



THE UNIVERSITY OF CHICAGO

Social & Behavioral Sciences Institutional Review Board (IRB) Manual

Social & Behavioral Sciences Institutional Review Board
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Effective Date & Applicability:

This policy manual applies as follows:

- To **ALL** research initially approved on or after January 21, 2019.
- To some research approved prior to January 21, 2019:
 - For federally funded research, the IRB may decide (on a case-by-case basis) to apply the [Three Burden-Reducing Provisions](#) as well as some or any of those revisions in this policy manual that do not conflict with the pre-2018 Common Rule. Projects approved utilizing the three burden-reducing provisions will comply with the revised Common Rule as required on January 21, 2019.
 - For projects not otherwise subject to the Common Rule, the SBS IRB Office or SBS IRB may apply some or all of the revisions in this manual on a case-by-case basis.

When the research invokes multiple regulatory frameworks (e.g., Common Rule, DOJ, HIPAA, Illinois laws, etc.), all will be considered and applied as required. For those projects not transitioned (or only partially transitioned) to the new policy, the previous version of this policy manual will apply as applicable.

This manual will be further updated as OHRP provides additional guidance related to the revised Common Rule.

PREFACE

The policies and procedures set forth in this manual adhere to the ethical principles and guidelines for the protection of research participants summarized in the [Belmont Report](#), and comply with applicable federal regulations and state laws related to human subjects protections. Both the membership of the Institutional Review Board (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.

Note on Flexibility:

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. The SBS IRB applies commensurate protections for research projects that fall out of the scope of the FWA. As noted in the preamble of the revised [Common Rule](#), institutions are allowed a wide degree of flexibility with regard to making determinations related to ethical oversight of research not regulated by the Common Rule. 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. This approach does not create a two-tiered application of ethical principles or protections; rather, it allows for an appropriate level of flexibility without compromising human subjects protections. The IRB encourages consultation at all stages of the research process.

I. GENERAL POLICIES AND PROCEDURES

A. Jurisdiction

The policies and guidance in this manual apply to 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, etc.) including

- research that is sponsored by this institution,
- funded or unfunded research conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities,
- funded or unfunded research conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, and/or
- research involving the use of this institution's non-public information to identify or contact human research subjects or prospective subjects, regardless of sponsorship.

The University has authorized the Social and Behavioral Sciences (SBS) IRB to review and approve non-exempt human subjects research from the social and behavioral sciences. SBS IRB Staff (in consultation with the IRB Chair or Vice-Chair, if necessary) will determine whether the research constitutes human subjects research or meets the exemption requirements when they review the submission.

The SBS IRB committee is an administrative body established to protect the rights and welfare of human research subjects enrolled in research. It 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 has the authority to approve, require modifications of, defer, 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.

To effectively ensure the protection of research participants, the IRB's decision-making must be independent from coercion or undue influence. Any attempt to inappropriately influence the IRB or IRB staff in the performance of their duties will not be tolerated and should be reported immediately to the IRB Chair, Dean's Office, and/or the Institutional Official (IO). The performance of research involving human subjects without IRB approval or exemption is considered noncompliance with human subjects protection requirements and will be handled as described in this policy.

The University of Chicago maintains a Federalwide Assurance of Compliance (FWA) with the Office for Human Research Protections (OHRP) for federally-sponsored research. The SBS IRB is covered under this Assurance.

B. IRB Membership

The requirements for the composition of the IRB are described in the Common Rule. The SBS-IRB complies with these requirements.

The 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 (professional competence) and the diversity of their backgrounds, including considerations of their gender, 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 (including policies and resources) 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.

When the IRB reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

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 shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

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 supersede 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

IRB:

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-related records are retained for at least three years.

For non-exempt research involving human subjects covered by the Common Rule (or exempt research for which limited IRB review is required) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

Investigators:

Records pertaining to research that is conducted must be retained for at least three years after completion of the research. All records must be 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. In addition, investigators are responsible for maintain records beyond three years when required by other laws, university policies, agreements, etc. (e.g., HIPAA, journal requirements, sponsor requirements, DUA agreements, etc.). University

Policy 2708, Managing University Records can be found at <http://adminet.uchicago.edu/admincompt/finpolic/2708.shtml>.

G. Human Subjects Protection Training and IRB Educational Sessions

The SBS IRB requires human subjects protection training for the individual(s) responsible for the overall design and/or conduct of the study (e.g., the PI), as well as any research study personnel considered engaged in human subjects research activities (e.g., recruiting, obtaining consent, collecting data, interacting or intervening with human subjects, analyzing identifiable data, etc.). Individuals conducting both exempt and non-exempt human subjects research are subject to this requirement. 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.

Note: additional or more frequent training required for research personnel as the result of an agreement or award is the responsibility of the Principal Investigator (e.g., HIPAA training, Responsible Conduct of Research, Good Clinical Practice, etc.).

H. Principal Investigator (PI) Status

- Student researchers cannot serve as the principal investigator (PI) on a research study.
- University Research Administration (URA) sets the policy on who can serve as a principal investigator. Those who are ineligible and wish to serve as PIs on externally funded projects must request an exception from URA (see <https://ura.uchicago.edu/page/principal-investigator-eligibility>).

I. Posting of Clinical Trial Consent Forms

The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

Federal guidance and instructions regarding the implementation of this requirement are available at <https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html>.

J. IRB Review of Grant Applications

The IRB requires notification of any funding and awards and affiliation of the award(s) to the protocol in the AURA system (when applicable). Once a project is approved, any changes to funding must be submitted and approved by amendment.

The revised Common Rule removes the requirement that the IRB formally review the federal grant application or proposal for consistency with the protocol submitted to the IRB. Unless required by

the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the SBS IRB will no longer conduct formal congruency review of Federal grant applications or proposals when research is subject to the revised Common Rule. The IRB will, however, continue to require notification of the funding source in order to determine if additional requirements and/or regulations apply.

II. Review and Approval Process

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. Exempt Determinations and Limited IRB Review

The Common Rule specifies the categories of research that are exempt from the human subjects protection regulatory requirements (see Appendix 2). In addition to those allowed under the Common Rule, the SBS IRB recognizes an additional category of research that can receive exemption for minimal risk, non-federally funded research. This additional category of activities can also be found in Appendix 2. 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, if necessary) will determine whether the research meets the exemption requirements. When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Chair or designated member of the IRB, and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications of, or disapprove the project.

Proposed modifications to the aspects of research subject to limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB.

Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

Limitations on Exemptions:

Children:

- Exemption #2 (i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for

research involving observations of public behavior when the investigator does not participate in the activities being observed.

- Exemption #2 (iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children.
- Exemption #3 does NOT apply to research involving children.

Prisoners:

- Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners.

C. Research that is Eligible for Expedited Review Procedures

Common Rule specifies 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.

The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures.

The expedited review procedure may not be used for:

- 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.
- 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. The limited IRB review that is required for certain exempt research may be conducted using expedited review procedures.

Continuing review of research is not required for research that qualifies for expedited review unless the IRB determines that it is required for a specific project and documents the rationale within the IRB record.

¹ HHS regulations define "minimal risk" 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 Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB.

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).

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 Common Rule requires that the IRB conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, but not less than once per year except as described in § .109(f).

Unless the SBS IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:

1. Research eligible for expedited review in accordance with § .110;
2. Research reviewed by the IRB in accordance with limited IRB review;
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, **or**
 - b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Please note that the SBS IRB may determine that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine that continuing review is required when:

1. Required by other applicable regulations;
2. The research involves topics, procedures, or data that may be considered sensitive or controversial where additional oversight may be warranted;
3. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
4. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
5. An investigator has a history of noncompliance

When the SBS IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

For research not requiring continuing review, the SBS IRB may send yearly, automated messages to investigators with open protocols, reminding them of the requirements for open studies and prompting them to close projects when applicable.

Note: in March 2015, the SBS IRB adopted a policy that allowed for approvals of up to three years for non-federally-funded research that is minimal risk and meets certain other criteria. Due to the

change in regulations, this policy is no longer in effect for new studies approved on or after 08/20/2018. See Appendix 3 for additional information.

For research requiring continuing review, 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 review. 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 promptly report proposed changes in a research activity to the SBS IRB (or SBS IRB office for exempt research), and must conduct the research activity in accordance with the terms of the current approval until any proposed changes have been reviewed and approved by the IRB or IRB office, except when necessary to eliminate apparent immediate hazards to the subject. This requirement applies to all research approved by the SBS IRB and SBS IRB office, including exemptions, any aspects of exempt research subject to limited IRB review, and research for which continuing review is not required.

Minor changes proposed for previously IRB approved research may be reviewed in an expedited manner. 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 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: The IRB will determine the interval for continuing review. In general, exempt research, exempt research with limited IRB review, and research eligible for expedited IRB review will not be subject to continuing review. For research requiring continuing review, the approval period may not exceed 365 days. 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

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; votes, however, 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.

B. Primary and Secondary Reviewers, and Consultants

Prior to the meeting, the SBS IRB Staff 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 prior to each full board meeting. 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 an 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 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 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.

General Requirements:

The following specific requirements for consent, whether written or oral, apply to research subject to the revised Common Rule:

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR)
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR
4. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information
5. Except for broad consent
 - Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. In general, consent forms less than 4 pages are considered to already be concise.
 - Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate
6. No informed consent may include any exculpatory language through which the subject or the LAR 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.

D. Elements of Consent:

Exempt Consent Elements (including limited IRB review):

In general, some form of consent or permission is required for exempt research (especially when interacting/intervening with participants) unless justification is provided.

While there are no specific consent requirements for exempt research, general elements to include are:

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures/activities
- A description of any reasonably foreseeable risks or discomforts to the subject (as applicable)
- A description of any benefits to the subject or to others that may reasonably be expected from the research (as applicable)
- A statement that participation is voluntary and the refusal to participate or the decision to withdraw will involve no penalty or loss of benefits to which the subject is otherwise entitled
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (address audio recordings, video, use of quotations, use of identifiers, use of data for other studies, etc.)
- Investigator contact information for answers to pertinent questions about the research
- SBS IRB office information for answers to questions about research subjects' rights

IRB-Reviewed Elements of Consent (general, for research subject to the Common Rule):

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed, and identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research
- An explanation of whom to contact in the event of a research-related harm or injury to the subject (can be the same as the person above)
- An explanation of whom to contact for answers to pertinent questions about research subjects' rights (e.g., SBS IRB office)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional IRB-Reviewed Elements of Informed Consent (as appropriate, for research subject to the Common Rule):

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

HIPAA Authorization Elements: HIPAA Authorization language is subject to IRB review when combined with the research consent form/information. The individual must be provided with a copy of the Authorization. The elements for a valid HIPAA authorization can be found in the HIPAA section of this policy.

Elements of Broad Consent (for research subject to the Common Rule)

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted under the revised Common Rule. Broad consent is not currently recognized in FDA regulation or guidance.

Investigators must include information regarding the circumstances under which broad consent will be obtained, the proposal for tracking of responses, and the proposed consent form(s) (or oral script if a waiver of documentation of consent is sought) and any other consent materials (e.g., information sheet, audiovisual materials, etc.) in their submission to the IRB. The SBS IRB will review the information provided with the aid of a checklist to ensure that all requirements are satisfied. The outcome of the IRB's review will be communicated to the investigator.

When investigators propose research involving the use of identifiable private information and/or identifiable biospecimens research for which broad consent was obtained, the investigators must include documentation of the IRB approval for the storage or maintenance of the information or specimens and a copy of the consent form and/or other materials. The SBS IRB will review the information provided with the aid of a checklist to ensure that all requirements are satisfied. The outcome of the IRB's review will be communicated to the investigator.

Elements:

- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)
- A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite)
- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject
- An explanation of whom to contact for answers to questions about the subject's rights (e.g., SBS IRB Office)
- An explanation of whom to contact for answers to questions about storage and use of the subject's identifiable private information or identifiable biospecimens
- An explanation of whom to contact in the event of a research-related harm

E. Screening, Recruiting, or Determining Eligibility

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects for inclusion in the research. Pursuant to the revised rule, the SBS IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective subject or the subject's LAR if either of the following conditions is met:

1. The investigator will obtain information through oral or written communication with the prospective subject or LAR, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a subject (including the use of their identifiable private information or biospecimens) in other research activities.

F. Documentation of Informed Consent

Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy must be given to the person signing the ICF. An original, signed consent form for each subject must be kept by the investigator.

The ICF may be either of the following:

1. A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or
2. A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR and that the key information required by § .116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. When this method is used:
 - The oral presentation and the short form written document should be in a language understandable to the subject; and
 - There must be a witness to the oral presentation; and
 - The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and
 - The short form document is signed by the subject;
 - The witness must sign both the short form and a copy of the summary; and
 - The person actually obtaining consent must sign a copy of the summary; **and**
 - A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

G. Waiver of Documentation of Consent

Under the Common Rule, there are three conditions under which an IRB may waive the requirement for an investigator to obtain a signed consent form:

1. 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. Waivers of the signature requirement are often granted for telephone and online surveys and questionnaires.
2. 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. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject to the research, and the subject's wishes will govern.
3. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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

H. Waiver or Alteration of Consent

When reviewing research, the SBS IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the Common Rule and summarized below. The IRB's determination will be documented in the IRB record and communicated to the investigator.

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the SBS IRB must determine and document that the below criteria are satisfied.

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Restrictions when research is subject to the Common Rule:

1. Waivers:
 - If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens under the Common Rule regulations relating to broad consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. Alterations:

- An IRB may not approve a request to alter or omit any of the six general requirements for informed consent.
- If a broad consent procedure is used, an IRB may not alter or omit any of the elements of broad consent.

Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs:

These requirements and restrictions apply to research subject to the Common Rule. In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an “Alteration”), under this provision the SBS IRB must determine and document that the below criteria are satisfied.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs;
 - Procedures for obtaining benefits or services under those programs;
 - Possible changes in or alternatives to those programs or procedures; or
 - Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

Restrictions:

1. Waivers –

- If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the Common Rule requirements for broad consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. Alterations –

- An IRB may not approve a request to alter or omit any of the 6 general requirements for informed consent.
- If a broad consent procedure is used, an IRB may not alter or omit any of the elements of broad consent

I. 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.

V. Special Populations: Additional Safeguards

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards must be included in the study 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, in some instances depending on the design of the study, students may feel pressured to participate in research. Therefore, when appropriate, investigators should make every effort to clarify 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), but investigators should be aware that the age of majority may vary even within the United States (e.g., 19 in Alabama). 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

The investigator must make adequate provisions for soliciting the assent³ 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

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.

³ "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

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.

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 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 SBS IRB does not often review federally funded projects subject to Subpart B. 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 is secondary analysis of data that includes, or may include, data from prisoners, then 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 described below. Instead, the IRB's review will focus on whether the proposed data security procedures are adequate. For other studies without federal funding, investigators will

select prisoners as a population in the IRB application, and the IRB will consider the elements below and apply commensurate protections, but will generally not document the specific findings under Subpart C (unless otherwise required).

Definitions and Requirements Pertaining to Research Involving Prisoners Subject to Subpart C:

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.⁴

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.

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:

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

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:
 - (i) 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;
 - (ii) 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;
 - (iii) 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) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
 - (iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in

⁴ "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.

which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

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;

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.

Permitted Research Involving Prisoners funded by DHHS.

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.

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.

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.

H. 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.
- Information about the language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator is 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.

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).

I. Non-English Speakers

Investigators should clearly indicate when non-English speakers will be included in the research and where translated materials will be used.

For non-exempt, federally funded research, or greater than minimal risk research, copies of translated versions of informed consent document(s) and any other written materials (recruitment, instruments, instructions, etc.) to be used with participants must be submitted along with a description of who provided the translations.

For other research, translations and translation certifications are not generally required, but the IRB reserves the right to request them.

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

1. 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.

2. 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.

VII. Other Federal Agencies and Regulations

A. HIPAA

Background: The HIPAA Privacy Rule affects research and researchers when either:

- Research creates or generates PHI, or
- Research requires access to and/or use of PHI.

A Privacy Board reviews requests for waivers or alterations of HIPAA Authorization. Under the Privacy Rule, an IRB may serve as a Privacy Board for IRB-reviewed research.

Protected Health Information (PHI):

Health information that is individually identifiable and created or held by a covered entity. Health information is considered individually identifiable when it contains one or more of the 18 HIPAA identifiers or when there is otherwise a reasonable basis to believe the information can be used to identify an individual. For more information, see [45 CFR Parts 160 and 164](#) or [Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule](#).

HIPAA Identifiers:

<ol style="list-style-type: none">1. Name2. All geographic subdivisions smaller than a state (street address, city, county, precinct, zip code) Note: in some cases, data can be considered de-identified under HIPAA and retain first 3 digits of the geographic unit to which the zip code applies, but only if the zip code area contains more than 20,000 people3. Dates (for dates directly related to the individual, all elements of dates, except year are considered identifiers under HIPAA: e.g., date of birth, admission date, discharge date, date of death)4. Ages over age 895. Telephone numbers6. Fax numbers7. Email addresses	<ol style="list-style-type: none">8. Social security numbers9. Medical record numbers10. Health plan beneficiary numbers11. Account numbers12. Certificate/license numbers13. Vehicle identifiers and serial numbers, including license plate numbers14. Device identifiers and serial numbers15. Web universal resource locators (URLs)16. Internet protocol (IP) address numbers17. Biometric identifiers, including fingerprints and voiceprints18. Full face photographic images and any comparable images19. Any other unique identifying number, characteristic, or code
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Covered Entity:

1) A health plan, 2) A health care clearinghouse, or 3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA. Individuals, organizations, and agencies that meet the definition of a covered entity under HIPAA must comply with the Rules' requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. If a covered entity engages a **business associate** to help it carry out its health care activities and functions, the covered entity must have a written contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do, and requires the business associate to comply with the requirements to protect the privacy and security of protected health information. In addition to these contractual obligations, business associates are directly liable for compliance with certain provisions of HIPAA.

Authorization:

Although similar to informed consent, Authorization focuses on privacy risks and the use or disclosure of PHI. An Authorization must state how, why, and to whom the PHI will be used and/or disclosed for research purposes. An Authorization may not require an expiration date; consult state and/or local law for applicable requirements. A research participant, however, has the right to revoke (in writing) his/her Authorization at any time. The participant or the participant's authorized representative must be given a copy of the Authorization and researchers must keep a signed copy of participant's Authorization for six years. A copy of the signed Authorization must be provided to the individual signing it if the covered entity itself is seeking the Authorization.

HIPAA Authorization Elements: HIPAA Authorization language is subject to IRB review when combined with the research consent form/information.

- A specific and meaningful description of the information to be used or disclosed

- The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes
- The name or identification of the persons or class of persons authorized to receive disclosures of the PHI and to use the PHI for research-related purposes
- A description of each purpose of the use or disclosure
- An expiration date or event, or a statement "end of research study" or "none" when appropriate (ex: for a research database). Check state law requirements
- A statement that the individual may revoke the authorization if done in writing to the principal investigator; however, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such Authorization before it was revoked
- A statement that an individual's clinical treatment may not be conditioned upon whether or not the individual signs the research Authorization. However, participation in research may be conditioned on a signed Authorization, including treatment protocols
- A statement that information disclosed under the Authorization could potentially be redisclosed by the recipient and would no longer be protected under HIPAA
- The individual's signature (or that of his/her authorized representative as determined by law) and date

Waiver or Partial Waiver of Authorization:

The requirement to obtain Authorization may be waived if all of the following criteria are met:

- Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on:
 - An adequate plan to protect the identifiers from improper use and disclosure
 - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless a health or research justification for retaining the identifiers exists, or retention is required by law)
 - Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule
- The waiver will not adversely affect the privacy rights and the welfare of the individuals
- The research could not practicably be conducted without the waiver
- The research could not practicably be conducted without access to and use of the PHI

Authorization may be waived for all, or only some uses of PHI for a particular study. For instance, a "**partial waiver**" permits the use of PHI for recruitment purposes only (i.e., to allow identification and, as appropriate, contact of potential participants to determine their interest in study participation).

Alteration of Authorization:

The requirement to obtain Authorization for use of PHI may also be "altered" for a specific study. An alteration allows a change in certain Authorization requirements, while still requiring authorization for the use of PHI. Examples include making an exception to the required language in an authorization or to the requirement to obtain a signed Authorization. To be granted, an alteration must meet the same criteria as a waiver or partial waiver.

Reviews Preparatory to Research:

The Privacy Rule also permits certain activities involving use or disclosure of PHI without Authorization. The “preparatory to research” provision permits researchers to use PHI for limited purposes, such as a feasibility assessment (e.g., whether a sufficient population exists to conduct research). However, the Privacy Rule does not permit the researcher to collect or remove PHI. To comply with both the Privacy Rule **and** human subjects research-related regulations, researchers are permitted to review PHI, but identifiers may not be recorded; and researchers may **not** use the preparatory to research provision to identify or recruit specific individuals for a study (as collecting data, beginning recruitment, analyzing data for pilot/development work, etc. would be considered human subjects research activities that would need to be covered by IRB approval or exempt review as applicable).

To conduct a review preparatory to research for a feasibility check, a researcher must work through the covered entity in charge of the records for the procedures required by the entity. The investigators will likely be asked to provide all of the following representations to the steward of the records (generally through a request form of some type):

- The use or disclosure is requested solely to review PHI as necessary to develop a research protocol or for similar purposes preparatory to research
- PHI will not be removed in the course of review
- The PHI for which use or access is requested is necessary for the research

B. OTHER FEDERAL AGENCY LINKS

- [Office for Human Research Protections \(OHRP\)](#)
- [Food and Drug Administration \(FDA\)](#)
- [Comparison of FDA and OHRP Regulations](#)
- [Office for Civil Rights \(HIPAA Privacy rule\)](#)
- [Department of Defense \(DOD\) Department of Energy \(DOE\)](#)
- [Department of Education \(ED\)](#)
- [Department of Justice \(DOJ\)](#)
- [Environmental Protection Agency \(EPA\)](#)
- [National Science Foundation \(NSF\)](#)
- [National Institutes of Health \(NIH\) Department of Veteran’s Affairs \(VA\)](#)
- [International Conference on Harmonisation : Good Clinical Practice \(ICH-GCP\)](#)

Appendix 1: Definitions

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Human subject means a living individual about whom an investigator (whether professional or student) is conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Legally authorized representative means 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 the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that 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.

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

- (i) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- (ii) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (iii) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

Appendix 2: Exemption Categories

The 8 Common Rule Categories:

Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the additional requirements of the revised Common Rule, except as specified.

Note: Other than exempt category 6, these categories do not apply to research that is also FDA-regulated.

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

or

 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *"When appropriate, there are adequate*

provisions to protect the privacy of subjects and to maintain the confidentiality of data.”

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding Secondary research for which consent is not required:

4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - (i) The identifiable private information or identifiable biospecimens are publicly available;
 - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 [‘HIPAA’], subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); **or**
 - (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects

also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

- (i) If wholesome foods without additives are consumed, **or**
- (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the
level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Exempt categories 7 & 8 always require limited IRB review and are only available when broad consent will be (or has been) obtained.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § .111(a)(8):

- (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § .116(a)(1) – (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
- (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § .117 (See Sections 8.6 and 8.7); **and**
- (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § .116(a)(1) through (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § .117 (See Sections 8.6 and 8.7);
- (iii) An IRB conducts a limited IRB review and makes the determination required by § .111(a)(7): *“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data”* and makes the determination

that the research to be conducted is within the scope of the broad consent referenced in 8.i above; **and**

- (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Additional category of activities eligible for exemption:

Minimal risk, non-federally funded research with adults that includes 1) benign tasks (e.g., card sorting, simple computer activities, taking photographs) **and/or**, 2) the collection of physical and biometric data by simple, non-invasive means (e.g., use of an eye tracking device, pedometers, heart rate monitor; obtaining weight, height, or other non-invasive measurements; etc.) when all other activities fall under one or more of the exemption categories established by the Common Rule.

The SBS IRB office staff, in conjunction with the IRB or IRB Chair when necessary, will determine the applicability of this category to specific projects.

Please note that studies involving imaging (such as MRIs) and genetic testing are not included in the activities eligible for exemption.

Appendix 3: SOCIAL AND BEHAVIORAL SCIENCES IRB THREE-YEAR APPROVAL POLICY

NOTE: Three year approvals will no longer be issued on or after August 20, 2018 (replaced with no continuing review required for minimal risk research as described in the main policy).

Ongoing projects with three year approvals are still subject to the rules stated below unless the IRB decides to transition individual studies to comply with the revised policy. In all cases, investigators are still required to submit an amendment to request review of any changes, including the addition of new funding.

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.