

**Illinois Department of Public Health
INSTITUTIONAL REVIEW BOARD (IRB)
PROCEDURES MANUAL**

Illinois Department of Public Health
Institutional Review Board (IRB)
122 South Michigan Avenue, Seventh floor
Chicago, Illinois 60603

(312) 814-5173

DPH.IRB@illinois.gov

<http://www.idph.state.il.us/irb>

Summary of IRB Procedures Manual Changes

Section	Effective Date	Summary of Change
Table of Contents	03/05/12	Corrected page numbers beginning at Section 3.1
4.2	03/05/12	Clarified information on meeting times

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1.0 PURPOSE AND AUTHORITY OF THE IRB

1.1 Purpose of the IRB

The Illinois Department of Public Health (IDPH) Institutional Review Board (IRB) protects the rights and welfare of individuals who participate in research under the jurisdiction of the IDPH educates investigators and protects IDPH. The IDPH IRB works to ensure that the rights and welfare of research participants are adequately protected; that the risks to individuals are minimized, are not unreasonable, and are outweighed by the potential benefits to the individual or by the knowledge to be gained; and that the proposed research design and methods are adequate in light of the stated research objectives.

1.2 Authority of the IRB

The IDPH IRB is registered with the federal Office of Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (HHS) and has adopted the *Illinois Department of Public Health Policy on Protection of Human Research Subjects*.

The operation of the IDPH IRB is subject to the human subjects protection rules, policies, and guidelines contained in the following documents:

- Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, as revised June 18, 1991
- Title 45, Code of Federal Regulations, Part 164, Privacy Rule—Security and Privacy
- 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

As provided in these documents, the IDPH IRB has the following powers:

- Human subjects research in the jurisdiction of IDPH may not proceed until the protocol has been reviewed and approved by the IRB.¹ In the course of its deliberations, the IRB may approve proposals, disapprove proposals, or defer final approval until review issues have been resolved.
- The IRB may prescribe scientific and ethical restrictions or conditions under which a project may be conducted, require substantive changes in project plans, and determine the nature and frequency of interim review procedures necessary to ensure continued acceptable conduct of the project.
- Negative IRB decisions (disapprovals, restrictions or approval conditions) are binding, are not subject to administrative override, and may be rescinded only by action of the board. Projects approved by the board are subject to further review, disapproval, or restrictions by the IDPH Director.

¹At the discretion of the IDPH IRB Chair, research in the jurisdiction of IDPH may be forwarded for review by an alternate IRB designated on IDPH's Federalwide Assurance (FWA). Reliance on the IRB of another FWA institution requires documentation of an IRB Authorization Agreement signed by the institutional official of the respective FWA institutions.

- The IRB may suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to participants.

2.0 MANAGEMENT AND SUPPORT OF THE IRB

2.1 IRB Support Staff

Current staff includes the IRB Manager and the IRB Review Coordinator.

2.2 IRB Manager

The IRB Manager is responsible for implementing the operations of the IDPH IRB and for ensuring compliance with applicable federal and state laws and regulations and departmental policies and procedures. The IRB Manager:

- Acts as the IDPH human subjects protection administrator;
- Is responsible for compliance with IRB policies and procedures, federal regulations and state and local laws relative to the conduct of human subjects research studies;
- Provides guidance regarding the interpretation of regulations, laws, and policies to investigators, staff and administrators;
- Maintains IDPH's FWA and ensures compliance with the terms of the FWA;
- Assigns review workload to IRB staff and provides consultation to IDPH IRB members during review of research proposals;
- Ensures that IRB decisions are enforced and monitors ongoing human research projects that have been approved by the IRB;
- Ensures that communications to investigators include requirements to promptly report noncompliance, adverse events, unanticipated problems involving risks to research projects, changes in research activities, noncompliance with IRB requirements to the IRB, IDPH officials, OHRP, and sponsoring federal agencies as required;
- Maintains the credibility of the review process through constructive contacts with investigators, agency managers and administrators ;
- Promotes communication to ensure a high level of awareness at IDPH regarding the ethical conduct of research and safeguarding the rights and welfare of subjects;
- Provides professional liaison with federal and state agencies;
- Coordinates the IDPH IRB process with IRBs of other institutions;

- Plans, develops and proposes policies and procedures concerning the review and approval of human subjects research and the confidentiality of personal records;
- Supervises IRB staff;
- Manages IRB resources to optimize research review objectives;
- Prepares regular reports to the IRB Chair and IDPH senior management about research applications received and reviewed, past and present and ongoing timeliness measures of the review process;
- Provides information and technical support to the IDPH IRB Chair; assists the IDPH IRB Chair to efficiently and effectively run the IDPH IRB meetings;
- Screens research proposals for compliance with scientific, ethical, and legal standards for conducting research;
- Acts as the initial IRB point of contact for questions regarding research applications, scientific, legal, ethical, and programmatic implications of proposed research design and protocols;
- When appropriate, directs inquiries to the IRB Chair, appropriate staff at IDPH and other institutions for response as appropriate;
- Analyzes policy manuals, application forms, instructions to investigators, review worksheets, etc., to identify and recommend ways to improve the quality and timeliness of reviews of research proposals and to accommodate increasing workloads;
- Completes Documentation of Findings forms for IRB reviews;
- Completes all required human subjects training requirements.

2.3 IRB Review Coordinator

In consultation with the IRB Manager, the IRB Review Coordinator provides professional staff support to the IRB, including:

- Screening applications for completeness, reviewing (if present) corresponding project files, and evaluating the application's conformity with board approved procedures;
- Prepares correspondence for review by the IRB Chair and IRB Manager;
- Prepares minutes of IRB meetings based on correspondence to investigators and meeting notes;
- Coordinates continuing review of active research by screening project files at least annually to ensure compliance with board-approved methods and procedures;
- Organizes and coordinates the IRB workload of active research projects using the IRB Access Database and maintaining project files;

- Prepares reports for the IRB including logs of all protocols and specification of approval mechanism (expedited review vs. full review) ;
- Screens and directs all telephone inquiries and mail;
- Arranges for meeting rooms and travel arrangements;
- Prepares meeting agendas, meeting minutes, and distributes IRB materials to IRB members;
- Ensures that necessary printed and electronic materials are available in Springfield and Chicago for IRB members to review during IRB meetings;
- Notifies investigators by e-mail of the need to submit a *Progress Report* for continuation review and approval;
- Facilitates required training and provides training resources on human subjects protection to investigators and IRB members;
- Works with the web coordinator to maintain the IRB website and ensures that information on the website is current;
- Facilitates and monitors required training in the protection of human subjects for IRB staff, IRB members, and investigators;
- Maintains IRB access to IDPH's FWA documentation, copies of pertinent federal and state regulations, policies, and guidelines related to the involvement of human subjects in research, and institutional policies and procedures;
- Ensures that IRB records are maintained per HHS regulations, and that records are accessible, upon request, to authorized HHS officials;
- Ensures certification of IRB approval of research to the appropriate HHS agency for HHS-conducted or supported research;
- Ensures that all cooperating performance sites in HHS-conducted or supported research conducted primarily under the direction of IDPH have appropriate OHRP-approved assurances and provide certifications of IRB approval to the appropriate federal authorities;
- Maintains a current IRB membership list, as specified in Section 4.5.5;
- Ensures that cooperative IRB review arrangements are documented in writing, in accordance with OHRP guidance;
- Ensures that any independent investigator that uses another institution's IRB also has documented his/her commitment to IDPH's human subjects protections requirements and the IDPH IRB's

determinations.

3.0 IRB ORGANIZATION AND MEMBERSHIP

3.1 Composition of the IRB

The ID PH IRB has five to 12 full members with additional alternate members who participate in reviews, as well as the capability to supplement the board with ad hoc members under specified circumstances. Members have diverse backgrounds to promote complete and adequate review of research activities conducted within the jurisdiction of IDPH. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of research participants.

In addition to possessing the professional competence necessary to review specific research activities, the IRB is qualified to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB therefore includes persons knowledgeable in these areas. As necessary, the IRB also will include persons who are knowledgeable about and experienced in working with vulnerable populations.

The IRB includes at least several members whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas. The IRB includes at least one member who is not otherwise affiliated with IDPH, and who is not part of the immediate family of a person who is affiliated with ID PH. The IRB has at least one member who is a physician licensed to prescribe drugs in the State of Illinois. Every effort is made to include members who mirror the ethnic and racial composition of subjects who participate in the research under review. The IRB will include at least one ad hoc member who serves as a prisoner representative during the review of research involving prisoners.

3.2 Board Members

3.2.1 Appointment

Recommendations for IRB membership are solicited by the IRB Chair from Deputy Directors, board members, and as needed, from IDPH, professional and human service agencies and organizations. Candidates for IRB membership are submitted for consideration and formal appointment by the IDPH Director. The Director appoints candidates to the board who are IDPH employees with the concurrence of management. Board members who are not employees of IDPH are appointed as official volunteers with IDPH. Volunteer status provides members with the services of the Office of the Attorney General in the event that legal representation is required as a result of participation in IRB business.

3.2.2 Length of Service

Board members serve an initial term of one year upon their first appointment. To assure continuity of board operations, members may be appointed for terms of one, two, or three years following expiration

of their first term.

3.2.3 Duties

Members of the IDPH IRB are expected to contribute time necessary to complete IRB business. The IRB meets at least four times per year and on an ad hoc basis when the need arises. Depending on the workload, members may spend up to four to eight hours per quarter reviewing proposals prior to a board meeting. IDPH employees appointed to the board are authorized by their agency to set aside time from their regular duties for review preparation, meeting attendance, and other board business.

During the review of research proposals, members do not participate as representatives of an IDPH office. Rather, each member brings to the review task his/her own expertise, principles, and points of view based on his/her own unique experiences and background. Members are expected to indicate if they have a conflict of interest with any research proposal under consideration.

During the review of each research proposal under consideration, whether the review is conducted through the expedited or full board review process, the duties of board members include, but are not limited to, determining that:

- The application pertains to human subjects research;
- Risks to subjects are minimized, and are reasonable in relation to anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result;
- The selection of subjects is equitable based on the purposes of the research and the setting in which the research will be conducted;
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and that it is appropriately documented, in accordance with and to the extent required by state and federal statute and regulation;
- Approval of a waiver of consent or waiver of authorization is extended only when all regulatory criteria have been satisfied;
- When appropriate, adequate plans are in place to monitor study procedures to ensure the safety of subjects;
- Adequate plans are in place to protect the privacy of subjects and to maintain the confidentiality of identifiable personal records;
- Additional safeguards are in place to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically and/or educationally disadvantaged persons;
- All relevant and applicable statutes and regulations are followed.

3.2.4 Severance

IRB members may resign from the IRB upon approval of the IDPH Director and written notification to the IRB Chair.

If a member fails to attend more than three consecutive meetings, violates the confidentiality rules specified under Section 4.4 of this document, or otherwise behaves in a manner that is inconsistent with the mission of the IRB, the IRB Chair may recommend that the Director discharge the individual from board membership.

3.3 Chairperson

3.3.1 Appointment

A candidate under consideration for the position of IRB Chair must be a physician and have been a member of an IRB or Data Release and Research Committee (or equivalent) for not less than two years and must be affiliated with IDPH or a local health department. Affiliation is defined as being an employee of, or consultant with, one of these agencies.

Candidates for chair of the IRB are appointed by the IDPH Director based on demonstrated knowledge and experience, commitment to the mission of the IRB, the ability to command the respect of members of the IRB, and the recommendations of the outgoing chair. Candidates also are sought on the basis of their ability to run meetings in an efficient and effective manner, and to provide leadership and facilitate problem solving during meeting deliberations.

3.3.2 Length of Service

The IRB Chair is appointed to an initial term of one year. Upon successful completion of an initial term, the Director will invite the IRB Chair to accept reappointment for up to two consecutive terms of one to two years each. At the conclusion of a term as chair of the IRB, a chairperson may be appointed to continue to be a member of the board.

3.3.3 Duties

In addition to the duties of a member, the IRB Chair's duties include, but are not limited to, the following:

- Reviewing protocols to make determinations, e.g. exempt status, meets criteria for expedited review; approval under expedited review, etc, and similar responsibilities of the chair, as described in 45 CFR 46;
- Conducting board meetings following a prepared timed agenda. (As necessary, meetings may be carried out in accordance with the *Roberts Rules of Order*);
- Directing board deliberations to focus on essential review concerns;
- Probing board consensus on critical review issues by eliciting individual votes;

- Leading the board to develop clear disposition instructions for correspondence to investigators by the IRB Manager;
- Serving as a voting member for the purpose of 1) breaking a tie vote; 2) satisfying quorum requirements if meeting attendance falls short by one board member; and 3) participating in the expedited review of proposals;
- Sharing with the IRB Manager in ensuring IRB compliance with *Illinois Department of Public Health Policy on Protection of Human Research Subjects* and *IDPH IRB Procedures Manual*, and ensuring appropriate oversight mechanisms have been implemented to ensure compliance with the determinations of the IRB;
- Identifying and recommending ways to improve the quality and timeliness of reviews of research proposals and to accommodate increasing workloads;
- Delegating authority for conducting expedited reviews to one or more IRB members;
- Sharing with the Director in making recommendations for appointment of new board members and in selecting candidates for Chair;
- Reviewing and signing meeting minutes prepared by the IRB Review Coordinator;

The IRB Chair may delegate to the IRB Manager authority to carry out the following duties (per 45 CFR 46.110):

- Signing all official IRB correspondence

3.3.4 Appointment of Chair Pro Tem

If unable to attend a meeting, the Chair should inform the manager, if possible, at least three weeks prior to the scheduled meeting date. Under this circumstance, the Chair has the authority to appoint another qualified member of the IRB to serve as Chair pro tem for that meeting.

3.3.5 Severance

The Chair may resign from his/her duties as Chair upon written notification to the Director.

If a Chair fails to attend more than two consecutive meetings, violates the confidentiality rules specified under Sec. 4.4 of this document, or otherwise behaves in a manner that is inconsistent with the mission of the IRB, the IRB may recommend the Chair's severance from board membership to the Director by a vote at a meeting of the full board.

3.4 Use of Consultants

If a proposal requires expertise beyond those represented on the IRB, the Chair may seek verbal advice or written consultation from outside professionals. When consultation is obtained, however, the board remains responsible for independently determining the scientific and ethical acceptability of the

proposal. Consultation with outside experts shall preserve the anonymity of the investigator, or, if this is not possible, shall be conducted in a confidential manner. Consultants may participate in the discussion of a proposal at the meeting, but may not be present during or participate in the voting process. Copies of the consultant's viewpoint are distributed to all board members prior to the meeting.

3.5 Board Member Education/Training

Under the *Illinois Department of Public Health Policy on Protection of Human Research Subjects*, members of the IDPH IRB are required to complete training in the protection of human subjects. IRB members must complete the training requirement before they participate as voting members. A refresher course is required every three years.

IRB members may satisfy this education and training requirement by completing a course in the protection of human research subjects approved by the IDPH Chair and submitting to the IRB written documentation of the content of the training and the date it was completed. Successful completion of the tutorial offered by the National Institutes of Health (NIH) Office of Extramural Research, [Protecting Human Research Participants](#), may be used to fulfill the requirement for education in the protection of human subjects. A Spanish language version is also available: [Protección de los participantes humanos de la investigación](#).

In addition to the required member training, in-service training in a variety of applied topics relevant to reviewing human subjects research may be provided during each board meeting. The IRB Manager's report at the beginning of each board meeting also provides timely information on topics relevant to the work of the IRB. Topics covered include regulatory updates, state legislative and policy developments, and current or future IDPH IRB quality improvement initiatives.

IRB members will receive a *Board Member Handbook*, which includes additional resource materials useful for reviewing research proposals.

3.6 Reimbursement

IDPH employees appointed to the IRB receive mileage reimbursement from their own organizational units based on Central Management Services (CMS) procedures. Members who are not IDPH employees are reimbursed by the Director's Office for mileage to and from meetings at the standard state rate.

3.7 Conflict of Interest

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Conflicts of interest may arise for either financial or personal reasons. At the beginning of each IDPH IRB meeting the Chair shall ask IRB members to disclose any potential conflicts of interest they may have with any item on the agenda, and this shall be noted in the meeting minutes.

Members who have a significant conflict of interest (e.g., being the principal investigator or co-principal investigator, a contributor to the design of the research, or a member of the research staff) must recuse themselves from consideration of the research proposal. Members who recuse themselves must leave the meeting room during discussion of and voting on the research proposal, and are not counted in the

quorum for consideration of that agenda item. Members who have a less significant conflict of interest (e.g., the proposal was developed by an investigator in the same organizational unit, but the member did not make a direct contribution to the research) may remain in the room during consideration of the proposal, but should not participate in the discussion except to answer questions, and must abstain from the vote. Members who abstain from voting are counted in the quorum for consideration of that item.

The Chair of the IRB shall be the final arbitrator regarding whether a member's conflict is significant enough to require recusal from consideration of an agenda item. If the Chair has a conflict of interest, the board shall decide if the conflict is significant enough to require recusal. If recusal of the Chair is required, the Chair shall designate a Chair pro tem to chair the meeting until the Chair is able to return to the meeting.

3.8 Undue Influence

IRB staff and members have numerous interactions with investigators and others in the performance of their assigned roles. IRB members or IRB staff who experience undue influence should first report the occurrence to the IRB Chair, who will attempt to mediate or resolve the concern, in consultation with the IDPH Ethics Officer, as necessary. If an IRB Chair experiences undue influence, he/she should first report the occurrence to the IDPH Ethics Officer, who will attempt to mediate or resolve the concern, in consultation with the institutional official as necessary or appropriate.

Any other individual who believes that undue influence is being exerted on IDPH staff, members, or the IRB Chair should report this concern to the IDPH Ethics Officer and/or the Director.

The role of the IDPH Ethics Officer is to investigate and resolve any reported attempt to inappropriately pressure IRB staff or IRB members because of that individual's role, i.e., to exercise undue influence.

3.9 Liability Coverage

State law provides that state officers, employees and volunteers may request representation by the Illinois Attorney General in any action or proceeding for damages in which the officer, employee, or volunteer has been named a defendant. Representation from the Office of the Attorney General applies to legal claims arising from acts or omissions that occurred while performing, or in good faith purporting to perform, official duties.

Representation from the Office of the Attorney General is available to all board members who are state employees or volunteers of state agencies for their acts or omissions, if such acts/omissions are determined to be in good faith and within the scope of their official duties and responsibilities as member of the IDPH IRB. Where representation from the Office of the Attorney General is provided, board members are protected from judgments against the state of Illinois.

To provide representation from the Office of the Attorney General, IRB members who are not state agency employees are officially appointed as volunteers of the IDPH for purposes of performing their official IRB duties.

4.0 IRB OPERATIONS

4.1 Open Meetings Act

Full IRB review of research applications must occur at meetings subject to the Open Meetings Act [5 ILCS 120].

4.2 Meeting Schedule and Venue

The IRB has scheduled meetings four times a year, on the third Thursday during the second month of each calendar quarter. When necessary, ad hoc meetings will be held on the third Thursday of the first and third months of each calendar quarter. To accommodate board members who live in Springfield as well as the Chicago areas, meetings generally are held by video conference linking IDPH offices in Chicago and Springfield.

4.3 Distribution of Materials

Review materials and information are mailed to all board members approximately one week before each scheduled meeting. Review materials are distributed by e-mail prior to the meeting and also printed for IRB member meeting attendees as follows:

Material	E-mailed prior to meeting	At least one paper copy will be available at each meeting site*
Meeting agenda	√	√
Minutes from previous meeting	√	√
Abstracts and consent forms for research applications undergoing full board review	√	√
Review summaries completed by primary reviewers	√	√
<i>New requests for full board review</i>	√	√
<i>Progress Reports</i> for full board review	√	√
<i>Study Amendment Requests</i> for full board review	√	√
An updated log of --applications reviewed under expedited procedures -- <i>Progress Reports</i> reviewed under expedited procedures -- <i>Study Amendment Requests</i> reviewed under expedited procedures -- <i>Final Study/Closure Report</i> approvals --Canceled and completed projects --Exempt applications reviewed -- <i>Unanticipated Problems and/or Adverse Events reports, if any</i> --Suspensions and other board actions, if any	√	√

* Electronic versions may be substituted for paper copies, provided at least one laptop with an electronic version of the documents is available for viewing by members in both Springfield and Chicago.

Either at or before the meeting, IRB members may ask questions, raise issues, and/or ask for full board consideration regarding any actions taken under expedited review authority.

4.3.1 Appeals of IDPH IRB Decisions

Investigators have the right to appeal IRB decisions, including disapprovals, terminations of approval, restrictions on study design and/or study procedures, and approval conditions. Appeals must be submitted in writing to the IRB within 60 days of the written notice to the investigator of the IRB decision. Appeals should provide a rationale for why the IRB's decision is in error, is not consistent with the *Illinois Department of Public Health Policy on Protection of Human Research Subjects* and/or the *IDPH IRB Procedures Manual*, or is consistent with these policies and procedures but is unreasonable given the circumstances and constraints of the proposed research.

All written appeals, including those of decisions made through the expedited review process, will be placed on the agenda of the next meeting of the IRB, which may be convened on an ad hoc basis upon the request of the IRB Chair, IRB members, or the IRB Manager. Investigators may request to be present at the meeting during consideration of the appeal to answer questions from IRB members and/or to clarify aspects of the proposed research they believe the IRB has not adequately taken into consideration. The investigator must leave the meeting prior to final consideration of the appeal.

A motion for disposition of the appeal, and the rationale for that disposition, is made by the primary reviewer of the proposal. After the motion is seconded, the Chair opens the floor to debate on the motion. After debate, the Chair puts the question to vote. Votes are taken by a show of hands and a simple majority is needed for the motion to pass.

4.4 Confidentiality of IRB Materials

All materials listed below are considered sensitive information and shall not be disclosed to or discussed with any individual who is not a IDPH IRB member, except on an as needed basis, e.g. with supervisors or IDPH senior staff, or during discussions related to Data Release and Research Committee or involving the Data Steward or IDPH Responsible Individual (or equivalent individuals). In addition, the IRB Chair, the primary reviewer of the proposal, the IRB Manager, the IRB Review Coordinator, IDPH Responsible Individuals and Data Stewards may discuss the proposal with the principal investigator and his/her staff prior to the meeting; only the IRB Chair, the IRB Review Coordinator, or the IDPH Responsible Individual may discuss the disposition of the proposal with the principal investigator and his/her staff after the meeting.

4.4.1 Sensitive Information

The following materials are classified as sensitive information:

- Proposals submitted to the IRB, unless and until they have been approved by the board;
- Disapproved proposals and proposals canceled before approval;
- Oral and written arguments, opinions and decisions (votes) by individual board members during the review process;
- Meeting minutes that summarize discussion and votes in anonymous form, except for abstentions and recusals;

- Written reviews of proposals by outside consultants;
- Correspondence between the IRB and the investigator prior to approval of the proposal;
- Correspondence with investigators of disapproved proposals shall remain classified as sensitive information;
- Any identifiable personal records and/or information pertaining to agency clients, employees, or members of the general public made available to the IRB in the process of review are classified as confidential information and shall be treated as such under applicable laws;

Board members should keep review documents and correspondence classified as sensitive information in a secure location at all times. Review documents and correspondence transmitted as e-mail attachments to board members shall be accompanied with a statement that the materials contain sensitive information and should be opened only by the intended recipient.

4.4.2 Retention of Sensitive Information

To minimize storage of paperwork related to IRB business, members may dispose of all review materials (except identifiable personal records, which shall be shredded) by discreet recycling when the meeting is completed.

All other board-related paperwork (correspondence, agendas, etc.) may be discreetly recycled after the meeting to which they pertain has been completed. Primary reviewers may request that IRB staff maintain materials related to proposals for which a member is the primary reviewer until the project is completed or canceled.

4.5 Recordkeeping

4.5.1 Research Project Files

The IRB staff maintains separate project files (electronic, paper or a combination thereof) for each research proposal. Upon submission, proposals are assigned a project code.

Each project file contains, in order from front to back:

- A *Face Sheet* created by the IRB database;
- The *Research Abstract*;
- The original signed and executed Data Use/Security Agreement, if a) identifiable personal records maintained by IDPH are used or disclosed for the research, b) other records deemed to require such an agreement by an IDPH program are used or disclosed for research;
- IDPH IRB approval letter, and an approved proposal, with addendums as applicable, which reflects board-negotiated revisions in the original proposal, and which officially represents how the research

will be conducted.

- Documentation of training in the protection of human subjects completed by the principal investigator(s);
- A *Documentation of Findings* as required under HHS regulations (See Section 4.6.4) based on the IDPH IRB review of the proposal;
- All other correspondence and documentation related to the project, in reverse chronological order;
- Pre-review issues completed prior to full board review of the proposal originally submitted (A summary of these issues is acceptable.)

The IRB staff maintain electronic and/or paper files of all proposals submitted for review. Hard copies of outdated versions of proposals are discarded from paper files if an electronic file is maintained.

4.5.2 Record Storage and Retention

Proposals reviewed by the board and all materials and documents related to the board review are maintained in either individual project files stored in locked file cabinets in the IDPH IRB file room or electronic files. Only IRB staff has direct access to materials in the locked file cabinets or electronic files.

Project files are retained by IRB staff for at least 12 months after the project is completed or canceled. Additional retention of files is based on state recordkeeping requirements. Within these retention parameters, all project files are accessible for inspection and copying by authorized representatives of the HHS at reasonable times and in a reasonable manner.

Materials which have historical value may be selected and retained in the State Archives indefinitely.

4.5.3 IRB Correspondence

IRB correspondence is prepared by the IRB Review Coordinator for review by the IRB Manager and IRB Chair. Correspondence is written to represent the consensus view of the IRB; however if a strong minority viewpoint is expressed in the meeting it will be included in the correspondence. Draft correspondence must be reviewed for accuracy and tone by the primary reviewer before it is mailed to the investigator. Other IRB members may request that they also review and comment on draft correspondence. IRB correspondence is signed by the IRB Chair or the IRB Manager on behalf of the IRB.

Correspondence is sent to investigators via e-mail and/or first class mail. Copies of all written correspondence and e-mails are included in the project files maintained by the IRB.

4.5.4 IRB Meeting Minutes

Meeting minutes are drafted by the IRB Review Coordinator after all IRB disposition letters have been conveyed to investigators. The review of a proposal is described in the minutes based on board correspondence to investigators. The meeting minutes include:

- The time the meeting was called to order;
- Attendance and quorum verification;
- For meetings conducted by teleconference, documentation of which members were present via teleconference and that the criteria for members' participation via conference call have been satisfied ;
- Documentation of the acceptance of the minutes of the previous board meeting;
- Manager's report;
- Documentation of in-service training, if conducted during the meeting;
- Documentation of whether any member in attendance has a personal or financial conflict of interest with respect to any item on the meeting agenda, and a brief description of the proposal, *Progress Reports*, *Study Amendment Requests*, or unanticipated problems and/or adverse event reports submitted for full board review, along with a description of the IRB's deliberations, actions, and votes on each item. The minutes document the basis for requiring changes or for disapproving research and include a summary of controverted issues, if applicable;
- A list of new proposals, *Progress Reports*, and *Study Amendment Requests*, reviewed under expedited procedures, and any board member comments and questions;
- Other IRB actions;
- The time the meeting was adjourned.

4.5.5 IRB Member List

The IRB staff maintains a current IRB membership list, including names; earned degrees; human subjects training certifications; relevant experience such as board certifications, licenses, etc., sufficient to describe each member's principal anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution. Changes to board membership are reported promptly to the OHRP.

4.5.6 Written Procedures

IRB staff maintains current written procedures for the IDPH IRB. Written procedures are codified in the *IDPH IRB Procedures Manual*, which is approved by the IDPH Director, available on the IDPH IRB website: <http://www.idph.state.il.us/irb> and included in the IDPH IRB Board Member Handbook. Except for non-substantive changes, review and comments on revisions and/or additions to procedures and forms are solicited from board members prior to adoption. Proposed revisions and/or additions to procedures and forms are prepared by IRB staff and distributed in mark-up format to the IRB. Formal adoption of revisions to the *IDPH IRB Procedures Manual* is by vote at a convened IRB meeting.

4.5.7 Research Tracking System

The IRB maintains a database to manage and track active as well as completed research protocols. The database serves as a historical record of all proposals reviewed by the Board. It also is used to produce a list of projects due for continuation review before each review cycle; to generate routine IRB correspondence; to evaluate IRB workload; and to prepare the *Activity Reports* published by the IRB.

4.6 Methods of Documentation

4.6.1 Education and Training

Principal investigators and research staff who have contacts with human subjects or identifiable records must attest to completion of training in protection of human research subjects before their proposals can be approved. The IRB will accept certificates of completion of such training from recognized institutions.

4.6.2 Informal Review and Consultation

The IRB Chair, IRB Manager and IRB Review Coordinator provide consultation to investigators, students, program managers, and IDPH employees on a wide variety of topics related to the human subjects protection program. Many consultations involving the IRB Chair involve inquiries about whether a specific activity constitutes research. (See Section 5.1, *IDPH IRB Procedures Manual*, Determining if an Activity Requires IDPH IRB Review and Approval).

A written determination about whether an activity constitutes research must be based on submission of information in an *Exempt Determination Request*. Files documenting each exempt review are maintained in a central file cabinet in the IRB. At a minimum, the file includes the name and affiliation of the person submitting the *Exempt Determination Request*, a written description of the activity in question, a written determination about whether the activity constitutes research, and the date the determination was made. Each activity described in an *Exempt Determination Request* is entered into the IRB database maintained by the IRB.

4.6.3 Exemptions From Review Policy

Activities described in the *Exempt Determination Request* that are found to be research may still be exempt from IDPH IRB review and approval if they fall into one of the exempt categories in the *Illinois Department of Public Health Policy on Protection of Human Research Subjects and 45 CFR 46*. Exempt research activities are entered into the IRB database, but are not subject to annual review. However, the investigator is notified at the time of the initial exempt determination that if the activity changes in a manner such that it may no longer be exempt, he/she must update the *Exempt Determination Request* and submit it to the IRB. If information on the form indicates the study is no longer exempt, the investigator must submit a *Request for Expedited Review of Research* for expedited or full board review.

4.6.4 Findings Required by Regulation

Upon conditional approval or approval of a project reviewed by either expedited or full board procedures, the IRB Manager will complete a *Documentation of Findings* form. This form includes information abstracted from the proposal submitted by the investigator as well as the results of the review of the proposal. The form meets requirements in 45 CFR 46 and 45 CFR 164.512(i) for

documenting the findings and actions of the IRB, including:

- Project title, principal investigator and primary reviewer;
- Type of review conducted and approval date;
- Justification for expedited review, if applicable;
- Period of IRB approval;
- Level of risk to subjects;
- Additional protections for pregnant women and human fetuses involved in research, if applicable (45 CFR 46, Subpart B);
- Additional protections for prisoners involved in research, if applicable (45 CFR 46, Subpart C);
- Additional protections for children involved in research, if applicable (45 CFR 46, Subpart D);
- Waiver of some/all elements of consent for study participation, if applicable (45 CFR 46.116(d));
- Waiver of written documentation of consent; oral consent will be obtained, if applicable (45 CFR 46.117(c));
- Waiver of parental permission for study participation of a child, if applicable (45 CFR 46.408(c));
- Waiver of authorization for disclosure of individually identifiable private information and/or protected health information, if applicable (45 CFR 46.116(d)); 45 CFR 164.512(i).

The completed *Documentation of Findings* form is signed by the IRB Chair, a copy is mailed to the investigator and/or the IDPH staff with the IDPH IRB approval letter, and the original is filed in the project file.

4.6.5 Review by Another IRB

In the course of review, the IRB may request documentation of study approval by the funding agency's IRB, from the IRB of the investigator's home institution, or from other IRBs which retain jurisdiction over the research. Such documentation is included in the project file maintained in the IRB.

5.0 REVIEW PROCESS

5.1 Determining if an Activity Requires IDPH IRB Review and Approval

Activities that include many of the features of research may not necessarily require review and approval by the IDPH IRB. Some activities resemble research but actually are not research as defined in the federal regulations. Other activities meet the definition of research but are exempt from needing IDPH

IRB review and approval.

5.1.1 Research Versus Non-research Activities

Research is defined in the federal regulations (45 CFR 46.102d) as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” There are a variety of activities that employ many of the features of research, such as rigorous design, systematic data collection and statistical analyses, which are nevertheless not considered research under this definition. The key to distinguishing between research and non-research activities is to determine the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of similar activities that are not research may be to prevent or control disease in a population or to identify methods of improving services to a group of clients or customers.

Some activities conducted by or on behalf of institutions which involve systematically collecting and analyzing data are not research. Included in this category are audit activities, resource and/or drug utilization studies using institutional records, and client outcome monitoring in which individual level data are routinely collected and analyzed to determine the extent to which clients are experiencing the intended outcomes of a program. Client satisfaction and needs assessment surveys, which only collect information from clients who are eligible to receive program services also are included in this category. If the primary intent of these activities is to support the administration of the program, and if data collection is limited to information needed to administer the program, these activities are not considered research. The HIPAA Privacy Rule classifies such activities as part of “health care operations” and not research. However, identifiable data collected through such activities could be used secondarily for research, in which case IDPH IRB review and approval would be required.

Program evaluation, surveillance activities, disease investigation and/or emergency response activities, and quality assurance and/or quality improvement are activities that may or may not constitute research requiring IRB review. The IDPH IRB uses the following guidelines to determine when activities in these categories constitute research that requires IRB review and approval:

- Program evaluation activities in which the primary intent is to assess the success of an *established* program or intervention in achieving its objectives in a specific population, and in which the information gained will be used only to provide feedback to the program, to ensure service quality, or to make improvements in the program, are not considered research. However, when the primary intent is to test a new, modified, or previously untested intervention, service or program in a defined population to determine whether it is effective, the evaluation is research. The systematic comparison of standard or nonstandard interventions in an experimental-type design also is research.
- Surveillance activities that involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in a population and that are authorized by state statute or regulation which specify the intent of the activity, its purpose, and uses of the data, are not considered research. Quality control activities that assess, for example, completeness of reporting of surveillance data by matching case records with records from other databases are not considered research. However, when health-related data are collected in surveillance systems and analyzed with the primary intent to produce knowledge applicable to other

populations and settings from which the data were collected, or to contribute to new knowledge about the health condition, the activities are likely to be research. Surveillance systems that involve longitudinal data collection systems (e.g., follow-up surveys and registries) that allow hypotheses testing, which collect more information than the occurrence of a health-related problem, in which etiologic analyses can be conducted, or in which cases may be identified to be included in subsequent studies, are likely to be research.

- Disease investigation and/or emergency response activities authorized under state statute or regulation that are undertaken to identify, characterize and solve an immediate health problem, and in which the information gained will directly benefit those participants involved in the investigation or their communities, are not considered research. However, when biological samples are stored for future use intended to produce generalizable knowledge, or when additional analyses are conducted beyond those needed to solve the immediate health problem, the activity may have a research component. When investigational new drugs or devices are used, or when drugs are used off-label, the activity is almost always considered research. Whenever a systematic investigation of a nonstandard intervention or a systematic comparison of standard interventions occurs, the activity is research.
- Quality assurance and/or quality improvement activities in which existing individual level data are collected and analyzed and in which there is a formal commitment in advance of data collection to a corrective action plan related to any of a number of possible outcomes of the analysis are not considered research. However, prospective interventional activities, which may involve systematic comparison of standard or nonstandard therapies, are considered research even when conducted by the entity responsible for quality assurance and/or quality improvement.
- Activities conducted for educational purposes may fall into a category that would not be considered research if the activity was not conducted primarily for educational purposes. For example, the design of a thesis or dissertation project might be classified as program evaluation or a quality improvement activity rather than research if it was being conducted primarily to support the administration of a program or to develop a corrective action plan. However, as the primary intent of the activity is related to training in research methods in partial fulfillment of requirements for an advanced degree, the educational activity is considered research.
- In consultation with IDPH program staff, investigators may consult with the IRB Chair of the IRB if they have questions about whether a specific activity is considered research.

5.1.2 Research Exempt From Review

Once an activity is determined to be research, a determination should be made as to whether the activity involves human subjects as defined in the federal regulation. Human subject means “a living individual *about whom* an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

If the activity is determined to be research that involves human subjects, a determination should be made about whether the research falls into a category of research that is exempt from needing review and approval by the IDPH IRB. To qualify for exemption from IDPH IRB review, a research proposal must fall into one of the categories that are listed in Section XI of the *Illinois Department of Public Health*

Policy on Protection of Human Research Subjects and 45 CFR 46.101(b).

5.1.3 Procedures for Determining if an Activity Requires IDPH IRB Review and Approval

IDPH does not require investigators to seek a formal determination of "exempt" from the IDPH IRB when the activity clearly falls outside common rule and FDA definitions of human subjects research and other requirements including Illinois statutes and regulations. Investigators may consult informally with IRB staff to facilitate a self-determination. Investigators may alternatively request from the IRB explicit exempt/not exempt determinations in cases that do not fall clearly into the category of non-research activities, rather than making an assumption that may later be determined to be incorrect. Requests for an explicit determination will be made through the research application process. Contact should be made at least 60 days prior to any planned contact with potential subjects or access to individually identifiable personal records. After discussion with the IRB staff, the agency employee or outside investigator will be advised whether to submit an *Exempt Determination Request* to the IRB. IDPH staff and outside investigators will be informed in writing about whether the planned activity requires submission of an application for review and approval by the IDPH IRB.

5.2 Research Application Submission Procedures

Investigators planning to submit a proposal to the IDPH IRB should contact IDPH Responsible Individuals to discuss their proposed research before completing and submitting their application for review. Detailed information about submission procedures is available in *Instructions for Extramural Investigators*. Investigators not affiliated with IDPH must sign an *Investigator Agreement* and submit it with their application to the IDPH IRB. The investigator's home institution may be permitted to rely on the IDPH IRB if they have an IRB Authorization Agreement with IDPH.

5.2.1 Research Application Forms

Research proposals must be submitted on the official *Application* available on the IRB's website: <http://www.idph.state.il.us/irb/>. Investigators may cut and paste relevant information from project narratives developed for applications to a federal, public or private funding source into the IDPH IRB *Application*. However, investigators must follow the instructions the application forms and provide all the required information. In general, the narrative sections of the application should be no more than several pages in length. However, the research application must be complete, and must include all relevant appendices and data collection instruments. HHS regulations at 45 CFR 46.103(f) require institutional certification that the proposed research has been reviewed and approved by the IRB when research is supported by a federal department or agency. In order to be in compliance with the regulations, investigators must submit copies of the federal grant proposal with the application for IRB approval.

5.2.2 Submission Timelines

Full Board Review: Research applications requiring full board review must be submitted as Word or searchable pdf files to DPH.IRB@Illinois.gov state.il.us by the published deadline date for each board meeting, which is posted on the IRB website. IDPH program staff will contact investigators within two weeks regarding any recommended revisions to the application. When requested by IRB staff,

investigators should make revisions within one week, and submit a revised application with original signatures (and, if requested, paper copies) to the IRB for distribution to the full IRB.

Expedited Review: Research applications that qualify for expedited review may be submitted to IRB at any time. Research applications eligible for expedited review must be submitted as Word or searchable pdf files to DPH.IRB@illinois.gov. IDPH program staff will notify investigators within two weeks of any revisions needed in the application. The IRB Chair may request additional revisions. Investigators will then be asked to submit a revised application with required signatures (and only if requested, paper copies) to the IRB.

5.2.3 Nonscheduled Review

At the discretion of IRB staff, nonscheduled reviews of proposals that do not qualify for expedited review may be conducted by teleconference. Reviews conducted by teleconference are subject to the same quorum requirements that apply to regularly scheduled meetings of the IRB.

Nonscheduled reviews are limited to the following:

- Initial review of a proposal, or review of an investigator's response to the board's review issues when consideration of the proposal has been deferred at a scheduled meeting, when delay until the next regularly scheduled board meeting would make the conduct of the proposed research difficult or impossible or would unacceptably affect the soundness and integrity of the ongoing research;
- IRB consideration of any *Unanticipated Problems and/or Adverse Events* reports involving risks to subjects or others, or serious and continuing noncompliance with board-approved procedures.

Investigators who believe their circumstances justify IDPH IRB consideration through a nonscheduled review process may contact the IRB staff to request a nonscheduled review.

5.2.4 Cooperative Review

The IDPH IRB may, at its own discretion, establish *IRB Authorization Agreements* to reduce the number of proposals that require review by more than one IRB when the research is in the jurisdiction of more than one institution.

5.2.5 Reliance on the Review of Another IRB

Procedures are available for the home institution of an investigator who is submitting an application to the IDPH IRB to rely on the IDPH IRB review rather than to conduct their own IRB review of the research. These procedures are intended to minimize redundant reviews and to conserve time and resources for both the investigator and IRB members and staff. Establishing an *IRB Authorization Agreement* documents an arrangement in which one institution relies on the review of an IRB at another institution for a single research proposal or group of research proposals. This agreement must be signed by the signatory official of each institution and kept on file at the IRB offices of the respective institutions.

In some instances, the IDPH may rely on the review of an IRB at another institution. An example would be a situation in which IRB review is required for the use of a non-approved device or drug in a

surveillance activity or an emergency disease investigation. If a central IRB has authority to conduct such a review on behalf of local study sites, IDPH may elect to rely on that review to expedite early implementation of the protocol in the field. The IRB Chair will make the determination about whether to rely on the review of another IRB.

If a decision is made to rely on the review of another IRB, the application submitted to the reviewing IRB must be submitted to the IDPH IRB, along with documentation of IRB approval and of any restrictions or conditions on the research imposed by the reviewing IRB. If the IDPH IRB is satisfied with the review done by the home institution, the IRB will initiate establishment of an *IRB Authorization Agreement* between the investigator's home institution and IDPH in whose jurisdiction the research would be conducted. If the IDPH IRB is not satisfied with the home institution IRB review, the proposal will be referred to the IDPH IRB for independent review. If relying on the home institution IRB review, the research may not commence in the IDPH until the *IRB Authorization Agreement* has been signed by the respective institutional officials and additional IDPH requirements have been met. The IRB will open a project file for the research reviewed by another IRB. *Progress Reports* submitted for continuation review and documentation of continuation approval will be requested from the reviewing IRB by the IDPH IRB.

5.2.6 "Just-In-Time" Review Procedures

Applications for federal funding for research may qualify for "just-in-time" review procedures. Under these procedures certification of IRB approval is not required at the time of application for federal funding, but may be deferred until just prior to an award being made, but at least 60 days prior to contacts with potential human subjects. Investigators should verify with their federal project officer that "just-in-time" procedures will apply to their grant application. If so, investigators should submit their proposal for IDPH IRB review when they are informed that the application for federal funding has received a score in the fundable range, or when they learn that the proposal may be funded.

5.2.7 Human Subjects Protection Training Requirements

The IDPH training requirements are grounded in federal recommendations and reflect a belief that appropriate education and training is an important component of an effective system of human subjects protection.

All principal investigators and co-principal investigators submitting new research proposals to the IDPH IRB must have completed training in human subjects protection before their research will be approved. All research staff who have contact with human subjects and/or identifiable records (e.g., interviewers and data analysts) also are required to complete the training before they will be authorized to have contact with human subjects or identifiable records. Refresher training is required every three years. If their training is more than three years old, investigators of ongoing research projects must complete refresher training before continuation approval for their research will be extended. Research staff of ongoing research projects must complete refresher training before they will be authorized to have continued contact with human subjects and/or identifiable records.

Investigators may satisfy this education and training requirement by:

- Completing a course in the protection of human research subjects at their home institution and

submitting to the IRB written documentation of the training and the date it was completed;

- Successfully completing the tutorial offered by the NIH Office of Extramural Research, [Protecting Human Research Participants](#), or the Spanish language version [Protección de los participantes humanos de la investigación](#).

5.2.8 Applications that Request Use or Disclosure of Identifiable Confidential Records

Some existing state statutes and regulations have established criteria for defining what constitutes an identifiable record. In general, an individual record must meet requirements in [45 CFR 164.514\(b\)\(2\)](#) to be considered not individually identifiable. Either a) all 18 data elements listed in 45 CFR 164.514(b)(2)(i) must be removed from the record; or b) a statistician, using generally accepted statistical and scientific principles and methods, must document that the risk is very small that the information could be used alone or in combination with other reasonably available information (by the anticipated recipient) to identify the subject of the information. The determination should take into account existing best practices for balancing confidentiality and data use. The statistician must document the methods and results of the analysis that justify such a determination. This determination must be accepted by IDPH.

Use and/or disclosure of individually identifiable confidential records and/or protected health information for research purposes requires the written consent and, if required by HIPAA, authorization of the person to whom the information pertains. In some situations, however, it may be impractical to obtain written consent or authorization for the research use or disclosure. In this case, the investigator may ask the IDPH IRB to approve a waiver of the consent and if required by HIPAA, a waiver of authorization. The IDPH IRB can approve such waivers only if requirements in applicable statutes and regulations are satisfied.

Requirements that must be met for the IDPH IRB to approve a waiver of consent or authorization depend on the information that is being requested. The most common applicable laws and regulations that must be satisfied are:

- All requests for research use and/or disclosure of identifiable personal record information and/or protected health information must satisfy the requirements in 45 CFR 46.116(d);
- All requests for research use and/or disclosure of protected health information by covered programs at IDPH must satisfy the requirements in 45 CFR 164.512(i);
- All requests for research disclosure of identifiable personal information (including protected health information) from IDPH must satisfy the requirements in relevant statutes and rules.

Applications require investigators to provide information needed by the IDPH IRB to determine whether requirements for the waivers can be satisfied. Investigators requesting information subject to other requirements in law or regulation are advised to provide information to allow the IDPH IRB to determine that those requirements have been met.

Disclosure of identifiable personal record information held by IDPH for research purposes is subject to the establishment of a *Data Use Agreement*. This agreement is sent to the investigator for signature

after the IDPH IRB approves the research proposal. After signing the agreement, the investigator must return it to the IDPH Responsible Individual. The IDPH Responsible Individual will provide an electronic copy of the executed agreement to the IRB staff for filing. The agreement remains in effect until all terms of the agreement, including permanent destruction of the ability to identify the records disclosed, have been satisfied.

Identifiable personal record information may be used only for purposes that are described in the *Data Use Agreement*. Investigators are not authorized to re-disclose or provide access to the record information to other individuals or organizations without the prior written approval of the IDPH IRB. Investigators are not allowed to link IDPH data with other data, attempt to de-identify identifiable personal record information for the purpose of re-disclosing, public release, or providing access to the record information without the prior written approval of the IDPH IRB.

Use of record information for thesis, dissertation or other educational purposes not described in the original proposal approved by the IDPH IRB must be submitted for review and must receive prior approval before student use of the personal records will be authorized. Any such unauthorized use or disclosure of personal records is a violation of terms of the confidentiality agreement. The principal investigator will be held accountable for each violation.

5.3 Review and Approval Considerations

The IRB is guided by federal regulations, the Belmont Report, institutional policies, applicable state laws and regulations, and the *Illinois Department of Public Health Policy on Protection of Human Research Subjects*. Review also must include consideration of local laws, regulations and policies that may apply to the research activity. In Illinois, laws that may apply to research include abuse reporting, mandatory disease reporting, disclosure of information about HIV testing or treatment for STDs, and release of identifiable information.

The *IDPH IRB Review Guide* provides a comprehensive checklist of issues relevant to human subjects protection review. Primary reviewers should complete the *IRB Review Guide* for their assigned proposal and turn it in to the IRB. The IRB Review Coordinator will make copies and distribute the *IRB Review Guide* summary checklist to members at the meeting.

The following review criteria are carefully considered in the IDPH IRB review of research proposals.

5.3.1 Study Design and Scientific Merit

The Data Release and Research Committee initiates the review with an assessment of the overall scientific merit and the logical and technical soundness of the proposal. The proposal should discuss the relevant literature or describe the context in which the study will occur to provide an adequate conceptual framework. The objectives, research questions and/or hypotheses of the study should be clearly stated, and the proposed methods and study instruments should produce data relevant to the study objectives, and be consistent with the goals of advancing scientific knowledge and public health. Plans for data analysis should be well-defined and likely to produce results related to the study purposes, objectives and hypotheses. The investigator should have appropriate qualifications to conduct the project, or adequate supervision by a qualified professional if the investigator is a student.

5.3.2 Benefits and Risks

The IRB continues the review with an assessment of the overall ethics of the proposal. A fundamental task in the board's review of proposals is to balance the anticipated benefits and risks of the research activity. Benefits accruing from research may include direct, personal benefits to the participants, such as increased medical oversight of a condition or disease, or the opportunity to obtain treatments, assessments and/or services not otherwise available. Benefits also include general societal benefits in the form of new scientific or applied knowledge. Compensation to participants is not considered a benefit in the risk/benefit analysis, nor is the fact that participants may find it rewarding to participate. Risks include any research activities that potentially may harm the research participant psychologically, physically, socially, economically, legally, or otherwise. Risks may range from physical injury from biomedical or pharmaceutical research to mere inconvenience from participation in survey research. In assessing risks inherent in a proposal, reviewers will consider both the magnitude and probability of the harm occurring. If the balance between risks and benefits is unfavorable, the IRB will explore options for reducing risks and/or increasing benefits.

5.3.3 Selection of Participants

Research proposals should clearly define who will be enrolled as subjects in the research and explain why these subjects are being selected. Justification for inclusion and exclusion criteria are reviewed carefully to determine if subject selection is equitable and appropriate for study objectives. Justification must be provided for limiting subject population to an ethnic group, gender or age. The IRB will consider whether participants will share benefits in proportion to burdens imposed by the research.

5.3.4 Vulnerable Participants

If vulnerable populations are included, the IRB will consider whether the research could be done with a non-vulnerable population or whether additional safeguards are necessary to protect vulnerable subjects. Federal regulations for the protection of human subjects (45 CFR 46) require additional protections for the inclusion of pregnant women and fetuses (Subpart B), prisoners (Subpart C), and children (Subpart D) in research. Other vulnerable populations that may require additional safeguards include persons that are decisionally-impaired, disabled, institutionalized, and/or socially or economically disadvantaged.

5.3.5 Participant Recruitment

The IRB will examine the procedures for identifying, contacting and recruiting potential participants. Unless otherwise specified, investigators should not make first contact with potential participants identified using IDPH data. If the investigator proposes to identify and sample the study population from confidential state agency records, contact must first be made by agency employees and individuals must be provided, at a minimum, the option of refusing further contact regarding the research. Recruitment procedures must be free of coercion or undue influence and must present information in a format and language that the intended population can understand.

5.3.6 Informed Consent

The informed consent process must ensure 1) that adequate information is provided, 2) that comprehension is verified, and 3) that participation is voluntary. The review will consider the

appropriateness of the individual(s) who will obtain consent, as well as the location and timing of the consent process. The investigator must provide complete information about the proposed research and the individual's role in the research in an environment and manner that is free of coercion or undue influence and in a format and language that potential subjects can understand. Consent/assent documents must contain all required consent elements, and be written at an appropriate reading level and language for the intended study population.

Research proposals involving vulnerable populations merit special consideration to determine whether subjects are capable of understanding the research and providing informed consent, and to minimize the potential for coercion or undue influence in the consent process. The IRB must ensure that there are adequate safeguards in place to protect the interests of vulnerable subjects, i.e., requiring a consent witness or subject advocate. Assent to participate in research generally is required from persons who are decisionally-impaired and/or legally incompetent, as well as children less than 18 years of age. In addition, permission must be obtained from parents, legal guardians, or family members who may legally provide consent, and, in some cases, from the social worker assigned to potential subjects.

Waivers or alterations of consent requirements may be approved by the IRB provided the conditions delineated in 45 CFR 46, the HIPAA Privacy Rule, and other relevant federal regulations, state statutes and rules, when applicable, have been documented to the satisfaction of the IDPH IRB. The general requirement for written (i.e., signed) consent may be waived if conditions in 45 CFR 46.117(c) are satisfied.

If signed consent is waived, verbal consent (e.g., in the case of telephone surveys) or implicit consent (e.g., in the case of mailed surveys) must be obtained. State laws which allow minors to obtain family planning services, treatment for STDs, outpatient substance abuse treatment and outpatient mental health treatment without parental permission, may help justify waiver of parental permission for participation in research related to these services. However, requirements for waiver of parental permission in 45 CFR 46.408(c) also must be satisfied.

5.3.7 Privacy and Confidentiality

The IRB will carefully consider possible risks to participant privacy and confidentiality in all phases of the proposed research: sampling, recruitment, consent procedures, and proposed methods and setting for data collection. The IRB may require alterations in the proposed study to minimize privacy and confidentiality risks. Research that may pose special concerns may include surveys or interviews in which sensitive information regarding the subject's personal experiences or behavior is collected, genetics research, and/or research which collects personal information or physical specimens for possible future use in unspecified research may be retained.

5.4 Procedures: Initial Full Board Review of Research

5.4.1 Pre-review Procedures

Research proposals requiring full board review are pre-reviewed before being placed on the agenda of a convened meeting of the IRB. Pre-review is intended to determine if the proposal is complete, responsive to instructions in the application forms, and ready for full board review with a relatively low chance of approval being deferred. Pre-review is conducted by IRB staff using the completed electronic

application submitted by the investigator that has been approved by the IDPH Responsible Individual. IRB staff will communicate by e-mail to the investigator. The investigator will be asked to incorporate responses to the pre-review issues and/or concerns into a revised research application.

Pre-review is an administrative review process and does not represent an official review by the IRB. The investigator is free to accept or to reject the advice provided in the pre-review. However, the intent of pre-review is to alert the principal investigator to issues that are likely to be raised in the IRB review, and failure to respond to the pre-review issues before the board meeting could delay approval of the proposed research.

Investigators are allowed seven calendar days to submit an electronic copy of the revised research application to the IRB. At the same time, the IRB must receive a clean, revised research application with all required signatures at least one week in advance of the convened meeting.

Investigators are asked to be available by telephone during the time their proposal is discussed in the meeting. If questions arise that cannot be answered, the review coordinator will contact the investigator and patch him/her into the meeting by conference call.

If a proposal is unusually complicated, or if considerable uncertainty or concerns exist about critical aspects of the research, the investigator may be invited to attend a subsequent board meeting to provide additional information or to respond to specific review concerns. Investigators may request to attend initial or subsequent meetings to provide information about their proposal. The investigator must leave the meeting prior to the discussion and disposition vote by the board.

5.4.2 Board Meeting Review Procedures

Board members with any conflict of interest with the proposal under review will be expected to abstain from voting. If the conflict is significant (e.g., the board member is the principal investigator or a member of the research team), the member will be expected to recuse himself/herself from the discussion of the proposal and leave the room.

The primary reviewer uses the *IDPH IRB Review Guide* to present the proposal to the IRB at the convened meeting. While the *Review Guide* provides a comprehensive list of topics to be considered in reviewing human subjects research, only those issues that raise concerns need to be presented by the primary reviewer. After summarizing the risks to subjects in relation to the benefits of the research, the primary reviewer will make a motion for disposition of the proposal. When the motion is for approval or conditional approval, the primary reviewer also will recommend the length of the approval period based on criteria discussed in Section 5.6.

After a motion is made and seconded, the Chair will recognize other board members who wish to make comments about the risk/benefit ratio of the proposed research. (Note: consideration of risk/benefit ratios implicitly involves consideration of issues related to the integrity of the study design.) Other members who wish to speak to the same question will be recognized, in turn, by the Chair. When comments about risk/benefit ratios are concluded, the Chair will ask if any members wish to speak to issues related to recruitment, consent and/or waiver of consent, and will recognize members in turn. Finally, the Chair will ask if any members wish to speak to issues related to general study methods and procedures, data collection instruments and procedures, and language in consent documents. The Chair

may then open the floor to general discussion.

After deliberation, the Chair will ask the primary reviewer if he/she wishes to amend or withdraw the motion on the floor. If the primary reviewer withdraws the motion on the floor, he/she will be asked if he/she wishes to introduce a new motion. The Chair will then ask any other members if they wish to amend the motion on the floor. With the assistance of the IRB Manager, the IRB Chair will then restate the motion, including any amendments, before the formal vote is taken. Disposition of the proposal is determined by a simple majority vote of members present. The IRB Chair votes only to break a tie. If the motion does not pass, the floor is open to disposition motions introduced by other board members. The process continues until the board has approved a disposition motion by a simple majority of members present at the meeting. Disposition options include: approve, conditionally approve, defer consideration, disapprove, suspend approval, and terminate approval, and are further described in the *Members' Handbook*.

5.4.3 Procedures for Reporting Review Findings to Investigators and to Agency Administrators

Following the meeting, the IRB Review Coordinator will prepare in writing the board's disposition decision and any remaining review issues and/or required revisions for transmission to the investigator. Upon request, the primary reviewer, and any other member in attendance at the meeting who asks, may review and comment on draft board correspondence before it is mailed to the investigator. Board correspondence is mailed to investigators no later than five working days after a scheduled board meeting. If a proposal is granted approval or conditional approval, the IRB Manager, with the assistance of the IRB Review Coordinator completes the *Documentation of Findings* form and includes it in the project file. This form is attached to and becomes a part of the minutes.

If a proposal is not approved at the meeting, investigators must submit a substantive response to the stipulated approval conditions or to the review issues raised during review of his/her proposal within 90 days of the review. The IRB will e-mail the investigator about two weeks prior to the 90-day deadline to inquire if a response will be submitted. If no response is received, the proposal will be canceled, and the investigator will be required to submit a new research application for review at a convened meeting.

If a proposal is conditionally approved at the meeting, the investigator's response to the IRB will be reviewed by the IRB Manager and the IRB Chair. Board members with special expertise in the subject area of the research may be asked to join the review, and any member may request to participate in the review.

If the investigator's response satisfies the approval conditions stipulated by the IRB, an approval letter is drafted by the IRB Review Coordinator for signature by the IRB Chair. The IRB Responsible Individual will receive copies of the approved proposal, and the *Documentation of Findings* which documents that all statutory and regulatory requirements for conducting the research have been met. A portable document format (PDF) of the approval documents also are sent to the investigator. Copies are sent to Deputy Directors in offices affected by the research, and are filed in the project file.

The final approval letter informs the investigator of the following:

- The approval/anniversary date, determined by the date of the IRB meeting at which the proposal was granted approval or conditional approval;

- The approval period determined by the IRB at the time of approval. A *Progress Report* is required before the anniversary date if the project extends past the approval period;
- That no changes in study purposes, design or methods may be initiated prior to review and approval by the IRB, except when necessary to eliminate apparent immediate hazards to the subject;
- That adverse events and unanticipated problems involving risks to subjects or others must be reported promptly to the IRB;
- That study completion requires submission of a final report.

Included with the approval letter will be the following:

- Copies of all board approved consent and assent forms, recruitment and consent scripts, and contact letters, stamped with the period of approval;
- The *Documentation of Findings* form, which specifies the board's findings with respect to level of risk, length of approval period, special protections for vulnerable populations, and the approved rationale for waiver of consent or authorization, if applicable.

If action on a proposal is deferred during the meeting due to unresolved issues and concerns or incomplete information, the investigator will be instructed to address the review issues and incorporate them into a revised application for review at the next convened meeting of the IRB. An electronic copy of the revised application will undergo pre-review to determine if it is ready for resubmission to the full board.

5.5 Procedures: Initial Expedited Review of Research

To qualify for expedited review, a research proposal must incur no more than minimal risk for participants and must involve only one or more of the activities that are listed in Section X of the *Illinois Department of Public Health Policy on Protection of Human Research Subjects*.

When discussing research plans with investigators prior to submission of the application for review, IDPH Responsible Individuals will generally be able to determine whether the proposal qualifies for expedited review. Incoming proposals are screened by IRB staff to ensure they meet expedited criteria and that they are reasonably complete, responsive to instructions in the application forms, and ready for review, before they are assigned for review.

If a proposal is eligible for expedited review, the IRB Chair or his/her designee(s) will review the proposal.

If two reviewers are assigned by the Chair and disagree over the disposition of a proposal, the IRB Chair will become a third reviewer and the majority decision will prevail. Expedited reviewers may use the *IDPH IRB Review Guide* and should apply the same review criteria to proposals as in a full board review. Expedited reviewers may exercise all the authorities of the IRB, and review disposition options are the same as in full board reviews (See Section 5.4.2), except that proposals may not be disapproved through

the expedited process. If expedited reviewers believe that a proposal should be disapproved, it will be placed on the agenda for consideration at the next convened meeting of the IRB.

Following the review, the IRB Manager will prepare in writing the board's disposition decision, including approval conditions, any remaining review issues, and/or required revisions, for transmission to the investigator. Investigators can expect to receive board correspondence within several days of the expedited review. If the proposal is granted approval or conditional approval during the initial expedited review, the IRB Manager completes the *Documentation of Findings* and includes it in the project file.

If a proposal is conditionally approved by expedited review, the investigator must incorporate a response to the IRB's approval conditions in a revised application and submit the revised application with all required signatures to the IRB. The IRB Manager will review the revised application. If the IRB Manager determines that the investigator's response satisfies the approval conditions stipulated by the IRB, the IRB Review Coordinator will draft an approval letter for the IRB Chair's signature. The approval date for the study is the date of the initial expedited review. Procedures for reporting IRB findings to investigators and to agency administrators are the same as for full board reviews.

If a decision regarding an application is deferred during the expedited review conference due to unresolved issues and concerns or incomplete information, the investigator will be instructed to address the review issues and incorporate them into a revised application submitted electronically for review at another expedited review conference. If instructed, the investigator should submit an original revised application with all required signatures and two paper copies to the IRB. The revised application will then be scheduled for another telephone review conference. The approval date for the study is the date of the expedited review conference at which the proposal is either approved or conditionally approved.

If a proposal is not approved at the expedited review conference, investigators must submit a substantive response to the approval conditions stipulated or review issues raised *within 90 days of the review*. The IRB will e-mail the investigator about two weeks prior to the 90-day deadline to inquire if a response will be submitted. If no response is received, the project file will be canceled, and the investigator will be required to submit a new research application for subsequent expedited review.

5.6 Criteria for Determining Frequency of Continuing Review

During the initial review of the research proposal, the IRB considers a number of factors in establishing the period of approval for the study. The length of approval in turn establishes the frequency of continuing review. Criteria that are used in making this determination include, but are not limited to, the following:

- The nature of the study;
- The degree of risk involved;
- The vulnerability of the study population;
- Evidence of noncompliance with IRB requirements and/or any applicable policies, laws, or

regulations.

Investigators are informed of the study approval period for their research in their original approval letter, and in their continuation approval letters, from the IRB.

5.7 Continuing Review of Research

Principal investigators of ongoing research projects are required to submit a *Progress Report* for continuing review at intervals commensurate with the degree of risk posed by the research, but not less than once per year, as determined by the IRB. Continuing review of research is conducted by the convened IRB, with recorded vote on the disposition, unless the research is eligible for expedited review. Generally, if research did not qualify for expedited review at the time of initial review, it will not qualify for expedited review at the time of continuing review until all contacts with subjects are completed.

5.7.1 Submission of *Progress Reports*

The IRB Review Coordinator notifies investigators by e-mail of the need to submit a *Progress Report* for continuation review and approval. The investigators are to submit *Progress Reports* at least four weeks prior to the expiration date of the current IDPH IRB approval. However, if any unanticipated problems or adverse events occur during the current approval period or if there are any changes to the protocol that would require a full board review then investigators are to submit *Progress Reports* and the other relevant documents eight weeks prior to the expiration date of the current IDPH IRB approval. *Progress Reports* eligible for expedited review are reviewed outside the meeting but are placed on the agenda of the convened meeting for information only.

Progress Reports must be submitted on the *Progress Report* form available at: <http://idph.state.il.us/irb>. *Progress Reports* may be submitted as Word files by e-mail attachment to DPH.IRB@illinois.gov.

Investigators are required to submit the following information in their *Progress Report*:

- The current status of the project in terms of whether recruitment and enrollment is ongoing, whether contacts with subjects is completed, or whether the study involves only use of existing records;
- A general overview of study activities to date;
- Study amendments implemented since the initial review for new studies or the previous continuation review for ongoing projects;
- The number of subjects targeted for enrollment during the entire study, the number approached for participation since the last review, the number of subjects who declined, were ineligible, currently enrolled, and the cumulative total of subjects enrolled to date;
- Any new literature, findings, or other relevant information that may affect study goals, objectives, procedures, and/or risks to participants;

- A description of any adverse events or unanticipated problems, including problems with recruitment, retention, field activities and complaints about research;
- A summary of remaining study activities to be conducted;
- The estimated study completion date;
- Information on who has access to confidential records for the research;
- Copies of recruitment and consent documents, if contacts with subjects are ongoing;
- List of staff having contact with human subjects or identifiable records and dates of latest human subjects protection training;

Research involving only the secondary use of identifiable records in which no subjects were directly recruited and enrolled are not required to provide information on the numbers of subjects.

Staff training in the protection of human research subjects must be current (within three years) in order for continuation approval for their research to be approved.

For completed studies, investigators also must submit a copy of a final report. If the study requires a *Data Use Agreement* for disclosure of identifiable records, investigators must provide written assurance that all terms of the agreement have been satisfied. Usually this requires written certification that all data elements that could directly or indirectly identify individuals have been permanently removed and destroyed.

5.7.2 Procedures for Continuing Review

When a *Progress Report* arrives at the IRB, the IRB Review Coordinator screens each for completeness, reviews the corresponding project file, and evaluates the project's conformity with board-approved procedures. Consent forms submitted with the *Progress Report* are compared to board-approved forms and deviations from the approved forms are noted. Project staff training in human subjects protection is reviewed to determine it has been completed within the last three years. Any deviations from board-approved procedures are noted in a report provided to the IRB Manager. If deviations from approved procedures are noted and/or if training is out of date, the IRB Review Coordinator will contact investigators and work with them to submit information necessary to bring the project back into compliance.

Following initial review by the IRB Review Coordinator, the IRB Manager conducts his/her own review of *Progress Reports* and project files prior to the scheduled board meeting. Any information needed to allow continuation approval in the meeting is solicited from the investigator prior to the meeting. As necessary, the IRB Manager consults with the IRB Chair (or for full reviews, the primary reviewer) prior to the meeting to provide feedback regarding recruitment and consent documents, and any issues that arose during review of the project file, and or discussions with the investigator.

Full Board Continuing Review: *Progress Reports* for research reviewed by the full board during initial review are reviewed by the full board for continuing review, unless the research is permanently closed to the enrollment of new subjects and all contacts with subjects for research purposes have been

completed, or meet criteria for expedited review. Full board continuing review generally is conducted by the original primary reviewer (if available). The primary reviewer and all IRB members receive a copy of the complete *Progress Report* and current consent forms. The IRB staff and primary reviewer have access to the project file, and have copies of all recruitment and consent documents and published articles submitted with the *Progress Report*.

The primary reviewer presents the *Progress Report* to the IDPH IRB at a convened meeting prior to the anniversary date. The primary reviewer provides a brief overview of the research and progress made over the past year, the number of subjects accrued, any changes in risks or benefits to subjects, a summary of any recent literature, any interim findings, and amendments or modifications to the research since the last review. Unanticipated problems and/or adverse events or concerns regarding conduct of the research are discussed, and remaining study activities are noted. Following presentation, the primary reviewer makes a motion regarding continuation approval and the IRB votes on disposition. The motion will include recommendations for revising the consent form based on changes in risks, and changes in the period of approval, as applicable.

Expedited Continuing Review: *Progress Reports* for research reviewed under expedited review authority during initial review generally are reviewed under expedited authority for continuing review, provided there have been no serious or unanticipated events, or changes in procedures that could increase risk to participants. Certain categories of research originally reviewed by the full board are eligible for expedited review if they meet the relevant criteria. Expedited continuing review is conducted by the IRB Chair or his/her designee prior to the project's expiration date. *Progress Reports* reviewed under expedited review are included in the next IRB meeting distribution materials and listed on the meeting agenda for informational purposes. Any IRB member who has questions about a *Progress Report* eligible for expedited review should contact the IRB prior to the meeting, but also may raise issues or questions in the meeting.

No Evidence of Progress: If the *Progress Report* includes no evidence of progress toward completion of the research for two consecutive years, the IDPH IRB may extend continuation approval for less than one year, and will ask the investigator to submit a *Study Amendment Request* describing detailed plans to complete the research and a firm date for completion. If the *Study Amendment Request* is approved, the investigator will be expected to complete the research by the specified date, with extensions beyond that date subject to approval by the full IRB. If the *Study Amendment Request* is not approved before expiration of continuation approval, study approval will expire. After study approval expires, the investigator has 30 days to reinstate study approval or approval is permanently canceled.

Continuing Review Dispositions: Disposition options for continuing review of research parallel the disposition options for initial review, listed in Section 5.4.2. However, as research undergoing continuing review already has an approval period established with an anniversary date at which approval expires, the implications of various dispositions are different than during initial review, as follows:

- Projects that receive conditional continuation approval must receive final continuation approval prior to expiration of the specified approval period. If a project fails to receive final continuation approval before the expiration of the approval period all study activities involving human subjects and/or use of confidential records must cease immediately. The only exception is if continued subject participation in the research is necessary for the subject's safety. After study approval

expires, the investigator has 30 days to reinstate study approval or approval is permanently canceled.

- Projects in which continuation approval is deferred must receive final continuation approval prior to expiration of the approval period, or all study activities involving human subjects and/or use of confidential records must cease immediately. The only exception is if continued subject participation in the research is necessary for the subject's safety. If the continuation approval must be extended by the full board, the investigator's response to the review issues will be considered at the next meeting; hence, the approval period will expire prior to continuation approval being extended. After study approval expires, the investigator has 30 days to reinstate study approval or approval is permanently canceled.
- In rare instances, approval for conducting the research may be suspended or terminated during the continuation review process. While approval may be suspended under expedited authority, approval can be terminated only by action of the full IRB. While this disposition results in the research approval being permanently canceled, the investigator is free to submit a new proposal for consideration at a later date.

Reporting Continuing Review Findings to Investigators: Investigators are informed by letter or email of the IRB's decision regarding continuation prior to the project's anniversary date. Once continuation approval conditions or review issues have been resolved, investigators will receive a continuation approval letter. For projects involving direct contact with human subjects, continuation approval letters will be accompanied with the contact letter(s), consent form(s), and telephone script(s) stamped "approved" through the next project anniversary date. These approved forms must be used for all recruitment and enrollment activities.

5.7.3 Resubmission Requirements

Research initially reviewed and approved by the full board that continues to have active contacts with subjects for enrollment and/or data collection purposes must be resubmitted as a new application for full board review every five years. The resubmission must be made on the current research application form, and must provide all the information needed for the initial review and approval with an emphasis on describing continuing study activities. Investigators will be reminded of this requirement when continuation approval is extended during the fourth year after initial approval of the research. The IRB will send another reminder to the investigator that a five-year application is required 60 days prior to the application submission deadline.

5.7.4 Expiration of Study Approval

If the investigator fails to submit a *Progress Report*, fails to respond to conditions or review issues required by the board during the continuation review, and/or fails to provide documentation of current training in the protection of human participants before the project anniversary date before the end of the current approval period, study approval may expire. If study approval expires, all research activities, including contacts with human subjects and/or use of any identifiable records, must cease immediately. The only exception is if continued subject participation in research is necessary for the subject's safety. In that event, the IRB Manager must be immediately notified by the investigator.

IRB approval for an expired study must be reinstated no later than 30 days from the expiration date. On the expiration date, the IRB Review Coordinator sends the investigator a letter directing that all research activities be cease immediately, except if continued subject participation in study activities is necessary for the subject's safety. The letter also explains the consequences of failing to reinstate study approval within 30 days. If all materials needed to reinstate continuation approval are not received within 30 days, IRB approval will be permanently canceled due to noncompliance with federal regulations (45 CFR 46) and *Illinois Department of Public Health Policy on Protection of Human Research Subjects*. The following will then occur:

- The IRB will notify the head of the investigator's department or division, the IRB at the investigator's home institution, and the investigator's funding agency of this action;
- If it is federally supported research, the federal Office of Human Research Protections will be notified of this action;
- The investigator will be required to immediately return all identifiable personal record information disclosed for research purposes. Failure to immediately return identifiable personal record will be reported to IDPH's General Counsel for further action.

Approval to continue the canceled research will require submission of a new application for review and approval by the IDPH IRB.

5.7.5 Independent Verification That No Material Changes Have Occurred Since the Previous Review

The IRB may determine that a project needs verification from sources other than the investigator that the project is being conducted in compliance with procedures approved by the IRB and that no material changes have occurred since the previous review. Factors considered by the IRB in determining the need for such verification include, but are not limited to:

- Projects conducted by investigators who previously have failed to comply with the requirements or determinations of the IRB and/or applicable laws and regulations;
- Complex projects involving unusual levels or types of risks to participants;
- Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in *Progress Reports* or from other sources.

Outside verification may be obtained 1) by conducting inquiries or site visits with or without formal audits of study procedures, to collect information to report back to the IRB; or 2) by having third parties observe the consent process and conduct of the research. As necessary and/or appropriate, this determination will be made by the IRB at any time during the approval period of a project, or prior to extending continuation approval for the research. If necessary to address immediate concerns about noncompliance and/or risks to subjects, this decision may be made by the IDPH IRB Chair or his/her designee. Written notice of intent to conduct a site visit, which may include an audit of study activities, or to have third parties observe the consent process, will be provided to the investigator no less than 48 hours before the planned site visit. Such written notice will include an explanation of the reasons for the site visit and an outline of the study procedures and materials that will be reviewed.

5.8 Study Amendments

Investigators must request IDPH IRB review and approval of all proposed changes in approved research. Such requests are submitted for review on the *Study Amendment Request* form. Changes to an approved protocol may not be initiated without prior approval of the IRB, except when necessary to eliminate immediate hazards to participants.

5.8.1 What Requires Review

Study amendments requiring review include, but are not limited to:

- Revisions to study methodology, including study eligibility;
- Addition of new study sites;
- Revisions to recruitment materials or methods;
- Revisions to contact and consent procedures;
- Revisions to consent forms;
- Implementation of additional instruments, or revisions to approved instruments;
- Requests for additional IDPH records;
- Contact with participants for research purposes when all previous study activities were restricted to records and datasets;
- Requests to link study datasets to additional datasets not previously approved by the IRB.

5.8.2 Submission of Study Amendments

Study amendments must be submitted on the *Study Amendment Request* form available at: <http://www.idph.state.il.us/irb>. Study amendments should be submitted as Word files by email to DPH.IRB@illinois.gov. Unless otherwise determined by the IRB staff, paper copies are not required.

A study amendment should clearly indicate the proposed revision(s) and provide a rationale indicating how the proposed amendment relates to overall study objectives and the research questions under analysis. The investigator also should describe any problems with current approved procedures, study recruitment, or other issues that may necessitate the proposed revision(s). Any proposed instruments, protocols, and other documents to be used if the amendment is approved should be attached to the *Study Amendment Request* form.

5.8.3 Procedures for Reviewing Study Amendments

Upon receipt of a study amendment, the IRB Manager will screen the proposed revision(s) and determine the appropriate level of review. Minor changes in previously approved research during the

period for which approval is authorized qualify for expedited review. Examples include minor revisions to consent forms, minor changes in study incentives, requests for additional identifiable records, or minor changes to study instruments. In general, study amendments are reviewed under expedited review procedures if the proposal was eligible for expedited review at initial review. Expedited reviews are conducted by the IRB Chair or his/her designee.

Study amendments for projects that were reviewed by the full board at initial review may require full board review. If a proposed amendment introduces procedures or methods that may significantly increase risks to participants, involves a significant change to currently approved procedures, or incorporates an OHRP-designated vulnerable study population, the study amendment will be forwarded to the full board for review at a convened meeting. Study amendments reviewed by the full board are presented by the primary reviewer or by an alternate designated by the IRB Manager if the primary reviewer is not available. Voting on study amendment dispositions follows the same procedures as for the initial and continuing review of research.

Investigators are informed by letter of the IRB's decision regarding review of a study amendment. Once approval conditions or review issues have been resolved, the investigator will receive a study amendment approval letter. If the study amendment requires changes in consent documents, the newly approved consent documents stamped with the period of approval will be enclosed with the approval letter. If the study amendment requires changes in the *Data Use Agreement*, which authorizes disclosure of individually identifiable personal record information, an addendum to the agreement for signature by the investigator will be enclosed with the approval letter. When signed by the appropriate agency administrator the addendum authorizes disclosure of the additional confidential record information needed for the research. A copy of the signed addendum is sent to the investigator and to the program manager responsible for disclosing the data to the investigator.

5.8.4 Procedures for Ensuring Prompt Reporting to the IDPH IRB of Proposed Changes in a Research Activity

Investigators are informed at multiple points during the ongoing review process of the importance of promptly reporting proposed changes to approved research activities to the IDPH IRB:

- Investigators are informed in the initial approval letter that changes in study purposes, design or methods may not be initiated prior to review and approval by the IRB, except when necessary to eliminate apparent immediate hazards to subjects;
- Investigators are required to complete and sign an agreement with their application that stipulates in part that investigators will report promptly any proposed changes in the research conducted under the agreement;
- The IDPH IRB *Progress Report* form and the *Study Amendment Request* form include a statement that documents the investigator's responsibility to report to the IRB any study modifications and that no modifications will be put into effect without prior IDPH IRB approval;
- During continuation reviews and reviews of study amendments, IRB staff routinely compares submitted forms with project files to determine that changes in approved study activities have not occurred without prior review and approval by the IDPH IRB.

5.9 Unanticipated Problems and/or Adverse Events

An unanticipated problem is an incident, experience, or outcome affecting subjects or others that 1) is unexpected given the approved research procedures and the characteristics of study subjects; 2) is related or possibly related to participation in the research; and 3) may place subjects or others at a greater risk of physical, psychological, economic, or social harm.

An adverse event is an untoward or unfavorable *medical* occurrence in a human subject (e.g., abnormal sign, symptom, or disease) that 1) is unexpected in nature, severity or frequency; 2) is related or possibly related to participation in the research; and 3) may place subjects at a greater risk of physical or psychological harm.

All unanticipated problems and reportable adverse events must be reported to the IDPH IRB. The promptness of the report and the level of review depend on a number of factors which include, but are not limited to, the following:

- Whether the unanticipated problem or adverse event increases risks to subjects or others;
- Whether the unanticipated problem or adverse event is possibly related to study procedures;
- Whether the unanticipated problem or adverse event occurred at a study site in the jurisdiction of the IDPH IRB.

5.9.1 Procedures for Reporting Unanticipated Problems and/or Adverse Events

Reports of unanticipated problems and/or adverse events must be submitted on the *IDPH IRB Unanticipated Problems/Adverse Events* form available at: <http://www.idph.state.il.us/irb>.

Unanticipated problems related to recruitment, consent and/or other study procedures do not need to be immediately reported to the IRB on an individual basis if they do not involve risks to subjects or others. However, the incidence and a description of these unexpected problems must be included in the *Progress Report* submitted at least annually.

Adverse events that may reasonably be expected to arise as a result of research procedures must be described in the consent form and do not need to be immediately reported to the IRB on an individual basis, unless otherwise specified. However, the incidence and a description of these expected adverse events must be included in the *Progress Report* submitted at least annually.

Unexpected adverse reactions to drugs and/or medical procedures, or to the administration of psychological assessments or instruments designed to collect personal or sensitive information from subjects, that is possibly related to the research must be promptly reported to the IDPH IRB.

Unanticipated problems possibly related to any aspect of the research that involve risks to subjects or others, including potential breaches of confidentiality must be promptly reported to the IDPH IRB.

For adverse events and unanticipated problems involving risks to subjects and others that are possibly related to the research, including potential breaches of confidentiality, the following reporting

guidelines should be used:

- Adverse events occurring with greater frequency or at a higher level of severity, or than anticipated, or potential breaches of confidentiality: Investigators must submit an *IRB Unanticipated Problems/Adverse Events* form to the IDPH IRB within 24 hours of the event. Forms should be submitted as Word files to DPH.IRB@Illinois.gov.

For other adverse events or unanticipated problems that involve risks to subjects or others: Investigators must submit an *IDPH IRB Unanticipated Problems/Adverse Events* form to the IDPH IRB within five working days of the event. Forms should be submitted as Word files to idphirb@idph.state.il.us.

5.9.2 Procedures for Reviewing Unanticipated Problems and/or Adverse Events

The IRB Manager reviews all *Unanticipated Problems/Adverse Events* forms as they are submitted with the IDPH IRB Chair or his/her designee. If the problem and/or event is of sufficient importance, it may require review by a subcommittee comprised of the IRB Manager, primary reviewer (or other board member for projects that did not undergo full board review) and IRB Chair. If the reported event appears to be related to study procedures the reviewers evaluate the consent form language describing the risk and determine whether participants already enrolled in the research should be appropriately advised. If applicable, reports by the coordinating institution's Data and Safety Monitoring Board (for multi-site clinical research), or additional information from the investigator may be requested.

Unanticipated problems and adverse events involving risks to subjects or others are reported to the full board and documented in the minutes of the meeting. The full board may determine that additional action needs to be taken in response to the report. Additional action could include, but is not limited to, requiring additional revisions in the consent form, advising or requiring that the study be modified to reduce risks to subjects, taking actions to notify study subjects about risks, including a confidentiality breach, or rescinding study approval if the risks are determined to outweigh anticipated benefits of the research.

Documentation of all reports of unanticipated problems and/or adverse events involving risks to subjects and others, and any action taken by the subcommittee and/or the full IRB are placed in the project file. If the IRB has serious concerns about the research, and/or the safety and welfare of subjects, the IRB Chair will inform the investigator, his/her home institution IRB, the coordinating center IRB and/or the funding agency, and OHRP, in writing.

5.9.3 Procedures for Ensuring Prompt Reporting to the IDPH IRB of Any Unanticipated Problems and/or Adverse Events

Investigators are informed at multiple points during the ongoing review process of the importance of promptly reporting any unanticipated problems and/or adverse events to the IDPH IRB:

- Investigators are informed in the initial approval letter that unanticipated problems and/or adverse events must be reported to the IDPH IRB;
- Investigators not affiliated with IDPH are required to complete and sign an *Investigator Agreement*,

which stipulates in part that investigators will report immediately to the IDPH IRB any unanticipated problems involving risks to subjects or others in the research conducted under the agreement;

- The IDPH IRB *Progress Report* form and *Study Amendment Request* form include a statement documenting the investigator's responsibility to report to the IRB any unanticipated problems and/or adverse events that may increase risks to subjects and that are related or possibly related to participation in the research.

5.10 Noncompliance Procedures

Noncompliance with board-approved procedures may involve relatively minor or technical violations, which result from inadvertent errors, inattention to detail or inadequate training and supervision of research staff. Noncompliance also may involve more serious violations of IDPH IRB approved procedures, which pose tangible risks to subjects and/or violations of their rights and welfare. Violations of IDPH IRB approved procedures for protecting the confidentiality of individually identifiable personal record information disclosed for research may involve violations of state or federal laws or regulations under which such information is used or disclosed, and will always be considered as serious noncompliance.

IDPH IRB procedures for responding to investigator noncompliance are based on the seriousness of the violation, the frequency of the violations, and any history of violations the investigator may have.

5.10.1 Minor Noncompliance

If the noncompliance is not serious and appears to be inadvertent, and if the investigator does not have a history of noncompliance, the IRB Chair will respond to the noncompliance by communicating with the investigator and attempting to correct the situation through a formal or informal educational intervention. The investigator may be asked to complete continuing education in the protection of human subjects, or may be asked to propose a corrective action plan to the IRB. The IRB will be informed of the noncompliance and the action taken by the IRB Chair to correct the situation.

5.10.2 Serious Noncompliance

If noncompliance results in tangible risks to subjects and/or violation of their rights and welfare, or if it involves violations of state or federal laws, the IRB Chair will inform the investigator in writing of the nature of the noncompliance and the steps that must be implemented to correct the noncompliance. The noncompliance will be placed on the agenda of the next IRB meeting for consideration of whether additional steps should be taken to correct the noncompliance. The full board may adopt a corrective action plan which includes, but is not limited to, an educational intervention and submission of additional documentation explaining how and why the noncompliance occurred and how it will be prevented in the future. The investigator's immediate supervisor, the IRB in the investigator's home institution, the IDPH Director and Deputy Director of the program area in which the research is being conducted will be informed of the noncompliance and the IRB's action. The funding agency and IDPH Legal Counsel may be informed, depending on the seriousness of the noncompliance, and whether any state or federal laws have been violated.

5.10.3 Serious and Continuing Noncompliance

If an investigator exhibits serious and continuing noncompliance with board-approved procedures the IRB Chair or his/her designee will present a report to the full board with a recommendation that project approval be suspended or permanently canceled.

If project approval is suspended, the IRB will stipulate the conditions for reinstatement of IDPH IRB approval or the review issues the investigator must respond to before reinstatement will be considered by the IRB. The investigator's response to the re-approval conditions may be reviewed, and study approval reinstated, by a board subcommittee. The investigator's response to review issues must be considered at a scheduled board meeting, after which the board will vote either to reinstate or to permanently cancel study approval.

If project approval is permanently canceled by vote of the full board due to serious and continuing noncompliance, the following will occur:

- The IRB will notify the head of the investigator's department or division, the IRB at the investigator's home institution, and the investigator's funding agency of this action;
- If it is federally supported research, the federal Office of Human Research Protections will be notified of this action;
- The investigator will be required to immediately return all identifiable personal record information disclosed for research purposes. Failure to immediately recover and return identifiable personal record information will be reported to IDPH Legal Counsel for further action.

5.10.4 Noncompliance Prior to Initial Study Approval

In some instances, serious noncompliance with *Illinois Department of Public Health Policy on Protection of Human Research Subjects* and/or violations of state or federal laws or regulations may be detected during the initial review of a research proposal. Detection of serious noncompliance or violation of law during the initial review of a research proposal is sufficient grounds for disapproval of the research proposal. If serious noncompliance or violation of law is discovered during the initial expedited review of a proposal, the IRB Chair or primary reviewer may make a motion for disapproval of the proposal at the next scheduled meeting of the IRB.

5.11 Study Completion/Cancellation

Upon completion of a research project the principal investigator is required to submit a final project report. The following documents will be accepted as the required final report: a published article based on the research; a report prepared for the institution that funded or sponsored the research; a thesis or dissertation based on the research. Final reports may be submitted as electronic documents. The investigator should consult with IRB staff if there is a question about what will be accepted as the final project report.

If the project required a *Data Use Agreement* for the disclosure of individually identifiable personal record information, the investigator must meet all requirements in the agreement before the study file can be closed. At a minimum, this requires the investigator to return all datasets or certify in writing the

destruction of all data elements that could directly or indirectly identify individuals whose records were disclosed for the research as soon as the purposes of the research have been accomplished.

For research that involves collecting primary research data from subjects, the investigator will be asked to certify that all terms and conditions in the study consent and/or assent forms have been fulfilled, including that identifiers have been permanently removed from study records and destroyed. The investigator should use the *Certification That Research Records Have Been Destroyed or De-identified* form to document that this requirement has been met.

When the final report and written assurance that identifiers have been destroyed are received by IRB, the principal investigator is informed by letter that the requirements to the IDPH IRB have been completed and the project file is closed.