

Illinois Department of Public Health Policy on Protection of Human Research Subjects

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FOREWORD

The Illinois Department of Public Health Policy (IDPH) on Protection of Human Research Subjects is based on current federal regulations (45 CFR, Part 46), applicable state statutes and regulations, and IDPH policies. Under the Policy, all research involving human subjects conducted under the terms of IDPH's Federalwide Assurance within IDPH jurisdiction must be reviewed and approved by the Illinois Department of Public Health Institutional Review Board (IRB) or by another IRB designated under IDPH's Federalwide Assurance.

The policy is effective immediately.

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I. POLICY

The Illinois Department of Public Health (IDPH) has adopted the IDPH Policy on Protection of Human Research Subjects (Policy). Under the Policy, the IDPH is responsible for safeguarding the rights and welfare of persons who serve as human subjects in research and related activities sponsored or conducted by IDPH, or whose personal records held by IDPH are disclosed for research purposes. IDPH is committed to the highest ethical standards for all research involving human subjects, which must be guided by the ethical principles articulated in “The Belmont Report.”

No administrative unit within IDPH shall permit or engage in the conduct of human subjects research or related activities until the plans or protocols for such activities have been reviewed and approved by the IDPH Institutional Review Board (IRB) or by another IRB designated on IDPH’s Federalwide Assurance (FWA) unless the research has been specifically exempted from this review requirement by this policy.

Review of research and related activities by the IDPH IRB shall determine that the rights and welfare of human subjects are adequately protected; that risks to human subjects are minimized, not unreasonable, and outweighed by the potential benefits or knowledge gained by them; and that the proposed project design and methods are adequate and appropriate regarding the purpose of the project.

II. APPLICABILITY

This policy applies:

1. Whenever IDPH becomes engaged in research. This occurs whenever (a) employees or agents¹ of IDPH intervene or interact with living individuals for purposes of research in connection with their institutional responsibilities or use of any IDPH facility; (b) employees or agents of IDPH obtain or use individually identifiable private information for purposes of research; or (c) the IDPH conducts or sponsors human subject research even when all activities involving human subjects are carried out by a subcontractor or collaborator;
2. Whenever IRB approval is required by state law, state regulation, or IDPH policy. Unless otherwise specified, release of identifiable data held by IDPH for the purposes of research requires IRB approval;
3. Whenever IDPH engages in research involving human subjects and conducted or supported by any federal agency that has adopted the Federal Policy for the Protection

¹ Agents include individuals who have contracts or other formal relationships with the IDPH.

of Human Subjects (a.k.a. “common rule”). IDPH will comply with the terms of the FWA unless the research is exempt from the requirements of common rule or the conducting or supporting agency determines that the research shall be covered by a separate assurance; and/or

4. Whenever research is as defined in the federal regulations (45 CFR 46.102(d) as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Additional information about distinguishing research from other activities is included in the IDPH IRB *Procedures Manual*.

III. POLICY IMPLEMENTATION AND COORDINATION

The IDPH Director’s Office shall be responsible for ensuring administrative support to the IDPH IRB. The IRB Manager shall serve as a human research review liaison and coordinate with federal regulatory agencies, research organizations that maintain IRBs, and IDPH management.

IV. DEFINITIONS

“**Common rule**” is the federal regulation for the protection of human subjects. The rule is codified for the Department of Health and Human Services (HHS) in Title 45 CFR Part 46.

“**Disclosure**” means the release, transfer, provision of, access to, or divulging in any manner of information outside the entity holding the information.

“**Federalwide Assurance (FWA)**” means the written assurance of compliance with the federal regulations for the protection of human subjects which institutions must provide as a condition for the receipt of federal research funds. Each institution must renew its FWA every three years.

“**Health information**” means any information created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual.

“**Human subject**” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

“**Individually identifiable**” means that a record contains information that reveals or can likely be associated with the identity of the person or persons to whom the information pertains.

“Interaction” includes communication or interpersonal contact between investigator and subject.

“Intervention” includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

“Investigator” means a research professional or student engaged in the conduct of research under this policy.

“Legally authorized representative” means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

“Personal records” means any information obtained or maintained by IDPH which refers to a person and is declared exempt from public disclosure, confidential, or privileged under state or federal law.

“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 includes information an individual provides for specific purposes that the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to obtain the information needed to constitute research involving human subjects.

“Protected health information (PHI)” means individually identifiable health information created or received by a health care provider, health plan or health care clearinghouse that is transmitted or maintained in any form or medium.

“Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and services programs may include research activities.

“Use” means, with respect to individually identifiable information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity that maintains the information.

V. IDPH IRB COMPOSITION

The IDPH IRB shall have at least five (5) members with varying backgrounds to perform complete and adequate review of research activities commonly conducted within the jurisdiction of IDPH. The IDPH IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of its members with consideration to race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IDPH IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Therefore, the IDPH IRB shall include persons knowledgeable in these areas. IDPH IRB reviews also shall include, as needed, persons who are knowledgeable about and experienced in working with vulnerable populations such as children, prisoners, pregnant women, and physically or mentally disabled persons.

The IDPH IRB shall not consist entirely of men nor entirely of women, nor shall it consist entirely of members of one profession. The IDPH IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. The IDPH IRB shall include at least one member who is not otherwise affiliated with Illinois state agencies and who is not part of the immediate family of a person who is affiliated with Illinois state agencies.

No IDPH IRB may have a member participate in the IDPH IRB's initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IDPH IRB. Conflicts of interest may arise for either financial or personal reasons. IDPH IRB members shall disclose any potential conflicts of interest they may have to the IDPH IRB prior to the discussion of a research proposal.

The IDPH IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond, or in addition to, that available on the IDPH IRB. These individuals may not vote with the IDPH IRB.

VI. REVIEW OF RESEARCH BY THE IDPH IRB

The IDPH IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

The IDPH IRB shall require that the information given to subjects as part of informed consent is in accordance with Section XVII of this policy. The IDPH IRB may require that information, in addition to that specifically mentioned in Section XVII, be given to the subjects when, in the

IDPH IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

The IDPH IRB will require documentation of informed consent or may waive documentation in accordance with Section XVII of this policy.

The IDPH IRB shall notify investigators and the IDPH program engaged in, sponsoring, or disclosing data for research in writing of its decision to approve or disapprove of data release, the proposed research activity, or of modifications required to secure IDPH IRB approval of the research activity. If the IDPH IRB decides to disapprove a research activity, it shall include in its written notification a statement defining the reasons for the decision and give the investigator an opportunity to respond in person or in writing.

The IDPH IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk but not less than once per year. The IDPH IRB shall have authority to observe, or have a third party observe, the consent process and the research, and the authority to conduct site visits and interviews to audit the research for compliance with IRB-approved procedures. The IRB may require review more often than annually for ANY research activities, including:

- Research that involves withdrawal of therapy when there may be significant morbidity or mortality;
- Research that involves an invasive procedure (that would not otherwise be done);
- Research in which there are serious risks to participants and non potential benefits; or
- More than minimal risk research involving a vulnerable population with no prospect of direct benefit to the individual participants.

VII. CRITERIA FOR IDPH IRB APPROVAL OF RESEARCH

To approve research covered by this policy, the IDPH IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized by using procedures that (a) are consistent with sound research design and do not unnecessarily expose subjects to risk, and (b) whenever appropriate, are already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any benefits are expected, and to the importance of the knowledge that may reasonably be expected to result from proposed research. In evaluating risks and benefits, the IDPH IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IDPH IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the

research on public policy) as among those research risks and benefits that fall within its purview.

3. Selection of subjects is equitable. In making this assessment, the IDPH IRB is to take into account the purpose(s) of the research and the setting where the research will be conducted. The IDPH IRB is to be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons.
4. Informed consent is sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, Section XVII of this policy.
5. Informed consent is appropriately documented in accordance with, and to the extent required by, Section XVII of this policy.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Additional safeguards have been included in the study to protect the rights and welfare of subjects when some or all of the subjects are likely to be vulnerable to coercion or undue influence such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
9. All relevant Illinois statues and regulations regarding human subjects in research and individually identifiable records release are followed.

VIII. ADMINISTRATIVE REVIEW AND APPROVAL

Research covered by this policy that has been approved by the IDPH IRB also may be subject to further administrative review by the IDPH program in whose jurisdiction the research is being conducted. After an IDPH program staff member or the IRB Chair consults with the Director, he/she may disapprove research that has been approved by the IDPH IRB and shall provide a rationale for doing so. However, the IDPH Director may not approve the research if it has not been approved by the IDPH IRB.

IX. SUSPENSION OR TERMINATION OF IDPH IRB APPROVAL OF RESEARCH

The IDPH IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IDPH IRB's requirements, found to be in violation of relevant statutes and regulations, or to be associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of reasons for the IDPH IRB's action and shall be reported promptly to the investigator, appropriate IDPH officials, and the HHS Office for Human Research Protections.

X. EXPEDITED VERSUS FULL BOARD REVIEW

Following initial screening of research proposals by the IDPH IRB staff, proposals are assigned to one of the following two review categories:

Expedited Review

Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more IRB members designated by the IRB Chair. In reviewing the research, the reviewers may exercise all the authorities of the IDPH IRB except to disapprove the research. A research activity may be disapproved only after review at a convened meeting of the full IDPH IRB.

Applicability

1. Research activities that (1) present no more than minimal risk to human subjects and (2) involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion in this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
2. The categories in this list apply regardless of the age of subjects except as noted.
3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to the subjects' financial standing, employability, insurability, reputation; or be stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified (i.e., secret) research involving human subjects.

5. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review -- expedited or convened -- utilized by the IRB.
6. Categories two (2) through 11 below pertain to both initial and continuing IRB review.

Research Categories

1. Minor changes in previously approved research during the period for which approval is authorized.
2. Research involving access to materials (data, documents, records, or specimens) that have been collected or will be collected for non-research purposes, such as surveillance, medical treatment or diagnosis, and does not involve direct contact with human subjects. (Note: Use or disclosure of identifiable personal information obtained or maintained by IDPH is subject to requirements in relevant state laws and regulations. Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
3. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, and where any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation. (Note: If information obtained pertains to sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, or abuse (physical, sexual, or emotional), and is likely to cause the subject undue stress, fatigue, or other psychological or emotional reactions, a full board review may be required.)
4. Research on characteristics or behavior of an individual or a group where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. This includes, but is not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviors.
5. 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 (21 CFR Part 312) is not required. (Note: Proposals are not eligible for expedited review when research is on marketed drugs that either significantly increase risks or decrease the acceptability of risks associated with the use of the product.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is

cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

6. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight-week period, and collection may not occur more frequently than two times per week; or
 - b. From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight-week period, and collection may not occur more frequently than two times per week.

7. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

8. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography,

ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

9. Collection of data from voice, video, digital, or image recordings made for research purposes.
10. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
11. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or 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.
12. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. Where the remaining research activities are limited to data analysis.
13. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories two through four or categories six through twelve do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Any proposal that in a reviewer's judgment exceeds the criteria for expedited review shall be subject to full IRB review and approval.

Full Board Review

All research and related proposals not eligible for expedited review under the foregoing categories are subject to full IRB review at a scheduled meeting at which a majority of the

members of the IDPH IRB are present, including at least one member whose primary concerns are in a non-scientific area. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Reviews may take place by teleconference or videoconference.

In special circumstances, unscheduled reviews may be conducted. Unscheduled reviews shall be subject to the same quorum requirements that apply to meetings of the IDPH IRB. At the discretion of the IRB Chair or his/her designee, unscheduled reviews shall be limited to reviewing 1) responses where investigators are specifically asked by the IRB to provide clarifications or modifications to research proposals, 2) proposals, whereby waiting for the next regularly scheduled IRB meeting, would make it very difficult or impossible to conduct the research proposed or would unacceptably affect the soundness and integrity of the ongoing research, and 3) proposals needing IDPH IRB consideration of any reported unanticipated problems or adverse events.

XI. ACTIVITIES EXEMPT FROM POLICY

For activities that are not clearly exempt, the IDPH IRB is responsible for reviewing preliminary determinations of exemption made by investigators and supervisors, and for making the final determination. Notice of concurrence for all exempt research will be conveyed in writing to the investigator. All non-exempt research covered by this policy will be reviewed by the IDPH IRB.

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from this policy:

1. Research and demonstration projects, which are conducted by or subject to the special approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - public benefit or service programs;
 - procedures for obtaining benefits under those programs;
 - possible changes to or alternatives to those programs; or
 - possible changes in methods or levels of payment for benefits or services under those programs,provided that:
 - a. The research is needed in emergency situations declared by the state and the agency heads and the timeliness of research is necessary for disease prevention and control; and
 - b. The research relies entirely on information obtained routinely for program management purposes in the course of, and as part of, the ongoing public benefit or service program; and

- c. Access to identifiable data used in the research is limited to staff of the agency that manages the program.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, provided that:
 - a. The research does not involve use or disclosure of an agency's non-public information for purposes of contacting human research subjects or prospective subjects;
 - b. The information obtained does not deal with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, or abuse (physical, sexual, or emotional), and is not likely to cause the subjects undue stress, fatigue, or other psychological or emotional reactions;
 - c. The information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to subjects;
 - d. Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation;
 - e. The research does not involve collecting information from subjects who are unable to provide legal consent for their own participation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph two of this section, if the human subjects are elected or appointed public officials or candidates for public office.
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 used by or disclosed to the investigators in such a manner that it is not identifiable, e.g., it does not contain information which reveals or can likely be associated with the identity of the person or persons to whom the information pertains.

All human subjects research that is exempt as specified in one through four of this section must be conducted in accordance with The Belmont Report² and conduct orderly accounting for such activities.

² The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1, 1979.

XII. PROPOSAL SUBMISSION REQUIREMENTS

Investigators are urged to consult the IDPH program staff and the IRB Chair regarding the application and review requirements before completing and submitting their proposals. The IDPH IRB may develop cooperative agreements with other institutions' review boards which may affect the review of research in the joint jurisdiction of these institutions. All proposals must be submitted to the IDPH IRB on the official application forms available on the IDPH IRB website: <http://www.idph.state.il.us/irb/>. Applicants are urged to note the instructions in the application forms and to provide an addendum for any required information not included in their project narrative. Proposals found incomplete or otherwise not in compliance with the instructions in the application forms may be returned to the applicant upon initial screening by IRB staff.

Investigators whose agency of affiliation (e.g., university) maintains an accredited human research review process must submit their proposals to their institution's human research review office prior to submitting the proposal to the IDPH Responsible Individual. (The investigator is not required to obtain final institutional IDPH IRB approval from his/her home institution prior to submitting the proposal to the IDPH IRB unless specified in writing by IDPH IRB staff.)

With permission, project narratives developed for applications to a federal, public or private funding source will be accepted in lieu of the project description portion of the IDPH application if they provide all the required information. In addition, the IDPH IRB may permit the use of IRB applications from other institutions to be supplemented with an abbreviated IDPH IRB application.

XIII. APPLICATIONS FOR FEDERAL FUNDING

Under the common rule, federal agencies require review and approval of research proposals involving human subjects by the designated institutional IRB of the applicant's institution prior to the initiation of research involving human subjects. Investigators applying for federal funding are responsible for confirming the specific review requirements with their federal project officer and for submitting certification of IRB approval for all activities involving human subjects to the funding agency prior to commencement of research activities.

Under "just-in-time" procedures adopted by the National Institutes of Health (NIH) and the U.S. Centers for Disease Control and Prevention (CDC), certification of IRB approval is not required at the time of application but may be deferred until just prior to funding and before contact with human subjects. For NIH and CDC applications, investigators should submit their proposal to the IDPH IRB when they are informed that the proposal has received a score in the fundable range or otherwise learn that the proposal may be funded.

Applications for funding to any other federal agency involving research with human subjects must be reviewed and approved based on the funding agency's requirements. Typically, the

requirement for IRB review and approval is within 60 days following the submission of the application to the funding agency.

Certain types of applications for funding may be submitted to federal agencies with the knowledge that human subjects may be involved within the period of support but definite plans for research are not described in the application. These include institutional-type grants when selection of specific projects is the responsibility of the IDPH; research training grants in which activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments or the prior completion of other defined activities. Such proposals may be approved by the IDPH IRB on the condition that all projects covered by the common rule will be reviewed and approved before they are initiated. Investigators will submit certification of all subsequent approvals to the funding agency prior to initiating activities involving human subjects.

XIV. INVESTIGATOR QUALIFICATION REQUIREMENTS

Investigators must provide evidence of competence and experience in the proposed research area. Professional research applications will be considered only if they include adequate documentation of the applicant's professional training and experience.

The only exception to this policy is in the case of student projects (i.e., projects serving professional research training purposes for graduate students, up to and including candidates for doctoral degrees currently enrolled in an academic degree curriculum). Research proposals submitted by students must be signed by the IRB Chair of their academic department or the chair of their thesis/dissertation committee. Research applications by post-doctoral trainees are considered professional applications and are subject to all departmental application and review standards that apply to professional research activities in general.

XV. INVESTIGATOR'S RESPONSIBILITY

Investigators who conduct research under this policy have the following responsibilities. Failure to fulfill these responsibilities may result in suspension or termination of IDPH IRB approval to conduct research.

1. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all the provisions of this policy.
2. Investigators who intend to involve human research subjects in their research will not make the final determination of exemption from applicable federal and state regulations from this policy.

3. Investigators will initiate study activities only after written certification of study approval from the IDPH IRB has been received (and as applicable, the *Data Use Agreement*).
4. Investigators are responsible for adherence to contact and consent procedures specified by the IDPH IRB and for providing a copy of the IRB-approved consent document to each subject at the time of consent, unless the IDPH IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the IDPH IRB.
5. Investigators will promptly report proposed changes in previously approved human subject research activities to the IDPH IRB. The proposed changes will not be initiated without IDPH IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
6. Investigators are responsible for reporting progress of approved research to the IRB as often as and in the manner prescribed by the IDPH IRB on the basis of risks to subjects but no less than once per year.
7. Investigators will promptly report to the IDPH IRB any serious adverse events or unanticipated problems involving risks to subjects or others.
8. Investigators are responsible for disclosing to the IDPH IRB whether they have a significant financial interest in the research, including information on the nature and/or monetary value of the interest.
9. Investigators are responsible for adhering to the conditions of the *Data Use Agreement* and certification of data destruction (or, if specified, return of data).
10. Investigators are responsible for following other specified requirements and conditions.

XVI. EDUCATION AND TRAINING IN THE PROTECTION OF HUMAN SUBJECTS

Members and staff of the IDPH IRB and investigators who are subject to this policy shall complete specified education and training in the protection of human research subjects. IDPH IRB members and staff shall complete this educational requirement within three months of their initial appointment to the IDPH IRB or IRB staff. Investigators shall provide documentation of their completion of appropriate education and training in the protection of human research subjects with their application for initial or continuing review of their research by the IDPH IRB. Investigators must complete appropriate retraining in the protection of human research subjects every three years.

XVII. GENERAL REQUIREMENTS FOR INFORMED CONSENT

The IDPH policy for follow back—contact with human subjects based on identifying information collected by IDPH—is that IDPH shall send the initial contact information (e.g., cover letter, brochure, consent forms, etc.) to the potential research subject. The investigator shall submit drafts of such documents after conferring with the IDPH Responsible Individual. Those requiring signatures will be signed by the Department. These documents should be at a literacy level appropriate to the subjects being recruited. The investigator should also consider the need to have such documents in the primary language of the recipient. The investigator will be responsible for the payment involved in processing such notifications.

Participation of subjects in research must be voluntary. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless this investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and to minimize the possibility of coercion, undue influence, or breach of confidentiality. The information that is given to the subject or to the representative shall be in language understandable to the subject or representative. No informed consent, whether oral or written, should 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 releases or appears to release the investigator from liability for negligence.

Basic Elements of Informed Consent

1. Except as provided in subsections three or four of this section, in seeking informed consent, the following information shall be provided to each subject or subject's representative:
 - a. A statement that indicates:
 - the study involves research;
 - an explanation of the purposes of the research;
 - the expected duration of the subject's participation;
 - a description of the procedures to be followed, and
 - Identification of any procedures that are experimental;
 - b. A description of any reasonably foreseeable risks or discomforts to the subject;
 - c. A description of any benefits to the subject or to others that may reasonably be expected from the research;
 - d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - f. For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;
 - g. An explanation of whom to contact for answers to questions about the research and subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - h. A statement 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 anytime without penalty or loss of benefits to which the subject is otherwise entitled.
2. When appropriate, one or more of the following additional elements of information also shall be provided to each subject:
- a. A statement that, regardless of other provisions for protecting confidentiality of information obtained during the research, professionals conducting research under the state agencies' jurisdiction are required to report suspected abuse or neglect of children and dependent adults;
 - b. 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;
 - c. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - d. Any additional costs to the subject that may result from participation in the research;
 - e. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - f. 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.
 - g. The approximate number of subjects involved in the study.

3. The IDPH IRB may approve a consent procedure that does not include or that alters some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IDPH IRB finds and documents that:
 - a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:
 - i. programs under the Social Security Act, or other public benefit or service programs;
 - ii. procedures for obtaining benefits or services under those programs;
 - iii. possible changes in or alternatives to those programs or procedures;
 - iv. possible changes in methods or levels of payment for benefits or services under those programs.
 - b. The research could not practicably be carried out without the waiver or alteration.
4. The IDPH IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IDPH IRB finds and documents that:
 - 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;
 - d. Whenever appropriate, the subjects will be provided with additional information after participation.
5. Except as provided in subsection 6 of this section, informed consent shall be documented by the use of a written consent form approved by the IDPH IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form may be either:

- a. A written consent document that embodies the elements of informed consent required by subsection 1 of this section. 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 1 of this section have been presented orally to the subject or to the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IDPH IRB shall require a written summary of what is to be said to the subject or the representative. Only the short form itself need be signed by the subject or representative. However, both the investigator and the witness shall sign both the short form and the summary, and the person actually obtaining consent shall sign 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.
6. The IDPH IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds either:
- a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject would be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will 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 the research context.

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

XVIII. AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH

Unless the IDPH IRB approves a waiver of authorization, use and/or disclosure of protected health information or individually identifiable information for research is subject to submission of a signed authorization to the entity that maintains the information. A valid Health Insurance Portability and Accountability Act (HIPAA) authorization must include the following elements:

1. A specific description of the information to be used or disclosed;

2. The name of the person or class of persons authorized to approve the requested use or to make the requested disclosure;
3. The name of the person or class of persons for whom the requested use is approved or to whom the requested disclosure is made;
4. A description of each purpose of the use or disclosure;
5. A statement of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization;
6. A statement explaining the extent to which information disclosed is subject to redisclosure by the recipient and no longer protected under state and/or federal laws;
7. A statement that the individual may revoke the authorization in writing, except to the extent that the entity has taken action in reliance on the authorization;
8. An expiration date or expiration event that relates to the individual or the purpose of the use or the disclosure; and
9. The signature of the individual granting the authorization and the date.

In addition, the authorization must be written in plain language. A copy of the signed authorization must be retained by the entity that approves the requested use or makes the requested disclosure, and a copy must be provided to the individual.

An authorization for the use and/or disclosure of protected health information (PHI) for research may be combined with any other type of written permission for the same research study; e.g., the required elements of a valid authorization may be combined with the required elements for informed consent for study participation in one consent document. Alternatively, authorizations for use and/or disclosure of PHI may be prepared on a document separate from the research consent form.

XIX. WAIVER OF AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION AND/OR INDIVIDUALLY IDENTIFIABLE PERSONAL RECORDS FOR RESEARCH

The IDPH IRB may waive authorization or consent for use and/or disclosure of protected health information and other individually identifiable personal records if all the following criteria have been met:

1. The research involves no more than minimal risk to subjects (45 CFR 46.116(d)(1) and 45 CFR 164.512(i)(2)(ii)(A));

2. The waiver of authorization will not adversely affect the rights and welfare of the subjects (45 CFR 46.116(d)(2));
3. The research could not practicably be carried out without the waiver of authorization or without access to and use of the protected health information and/or individually identifiable personal records (45 CFR 46.116(d)(3), 45 CFR 164.512(i)(2)(ii)(B)(C),;
4. Whenever it is appropriate, subjects will be provided with additional pertinent information about the research and/or waiver of authorization for use and/or disclosure, after the information is disclosed (45 CFR 46.116(d)(4));
5. The research protocol includes an adequate plan to protect the identifiers from improper use and/or disclosure and to protect identifiable information from redisclosure (45 CFR 164.512(i)(2)(ii)(A)(1), and an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (45 CFR 164.512(i)(2)(ii)(A)(2);
6. The research is of sufficient importance to outweigh the intrusion of the individual's privacy that would result from the disclosure of his/her protected health information and/or identifiable personal records;
7. Written assurance is provided that the protected health information and/or individually identifiable personal records will not be reused for other purposes or disclosed to any other person or entity, except as specifically required or permitted by law and approved by the IDPH IRB (45 CFR 164.512(i)(2)(ii)(A)(3); and
8. Written assurance is provided that no individual whose protected health information and/or individually identifiable personal records are used in the research will be identified in any written report resulting from the research.

XX. USE AND DISCLOSURE OF IDPH PERSONAL RECORDS FOR RESEARCH

In addition to the requirements in Section XIX above, the IDPH IRB may approve research use and/or disclosure of identifiable personal records held by IDPH without the authorization or consent of the person(s) to whom the records pertain, only when all the following conditions have been met:

1. The disclosure does not violate federal and state law or regulation;
2. The recipient of the individually identifiable records or record information will not use the information to contact or attempt to contact any person identified in the record or record information, unless and until IDPH obtains prior consent from the person to

whom the record pertains, or at a minimum, provides prior written notification to the person to whom the record pertains, and allows a reasonable amount of time for the person to deny the state agency permission to disclose the information for purposes of being contacted;

3. The recipient of the individually identifiable records or record information will not conduct record-level data linkages to gain more information about any individuals in the data unless such activities have been presented in the application and have been approved by the IDPH IRB;
4. Provision of the individually identifiable records or record information would not be unacceptably burdensome to ongoing departmental operations; and
5. The applicable IDPH program negotiates with the research professional receiving the records or record information in consultation with IDPH's Division of Legal Services a written and legally binding *Data Use Agreement* prior to disclosure. The agreements shall:
 - a. Specify the information sought and the conditions under which the investigator will have access to or copies of individually identifiable records or record information;
 - b. Establish specific safeguards to assure the continued confidentiality and security of the records or record information;
 - c. Ensure that the research professional will report or publish research findings and conclusions in a manner that does not permit identification of the person whose record was used, and ensure that research reports and publications will not include photographs or other visual representations contained in personal records;
 - d. Establish and notify the IDPH in writing that the research professional will destroy or return to the individual identifiers associated with the records or record information as soon as the purposes of the research project have been accomplished;
 - e. Prohibit any subsequent disclosure or third-party releases of the records or record information in individually identifiable form except as provided by law; and
 - f. Include the signature of the research professional, of any of the research professional's team members who require access to the information in identified form, and of the IDPH staff authorized to approve disclosure of identifiable records or record information for research purposes.

XXI. FINAL PROJECT REPORT REQUIREMENT

Approval of research and related proposals is contingent on the investigator's agreement to submit a report on his/her completed project to the IDPH IRB.

XXII. PUBLICATIONS

Unless an agreement specifies otherwise, an investigator not employed by any state agency may publish, at his/her own expense, the results of his/her research without prior review by IDPH provided that such publication acknowledges IDPH participation or cooperation and that such participation or cooperation does not imply endorsement of the publication by the IDPH. Upon request, the investigator shall furnish copies of any such publication to the IDPH.

XXIII. COMPLIANCE WITH FUTURE CHANGES IN HHS REGULATIONS (45 CFR 46)

If the IDPH finds that future changes in federal regulations fail to meet minimum requirements for the adequate protection of citizens, it will adopt a more restrictive version of the regulations and inform the IDPH IRB of this action.

APPENDIX A

CITATIONS

The *Illinois Department of Public Health Policy on Protection of Human Research Subjects* is based on federal regulations and guidelines, state statutes and regulations, departmental administrative policies, and the IDPH's Federalwide Assurance with HHS. These documents are cited below, along with guidelines for distinguishing between public health research and public health non-research activities.

1. Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, as revised June 18, 1991.
2. Title 45, Code of Federal Regulations, Part 164, Privacy Rule – Security and Privacy.

GUIDANCE DOCUMENTS

The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

Guidelines for Defining Public Health Research and Public Health Non-Research, Centers for Disease Control and Prevention, 1999.

Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions, CSTE 2004.