

Regulations of the Institutional Review Board (IRB)
(Human Subjects Committee)

Of the
Madlyn and Leonard
Abramson Center for Jewish Life

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I. Statement of Purpose, Authority, and Principles

A. Purpose

The purpose of the IRB is to protect the rights and welfare of human research subjects recruited to participate in all research activities, funded and non-funded, conducted under the auspices of the Madlyn and Leonard Abramson Center for Jewish Life (hereafter, **the Center**). In general, this protection extends to two classes of persons. These are: (1) residents, staff, family members, and participants in and of the Center and its programs who may be research subjects in projects conducted by the Center staff or by outside investigators (who are not Center staff); and (2) subjects or informants in research projects undertaken by Center staff conducted outside the Center.

B. Authority

The Institutional Review Board (IRB) has been given the authority to review research conducted at or by employees of the Center.

The IRB has the authority to approve, require modifications, disapprove, suspend or terminate all research activities, or proposed changes in previously approved research activities conducted in and by the Center in accordance with the definition of research given below. The IRB also has the authority to require progress reports from the investigators, oversee the conduct of all studies and place restrictions on research which falls under its jurisdiction based on the definition of research given below. (*45 CFR 46.109*).

A secondary purpose of the IRB is as a forum for the exchange of information about research that is being contemplated or undertaken. Because many departments and programs at the Center, or collaboratively with other institutions may sponsor research, the IRB represents one means of informing members, who represent diverse departments, of current and future research.

The Center's IRB is registered with and has filed assurances with the U.S. Department of Health and Human Services (DHHS), Division of Assurances and Quality Improvement, Office of Human Research Protections (OHRP).

The Center's Federal Wide Assurance number is FWA00000328, and the IRB number is IRB00000422.

C. Principles

The principles that govern the IRB in assuring that the rights and welfare of research subjects are protected are the *Belmont Report*, and the *Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects*. Research involving products regulated by the Food and Drug Administration are governed by CFR Title 21 Parts 50, 56, 312, and 812.

II. Definitions

The *Code of Federal Regulations Title 45 Part 46.102: Protection of Human Subjects* defines the following:

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

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

While the definition of human subjects is clear, Federal regulations specify “living individuals” in its definition of human subjects. In some cases, however (as in the case with autopsy), research may include a deceased individual, only with the consent of surviving family members, whether or not that deceased individual has offered assent or consent. This is currently the case in Pennsylvania in the case of post-mortems. Thus, the IRB will also be responsible for the appropriate protections in such cases.

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

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purpose by an individual and which the individual can reasonably expect will not be made public (for example a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

C. IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

D. Legally Authorized Representative is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research

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

F. Additional definitions. For purposes of clarity the Center IRB further defines the following:

1. Exempt Research. Exempt research refers to data collection from human subjects that may be carried out at the Center for non-research purposes and therefore is not to be reviewed by the IRB. Examples include marketing studies, quality assurance studies, employee and resident satisfaction surveys (exempt research defined further 45 CFR 46.101(b)). The IRB of the Center may require review of some forms of HHS-exempted research.

2. Protected Health Information, as defined in the Health Insurance Portability and Accountability Act, is any individually identifiable health information that is held or maintained by a covered entity or business associate. This includes identifiable demographic and other information related to the past, present, or mental health of an individual, or the provision or payment of health care.

3. Reviewable Research refers to all other research with human subjects. Review of this research is discussed in the section on the Review Process, below

4. Special Populations. Research undertaken at and by Center researchers has traditionally involved two classes of populations that are subject to special consideration. The IRB must be especially concerned with research with such populations. In general, these two populations are the cognitively impaired and minors. The IRB defines them as follows:

- The cognitively impaired: diagnosed with a medical condition leading to impairment in mental functioning
- Minors: Persons aged 18 years or less will be considered a minor

III. Composition of the IRB

The Center shall be made up of a Chair and at least five members as prescribed by *45 CFR 46.107*.

A. Leadership of the IRB

Policy

The IRB leadership shall be made up of Center employees and consist of a Chair, an Associate Chair and an IRB Administrator. Persons in these positions of IRB leadership will have overall responsibility to the Center's Human Protections Administrator (HPA) for the protection of human subjects and the administration of the Center's IRB.

Procedure

The Chair of the IRB shall be appointed by the President/CEO of the Abramson Center. The selection shall be made from the Research Scientists who are employees of the Abramson Center and members of the Abramson Center IRB. The Chair may appoint a Protempore Chair. The Associate Chair of the IRB shall be appointed by Chair from among the members of the Abramson Center IRB. The IRB Administrator shall be the Administrator of the Polisher Research Institute.

These positions shall be held for the duration of the time that the individuals are employed by the Center in those positions.

The general duties of the Chair, with the assistance of the Associate Chair and IRB Administrator as necessary shall be: conducting meetings of the IRB, and overall responsibility for the professional conduct.

The Associate Chair shall undertake these duties in the absence of or in concert with the IRB Chair.

Should both the Chair and the Associate Chair be absent or in conflict during IRB review, the Chair or Associate Chair may designate a regular IRB member as temporary Chairperson.

The duties of the IRB Administrator will be to coordinate the administrative function of the IRB. These will include, but not be limited to distribution, receipt, and preliminary review of initial and continuing review applications; scheduling and organizing the IRB meetings; preparation of materials for the meetings and the mailing of the meeting agenda, meeting minutes; IRB accreditation; and liaison between the IRB and

investigators, including the expression of the IRB's decisions and concerns to them. The Administrator will also be responsible for maintaining all IRB records and files.

It is the duty and responsibility of the Chair, Associate Chair and, IRB Administrator to pursue ongoing training in the protection of human subjects and ethical conduct of research. From time to time, as necessary the leadership of the IRB will develop training sessions for the general membership to assure that the membership is kept abreast of the changing federal requirements in the protection of human subjects.

B. IRB Members

Policy

Federal regulations specify that IRB must have at least five (5) members. The IRB must include persons with appropriate areas of professional competence, but Federal policy demands diversity of backgrounds and professions, appropriate mix of genders, and sensitivity to community needs and issues. The IRB must include at least one member whose primary concerns are in scientific areas and one member whose primary concerns are not in scientific areas. The IRB must also include one member who is not affiliated with the Center and whose immediate family is not affiliated with the Center. Federal guidelines also caution that IRBs should not become too big and therefore unwieldy in their performance. (45 CFR 46.107)

Procedure

The Center's IRB shall consist of at least 5 and no more than 16 active members. The IRB will contain the following Center employees: (1) The Chairman of the IRB and (2) the Associate Chair of the IRB; (3) The IRB Administrator; (4) the Medical Director; and (5) the Chaplain. While these titles and occupants may change or be empty the intent is to include permanent representation from research, medicine, administration, and the chaplaincy, as part of the permanent duties of these positions. All core appointment will be for the duration of employment in their positions by the Center. Core appointments for the Associate Chair of the IRB and the IRB Administrator will be automatic and will not require letters of appointment. For core positions for the Medical Director and the Chaplain, the IRB Chair will send a formal, written request to join the IRB to new occupants of these positions. The letters will include a copy of these the Center's *IRB Policies and Procedures*, a copy of *The Code of Federal Regulations Title 45 Part 46.102: Protection of Human Subjects*, the current schedule of meetings, and a copy of the current IRB membership list with contact information.

All other appointments to the IRB will be made by the Chair of the IRB, in consultation with the other current members. Persons nominated for these positions will receive the same letter with attachments as core members four and five.

At the discretion of the Chair alternates will be appointed to occasionally represent certain members when the member is unable to attend IRB meetings. Alternate members will also receive letters of appointment with attachments and have the same voting rights as the member they represent.

C. Classes of IRB members

Policy

The IRB membership shall consist of two classes of members: Voting members and Non-Voting members.

Procedure

Voting members will consist of active, permanent members of the Center's IRB and their alternates.

Non-voting members may include ex-officio members and other experts.

Ex-officio members. Are defined as members who the IRB may wish to attend periodically, but who do not vote. They will not be considered full members and not counted within the membership range of 5 to 16 persons.

Other experts. From time to time, as needed, the IRB may request the attendance of individuals who have expertise in areas not covered by the IRB members, but which is necessary for the review of a particular research project. These may include individuals with particular scientific and clinical expertise, as well as community or respondent representatives. Clearly, these persons are not full members and will not vote nor count towards a quorum. (*45 CFR 46.107(a)*)

D. Members Duties

Policy

It is the responsibility of each IRB member to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Center in accordance with *45 CFR 46, Protection of Human Subjects*.

Members who do not attend regularly jeopardize the ability of the IRB to secure a quorum and therefore to operate effectively. The IRB member must make a conscientious effort to attend scheduled meetings.

Procedure

Upon acceptance of a seat on the Center's IRB, members receive a copy of the Center's *IRB Regulations*, and the *Code of Federal regulations title 45, Part 46*, which they are required to become familiar with. To facilitate members' learning basic IRB concepts, all members will be required to complete a training course on IRBs. Evidence of completion (through a printout certification) of at least one web-based training session from an acceptable website should be provided to the IRB Administrator before the member is given voting privileges at an IRB meeting. Acceptable sites may be obtained from the IRB Administrator and include www.ohrp.gov and www.nih.gov.

Additional training will be accomplished periodically at meetings. At least two IRB meetings per year will include training. The subject matter of these training sessions will be at the discretion of the Chair. Attendance at training sessions will be noted in the minutes of the meeting.

The IRB Administrator of the Center will maintain an IRB reference section, which is available to all IRB members as well as investigators, research staff, and the general public.

IRB members are required to attend at least 75% of scheduled meetings per year and may have no more than one unexcused absence (absence without advance notification to the IRB administrator) per year. IRB members who fail to attend the required number of meetings or who accrue multiple unexcused absences may be replaced at the Chair's and IRB's joint discretion.

Potential termination of a member or members will be discussed at a regular or special meeting of the IRB. Termination will be accomplished by simple majority vote of all non-affected members, either in person or by mail or phone.

E. Leaves of absence

Policy

Members may request a leave of absence from IRB duties if workloads or other responsibilities make it difficult for that member to participate effectively.

Procedure

IRB members may request a leave of absence from the IRB by submitting a request in writing to the IRB Chair. The IRB Chair may use his or her discretion in deciding whether to seek a temporary or permanent replacement, depending on the IRB member's expertise and expected duration of the leave. If replacement is necessary, the Chair or his or her designate may, in consultation with other members, solicit an appropriate replacement.

Members on leaves of absence will not be counted toward the board quorum.

F. Termination of membership

Policy

Membership on the Center IRB shall be on a volunteer basis with the exception of the five-core members stated above.

Procedure

In order to vacate one's seat on the Center's IRB a member must submit a request in writing to the Chair. The Chair will acknowledge this request in writing and announce the resignation at the next convened meeting of the IRB where the membership will be asked for nominations for a replacement.

G. Compensation

Policy

There will be no monetary compensation paid to any member for serving on the Center IRB.

IV. Meetings of the IRB

Policy

The Center IRB shall meet as regularly as workload demands, but not less often than is required to perform continuing reviews of active projects.

Notification of meetings shall be in writing in order to give members time to mark their calendars and to review material for the coming meeting.

All Costs of the IRB meetings (meals, duplication, secretarial help, etc.) will be borne by the Center.

Procedure

In general, the IRB shall meet on the third Thursday of each month at 11:30, at the Center, in an appropriate meeting room. Meetings may be changed to a second or fourth Thursday if the third Thursday presents a conflict deemed significant. Meetings may be canceled due to lack of pressing business, inclement weather, or failure to meet a quorum (see below).

At the beginning of each calendar year, the Administrator of the IRB will circulate to members a list of dates for all 12 scheduled IRB meetings for the year.

A. Pre-Meeting Activities

Two weeks prior to the scheduled meeting, the Chair, in consultation with the IRB Administrator, will make a determination as to whether the upcoming meeting is to be held. If it is to be held, the Chair will circulate to members a notice of the impending meeting, and materials pertinent to the meeting. Those materials will include but not be limited to a written agenda, copies of the initial and continuing review application and all attachments of any projects being presented for review, the application and all attachments of any projects approved expeditiously and exempted from review since the last IRB meeting, a copy of the last meeting's minutes, and any other material pertinent to the upcoming meeting.

Alternate members will also receive a complete meeting agenda.

When consultants or experts are used to provide special expertise to the IRB in its review of a protocol, the research application and all attachments will be distributed to them also.

If the meeting is not to be held, the Chair will notify members of the cancellation and inform them of the date of the next meeting.

B. Meeting

At the convened meeting the Chair will open the meeting with the approval of the previous meeting's minutes by asking if there are any additions or corrections to the minutes.

Any member may propose additions or corrections. The proposed additions and corrections will be discussed and a vote will be taken by a show of hands regarding the proposed additions or corrections. A majority will be needed to change and/or accept the minutes. After the minutes are approved the chair will move onto announcements, followed by the review of proposals. Before beginning the review of the proposals the Chair will ask if there are any members who might have a conflict of interest with any of the projects on the agenda. If there are any, these will be noted in the minutes and that member will be informed that their participation in the review of the project where they have a conflict will be limited to supplying information about the project and they will be asked to leave the meeting room when the proposal is discussed and voted on. The Chair will then proceed with the project review.

Approval of a protocol requires a quorum vote. A quorum is defined as a simple majority of all active members excluding the Chair. The only time the Chair may vote is to break a tie. No proposal will be reviewed at a meeting where there isn't a quorum present.

C. Post Meeting Activities

1. Responsibilities of the Administrator following approval of a research protocol by the IRB

The Administrator will formally communicate the IRB's decision and requests in writing as soon as possible after the meeting. The letter will include any or all of the following

1. a description of the modifications to the protocol and/or consent documents;
2. the length of time the IRB has granted approval for, and any conditions imposed by the IRB;
3. whether or not the conditions affect the commencement of the project; and
4. the date the proposal must be presented for follow up review.

The IRB Administrator will include a copy of this communication as part of the project file.

After receiving final consent forms from the investigator, the IRB Administrator will stamp and date all pages of the consent form(s) with an expiration date (typically 12 months from the date of the IRB meeting where the project was approved). The IRB Administrator will then return the certified originals to the investigator for use in obtaining informed consent. The IRB Administrator will maintain copies in the IRB project file.

To facilitate the timely processing of continuation applications, the IRB Administrator will notify an Investigator in writing approximately six weeks prior to the expiration of IRB approval. The notification will include the deadline for submitting a continuation application or final report for the upcoming IRB meeting.

2. Responsibilities of the investigator(s) following approval of a research protocol by the IRB

Upon receipt of the IRB approval letter of the protocol and prior to commencing the research project the investigator will forward original copies of the approved consent form to the IRB administrator for certification. The IRB Administrator will then stamp forms with an approval and expiration date (see above) and provide certified originals to the investigator. The Investigator is required to use certified (stamped) forms to enroll research subjects in the study. The IRB Administrator will maintain a copy of the certified forms for the IRB project file.

It is the responsibility of the investigator(s) to immediately inform the IRB Chair in writing of any change in the research protocol, injury, adverse event, and termination of research.

It is the Investigator's responsibility to submit continuation applications and final reports in a timely fashion and in accordance with the scheduled IRB meetings. In general, continuing review and final reports should be submitted to the IRB Administrator by the first Monday of the month before the next scheduled IRB meeting to allow time to review and distribute the materials to the committee members.

A. Reporting changes in research protocol

The IRB will review minor protocol changes by expedited review. More significant protocol changes must be submitted to the IRB using a change in protocol form. The IRB Administrator can provide guidance on what constitutes minor but generally may include: a change in personnel used to obtain informed consent, a change in source of subjects, or other minor changes. The IRB Administrator has the authority to approve minor changes deemed to be administrative.

Changes in research protocol may mandate changes in the Consent Form(s). The approved revised consent forms will be stamped and dated by the IRB Administrator. The consent form will be certified using the same dates as the original consent form(s).

B. Reporting of Injuries and adverse events

Any injuries or adverse events that occur during the research protocol must be immediately reported to the IRB Chair at 215-371-1810 and followed with detailed documentation to the events. Actions taken to remedy either the injury or adverse event must also be included. See Section XI Adverse Events for more details.

C. Reporting termination of projects

Investigators who wish to terminate a project should submit a letter to the IRB indicating the reason why the study is ending, the number of subjects enrolled, and the status of any outstanding adverse events requiring follow-up

Upon termination of the project, investigators should submit a final report consisting of any human subjects issues that arose in the final year of the project, a brief summary of findings, and final report to any funding agency.

V. Record Keeping

Policy

Records of the IRB activities will be kept in accordance with *45 CFR 46.115 (a)(1),(3),(4), and (7)*

Proceedings of all IRB meeting shall be recorded in accordance with *45 CFR 46.115(a)(2)*

Procedure

The IRB must maintain adequate documentation of IRB activities. Adequate documentation of initial proposals and continuing proposals shall include: copies of the application for review, scientific evaluations if any that accompany the proposal, copies of approved sample consent documents, copies of all correspondence between the IRB and investigators, progress reports if required and, reports of injuries to subjects.

A separate file must be kept on each project presented to the IRB regardless of the project disposition or type of review.

In addition to project files, copies of approved IRB meeting minutes, a current IRB membership list with member's specialties and contact information and, a copy of the written IRB Policies and Procedures shall be maintained.

All record keeping shall be the responsibility of the IRB Administrator, will be kept in his/her office and be available to all members, research staff, Administration, Federal Agencies and IRB members.

In accordance with *45CFR46.115*, records will be maintained for a period of at least three years after the completion of the research.

Federal Guidelines specify that minutes of IRB meetings contain the following information: attendance at each meeting; beginning and end times; actions taken by the IRB; the vote of all actions including votes for, against and abstaining; the basis or reasons for requiring changes or for disapproval; and a written summary and discussion of controversial issues and their resolution for each protocol undergoing initial and continuing review.

In order to document the continued existence of a quorum votes will be recorded in the minutes using the following format: Total = 15; Vote: For=14, Opposed=0, Abstained=1.

The Chair and IRB Administrator, or the Chair's staff designate shall keep minutes of each IRB meeting. The minutes of each meeting will be typed and circulated as part of the agenda for the next meeting. Committee members shall review these minutes and will be given the opportunity to make any additions or corrections to the minutes. If any member has an addition or corrections to the minutes the additions or corrections will be discussed and voted on. As in all votes by the IRB a quorum and majority approval is required before the addition or correction will be incorporated into the revised minutes. The revised minutes will be circulated for the next meeting and voted on as above. No minutes of a meeting will become an official record of IRB proceedings until approved by the committee.

VI. Review of Research

Policy

Prior to commencement, research involving human subjects, whether, residents, families or employees or the use of medical information about residents of the Center, conducted by employees or outsiders must be reviewed by the Center's IRB. Requests for IRB review must be presented in writing via a formal application that is specifically designed by the IRB to collect information required for appropriate initial and continuing review.

The procedures for submitting an application for IRB review will vary according to whether the research involves any Center staff, families, or residents or only subjects outside the Center. In addition, outside investigators not affiliated with the Center's research division (Polisher Research Institute) are required to follow additional procedures in order to ensure compliance with policies of the Center.

As employees of the Center's research division, at times staff members of the Polisher Research Institute are involved in program development activities at the Center. Because these activities may or may not constitute research, additional procedures have been included to guide Center and Institute staff in determining whether to submit these activities for IRB review.

The Center therefore distinguishes procedures for four groups: 1) Polisher Research Institute staff proposing research that does not involve Center staff, families, or residents; 2) Polisher Research Institute investigators proposing research involving Center staff, families, or residents; 3) Center staff involved in program development activities at the Center; 4) Outside investigators proposing research involving Center staff, families, or residents.

Procedure

A. Application procedures

Researchers wishing to submit proposals for Initial Review or Continuation Review may obtain an application, instruction for completion and submission, examples of consent documents, a checklist for Informed Consent and a copy of the IRB's Policy and Procedures from the Center's web site or directly from the IRB Administrator.

The complete packet containing all of the required materials is to be submitted to the IRB Administrator. The IRB Administrator will perform the preliminary review of the material submitted which consists of a check to assure that the application is complete, all required additional components are present, and the consent forms contain all federally required elements, plus any additional requirements set by the IRB.

In addition, the following procedures are required of investigators:

1. Polisher Research Institute Investigators Proposing Research Outside of the Center. No additional requirements.

2. Polisher Research Institute Investigators Proposing Research Involving Center Staff, Families, or Residents. Research involving Center staff, families, or residents, requires sponsorship from the appropriate Center department head(s). Sponsorship, indicated through signature on the initial review form, means that the Department head a) is aware of the project and b) agrees to facilitate implementation of the research project.

If a change in department head occurs after the beginning of a research project involving Center staff, families, or residents, department sponsorship continues. However, to facilitate the continuation of research benefits and minimized risks to human subjects, it is the research investigator's responsibility to inform the department head of the study's protocol.

The Principal Investigator will take steps to train project staff to comply with 1) policies and procedures related to human subjects and 2) the Center's policies and procedures. For example, the PI may train project staff to enroll subjects, obtain informed consent, comply with the Center's HIPAA policies and procedures, and report adverse events and other reportable events.

3. Center Staff Involved in Program Development Activities. At times program development undertaken by non-research staff at the Center periodically draws upon the skills of research staff. Such program development does not necessarily but may constitute research (see definitions), depending on the specific circumstances. The involvement of Polisher Research Institute staff or outside investigators does not in and of itself constitute research. Only when systematic information is collected for the purpose of generalizable knowledge is the activity considered research.

Because Center staff are not routinely trained in human subjects issues, unless serving on the IRB or an employee of Polisher Research Institute, when a Polisher Research Institute staff person or external investigator is involved in program development and information is to be collected from human subjects (either Center staff or residents) in the process, the project should be submitted for initial IRB review.

The IRB Chair will review the project and make an initial determination if exempt status should be granted either because the project does not constitute research with human subjects or because it is exempt research (See Section VII.C. Exempt Status.)

4. Outside Investigators Proposing Research involving Center Staff, Families, or Residents.

All research proposed by outside Investigators must first be discussed with the IRB Chair.

A. Outside Investigator Responsibilities. It is the responsibility of the Outside Investigator to:

1. Seek and obtain the appropriate Center department head(s) as sponsor. The IRB Chair can facilitate this process. Sponsorship, indicated through signature on the initial review form, means that the Department head a) is aware of the project and b) agrees to facilitate implementation of the research project.

If a change in department head occurs after the beginning of a research project involving Center staff, families, or residents, department sponsorship continues. However, to facilitate the continuation of research benefits, it is the research investigator's responsibility to inform the department head of the study's protocol. It is the Administrator's responsibility to inform Outside Investigators of a change in department head of a sponsoring department.

2. Identify and include in the project plans an on-site monitor responsible for overseeing issues related to human subjects' protection The IRB Chair can facilitate this process. The monitor must be an employee of the Center or Polisher Research Institute who has received training in human subjects' protection. The monitor's role is to take steps to train project staff and monitor staff compliance with 1) policies and procedures related to human subjects and 2) the Center's policies and procedures. For example, the monitor may train project staff to enroll subjects, obtain informed consent, comply with the Center's HIPAA policies and procedures, and report adverse events and other reportable events.

3. Learn about the Center's policies and procedures and its IRB's policies and procedures. The Outside investigator will obtain from the Administrator two copies of the Center's policies and procedures and the Center's IRB policies and procedures. The Outside Investigator will familiarize him or herself and all outside project staff with the policies and procedures. The Outside Investigator and all outside project staff will sign one copy of each signifying that he or she has read and understands the policies and procedures/ The Outside Investigator will return signed copies to the IRB Administrator.

4. Submit proof of training in human subjects for all project team staff. The Outside Investigator must submit to the IRB Administrator a copy of a human subjects training certification for him or herself and all outside project staff from an acceptable federal web site offering training to investigators in human subjects issues. Acceptable sites include www.ohrp.gov and www.nih.gov.

5. Submit letter of support from Outside Investigator's Institution and proof of IRB approval from the Outside Investigator's institution or an external IRB. The Outside Investigator must include in the application a letter from his or her institution indicating their knowledge of and support for the proposed project.

If the Outside Investigator is affiliated with an institution that has an IRB, approval from BOTH the Center's IRB and the Outside Investigator's IRB are required. The Center's IRB may grant approval pending documentation of approval from the IRB of the institution with which the Outside Investigator is affiliated.

If the Outside Investigator's institution does not have an IRB generally approval from BOTH the Center's IRB and an external IRB are required. However, if the project meets the qualifications for expedited review, the investigator may request a waiver of the external IRB approval. The decision to grant a waiver requires full review by the Center's IRB.

When IRB approval is granted to a project under the direction of an Outside Investigator, it will be done so contingent upon compliance with policies and procedures of the Center. Before receiving final IRB approval, the outside investigator will be required to comply with Center policy for Outside Investigators. The policy covers but is not limited to: a) proof of PPD testing for all outside project staff; b) signed business associates agreements for all outside project staff, and c) requirements for contractual agreements with the Center. Once proof of compliance is submitted to the IRB Administrator, the Chair or Administrator may remove the contingency and grant final IRB approval.

B. Application Materials

For Initial Review applications materials will constitute:

1. A completed Application for Review, which will ascertain critical project information, including the purpose, location, procedures to be performed, as well as the benefits risks, and ethical issues involved in the project.
2. A one-page abstract of the research proposal and a copy of the proposed protocol, grant, study or any other document that defines the work to be done,
3. Any consent document(s) to be used,
4. For a study sponsored by a drug or device company the drug or device brochure,
5. Any advertisement used for recruitment,
6. If non-English versions of the consent will be used, these must be submitted in the translated language,
7. Surveys, questionnaires, or other such research tools,
8. A completed conflict of interest form for all investigators.
9. Certificate of human subjects training for all co-investigators and individuals authorized to obtain informed consent who are not staff members of Polisher Research Institute.
10. A CV or NIH Biosketch form for principal investigators. For other key personnel and personnel involved in data collection provide a brief description of the relevant qualifications and training of those individuals.
11. For outside investigators only, a letter of support from their institution.
12. For outside investigators only, proof of IRB approval (or pending approval) from their institution, proof of approval (or pending approval) from an external IRB, or a request to waive the external IRB requirement.

For Continuation Review applications materials will constitute:

1. A completed Continuation Review Application,
2. A copy of currently approved Consent document(s) with any proposed changes highlighted,
3. A clean (unstamped) copy of any proposed Consent document(s),
4. If non-English versions of the consent will be used, these must be submitted in the translated language,
5. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review,
6. If applicable any relevant multi-center trial reports,
7. Current surveys, questionnaires, or other such research tools,
8. Proposed survey's, questionnaires, or other such research tools,
9. A copy of the grant continuation application or interim report,

10. Any other relevant information, especially information about risks associated with the research.
11. An updated investigator conflict of interest form.
12. Certificate of human subjects training for all new co-investigators and new individuals authorized to obtain informed consent who are not staff members of Polisher Research Institute.
13. A CV or NIH Biosketch form for new principal investigators. For other new key personnel and personnel involved in data collection provide a brief description of the relevant qualifications and training of those individuals.
14. For outside investigators only, proof of continuation approval from the IRB of the investigator's institution or external IRB or indication that this requirement has been waived

The major difference between the Initial Review and Continuation Review application is that the Continuation Review application requires a status report on the progress of the research, which will include:

1. The number of subjects accrued;
2. A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
3. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
4. Any relevant multi-center trial reports;
5. Any other relevant information, especially information about risks associated with the research; and
6. A copy of the current informed consent document(s) and any newly proposed consent document(s).

VII. Types of Reviews and Determination of Review Category

Policy

Federal regulations require that all research studies involving human subjects be reviewed initially (Initial Review) and at least every 12 months (Continuation Review). For both initial and continuing review, the IRB recognized two categories of reviews: (1) Full Committee Review and (2) Expedited Review. In addition, upon initial review a project may be given the designation of Exempt Status, which does not require continuation review.

Procedure

To allow the IRB to determine which type of review is appropriate, the Investigator shall fill out an Initial Review or Continuation Review form provided on the Center's web site or directly from the IRB Administrator. After checking for completeness, the IRB Administrator will forward the package to the IRB Chair, with a recommendation as to whether the project should be considered for full or expedited review or be designated as exempt from review.

The IRB Chair will first review proposals to determine whether the proposed research fits with the interests, policies, and care program of the Center. In the case that concerns exist, or if specific approval by the Center's Administration is necessary, the Chair will refer the proposal for approval to the President of the Center or his/her designate.

The IRB Chair will then consider the IRB Administrator's recommendation and make a final determination on the cover form as to whether the project will receive full or expedited review or be designated as exempt from review. This determination will be marked on the coversheet of the IRB application.

The IRB Administrator will include applications designated exempt or granted expedited approval as “For Circulation” to the IRB on the next IRB agenda.

VIII. Initial Review

New research activities must be submitted to the IRB for initial review. The initial approval lasts for a period to be determined by the IRB, not to exceed 12 months. Although the review is not a scientific review, the IRB should be mindful that poorly designed or poorly conceptualized research poses an undue burden on human subjects, since it requests participation in an undertaking that is scientifically meaningless. The IRB’s decision whether to approve research will be guided by the following rule of thumb: (a) whether the research is ultimately publishable, usable or presentable; and (b) if not, whether it contributes in some way to an ongoing or evolving scientific research program.

A. Full Review

Policy

Generally full review is appropriate for research undertaken at the Center that involves collection of information from or about residents, since many residents may be considered as belonging to a special population (cognitively impaired). Research activities with Center staff, Center families, or with subjects outside the Center will also qualify for full board review if they pose more than a minimal risk to human subjects, involve invasive procedures, or involve identifiable data that would place a subject at risk of criminal or civil liability, or damage the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing.

Procedure

The Administrator will notify the investigator that the project will receive full review and the date of the IRB meeting at which the project will be reviewed.

The Investigator or a representative of the investigator is required to attend the IRB meeting at which their project is being reviewed. Investigators not affiliated with Polisher Research Institute proposing to conduct research with Center residents, staff, or families must attend the IRB meeting in person and may not send a representative to the meeting.

The Investigator will be asked to give a brief oral presentation about the purpose and human subjects aspects of their research. IRB members will have the chance to ask questions and request clarification of Human Subjects matters. When questioning is complete, the Investigator, or their representative, any member of the investigative team present and any IRB member who might have a conflict of interest will be asked to withdraw from the IRB meeting room. The IRB will then privately discuss the proposal.

The IRB will consider the following criteria when approving a research proposal:

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance to the knowledge that may reasonably be expressed to result.
3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The IRB will make decisions based on a consensus of opinion. The committee may (a) approve the protocol as submitted; (b) approve the protocol contingent on specific revisions to the protocol or Consent Form(s); (c) table the protocol for substantive changes; or (d) disapprove the protocol. Upon completion of the discussion the Chair will call for a vote by show of hands. After the vote the Investigator and others will return to the meeting room and the Chair will communicate the IRB's decision and requests if any.

B. Expedited Review

Policy

New research activities that qualify for expedited review: (a) present no more than minimal risk to human subjects, and (b) do not involve special populations. Expedited research may include research on individual or group characteristics or behavior (including but not limited to perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Expedited review procedure may *not* be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, *unless* reasonable and appropriate protections are put into place so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal

Procedure

If the Chair designates a project as eligible for expedited review, generally the IRB Chair or his or her designee will perform the expedited review. The Chair or his or her designee will consider the following criteria when approving a research proposal:

1. Selection of subjects is equitable
2. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
3. Informed consent will be appropriately documented
4. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The IRB member conducting the expedited review exercises all the authority of the IRB except that the reviewer may not disapprove a research protocol. If the IRB Chair or his or her designee grants expedited approval, he or she will mark the appropriate box on the tracking form for the application, site the appropriate reason, and return the application to the IRB Administrator. The IRB Administrator will notify the Investigator in writing that the project has received approval, and then circulate the project to the IRB. (See Section D for discussion of IRB's right to call for a full review of any proposal.)

C. Exempt Status

Policy

DHHS regulation *45 CFR 46.101(b)* describes six categories of research that may qualify for exempt status. Although the regulations do not address a maximum risk level, it is implicit within the concept of exempt research that there be very little, if any, associated risk.

At the Center, with *45 CFR 46.101(b)* in mind, exempt research shall refer to scientific research with human subjects or data derived from human subjects, but which the IRB deems as not requiring full or expedited review. In these projects, no identifying information will be recorded that can link subjects to the data and disclosure of the data could not reasonably place a subject at risk of civil or criminal liability or be damaging to the subject's financial standing, employability or reputation. Examples include record or chart reviews that do not record identifiable information or analysis of previously collected non-identifiable secondary data.

Other exempt research includes data collection from human subjects that may be carried out at the Center for non-research purposes and therefore is not to be reviewed by the IRB. Examples include marketing studies, quality assurance studies, employee and resident satisfaction surveys. Information collected from staff or residents at the Center for purposes of program development and/or implementation may also be considered exempt.

The designation as exempt must come from the IRB. Only the Chair, in consultation with other IRB members, if necessary, can make this determination based on *45 CFR 46.101(b)*.

Procedure

As in all other types of review the investigator must complete an Application for Initial Review and obtain department head approval, as appropriate. The IRB application if completed correctly will let the investigator know that there is a possibility that the proposed project will qualify for exemption. Upon receipt, the IRB administrator will forward the application to the IRB Chair for review with his or her recommendation about exempt status.

If the IRB Chair or his/her or designee determines that the application is exempt from IRB review, he or she will indicate exemption and the reason for exemption and return the application to the IRB Administrator. The IRB Administrator will notify the Investigator in writing that the project has received exempt status, and then will circulate the project to the IRB. (See Section D for discussion of IRB's right to call for a full review.)

D. Full Review of Projects designated as "For Circulation"

Policy

The IRB has the right to call for a full review of any proposal granted expedited approval or exempt status. The IRB will be notified within 30 days of the expedited approval or exempt status, and must call for review by or at the next convened meeting.

Procedure

Any IRB member may notify in writing or at a convened IRB meeting his or her desire to bring to full review any project designated as "For Circulation."

In the event that an IRB member requests that the full committee review such a proposal, the Administrator will contact the Investigator and schedule the project for the next IRB meeting.

The IRB will first vote on whether to consider the application for full review. A simply majority vote will determine whether full review will continue. The IRB's decision may override the expedited review decision of the Chair or his or her designee. The Chair and his or her designee shall abstain from this vote, except in the case of a tie.

If it is determined that the application will receive full review, and the IRB may consider reviewing the project immediately (depending on the availability of the Investigator, and other work before the IRB) or request that it be scheduled for a subsequent meeting. If the latter, the IRB Administrator will contact the Investigator and schedule the project for review, generally at the next IRB meeting.

IX. Continuation Review

45 CFR 46.109(e) requires continuing review of human subject research by an IRB at intervals appropriate to the degree of risk, but not less than once per year. Continuation review must be substantive and meaningful. Two types of continuation review may be undertaken, full review and expedited review. Generally a project undergoes the same type of review as initially indicated; however there are circumstances under which the type of review may change.

A. Full Review

Policy

Generally full continuation review is appropriate for the continuation of research undertaken at the Center that involves collection of information from or about residents, since they may be considered a special population. Continuation of research activities with Center staff, Center families, or with subjects outside the Center will also qualify for full continuation board review if they pose more than a minimal risk to human subjects, involve invasive procedures, or involve identifiable data that would place a subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.

Procedure

An Investigator may obtain an Application for Continuation Review from the Center's web site or directly from the IRB Administrator. The application questions are designed specifically for protocols that have been reviewed at least once before. The Investigator must complete all relevant questions and submit the completed application to the IRB Administrator.

Procedurally a Full Committee review of a Continuation Application will be conducted in the same manner as a Full Committee review of an Initial application. That is, the applications will be reviewed at a fully convened meeting, and require a quorum and, a recorded majority vote for approval. The criteria will include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards of human subjects.

The information in the status report will be used to assist the IRB in making its decision. When reviewing the current informed consent document(s), the IRB should insure the following:

1. The currently approved or proposed consent document is still accurate and complete;
2. Any significant new findings that may relate to the subject's willingness to continue participation are provided.

Notification of the IRB decision and requirements will be handled in the same manner as in Initial review.

B. Expedited Review

Expedited review may be used for initially expedited research in which there is no substantive change in protocol and no human subjects issues have arisen since the expedited approval was granted. Expedited review may also be used for continuing review of research previously approved by the convened IRB where (1) The research is permanently closed to the enrollment of new subjects: all subjects have completed all research-related interventions: and the research remains active only for long-term follow-up of subjects: or (2) Where no subjects have been enrolled and no additional risks have been identified: or (3) Where the remaining research activities are limited to data analysis and no Data Monitoring Board exists or (4) Where there are only minor changes in approved research, which is limited to correction of typographical errors in Protocol and IRB application.

Procedure

For review of an initially expedited project, an Investigator must obtain and complete an Application Continuation Review from the IRB Administrator. The application questions are designed to let the investigator know that the project might qualify for expedited review. The IRB Administrator will review the application for completeness and possible expedited review. If the protocol meets any of the above mentioned criteria for expedited review the IRB Administrator will forward the application to the IRB Chair with the recommendation that the project be expedited. Approval will be granted based on the judgment of the IRB Chair. If approved the Chair will check the approval box on the application and cite the reason for approval below the box. If the Chair does not approve or believes full committee review is warranted, he/she will refer the protocol for full committee review and the Administrator will notify the investigator of the decision and meeting date.

If the Chair grants expedited approval to the application, the IRB Administrator, after communicating the approval to the Investigator in writing, will have the application added to the "For Circulation" section on the agenda of the next IRB meeting.

X. Lapse in IRB Approval

Policy

The Principal Investigator is responsible for ensuring that the continuing review form is submitted to the IRB in an appropriate time frame, in order to avoid a lapse of IRB approval.

Implications for investigators:

- Investigators must plan ahead to meet required continuing review dates. If an investigator fails to submit a continuing review application to the IRB prior to the expiration date of the protocol, or the IRB does not review and approve a research study prior to the expiration date of the protocol, all

research activities (including recruitment, enrollment, involvement of current participants, scheduling of study visits, looking at new subject information and data analysis) must stop.

- Research activities may continue **ONLY IF** the IRB determines upon review that it is in the best interest of individual subjects to continue participating in the research interventions or interactions.
- When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. If subjects are studied after a lapse in approval for the research this activity becomes a research compliance issue and must be reported and explained to the IRB and to applicable regulatory or funding agencies.
- Data collected after an IRB protocol has expired may not be used for research purposes. If an investigator wishes to use data acquired after an IRB protocol has expired, he or she must petition the IRB to use the data and must provide written justification for requesting the use of the data.

Notification and study termination

The principal investigator is encouraged to submit the review to the IRB at least three weeks before the continuing review date. As a courtesy to investigators, the IRB issues reminder notices by e-mail to the principal investigator and/or research staff. The notice will be sent approximately ten weeks prior to the protocol expiration date. **Failure to submit and obtain approval for a continuing review by the due date will result in expiration of the IRB Approval** (i.e., the research is no longer IRB approved). A study that has been terminated cannot be reactivated. Before any research activities can resume, a new protocol must be submitted and approved by the IRB. Any studies carried out without an active approval, irrespective of receipt of IRB notices, are considered to be non-compliant.

XI. Study Closure

Policy

The principal investigator (PI) and/or the Institutional Review Board (IRB) may close approved protocols under certain circumstances. The PI is responsible for promptly closing out an IRB approved study if any of the following conditions exist:

1. All research/clinical investigation activities including data analysis and reporting are complete.
2. The PI never initiated the study.
3. All subjects have been enrolled; all data collection is complete and the only remaining activity is analysis of the data; the data are de-identified; and there are no identifying links or codes to the de-identified data.
4. The PI plans to leave the Institute and intends to continue the research activities at another institution.
5. The study has been open for a period of three or more years and there have been no subjects enrolled in the study.

The PI submits the request to close out IRB approval in writing to the IRB Administrator. The PI must complete a final review report unless he/she never initiated the study or it has been less than six months since the last IRB continuation review and no subjects have been enrolled in the last six months.

The PI cannot close out an active IRB approval if:

1. He/she is still following subjects or;
2. He/she is analyzing identifiable data (including data with codes or links to identifiers).

The IRB may notify a PI that IRB approval has expired and that the IRB has terminated IRB approval due to non-response from the PI to IRB requests.

If a study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB requires study closure unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen condition).

A. Final Reports

Final Reports, along with a close-out form, should be submitted within 30 days after completion of the study. Investigators should submit a final report consisting of any human subjects issues that arose in the final year of the project, a brief summary of findings, the number of subjects enrolled, the status of any outstanding adverse events requiring follow-up and final report to any funding agency. Final reports may be submitted by the investigator or his or her designee. The IRB Administrator will review all reports of study completion and, if needed, request further information from the investigator to clarify any questions that may arise.

Notice of the submission of Final Reports or closures will be presented to the Board at the next scheduled meeting; and copies of the reports and any supplement information will be made available for the members upon request.

XII. Informed Consent

Policy

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in a language understandable to the subject or representative. No informed consent, whether written or oral, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The IRB shall recognize three forms of consent in relation to research: (a) signed consent, (b) oral consent, and (c) no consent necessary.

The information given to the research subject is the same in cases of both oral and signed consent. However, the forms should be labeled differently. In the case of signed consent, the heading should be "Consent Form". In the case of oral consent, the heading should be "Information Form". Both are to be signed by the Investigator and dated, attesting to the fact that the material in it was discussed with the subject. When signed consent is required, the Investigator will keep the signed form. But a copy will be placed in the resident's chart in the case of a Center resident. In both oral and signed consent cases, a copy must be given to the Research Subject for informational purposes.

Investigators and staff obtaining informed consent are required to have training in human subjects protection, including the elements of informed consent.

A. Signed consent

Signed consent must be obtained in “instances of invasive research (blood samples, lab tests exceeding clinical treatment needs, experimental medication), drug trials, and for research where there is any element of risk”. Signed consent must also be gained from next of kin or proxy for individuals who are cognitively impaired and who assent to interviews, and for minors (see below). Signed consents are also generally required when research involves protected health information from a residents’ medical record (see section on HIPAA below).

B. Oral consent

Oral consent is sufficient for some or all subjects if the IRB finds either:

1. That the only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern;

OR

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

3. When the procedures involve interviews in which the subject’s identity is not recorded permanently on response forms (including audio-taped interviews), direct behavioral observation where an identity may be known (for example, a residential unit at the Center), and for psychological testing.

4. Research with focus groups requires only oral consent, with circulation of the project “information form”. But every effort must be made by the Investigator to insure that all participants understand the confidential nature of such groups. Measures should be taken to protect the identities of subjects within the group to the extent that they desire.

For projects beginning after April 2003, oral consent is generally not acceptable when the research involves protected health information from a residents’ medical record (see section on HIPAA below).

C. No consent

Consent is not necessary, in general, for projects that are deemed exempt from IRB approval, because there is no chance the identity of subjects being known and no risk to the subjects.

In general, the policy of the IRB is to request oral or preferably signed consent. However, Federal Guidelines stipulate that some or all informed consent requirements may be waived when: (a) the research involves no more than minimal risk; (b) the waiver of informed consent will not adversely affect the subject’s rights and welfare; (c) the study could not be carried out without the waiver, and (d) subjects will be provided with relevant information after completion of the study, where appropriate. Examples in which informed consent requirements may be waived according to Federal guidelines, include record or chart reviews, observation of behavior readily observable to the public, and secondary analysis of existing data sets. However, as noted above, most such proposals must undergo the Center’s human subjects review.

D. Consent and Cognitively Impaired Individuals

Research at and by the Center frequently involves cognitively impaired individuals, who may require special protection. Any research involving these groups shall be subject to the following special requirements related to informed consent.

Among cognitively impaired individuals, determination of the ability to provide informed consent is recognized to be a complex task and may benefit from both clinical judgment and standardized test results. Further, it is recognized that the ability to provide informed consent may fluctuate over time.

In cases of research with persons with cognitive impairment, for both oral and signed consent, it is the policy of the Center's IRB that every effort be made to respect the autonomy and the decision-making capacity of the research subject regarding consent. Even when subjects are incompetent to give fully informed consent, their verbal or nonverbal assent or dissent to participate in the study should be assessed and respected.

In cases in which capacity to make a decision is clearly diminished, consent of subjects' appointed surrogates, which the Center indicates as the residents' "responsible party," should be gained. In the rare case that no appointed surrogate is available, research cannot be undertaken, since a responsible party cannot be located with certainty.

Investigators are expected to put extra protections into place to ensure risks to cognitively impaired populations are minimized. At the same time, such protections should not unnecessarily impede the opportunity for this population to participate in research activities.

Procedure

The Investigator shall follow the IRB's written informed consent instructions which shall be part of the Application for Review and must be circulated to all investigators who request an application. The instructions shall also contain written examples of consent forms and a checklist of required consent components.

Investigators are expected to put extra protections into place to ensure risks to cognitively impaired populations are minimized. Such risks include physical, psychological, and emotional risks. For example, investigators should revisit ability to provide informed consent multiple times over the course of a longitudinal study, should ask subjects to express their understanding of what they have consented to, and assess their understanding of the risks and benefits of the study. At the same time, such protections should not unnecessarily impede the opportunity for this population to participate in research activities. So, for example, a subject may be given several opportunities to assent to participate in a research study, provided that the requests do not upset or agitate the subject. Provisions should be made to train project staff in how to interact with subjects who may be displaying agitation or other negative affect.

In determining whether an individual can provide informed consent, the investigator shall develop procedures that rely on clinical judgment and, if deemed appropriate, supplemental clinical tests. Investigators shall also develop procedures that recognize that the ability to provide informed consent may change over time. That is, during the course of a longitudinal study, investigators may choose to assess the subjects' ability to provide and obtain from them informed consent multiple times.

E. Consent Form Required and Optional Elements

All consent forms should be as short and as simply phrased as possible. Consent forms should be typed in large (preferably 14-point), bold print, labeled at the top "Consent Form" and on Center stationery for all Center projects. Consent form from outside organizations doing research at the Center should print their consent form on the letterhead of the institution conducting the research, and also label it "Consent Form" at the top. The text should be phrased so as to be intelligible to the particular people being studied, but they also must satisfy federal requirements as stated in federal regulations 45 CFR 46.116.

Complex consent forms should be broken up by headings (e.g., "Purpose," "Procedures," "Benefits").

Each form must contain the following:

1. A statement that the study involves research.
2. An explanation of the purpose of the research.
3. The duration of the subject's participation in the research.
4. A description of the procedures to be followed.
5. Identification of any procedures that are experimental.
6. Description of any reasonably foreseeable risks or discomforts to the subject.
7. Description of any benefits to the subject or others that may reasonably be expected from the research.
8. Disclosure of appropriate alternative procedures courses of treatment, if any, which might be advantageous to the subject.
9. Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and if applicable, a statement of the possibility that DHHS/FDA may inspect the records.
10. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether medical treatments are available if any injury occurs, and if so, what they consist of, or where further information can be obtained.
 - a. The Center is responsible for a Center investigator with a Center resident as subject.
 - b. Any other institution is responsible for their investigator with a Center resident as subject.
11. An explanation of whom to contact for answers to pertinent questions about the research, research subject's rights, and whom to contact in the event of a research-related injury to the subject
12. Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise.
13. A clear statement of the title of the study, the Principle Investigator and the specific number and total number of pages of the consent or information form (e.g., "page 2 of 5 pages").
14. Signed consent forms will, of course, include a place for the signature. For those not capable of signing, there must be a place for the signature of a surrogate decision-maker.
15. If protected health information is requested as part of the research protocol, language compliant with an authorization to release protected health information for the purpose of research, compliant with the Health Insurance Portability and Accountability Act (HIPAA) should be included.

The signed consent form must ask the subject to affirm that all the above conditions have been explained and are understood. The consent form must include a place for the subject's signature, the researcher's signature and the date. For those not capable of signing, there must be a place for the signature of a surrogate decision maker.

F. Training for Staff Involved in Obtaining Informed Consent

Staff involved in the obtaining of informed consent must receive appropriate training in the Center's policies and procedures.

In the initial application, investigators must identify who will be obtaining informed consent and what training they have had. They must supply documentation of training for all proposed staff involved in informed consent. Training modules are available at no cost from the Office of Human Research Protections www.ohrp.gov and from the National Institutes of Health www.nih.org.

In the case of special populations such as the cognitively impaired, staff involved in obtaining informed consent investigators may be required by the IRB to have additional training. For example, provisions should be made to train project staff in how to assess comprehension of subjects with cognitive impairment and how to interact with subjects who may be displaying agitation or other negative affect.

XIII. Reporting of Adverse Events

Policy

The Common Rule defines adverse events as "unanticipated problems" involving risks to study participants or others. All investigators and project staff involved and who are employed by the Center or conducting research at the Center are responsible for knowing the policies of the local IRB, adhering to these policies, and maintaining a copy of the policies. The principal investigator is also responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events.

The IRB has the authority to suspend or terminate approval of research at its site that has been associated with unexpected serious harm to participants. When the IRB takes such action, it is required to provide a statement of reasons for the action and to promptly report this action to the investigator, appropriate institutional officials, the Department or Agency head, Office for Human Research Protections (OHRP), and the FDA if an investigational new drug or device is involved.

Procedure

If any member of the IRB becomes aware of an adverse event, he or she shall report it to the IRB immediately in writing, within 3 days. The Chair will in turn review the event and determine, in consultation with one or more IRB members, whether immediate review by the full IRB is warranted or whether the event can be addressed at the next regularly scheduled IRB meeting. The Chair also has the right to temporarily suspend research activities until the full IRB can meet to review the events.

The IRB Chair shall contact the Principal Investigator in writing with his or her decision and the rationale within 3 working days of notification of the adverse event. The Chair may also request in writing that the Principal Investigator bring additional supporting material to the IRB meeting.

The IRB will review the written documentation and question the Principal Investigator or other individuals involved in the event. The IRB may request additional documentation from the Principal Investigator.

Based on their review, the IRB will determine whether the event was possibly related, probably related, or not related to the protocol, and if it is determined to be related, whether the research shall be permanently

halted or changes to the research protocol or consent form should be made. If determined to not be study related, the adverse event will be brought before the full IRB during continuation review.

The IRB Administrator will document the decision and its rationale and provide this information to the investigator and appropriate institutional officials (HPA), and, as necessary, the Office for Human Research Protection (OHRP) and/or the FDA.

XIV. Conflict of Interest

Overview

The Department of Health and Human Services (DHHS) offers guidance for institutions, IRBs and investigators regarding conflicts of interest in their publication “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection”. According to the DHHS, “a financial interest related to a research study may be a conflicting financial interest if it will, or may be reasonable expected to, create a bias stemming from that financial interest”. A conflict of interest exists when “a significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.” (42CFR50.605). The PHS threshold for significant financial interest is \$10,000 per year income or equity interests over \$10,000 and 5% ownership in a company (42CFR50.603, 45CFR94.3). Investigators are required to disclose potential conflicts of interests to the institutional official who will make a determination whether a conflict of interest exists. “Not all financial interests cause a conflict of interest and financial interests are not prohibited if they do not create bias or harm to subjects” (Federal Register, Vol. 68 (1) 3/31/03).

If the institutional official determines that an investigator does have a conflict of interest, the institutional official may impose conditions if necessary, to manage or reduce the conflict of interest including public disclosure of the conflict of interest, or other conditions as listed in 42CFR50.605.

A. Pertaining to IRB Members, Including Chairperson

Policy

In order to avoid a conflict of interest the chair of the IRB shall, with nominations and input from the IRB members, appoint new member to the committee on an as needed basis. See IRB Member for Center Policy and Procedure.

The IRB is responsible for ensuring that members who review research have no conflicting interest as addressed in 45 CFR 46, 107(e). No IRB may have a member participate in the IRBs initial or continuing review for a project in which the member has a conflicting interest, except to provide information requested by the IRB. See Full Committee Review for Center Policy and Procedure.

Procedure

IRB members complete out a COI affidavit form annually and are required to abstain from voting on any study in which they have a conflict of interest. Before voting on any matter, before the IRB, members are asked if they have a conflict to leave the room for that portion of the meeting. Such conflicts will be recorded in the meeting minutes.

B. Pertaining to IRB Chairperson

Policy

Additional precaution will be taken to avoid a conflict of interest of the IRB Chairperson when the chairperson is a principle in the research presented for review and to avoid the chairperson's unintended influence on the voting decisions of the IRB.

Procedure

To avoid any possible unintended influence on the voting decisions of the IRB, the IRB Chairperson will abstain from voting in all research approval votes except in situations of a tie vote. Under these circumstances the IRB Chairperson will cast the deciding vote, except in cases where the IRB Chairperson is a principle in the research being considered.

To avoid a conflict of interest at a fully convened meeting of the IRB where research is being reviewed in which the IRB Chairperson is a principle, the IRB Chairperson will turn the conducting of the meeting over to the Associate Chairperson or another member of the IRB who is not associated with the research being reviewed.

In the case of research proposed by the IRB Chair where the Chair is a principle, and there is a possibility that the research proposal is eligible for exemption or expedited review the protocol will be reviewed by a senior member of the IRB who is not affiliated with the Polisher Research Institute or the Center.

C. Pertaining to Investigators

Policy

Prior to IRB review of the proposal, investigators will disclose any financial or other relationship with the sponsor of the research, or with other entities whose financial interests would reasonably appear to be affected by the outcome of the proposed research.

Procedure

Investigators are required to complete a COI affidavit form for each study they are requesting IRB review in order to disclose financial or other relationships that could result in bias in the design, conduct, or reporting of the study, or potential harm to human subjects.

XV. HIPAA compliance

The Center has established a center wide policy in compliance with the Health Insurance Portability and Accountability Act of 1966 (HIPAA), which is in part hereby incorporated into this document.

Policy

A. **Privacy Regulations.** Privacy regulations establish the conditions and requirements for the use and disclosure of private health information (PHI). The term "research" is defined earlier in this document.

B. **Disclosure for Research.** Except as set forth in C below, PHI may not be used or disclosed for research unless the resident signs authorization. This form is different than the informed consent used for research

involving human subjects under both the 45 CFR 46 and or the Food and Drug Administration's (FDA) human subject protection regulations. While HIPAA Privacy Regulations add additional requirements, they are to be read in addition to the 45 CFR 46 and FDA requirements.

C. Exceptions to Authorization. Research may be conducted without an authorization if: (a) the requirements are waived by the Center's IRB after satisfaction of certain conditions as described below: (b) PHI is collected in preparation for research, as described below: (c) PHI is used for research of decedents, as described below: and (d) use of limited data sets.

1. Waiver by IRB. The IRB must identify and make a determination that the alteration or waiver of the authorization, in whole or in part satisfies the following three requirements:

- a. The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following:
 1. An adequate plan to protect the identifiers from improper use and disclosure.
 2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conducting research, unless there is a health or research reason for retaining the identifiers or such retention is otherwise required by law: and
 3. Adequate written assurances that PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by section 165.512(I)(2).
- b. The research could not be practicably be conducted without the waiver or alteration: and
- c. The research could not practicably be conducted without access to a use of PHI.

In granting the waiver, the IRB must provide a brief description of the PHI for which use or access has been determined to be necessary. The IRB must also make a statement that the alteration or waiver of the authorization has been reviewed and approved under either full review or expedited review: and the minutes or reviewing and approving action must be signed by the chair or other member, as designated by the chair, of the IRB..

2. Collection of PHI Preparatory to Research. The researcher represents that:

- a. The use or disclosure of the PHI is solely to review PHI to prepare a research protocol or for similar purposes preparatory to research.
- b. The researcher will not remove any PHI from the Center: and
- c. The PHI for which access is sought is necessary for research purpose.

The Center could use this exception to design a research study or to assess the feasibility of conducting a study.

3. Research on PHI of Decedents. The researcher must represent that:

- a. The use or disclosure being sought is *solely* for research on the PHI of decedents;
- b. The PHI sought is necessary for the research.
- c. If requested by the Center, documentation of the death of the individuals about whom information is being sought.

4. Limited Data Sets with a Data Use Agreement. This provision allows a "limited data set" of PHI. This includes removal of almost all of the identifiers required for de-identification, except for relating to location. If this method is to be followed, review this with the Privacy Office (Nursing Home Administrator).

D. Special Rules for Authorization.

1. Date. Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the " end of the research study:" and
2. Combined. Normally an authorization cannot be combined with any other document. However, an authorization for the use or disclosure of PHI for research may be combined with a consent for the SAME research to participate in the research, or with any other legal permission related to the research study.

E. Accounting for Research Disclosures.

1. In general, the HIPAA Privacy Regulations give individuals the right to receive an accounting of certain disclosures of PHI made by a covered entity.
2. This accounting must include disclosures of PHI that occurred during the earlier of six years prior to the individual's request for an accounting, or since the applicable compliance date, and must include specific information regarding each disclosure.
3. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose. Among the types of disclosure that are exempt from the accounting requirements are:
 - a. Disclosures made pursuant to an individual's authorization (including research):
 - b. Disclosures of limited data set researchers with a data use agreement.
4. Simplified Accounting. If the disclosures are made for research when no authorization is obtained and that involve at least 50 individuals participating in the research, the HIPAA Privacy Regulations allows for a simplified accounting of such disclosures by the Center.

F. Transition Provisions. Special transitional rules apply

1. Effect of Transitional Rules. Except for research, the HIPAA transitional rules provide that only information created or received before the effective date of the privacy rules, April 15, 2003, can be used or disclosed without satisfying the HIPAA requirements. Research, however, expands the transitional rules.
2. Expansion for Research. Under the HIPAA Privacy Regulations, the Center may use and disclose PHI that was created or received for research, either before or after April 15, 2003, if the Center obtained any one of the following prior to April 15, 2003:
 - a. An authorization or other express legal permission from an individual to use or disclose PHI for the research:
 - b. The informed consent of the individual to participate in the research: or

c. A waiver of informed consent by the IRB in accordance with 45 CFR 46 or an exception under FDA's human subject protection regulations

3. The HIPAA Privacy Regulations allow the Center to rely on such express legal permission, informed consent, or IRB-approved waiver of informed consent, which they create or receive before the applicable compliance date, to use and disclose PHI for specific research studies.

G. Special Rules When a Waiver was Obtained. If a waiver of informed consent was obtained prior to April 15, 2003, but the Center seeks an informed consent after this date, the Center must obtain the individual's authorization as required.

Procedure

A member of the Center *workforce* who desires to use the PHI for research purposes must first apply, in writing, to receive authorization from the Privacy Officer. The application must demonstrate that the communication will comply with all applicable requirements of the above policy.

If the Privacy Officer is satisfied that the research activity will comply with the policy, (s)he shall authorize the use for the activity.

The investigator will then apply to the IRB for approval of the study using the methods described earlier in the document, with the following exception, included among the documents submitted to the IRB will be the approval document from the Privacy Officer.

If the Privacy Officer is not satisfied that the activity will comply with this policy, (s)he will discuss it with the requesting party explaining why the activity cannot be approved.

The Privacy officer will assist with information systems to develop and maintain a master list of residents who are subject to research to track disclosure.

XVI. Review and Update of IRB Policy and Procedures

Policy

The IRB shall keep policies and procedures up to date in accordance with *The Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects*. Changes shall be made in consultation with the administration of the Center and be adopted by a vote of the full IRB. Ample time shall be allocated for review of modifications by the Center and IRB members.

Procedure

The Administrator and Chair shall review the policies and procedures periodically but no less than once every three years. The Administrator and Chair shall report on review findings at a full IRB meeting.

Proposed changes to the policies and procedures shall be drafted by the Administrator and Chair in consultation with materials provided by the Office of Human Research Protections. The new draft policies and procedures (or sections if only minor changes are made) shall be provided to the President of the Center for comment.

The new draft policies and procedures shall then be provided to the IRB for discussion. IRB members must be provided these materials at least 10 days in advance of the meeting so that a full consideration is possible.

The IRB may suggest modifications to the draft changes. Changes will be adopted by a majority vote of IRB members and are effective immediately, unless otherwise noted by the IRB.