of the IRBPH; number of meetings convened; and significant policy issues addressed. The report will be reviewed by the IRBPH prior to issuance. 18. **Publication of Reports** A. All papers prepared for publication or as reports to professional meetings (including student projects submitted as class assignments or as thesis) which utilize data gathered in the DOH must be reviewed by the Director or by a staff member whom he/she designates. This review is to ensure that confidentiality of patient data is maintained and that the conclusions appear to be supported by the data presented. B. If the Director determines that a need exists for the technical clearance of a paper prior to its publication, he/she may refer it to the IRBPH. C. The IRBPH's review will be of an advisory nature only. No endeavor will be made to change an author's views or conclusions.
VII. Contacts	Institutional Review Board for Public Health Chair Senior Deputy Director, Center for Policy, Planning and Evaluation Telephone Number: (202) 442-9032
VIII. Related Documents, Forms and Tools	1. Regular IRBPH Submission Forms 2. IRBPH Exemption Submission Forms 3. Continuation/Renewal Forms