

University of Chicago Social & Behavioral Sciences IRB Manual

Social & Behavioral Sciences Institutional Review Board
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PREFACE

The policies and procedures set forth in this manual are written in accordance with the U.S. Department of Health and Human Services regulations governing research involving human subjects at 45 CFR 46, and are in compliance with the principles of the 1979 *Belmont Report*, which specifies the ethical principles for the protection of human subjects. Both the membership of the IRB and any prospective researchers who intend to use human subjects in their research projects are reminded that this document establishes the basic minimum of policies and procedures and does not include every possibility for the variation in research protocols involving human subjects.

The University has authorized the Social and Behavioral Sciences (SBS) Institutional Review Board (IRB) to review and approve human subjects research from the social and behavioral sciences. The SBS IRB committee is comprised of faculty researchers, administrators and at least one non-institutional member and one member whose primary interests are non-scientific. The SBS IRB will apply the policies and guidance in this guidebook for all research involving human subjects that is conducted in the social and behavioral sciences disciplines and certain other academic areas in the university not served by other IRBs (e.g., Humanities, Graduate School of Business, Law School) and that is sponsored by this institution, conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects, regardless of sponsorship.

The review of human subjects research at the University of Chicago is a collaborative process intended to result in mutually acceptable research procedures that aid investigators in accomplishing their scientific objectives while protecting the rights and welfare of research participants. Every effort is made to adopt creative administrative and other means to reduce administrative burdens and maximize attention to the most important ethical issues. To this end, the IRB tries to be as flexible as possible and reviews each project as a separate case rather than simply imposing rigid requirements, and every attempt is made to take into account all factors in determining the outcome of the review. The IRB encourages consultation at all stages of the research process.

I. POLICIES AND PROCEDURES

A. Jurisdiction of the SBS IRB

The SBS IRB is an administrative body established to protect the rights and welfare of human research subjects enrolled in research that is conducted in the social and behavioral sciences disciplines and certain other academic areas in the university not served by other IRBs (e.g., Humanities, Graduate School of Business, Law School) and that is sponsored by this institution, conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects, regardless of sponsorship. The SBS IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by the SBS IRB may be subject to further review, and may be disapproved by officials of the institution. However, those officials may not approve research that has been disapproved by

the SBS IRB. Furthermore, all approved research is subject to continuing review and approval by the SBS IRB at least annually or as specified by the IRB (the approval period may be up to three years for studies that qualify under the SBS IRB's three-year approval policy).

The University of Chicago has a Federalwide Assurance (FWA) that has been reviewed and approved by the HHS Office for Human Research Protections. The SBS IRB is covered under this Assurance.

B. IRB Membership

The HHS regulations specify that an IRB must have at least five members. The membership must represent a variety of backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution. Also, the IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. There is no maximum limit to the number of individuals that may serve on the IRB.

In addition to possessing the professional competence necessary to review specific research activities, the SBS IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Therefore, the SBS IRB must include persons knowledgeable in these areas. No IRB, however, may consist entirely of members of one profession.

There are four types of IRB members who may vote:

1) **Affiliated members.** Individuals associated with the University of Chicago in a variety of capacities.

2) **Nonaffiliated members.** Nonaffiliated members are not currently affiliated with the institution and are not part of the immediate family of a person who is currently affiliated with the institution. They are expected to provide input regarding the local community (research context) and be willing to discuss issues and research from that perspective as well as to comment on the comprehensibility of the consent document.

3) **Scientific members.** Scientific members are expected to assess whether risks to subjects are reasonable in relation to anticipated benefits. These members should also be able to advise the IRB if additional expertise in a nonscientific or other scientific area is required to assess if the protocol adequately protects the rights, safety, and welfare of subjects.

4) **Non-scientific members.** Non-scientific members are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. Non-scientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the protocol adequately protects the rights, safety, and welfare of subjects, and/or to comment on the comprehensibility of the consent document.

Individual members of the IRB may meet more than one type as described above (i.e. a non-scientific member may be either affiliated or unaffiliated with University of Chicago).

The nonaffiliated members of the IRB should be drawn from the local community at large, and may include ministers, teachers, attorneys, businesspeople, prisoner representatives, and/or individuals who are members of advocacy groups. The nonaffiliated member(s) should be knowledgeable about the local community and be willing and able to discuss issues and research

from that perspective. When selecting the nonaffiliated member(s), consideration should be given to the type of community from which the institution will draw its research subjects.

The IRB must make every effort to ensure that it does not consist entirely of men or entirely of women, though appointment to the IRB should not be made solely on the basis of gender.

The SBS IRB is encouraged to invite individuals with expertise in specific areas to assist in the review of issues that require expertise or perspective beyond or in addition to that available on the IRB. Although these individuals may attend meetings and take part in the discussion of research protocols, they may not vote.

The Dean of the Division of Social Sciences appoints the SBS IRB Chair and Vice-Chair. The IRB chairperson should be a highly respected individual from within or outside the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of ensuring that the SBS IRB is a respected part of the institutional community will fall primarily to this individual. The SBS IRB must be, and must be perceived as, fair and impartial, immune from pressure either by the institution's administration, investigators whose protocols are brought before it, or other sources.

C. Duties of IRB Members

The IRB is appointed as an Institutional Committee. As such, the IRB members serve the institution as a whole, rather than a particular school or department. Therefore, members must not allow their own interests or those of their department to supercede their duty to protect the rights, safety, and welfare of research subjects.

IRB members, including the IRB Chair and Vice-Chair, are expected to commit to a three-year term and, during that time, to fulfill certain duties.

In general, IRB members (or their designated alternates) are expected to read all full board applications and research protocols; and, to attend and participate in the review discussion and vote on each proposed research protocol at the convened full board meetings to which they are assigned. In addition, IRB members are expected to participate on special subcommittees as assigned by the IRB Chair and contribute to discussions of regulations and interpretations that lead to policies and investigator guidance.

D. Delegation of Responsibilities

The Chair(s) are responsible for managing committee discussion and deliberation and ensuring that all members who may wish to comment, do so. The Vice Chairs are expected to participate on a regular basis in assisting the Chair with his or her IRB duties.

The Chair may appoint an IRB member to assist or act on his or her behalf in particular IRB matters on a case-by-case basis (e.g. If the Chair must recuse him/herself from the vote on a particular protocol and a Vice Chair or Acting Chair is not present to lead the meeting. This action would be noted in the minutes of a convened meeting). The Chair may also delegate any of his or her responsibilities as appropriate to other qualified (i.e. experienced) IRB member(s).

E. Conflict of Interest (COI)

The PI is responsible for disclosure to the IRB at the time a protocol is submitted if any research personnel involved in the protocol have any outside financial conflicts of interest that are or could be perceived to be related to the proposed research protocol. If there is a known or potential conflict of interest at the time of IRB submission, a separate letter of disclosure should be included

with the submission detailing the nature of the conflict. Any change to this status as related to a protocol should also be brought to the attention of the IRB.

Please refer to the University Research Administration (URA) website at http://researchadmin.uchicago.edu/policies_compliance/conflict_interest/ which provides references to current University policies for disclosure of individual financial conflicts of interest. The IRB will relay any conflict of interest disclosure to the Institutional Official and coordinate with the Official as to the appropriate measures or protections to be implemented or that may have already been implemented. Such measures typically include disclosure of the outside interest and the nature of the relationship to the proposed study in the Informed Consent form.

No IRB member may participate in the review of any project at a meeting or otherwise in which the member has a conflicting interest or in which the appearance of a conflict exists, except to provide information as requested by the IRB. In the case of such a conflict, this should immediately be reported to the IRB Chair. Except to provide requested information, members absent themselves when the IRB reviews research in which they have conflicting interests and their absence is recorded in the minutes. A conflict of interest is defined as a conflict between the private interests and the official responsibilities of a person.

F. Record Keeping and Retention

The SBS IRB staff prepares and maintains adequate documentation of the IRB's activities. In addition to written IRB procedures and membership rosters, such documentation includes electronic copies of all research proposals (including informed consent documents) reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects.

IRB records are retained for at least three years; records pertaining to research that is conducted must be retained for three years after completion of the research. All records are accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner.

G. Human Subjects Protection Training and IRB Educational Sessions

Researchers who submit to the IRB and will be obtaining consent from research participants, interacting or intervening with research participants to collect data, and/or analyzing data that contain identifiers are expected to have completed human subjects protection training and to provide proof of that training with their IRB submission – the SBS IRB accepts the CITI human subjects protection training course, the NIH human subjects training course, and may accept other sources of training on a case-by-case basis.

The IRB staff is available to provide education on a variety of topics related to ethical issues in human subjects research. The staff will design an educational program to meet researchers' particular needs upon request.

H. Student Research Projects and Principal Investigators

University Research Administration (URA) sets the policy on who can serve as a principal investigator (see <https://ura.uchicago.edu/page/principal-investigator-eligibility>). Student researchers cannot serve as the principal investigator (PI) on a research study.

For studies that are not externally funded, if an individual does not automatically qualify for PI eligibility under URA's PI eligibility policy, the individual may serve as a principal investigator if the appropriate Dean (or other individual with appropriate level of authority, such as an Assistant or Associate Dean) authorizes the individual to serve as PI. This authorization is provided to the IRB – the IRB will accept an email or letter from the appropriate individual in the Dean's office stating that the individual has been granted PI status for the study.

II. Review and Approval Process

There are three review procedures for research involving human subjects: exemption, expedited review, and full board review. Each of these is described below.

A. Administrative Pre-Review by IRB Staff

All submissions undergo administrative pre-review by the IRB Staff. The IRB Staff can request additional information about the research and/or request modifications to the application form, protocol, and/or informed consent documents prior to review by a member of the IRB. The IRB Staff also makes recommendations to the Chair and IRB members about the level of review (expedited or full board) a given project should undergo.

B. Research that is Exempt from the HHS Regulations at 45 CFR 46

The HHS regulations at 45 CFR 46.101(b) specify six categories of research that are exempt from the human subjects protection regulatory requirements. The exemption categories are set forth at 45 CFR 46.101(b). All human subject research that is exempt will be conducted in accordance with the principles set forth in the Belmont Report.

The SBS IRB Staff (in consultation with the IRB Chair or Vice-Chair, if necessary) will determine whether the research meets the exemption requirements when they review the submission.

C. Research that is Eligible for Expedited Review Procedures

The HHS Regulations at 45 CFR 46.110 specify conditions under which research may be reviewed by the IRB under expedited review procedures. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited review or full board review -- utilized by the IRB.

Research activities that meet both of the following conditions may be reviewed under expedited review procedures:

- (1) The research presents no more than minimal risk¹ to human subjects, and
- (2) The research involves only procedures listed in one or more of the allowed expedited review categories².

¹ HHS regulations define "minimal risk" at 45 CFR 46.102(i) as "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".

² The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review categories are set forth at <http://www.hhs.gov/ohrp/policy/expedited98.html>

The expedited review procedure may not be used for:

1. Research 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 will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
2. Classified research involving human subjects.

The expedited review procedure may also be used to review minor changes in previously approved research during the period for which approval is authorized. (45 CFR 46.110)

SBS IRB staff who are designated as alternate members of the IRB and have sufficient training and experience may review and approve submissions that qualify for expedited review, including new studies, amendments, and continuing reviews, without sending those submissions to a faculty member of the IRB. The determination of whether a submission that qualifies for expedited review should be sent to a faculty reviewer will depend on whether there are factors that merit input from a faculty reviewer – those factors could include the use of deception as a research technique, studies in which there are complex issues related to data confidentiality, or studies occurring in other countries where a faculty reviewer can provide additional expertise on the local context for research in that country.

D. Research Requiring Review by the Full Board

All research that does not meet exemption requirements or is not eligible for expedited review procedures will be scheduled for review by the full board at a convened IRB meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific. Disapprovals may only be made by the convened IRB. Full board procedures are discussed in detail below in Section III of this Manual.

E. Continuing Review

The HHS regulations require that the IRB conduct continuing review of all human subjects research at intervals appropriate to the degree of risk, but not less than once per year [45 CFR 46.109(e)]. However, the University of Chicago has opted not to apply the terms of its Federal-wide Assurance to projects that are not federally funded (i.e., has “unchecked the box”). In March 2015, the SBS IRB adopted a policy that allows approvals for up to three years for non-federally-funded research that is minimal risk and meets certain other criteria (see the end of this manual for the full description of the three-year approval policy).

The AURA software system sends automated reminders to researchers several times prior to the expiration date of IRB approval to remind the research team that a continuing review request should be submitted if the research is ongoing.

Continuing review must be substantive and meaningful, and must be conducted by the convened IRB, unless the research is appropriate for expedited review. Ordinarily, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time

of continuing review³. Continuing review must include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting continuing review, the IRB will review, at a minimum, the protocol and any amendments as well as a status report on the progress of the research, including (a) the number of subjects accrued; (b) a description of any unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research; a summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research; and (d) a copy of the current informed consent document. Review of the currently approved consent document must ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation should be provided to the subject.

F. Amendments

Investigators must report to the IRB any planned changes in the conduct of their research, since these may affect the protection of human subjects. Minor changes proposed for previously approved research may be reviewed in an expedited manner prior to the scheduled continuing review date (45 CFR 46.110). When a proposed change in a research study is not minor, then the IRB must review and approve changes at a convened meeting before changes can be implemented. The only exception is the rare circumstance in which a change is necessary to eliminate apparent immediate hazards to the research subjects. In this case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with protection of human subjects.

G. Categories of IRB Actions

As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or specify modifications required to secure IRB approval of the research activity. When the research is reviewed by the convened IRB, these actions will be taken by a vote from a majority of voting members. When reviewing research by expedited procedures, the IRB Chair (or Designee) can take any of the following actions except to disapprove a study.

For non-exempt research, the IRB may take one of the following actions as a result of its review of research submitted for initial review or for continuing review. The investigator will be notified of such actions in writing.

- *Approval*: The IRB has identified no revisions or questions about the research and the application is approved as submitted. The study has been found to meet the requisite criteria for approval and the research may be carried out as described.
- *Conditional Approval*: The IRB has identified specific minor revisions or clarifications and has determined that research will meet the requisite criteria for approval once these revisions and/or clarifications are addressed. This means that the study is approved in principle; however, no research activities may take place until an appropriately qualified group or individual appointed by the IRB has determined that the investigator has satisfied the conditions for approval. (Note: The individual appointed by the IRB may be an IRB member, an IRB staff member, or a consultant.)

The following revisions or clarifications may be required as conditions of approval:

- (1) Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the

³ There are specific conditions that must be met in order for continuing review of research that was previously reviewed and approved by the convened IRB to be reviewed under expedited procedures. See expedited categories 8 and 9.

research excludes children);

(2) Submission of additional documentation (e.g., certificate of ethics training);

(3) Precise language changes to the protocol or informed consent documents; or

(4) Substantive changes to the protocol or informed consent documents which conform to clearly stated parameters.

- *Deferral*: The IRB has identified substantive clarifications and/or modifications such that the research study does not qualify for Approval or Conditional Approval. The study will be eligible for reconsideration by the convened IRB once the investigator has addressed the clarifications and/or modifications.

- *Disapproval*: The IRB disapproves the study in principle and the research may not take place. This is decided when the research raises significant scientific or ethical concerns and/or fails to meet one or more of the requisite approval criteria. This action must be taken at a convened meeting.

Risk Level: For each new application the IRB will determine whether the research presents minimal risk or *greater* than minimal risk of harm to subjects. For amendments and continuing research, the IRB will determine whether the risk level has increased, decreased, or remains unchanged.

Approval Period and Additional Monitoring: For non-exempt research studies, the IRB will determine the interval for continuing review. For federally-funded research, the approval period may not exceed 365 days. For non-federally funded minimal risk research, the IRB may grant an approval of up to 3 years (see the full text of the SBS IRB's 3-year approval policy at the end of this Policy Manual). The IRB will also determine whether additional monitoring of the research is necessary. Methods of monitoring ongoing research may include, but are not limited to, site visits and observation of the research procedures and/or consent process.

H. Investigator Appeal of IRB Action

Investigators may appeal an IRB decision regarding the revisions required by the IRB to the protocol and/or informed consent form and/or other components of the IRB Application or the disapproval of a study. Appeals must be submitted in writing within 30 days of IRB notification of actions and should provide *new* information that would aid in evaluating the request for reconsideration. In addition, the IRB, IRB Chair or Designee may invite the investigator to appear before the IRB to supply information or answer questions. The appeal will be reviewed at a regularly scheduled convened meeting, usually within 30 days of receipt.

III. Procedures for Full Board Meetings

Except when an expedited review procedure or exemption is used, the IRB will review proposed research at convened meetings at which a quorum of members is present.

A. Quorum

A quorum is defined as greater than 50% of the IRB membership and must include at least one member whose primary concerns are in non-scientific areas. In order to meet quorum

requirements, a member's alternate may attend in the member's place. A member participating via telephone connection can be used to establish a quorum. A special consultant(s) cannot be used to establish a quorum.

Should the quorum fail during a meeting (e.g. due to recusal of those with conflicts, loss of a non-scientist, early departures), discussions may proceed; however, votes may not be taken.

The attendance of an IRB member who is not affiliated with University of Chicago is not required under the IRB regulations to achieve quorum. However, the IRB strives to achieve attendance of an unaffiliated IRB member whenever possible, and an unaffiliated member is present at nearly all IRB meetings. The IRB may vote without an unaffiliated member present in rare circumstances.

B. Primary and Secondary Reviewers, and Consultants

Prior to the meeting, the IRB Director and/or IRB Chair will designate a primary reviewer for each submission item (including new studies, amendments, and continuing reviews) included on the full board's agenda. A secondary reviewer may also be assigned.

The IRB may invite individuals with competence in special areas to act as consultants in the review of issues that require expertise beyond or in addition to that available on the IRB.

C. Meeting Materials Sent Prior to IRB Meetings

A meeting agenda, application materials and other documentation required for review are prepared by the IRB Staff and are made available to IRB members through a folder in UChicago Box, prior to each full board meeting. For unaffiliated members, the agenda and other meeting documents are sent via email prior to each full board meeting if the unaffiliated member is unable to access the UChicago Box folder. The meeting agenda, reports and the meeting minutes are maintained electronically on the shared UChicago Box folder of the SBS IRB Office.

D. Telephone Use

Convened Meeting Using Speaker Phone:

Should a member be unable to physically attend a convened meeting, but available by telephone, the meeting may be convened using a speakerphone. In this manner, the member who is not physically present will be able to discuss the protocol with the rest of the members via speakerphone. Members participating by speakerphone may vote, provided that they have had an opportunity to receive and review the meeting materials in advance of the meeting.

Meetings Conducted Via Telephone Conference Calls:

Meetings may be convened via a telephone conference call. A quorum (as defined above) must be present and participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place. "Telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Members who are neither present at the convened meeting, nor participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

E. Recusal of IRB Members

IRB Members with a conflict of interest must recuse themselves from discussion and vote

regarding any submission for which they have a conflict of interest.

Members who declare a COI on any matter will recuse themselves and not participate in the discussion (except to answer questions or provide information as requested by the IRB) or vote. The IRB minutes will reflect such recusals as they occur during meetings.

F. Discussion and Vote

At the meeting, the primary reviewer introduces the research and provides the first comments resulting from his or her in-depth review. After the primary reviewer has provided his or her comments, the IRB Chair will ask the secondary reviewer (if one is assigned) for his or her comments, and then any special consultants will be asked to provide their comments.

The discussion of each new research proposal, continuing review progress report, amendment, adverse/unanticipated event, protocol deviation or non-compliance on the agenda is led by the Chair and any designated reviewer(s). Discussion by all members present at the convened meeting is conducted on the necessary ethical and regulatory questions, controverted issues, determinations of scientific/scholarly validity, risk, benefit, and additional safeguards for vulnerable populations.

At the end of the discussion of an application, the Chair looks for a motion on an action. The Chair then calls for a vote on the motion and the members may vote by voice as well as by raising their hands. The Chair asks for votes for the motion, then against, and finally for abstentions. A simple majority carries the vote. The Chair will strive to build consensus as much as possible and may take a straw vote before a binding vote in order to assess whether additional discussion is needed. A deeply divided vote may indicate that further discussion or deferral is appropriate. IRB Staff will count the final vote and the vote is recorded in the minutes.

Members with a COI will recuse themselves from participating in the deliberation and vote for protocols or matters with which they have a conflict. In addition, recused members will leave the meeting room during the review and vote, unless requested by the IRB to remain to answer specific questions.

G. Minutes

Recording: IRB Staff will take minutes of each meeting. Minutes will be written in sufficient detail to show at least the following:

- Meeting attendance; including status of each attendee (member, consultant, etc.), and conflicts of interest, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Determination of the level of risk and the duration of approval;
- Voting results, including number for, against, members abstaining (listed by name), and members who recused themselves and reason for recusal.
- Consideration of the requisite criteria for approval as well as any additional criteria for the protection of vulnerable populations.

Approval: Draft minutes will be distributed to members prior to the next IRB meeting for review, typically as part of the agenda packet that is distributed to IRB members before each IRB meeting. Minutes will be approved by a vote of IRB members – a simple majority vote is

needed to approve the minutes. The minutes are stored in a UChicago Box folder accessible to the IRB staff.

H. Guests

At any given IRB meeting, there can be various observers present. IRB staff members attend IRB meetings to support the work of the committee. The Institutional Official, Director of Research Integrity, and attorneys from the University of Chicago Office of Legal Counsel may attend as guests. Other individuals who wish to attend one or more meetings must receive permission from the IRB Chair and/or IRB Director to do so.

Investigators and co-investigators may be called into the IRB meeting if needed to provide information about a study being reviewed. He or she will come only for that purpose and will leave before the final discussion and vote on the study.

Any guest at an IRB meeting may be asked to leave, at any time, at the discretion of the IRB Chair or IRB Director.

IV. Considerations in Ethical Review of Research and Minimizing Risks for Participants

A. Selection of Subjects

Defining the appropriate population of subjects for a research project involves a variety of factors, including scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. The IRB requirement to make a specific determination that the selection of subjects is equitable is based on the principle of justice, and helps ensure that the burdens and benefits of research will be fairly distributed. The Belmont Report recommends that, as a matter of social justice, there should be an order of preference in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons. In addition, those individuals who may already be burdened (e.g., by disabilities or institutionalization) should not be asked to accept the burdens of research unless there is the possibility of direct benefit, or if other appropriate subjects cannot be found (i.e., if the research concerns their particular disability or circumstance). The IRB will consider the extent to which a proposed subject population may already be burdened by poverty, illness, or chronic disabilities in deciding whether they are a suitable subject population.

B. Incentives

In making its determination about the appropriateness of a given incentive, the IRB will consider who the subjects will be, what incentives are being offered, and the conditions under which the offer will be made. Informed consent documents should include a detailed account of the terms of the incentive, including a description of the conditions under which a subject might not receive the full incentive.

While payments or incentives to subjects are allowable and appropriate, the University of Chicago does not allow financial incentives or bonuses (including gifts) to be paid or awarded to

investigator or any member of the study staff as an incentive to recruit subjects to a study or meet any special enrollment targets.

C. Informed Consent

Informed consent is a process. The consent form or script that will be used with potential research participants plays a central role in the IRB's review of the consent process, but the IRB will examine the issue of consent from a holistic perspective that takes into account all of the information provided to the IRB in the protocol and related materials. Because subject understanding is a necessary component of informed consent, information must be presented in a language and at a level that is appropriate for the population. In general, consent documents should be written in lay language at a 6th to 8th grade level.

The following information should be included in the informed consent document [45 CFR 46.116(a)]:

- A description of the purpose of the research.
- A description of the procedures that subjects will be asked to participate in or undergo.
- A description of any reasonably foreseeable risks, discomforts, or inconveniences that may be associated with the research activity.
- A description of any benefits (if any) subjects may reasonably expect to receive, as well as a description of the importance of the knowledge that may be gained from the research. Note that payments to subjects are not considered benefits and should not be listed as such in the consent document.
- A description of the procedures in place to maintain confidentiality and the extent to which subjects' identifiable private information will be kept confidential.
- Names and contact information for individuals (usually the PI or members of the research team) who would be knowledgeable to answer questions about the research.
- A statement that subjects can contact the SBS IRB with any questions about their rights as research subjects. Contact information for the SBS IRB should be provided to the participant.
- The statement reminding subjects that participation is voluntary and that they have the right to withdraw at any time without penalty (or loss of benefits or services, where appropriate).

The following information should be included when appropriate:

- A description of any alternatives to participating in the research project.
- In those cases where the research involves more than minimal risk and research-related injury (i.e. physical, psychological, social, financial) is possible, the consent document must include a statement as to whether compensation and/or treatment will be provided. Note that the consent document cannot contain exculpatory language that waives or appears to waive subjects' rights.

D. Documentation of Informed Consent

The IRB may approve procedures for documentation of informed consent that involve either (i) a written consent form signed by the subject or the subject's legally authorized representative (LAR), (ii) short form written consent form with oral presentation, or (iii) a waiver of signed consent (verbal or online "click" consent, for example). The conditions for use of the short form procedure are set forth in the HHS regulations at 45 CFR 46.117(b)(2).

Waiver of Documentation of Consent

The requirement for the participant's signature on the consent form can be waived if the research involves no more than minimal risk and does not involve any procedures for which written consent is required outside the research context. 45 CFR 46.117(c)(2). Waivers of the signature requirement are often granted under 45 CFR 46.117(c)(2) for telephone and online surveys and questionnaires. The participant's signature on a consent form can also be waived if the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. 45 CFR 46.117(c)(1).

E. Privacy and Confidentiality

For the majority of social and behavioral science research, ensuring confidentiality is the most important procedure to minimize risks to research participants. Researchers should implement appropriate precautions to maintain the confidentiality of the research data, in accordance with the sensitivity and identifiability of the data to be collected. Methods to protect confidentiality include coding data, separating face sheets and consent documents from survey instruments, limiting access to identifiable data, and storing records in secured locations. More elaborate procedures may be appropriate for research involving sensitive data that may involve a greater risk should confidentiality be breached. In some cases, the investigator may want to seek a Certificate of Confidentiality to protect the data from compelled disclosure. Research in which the primary risk to subjects is from a breach of confidentiality, and in which no identifiable information will be recorded save the consent document, is eligible for a waiver of signed consent under 45 CFR 46.117(c)(1).

V. Special Populations: Additional Safeguards

If the proposed research involves a population that may be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards should be included as appropriate to protect the rights and welfare of these subjects.

A. Students

Universities afford investigators with a ready pool of research subjects: students. When recruiting students, investigators should be aware of the possibility that students may feel pressured to participate in research and should make every effort to make clear that participation in research is voluntary and their decision whether to participate will not affect their academic standing or their relationship with the researcher, other faculty, and the University.

If offering participation in research as a way to receive course credit (or extra credit), there are two important issues to address: (1) participation in the research must be only one of a number of options; and (2) the other options must be roughly equivalent in terms of the amount of time

and effort required. For example, participation in a 30-minute survey should not be offered as an alternative to completing a 10-page term paper.

Another issue raised by the involvement of students as subjects is confidentiality. As with any research involving human subjects, the researcher should make every effort to protect the confidentiality of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol. This is especially important for research involving students, since other students are often members of the research team and may be involved in data collection and/or analysis. Researchers should ensure that their research staff understands the importance of protecting confidentiality. The SBS IRB Staff is available to provide educational sessions and guidance on this topic.

B. Employees

Many of the same issues arise when recruiting employees to participate in research. Just as student participation raises questions regarding the ability of students to truly exercise free choice because they may be concerned that grades or other important factors will be affected by their decision whether to participate, employees may be concerned that their decision whether to participate may affect performance evaluations or job advancement. Also, it may be difficult to maintain the confidentiality of personal medical information or research data when the subjects are employees.

C. Individuals with Cognitive Impairments

The primary ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders, or individuals who are active substance abusers, is that their disorders may compromise their capacity to understand and/or appreciate the purpose and risks and benefits of the research and to participate in the consent process in a meaningful way. Investigators should provide a rationale for involving cognitively impaired subjects, and should include additional means to protect the rights and welfare of these subjects.

Some individuals with cognitive impairments may be institutionalized, and this may further compromise their ability to exercise free choice. It is also important to protect the privacy of all subjects and the confidentiality of information gathered in research exploring emotionally sensitive topics, since some individuals would not want the fact of their institutionalization divulged.

It is important to note that all adults, regardless of their diagnosis or condition, should be presumed competent to provide informed consent unless there is evidence of a serious condition that would impair their reasoning or judgment. Individuals who have a diagnosed mental disorder may be capable of providing informed consent. Mental disability alone should not disqualify a person from consenting to participate in research.

Persons who have been determined to be incompetent by a judge will have a court-appointed guardian who must be consulted and provide consent before that individual can be enrolled in research. Note that legally authorized representatives (LAR) are generally not officials of the institution in which these individuals reside, since their supervisory duties may give rise to conflicting interests. Also, it should not be assumed that family members or others financially responsible for the individual are able to provide legally authorized consent, since they too may have conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances.

D. Children

The regulations provide additional protections for children involved in research, as set forth in 45 CFR 46 Subpart D. The IRB may approve research involving children as subjects only if the research fits into one of four specific categories. These categories are based on the level of risk and the possibility of direct benefit to individual subjects. In Illinois, children include all those who have not yet reached their 18th birthday (e.g., 0 through 17 years old). The risk categories for research in which children will be participants are set out at 45 CFR 46.404 through 45 CFR 46.407.

Requirements for Permission by Parents or Guardians and for Assent by Children

1. Adequate Provisions for Child's Assent [45 CFR 46.408(a)]

The investigator must make adequate provisions for soliciting the assent⁴ of child subjects when the children are capable of providing assent. In determining whether children are capable of assenting, the investigator should take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition.

Waiver of Assent. [45 CFR 46.408(a)]

If the IRB determines either of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- When the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

Even when the IRB determines that child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for adults. [See 45 CFR 46.116(d)].

Child's Dissent

Parents may overrule their child's dissent in cases where the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research, at the IRB's discretion. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, the IRB should be sensitive to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is high. Should the child not wish to undertake such experimental therapy, difficult decisions may have to be made. In

⁴ "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

general, if the child is a mature adolescent and death is imminent, the child's wishes should govern.

E. Wards of the State or Other Agency

Children who are wards of the state or any other agency, institution, or entity can be included in research meeting categories 45 CFR 46.406 or 45 CFR 46.407 only if the research is:

- (i) related to their status as wards; or
- (ii) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under this authority, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

F. Pregnant Women and Fetuses

The regulations provide additional specific protections for pregnant women and fetus involved in research (see 45 CFR Part 46 Subpart B).

G. Prisoners

The special vulnerability of prisoners makes consideration of their involvement as research subjects particularly important. Prisoners may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for research involving prisoners as subjects. The IRB may approve research involving prisoners as subjects if these special provisions are met.

For research studies that have no federal funding, if the only procedure involving data collected from prisoners is secondary analysis of that data (i.e., the data was collected from some individuals who were prisoners (or may have been prisoners) at the time of the data collection), the research team need not select prisoners as a category of participant in the IRB submission form and need not meet all of the criteria in 45 CFR Part 46 Subpart B that are described below. Instead, the IRB's review will focus on whether the proposed data security procedures are adequate. If the research team is requesting a waiver of consent for the secondary analysis of data collected from prisoners, it must satisfy the regulatory criteria for a waiver of consent.

Special Definitions Pertaining to Research Involving Prisoners

(1) Minimal Risk

For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk used for other populations. The definition for prisoners includes

reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons.⁵

(2) Prisoner

"Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

A. When Subjects Become Prisoners During the Course of the Research

If a subject becomes a prisoner after enrollment in research, the investigator is responsible for reporting in writing this situation to the IRB immediately. Upon its review, the IRB can either:

- (i) approve the involvement of the prisoner-subject in the research in accordance with this policy or
- (ii) determine that this subject must be withdrawn from the research.

B. Specific Findings of IRB Required to Approve Research

When the IRB is reviewing a protocol in which a prisoner is a subject, the IRB Committee must make seven findings as follows:

1. Research falls within at least one of four acceptable categories:

- A. A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
- A. A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- B. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
- C. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

2. Any Advantage of Participation Does Not Impact Prisoner's Ability to Weigh Risks

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

⁵ "Minimal risk" means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; AND
7. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

C. Permitted Research Involving Prisoners.

For research conducted or supported by HHS to involve prisoners, two actions must occur:

- (i) the IRB must certify to OHRP that it has reviewed and approved the research under the federal regulations; and
- (ii) OHRP must determine that the proposed research falls within one of the categories of permissible research described above.

If an investigator wishes to engage in non-HHS-supported research such certification is not required. However, the IRB will apply the standards of the federal regulations in reviewing the research.

D. Prisoners Who Are Minors.

When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility a prisoner) the special protections regarding the inclusion of children as subjects also apply.

E. Federal Bureau of Prisons.

The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons. Investigators should review the regulations at 28 CFR Part 512 when considering such research.

International Research

International research often requires additional safeguards to protect the rights and welfare of subjects. These include everything from the use of a translator if the person(s) seeking consent and/or collecting data is not fluent in the subject's language to waiving the requirement to obtain written consent due to local custom or because of risks subjects may face due to social or

political conditions. Investigators who will be conducting research internationally should provide the IRB with at least the following information:

- Information about where the research will be conducted (both the geographic location and the performance site, where applicable).
- A copy of local IRB or equivalent ethics committee approval, where possible. Depending on the local context, this may take the form of a letter of approval from a local IRB, a local university department sponsoring the research, a local institutional oversight committee, or an indigenous council.
- Information about the investigator's knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator's personal experience conducting research (or studying or residing) in the region.
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.
- The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how they will be minimized.
- Copies of the translated informed consent documents and instruments.

When composing an IRB protocol for an international research project, researchers should clearly demonstrate that the proposed procedures are appropriate given the culture, norms, and mores of local communities. Whenever practical, researchers should include local community representatives in the design of the research and consent processes to ensure that local concerns about research practices, goals, or uses of collective cultural or intellectual property are considered. Community collaboration in research design demonstrates concern for the ethical principles of justice (by articulating the equitable distribution of research risks and benefits in relation to community needs) and respect for persons (by recognizing the right of individuals to form groups with corporate agency).

VI. Audits, Unanticipated Problems, and Non-Compliance

A. Audits and Monitoring

To help ensure compliance with federal regulations and IRB policies regarding research with human subjects, and to ensure that human subjects are adequately protected, the SBS IRB staff and IRB members may conduct routine, targeted, or random audits of research protocol files subject to their jurisdiction. In addition, the IRB staff and members may request monitoring of approved projects that may take the form of routine, targeted, or random audits. These activities may include, but are not limited to the following:

- a. Request progress reports from investigators;
- b. Examine research records;
- c. Contact research subjects;
- d. Dispatch observers to the sites where research involving human subjects and/or the informed consent process is being conducted;
- e. Verify from sources other than investigators that no material changes in the study have occurred;
- f. Audit advertisements and other recruiting materials to confirm proper IRB approval;

- g. Review projects to verify from sources other than the investigator(s) that no material changes have occurred since previous IRB review; and/or
- h. Other monitoring or auditing activities deemed appropriate by the IRB.

Reporting of Audit Results to Full Board

The results of any targeted or random audits by the IRB members or staff will be reported to the full IRB on the agenda of the next regularly scheduled meeting. However, if the information gained during the monitoring or auditing process indicates that human subjects may be exposed to unexpected serious harm, the IRB may suspend or terminate approval of the research prior to the next regularly scheduled IRB meeting.

B. Unanticipated Problems Involving Risks to Participants or Others

Unanticipated problems involving risks to participants or other individuals, or that generate complaints from research participants, must be reported promptly to the SBS IRB.

Unanticipated problems include any incident, experience, or outcome that is:

- 1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol and related documents; and (b) the characteristics of the participant population being studied; AND
- 2) related or possibly related to participation in the research; AND
- 3) suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Some unanticipated problems involve social or economic harms rather than the physical or psychological harm typically associated with adverse events.

An unanticipated problem that is also a serious adverse event should be reported to the IRB within 1 week (7 days) of the researcher becoming aware of the event. A "serious adverse event" is any adverse occurrence that results in participant death; places a participant at immediate risk of death; results in a participant's inpatient hospitalization or prolongation of existing hospitalization; results in a persistent or significant disability/incapacity; results in a congenital anomaly/birth defect; or based on appropriate medical judgement, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Any other unanticipated problem (that is not a serious adverse event) should be reported to the IRB within 2 weeks (14 days) of the researcher becoming aware of the problem.

An unanticipated problem report can be submitted to the IRB online through the AURA software system. The IRB Director will initially evaluate any unanticipated problem report and consult with the IRB Chair as needed to determine whether the reported problem creates additional or new risks to participants or other individuals, and what appropriate remedial action should be taken by the research team to address the situation and, if needed, to notify research participants of the problem. For federally-funded research, unanticipated problems that create risks to subjects or others will be reported to the HHS Office for Human Research Protections (and other federal agency as appropriate).

If a study that is designated minimal risk enrolls more than the number of participants listed in the protocol, the IRB will not require that the research team submit an unanticipated problem

report or an amendment solely due to “over-enrollment.” The enrollment total in the protocol is regarded as an estimate of enrollment, not as a “hard cap” on enrollment – if the study is minimal risk, enrolling more than the number of individuals listed in the enrollment estimate in the protocol does not affect the risk/benefit ratio of the study. If a study is greater than minimal risk and enrolls more than the enrollment total listed in the protocol, the IRB will require an amendment to increase the enrollment total in the protocol and an explanation of whether the “over-enrollment” has affected the risk/benefit ratio of the study.

C. Protocol Deviations and Noncompliance

Deviation from the IRB-approved protocol as well as noncompliance with applicable University policies, regulatory requirements, and/or IRB determinations must be reported to the IRB. Such occurrences can have a negative impact on research participants. Protocol deviation and noncompliance can alter the risk-benefit ratio for participants or otherwise jeopardize the safety, rights, and welfare of subjects. Nevertheless, there are also times when it is necessary to deviate from the approved research plan or continue aspects of the research during a lapse in approval in order to protect research subjects.

Reported incidents will be considered *possible* noncompliance until a final determination is made by the IRB. The IRB will assess the severity of the event and, if necessary, require corrective action. Serious and continuing noncompliance will be reported to the appropriate institutional officials and regulatory agencies.

Definitions

Noncompliance. Failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB. In addition, failing to submit a continuing review application in a timely manner and permitting IRB approval to expire is considered noncompliance. However, it is not noncompliance when there is a need to deviate from the approved protocol or continue aspects of the research after expiration of approval in order to protect the welfare of research participants. Also, departure from the protocol that is due to a study participant’s non-adherence is not considered to be a protocol deviation, but may need to be reported to the IRB.

- *Minor Noncompliance.* These are incidents which are the result of an unintentional deviation or omission from the protocol that the IRB has approved or determined to be exempt. A minor noncompliance shall not have negatively affected the rights, safety, or welfare of the subjects. The conduct of unsubmitted or unreviewed human subjects research that would have qualified for an exempt determination had it been reviewed and determined exempt by the IRB staff in advance of initiating the research will also be considered minor noncompliance.
- *Serious Noncompliance.* Noncompliance that adversely affects the rights or welfare of participants. These are incidents of noncompliance involving non-exempt protocols where: the noncompliance increases the risk and/or decreases the benefit to individual subjects; the research takes place without appropriate IRB review and approval; egregious or intentional noncompliance occurs; and/or another situation exists which the IRB determines to be a serious noncompliance.
- *Continuing Noncompliance.* A pattern of noncompliance that indicates an inability or

unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.

Reporting Requirements and Procedures

Reports by the investigator:

Protocol deviations and noncompliance should be reported to the IRB as soon as possible. An initial report should be made to the IRB Director within *1 week* (7 calendar days) of when the investigator became aware of the event. The initial report must be followed by a formal report filed in the AURA software system within no more than *2 weeks* (14 calendar days) of when the investigator became aware of the event.

In some cases, reporting requirements may be met by submitting a preliminary report to the IRB Director, IRB, and other officials/agencies involved, with a follow-up report submitted at a later date when more information is available. These determinations will be made on a case-by-case basis, with the IRB Chair, IRB Director, investigator, institutional official(s) and/or others involved as appropriate. The primary consideration in making these judgments will be the need to take timely action to prevent avoidable harms to subjects and others.

Reports by other parties (e.g. research staff, general public, research subjects, etc.):

Whenever possible, reports should be submitted via the investigator. However, if the reporting party deems it necessary and/or wishes to remain anonymous to the investigator, he or she may contact the IRB directly.

Protocol deviations and/or noncompliance incidents may be discovered by IRB members or IRB staff as part of continuing review of nonexempt protocols, as part of a Quality Assurance or audit activity, or an incidental awareness (e.g., due to a news article, errant email or incidental finding of recruitment material). Such discoveries must be promptly reported to the IRB Director.

The reporting party should use their judgment when determining if an event is reportable. If an individual is unsure of whether there are grounds to report an event, he or she may call upon the IRB Director to discuss the situation informally.

Alternatively, individuals always have the option of making reports through the Whistleblower process. A protected disclosure is a good faith communication about an incident that constitutes improper governmental activity or may significantly threaten the health or safety of employees or the public, if the disclosure or intention to disclose was made for the purpose of remedying that condition.

Reports of possible noncompliance should include a complete description of the event and include sufficient detail to allow the IRB to make an assessment.

Special Considerations

Deviations from the IRB approved protocol that cannot wait for IRB review because of the immediate need to eliminate apparent hazards to the subject are not considered noncompliance.

The continued participation of enrolled subjects in research for which approval has expired is also not considered noncompliance if it is necessary to protect the best interests of enrolled subjects.

The determination of whether it is necessary to deviate from the approved protocol or to continue aspects of the research to protect subjects may initially be made by the investigator. This determination may be made for enrolled subjects as a group or for individual subjects. However, the investigator must submit a report to request IRB confirmation of agreement as soon as possible.

IRB Review and Actions

The IRB will fully investigate and review reports of possible noncompliance to determine if the event was (1) not noncompliance, (2) minor noncompliance, (3) serious noncompliance, or (4) continuing noncompliance. If necessary, the IRB will require corrective action. The IRB will attempt to resolve alleged instances of noncompliance without interrupting the conduct of the study, especially if the rights, safety, and welfare of subjects may be jeopardized by the interruption. All reports of potential noncompliance as well as the outcome of investigations that are substantiated will be noted in the protocol record.

If the IRB finds that no noncompliance occurred because: (1) the reported noncompliance was unsubstantiated, (2) the investigator deviated from the protocol in order to eliminate immediate and apparent hazards to subjects, or (3) continued participation of enrolled subjects in research for which approval has expired was necessary to protect the best interests of enrolled subjects, actions by the IRB may include but are not limited to:

- Requiring no further action.
- Requiring submission of an amendment to the protocol or consent form.
- Requiring submission of a continuing review application.

If minor noncompliance is found to have occurred, actions by the IRB may include but are not limited to:

- Requiring no further action.
- Requiring remedial training (e.g. online educational program, attendance at workshop, one-on-one training).
- Requiring re-consent of subjects.
- Requiring the submission of an amendment to the protocol or consent form.

Whenever appropriate, investigators will be assisted so that they can achieve compliance without the need for sanctions. However, if the investigator fails to cooperate with IRB requests to correct minor noncompliance, this inaction will be treated as continuing noncompliance.

If serious and/or continuing noncompliance is found to have occurred, actions by the IRB may include but are not limited to:

- Establishing a corrective action plan.

- Asking the Investigator to voluntarily halt the research until he or she is in compliance.
- Requiring the Investigator to participate in and complete further training.
- Requiring more frequent IRB review of the project.
- Requiring re-consent of subjects.
- Making recommendations to the Institutional Official (IO) for further sanctions, stipulations, or restrictions. Such recommendations could include (but are not limited to): the research data not be published, the data be destroyed, the data not be used in a dissertation or thesis, and/or that the University take away the researcher's privilege of conducting research with human subjects.
- Sharing information of noncompliance with other institutional units (e.g., Conflict of Interest Committee, University Research Administration, and Office of Legal Counsel) as deemed necessary.
- Suspending or terminating IRB approval for some or all parts of the research activity.

The IRB and, when appropriate, the institution will act promptly to ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements. The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or deviates from the approved protocol.

All serious and/or continuing noncompliance must be reported promptly to the Institutional Official (IO) and, for federally funded research, the appropriate department, agency head or sponsor. Reports will only be made to OHRP and/or FDA for research that is regulated by these oversight agencies per University of Chicago's Federalwide Assurance (FWA). Copies of reports or correspondence sent to outside agencies will be maintained by the IRB Office.

The IRB Director (or designee) is responsible for assisting the IRB Chair with the initial fact gathering and review of the possible noncompliance. The IRB Chair reviews the potential noncompliance and may make a decision on the action to be taken, may convene an ad hoc subcommittee to conduct an investigation and/or ask the convened IRB to make a decision. Incidences of potential serious or continuing noncompliance will generally be referred to the convened IRB for deliberation and a final decision on the process and/or the outcome.

If appointed by the Chair, an ad hoc IRB subcommittee may review the possible noncompliance, conduct interviews and hearings as needed, review pertinent data or findings of the investigation, and may make recommendations to the convened IRB as to a course of action.

The convened IRB reviews information gathered about the possible noncompliance, reviews pertinent data or findings of the investigation, deliberates, and makes a decision about the nature of the incident and course of action.

The IRB Director will confirm that corrective action has been taken (if applicable) or designate an IRB staff member to take on this task. The IRB Director is also responsible for notifying the Institutional Official (IO) about any serious or continuing noncompliance and will cooperate in notifying the funding agency and other regulatory bodies about the noncompliance, as appropriate. The IRB Director or Staff will notify the Investigator of the review outcome in

writing promptly.

If the IRB determines that the noncompliance is serious and/or continuing, the IRB Chair, in cooperation with the IRB Director, reports this in writing to the IO along with any further recommendations from the IRB for institutional action. Regulatory authorities or Sponsors may also be notified by the IO (or his or her designee) as applicable and required.

Suspension and Termination of IRB Approval

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. When the IRB suspends or terminates its approval it will include a statement of its reasons in writing and report the suspension or termination promptly to the investigator.

- **Suspension of IRB approval:** temporarily or permanently withdrawing approval for some or all research procedures short of permanently stopping all research procedures. Suspended research must undergo continuing review.
- **Termination of IRB approval:** permanently withdrawing approval for all research procedures. Terminated research is closed and does not require continuing review.

When study approval is suspended or terminated by the IRB, in addition to stopping all research activities, the IRB will, if appropriate, inform any subjects currently participating that the study has been terminated. The IRB will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare.

Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects will be authorized by the full IRB. The IRB Chair is authorized to issue orders immediately suspending IRB approval, in which case the decision will be reported to the full IRB for review.

SOCIAL AND BEHAVIORAL SCIENCES IRB THREE-YEAR APPROVAL POLICY

This policy describes the criteria under which a Triennial (3-Year) Approval may be granted, and the corresponding initial and ongoing review and approval procedures.

Policy Statements

IRB approval for a study will be valid for a (3) three year period if the study meets the following conditions:

- Poses no more than minimal risk or harms to human participants. Risk/harms in this context include the probability or magnitude of harm or injury (physical and psychological/emotional), occurring as the result of participation in a research study. Although most social and psychological risks are minimal and transitory, investigators must be aware of potential of harm;

AND

- Not subject to federal funding/oversight

When is a protocol not eligible for a 3-year approval?

Projects are not eligible for the 3-year approval period if they meet any of the following criteria:

- Studies that involve greater than minimal risk
- Research with federal funding/sponsorship, directly or indirectly, including federal training and center project grants.
- Research directed or overseen by a federal agency that has signed on to the Common Rule, including every agency within the U.S. Department of Health and Human Services
- Studies subject to FDA oversight
- Studies seeking or obtaining a Certificate of Confidentiality granted by NIH
- Studies with contractual obligations or restrictions that preclude eligibility for this policy, i.e. the non-federal sponsor or funder of the research requires annual IRB review of the study.
- Protocols that have been determined to meet exemption requirements (because exempt studies have no expiration date for IRB approval)
- Projects involving prisoners as research subjects

NOTE: research projects that involve prisoners **only** to the extent of analyzing secondary data about prisoners qualify for 3-year IRB approvals under this policy so long as the project is not federally-funded and meets the other criteria listed in this policy. As part of the IRB's review process, the IRB examines whether secondary data analysis projects include appropriate data security measures. If the only involvement of prisoners in a research study is that the research team will be analyzing secondary data about prisoners, the study can

still qualify for a 3-year IRB approval so long as the project is not federally-funded and meets the other criteria listed in this policy.

Inclusion/exclusion of any research project from this policy will be at the discretion of the University of Chicago Social and Behavioral Sciences IRB.

The 3-year approval period will not be available to any collaborating institution or investigator relying on University of Chicago's review *unless* verified in writing as acceptable by the other IRB. (An email from the relying IRB is sufficient for this purpose).

Changes in Funding Status:

It is the responsibility of the Principal Investigator to report to the IRB changes in funding status.

If the PI receives federal funding **less than one year into the three-year approval** of a study that originally qualified under this Policy, the PI must notify the IRB by submitting an amendment. The approval period will be decreased from three years to one year and the PI will be required to obtain continuing review by day 364 from the original approval date.

If the PI receives federal funding **after the first year of a three-year approval period**, the PI must submit an amendment and a continuing review application to the IRB. Upon approval, a new expiration date will be calculated by the IRB based on the approval date of the continuing review.

For any project that qualified for exemption, a change in funding must be reported to the IRB by submitting an amendment.