PREFACE

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

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

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

POLICIES AND PROCEDURES

Administration and Jurisdiction of the SBS IRB

Jurisdiction of the SBS IRB

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

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

IRB Membership

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

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

The SBS IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also 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 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 such as the National Alliance for the Mentally Ill. The nonaffiliated member(s) should be knowledgeable about the local community and be willing and able to discuss issues and research from that perspective. When selecting the nonaffiliated member(s), consideration should be given to the type of community from which the institution will draw its research subjects.

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

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

**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/](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. Examples of COI include serving on a dissertation committee for a project being reviewed or holding stock in a company for which the project is being performed.

**Record Keeping**

The SBS IRB staff prepares and maintains adequate documentation of the IRB’s activities. In addition to the written IRB procedures and membership lists required by the Assurance process 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. Minutes of the IRB meetings are kept in sufficient detail to record the following information: attendance at each meeting; actions taken by the IRB; the vote on actions taken (including the number of members voting for, against, and abstaining); the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

The IRB minutes are prepared by the IRB staff and sent to the IRB Chair and Vice-Chair for review and approval. If the IRB Chair or Vice-Chair request any revisions to the minutes, the
IRB staff revise the minutes as needed and the minutes are considered final when any revisions requested by the Chair and Vice-Chair have been incorporated into the minutes. The IRB does not vote to approve the minutes.

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

Education and Training

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

Review and Approval Process

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

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.

Projects that meet exemption requirements undergo administrative review by the SBS IRB Staff.

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

New and continuing projects may be eligible for expedited review if they both involve no more than minimal risk to subjects and meet one of nine specified expedited review categories.
Projects that involve more than minimal risk or do not fit into one or more of the categories for expedited review must be reviewed by the full board at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific. The IRB Director or IRB Chair will assign a primary and a secondary reviewer for those projects scheduled for full board review. These members are responsible for presenting the research to the committee at the convened meeting. Although these primary and secondary reviewers are responsible for the presentation of the research at the meeting, all members receive a copy of the complete submission, including the application, protocol, informed consent documents, and instruments, and are expected to participate in the review and discussion of the research at the meeting. The IRB Chair may invite ad hoc reviewers to assist in the review of research where additional expertise may be necessary. In order for a given project to be approved, it must receive the approval of a majority of those members present at the meeting.

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

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

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

Research that is Eligible for Expedited Review Procedures

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

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

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

The expedited review categories are set forth at [http://www.hhs.gov/ohrp/policy/expedited98.html](http://www.hhs.gov/ohrp/policy/expedited98.html)

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1 HHS regulations define "minimal risk" at 45 CFR 46.102(i) as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".

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

1. Research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

2. Classified research involving human subjects.

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

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.

Continuing Review

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

The AURA software system sends automated reminders to researchers several times prior to the expiration date of IRB approval to remind the research team that a continuing review request should be submitted if the research is ongoing. As a courtesy, the IRB office also sends all investigators a reminder to request renewal of IRB approval prior to the expiration date for approval of the research.

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

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

 Amendments

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

 Review of IRB Submissions

IRB members are assigned to review protocols based on relevant disciplinary and regulatory knowledge and experience with study contexts and populations. By applying this expertise during the review process, IRB members document the extent to which study design manifests the ethical principles of the Belmont Report and related institutional, local, state and federal regulations and policies governing the conduct of research involving human subjects. In cases where study procedures are determined to unnecessarily increase direct or indirect risks or burdens to study participants, the IRB may require modifications to these procedures as a condition of approval. In the event the IRB lacks the appropriate expertise to assess scientific merit and the research is judged by the IRB to have greater than minimal risk, the IRB may seek outside expertise to assist its evaluation of the proposed research.

 Student Research Projects

University Research Administration (URA) sets the policy on who can serve as a principal investigator (see https://ura.uchicago.edu/page/principal-investigator-eligibility). Student researchers cannot serve as the principal investigator (PI) on a research study. For studies that are not externally funded, if an individual does not automatically qualify for PI eligibility under URA’s PI eligibility policy, the individual may serve as a principal investigator if the appropriate Dean (or other individual with appropriate level of authority, such as an Assistant or Associate Dean) authorizes the individual to serve as PI. This authorization is provided to the IRB – the IRB will accept an email or letter from the appropriate individual in the Dean’s office stating that the individual has been granted PI status for the study.
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.

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.

For research that requires subjects to undergo only minor inconvenience or discomfort, a modest payment will usually be adequate. Reimbursement for travel, babysitting, and so forth may also be provided. In more complex research projects, IRBs tend to base their assessment on the prevailing payment practices within their institution or general locale. Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Because payments may vary according to a number of factors, the IRB will be familiar with accepted standards within the community as well as the anticipated discomforts and inconveniences involved in a particular study to judge the appropriateness of payments.

Please note that while payments or incentives to subjects are allowable and appropriate, the University of Chicago does not allow financial incentives or bonuses (including gifts) to be paid or awarded to investigator or any member of the study staff as an incentive to recruit subjects to a study or meet any special enrollment targets.

Informed Consent

Informed consent is a process. The consent form or script that will be used with potential research participants plays a central role in the IRB’s review of the consent process, but the IRB will examine the issue of consent from a holistic perspective that takes into account all of the information provided to the IRB in the protocol and related materials. Because subject understanding is a necessary component of informed consent, information must be presented in a language and at a level that is appropriate for the population. In general, consent documents should be written in lay language at a 6th to 8th grade level.
The following information should be included in the informed consent document [45 CFR 46.116(a)]:

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

The following information should be included when appropriate:

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

Documentation of Informed Consent

The IRB may approve procedures for documentation of informed consent that involve either (i) a written consent form signed by the subject or the subject’s legally authorized representative (LAR), (ii) short form written consent form with oral presentation, or (iii) a waiver of signed consent (verbal or online “click” consent, for example).

Oral Presentation Using Short Form

In some cases, it may be more appropriate to use the short form procedure to obtain consent from subjects [45 CFR 46.117(b)(2)]. The short form procedure includes the following two pieces:

A. A “short form” written informed consent document stating that the elements of consent have been presented orally to the subject or the subject’s LAR; and

B. A written summary of the information that is presented orally. A witness to the oral presentation is required. The witness must sign both the short form written informed consent document and a copy of the written summary. The subject or the LAR must sign
the short form written consent document. The person obtaining consent must sign a copy of the written summary of the information that is presented orally.

Where informed consent is documented using this short form procedure for non-English speaking subjects, the written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written informed consent document should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject. The IRB must review and approve all foreign language versions of the short form document before they can be used.

Telephone and Online Surveys

The requirement for written consent often can be waived in cases where a telephone survey or internet survey methodology is used, 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. The investigator should submit a copy of the script that will be used to seek consent from subjects. The consent script should include at least the following information:

- The purpose of the research
- The researcher’s name, contact information, and association with University of Chicago.
- A description of how confidentiality of participant responses will be maintained.
- A statement that participation is voluntary, and the participant can refuse to answer any questions or terminate their participation at anytime without penalty.
- Information about how to contact the SBS IRB if individuals have questions about their rights as research subjects.

The IRB may determine that additional information may be required based on the subject matter and risks to subjects.

Third Party Consent

When an investigator conducting research obtains identifiable private information about a living individual, that individual becomes a research subject, regardless of whether that person is the individual with whom the investigator is having an interaction. For example, if the research involves asking the primary subject to provide identifiable private information about a third party, that third party then becomes a subject in the research. As such, all of the regulatory requirements for protecting that individual obtain.

The IRB can determine whether informed consent needs to be sought from third party subjects, or whether it can be waived. In making this determination, the IRB relies on both the regulatory requirements for a waiver and the importance of the information to the research. Investigators whose research may involve so-called secondary subjects are encouraged to contact the IRB Staff to discuss how to best protect the rights and welfare of these subjects in a given project.
Privacy and Confidentiality

For the majority of social and behavioral science research, ensuring confidentiality is the most important procedure to minimize risk. Most researchers are familiar with standard precautions that should be taken to maintain the confidentiality of data, including coding data, separating face sheets and consent documents from survey instruments, limiting access to identifiable data, and storing records in secured locations. More elaborate procedures may be appropriate for research involving sensitive data that may involve a greater risk should confidentiality be breached. In some cases, the investigator may want to seek a Certificate of Confidentiality to protect the data from compelled disclosure. Research in which the primary risk to subjects is from a breach of confidentiality, and in which no identifiable information will be recorded save the consent document, is eligible for a waiver of signed consent.

Special Populations: Additional Safeguards

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

Students

Universities afford investigators with a ready pool of research subjects: students. One problem with student participation in research conducted at the University is that their agreement to participate may not be truly voluntary. For example, students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty in general (i.e., by seeming "uncooperative," not part of the scientific community). When recruiting students, investigators should be aware of the possibility that students may feel pressured to participate in research and should make every effort to make clear that participation in research is voluntary and their decision whether to participate will not affect their academic standing or their relationship with the researcher or faculty.

Offering participation in research as a way to receive course credit (or extra credit) is also controversial. There are two important issues to address when this is done: (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.
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.

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.

Children

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

1. **Adequate Provisions for Child's Assent [45 CFR 46.408(a)]**
   The investigator must make adequate provisions for soliciting the assent of child subjects when the children are capable of providing assent. In determining whether children are capable of assenting, the investigator should take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition.

   **Waiver of Assent. [45 CFR 46.408(a)]**
   If the IRB determines either of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:
   
   - The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
   - When the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

   **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.

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

C. **Adequate Provisions for Parents’ or Guardian’s Permission**
   The investigator must make adequate provisions for soliciting the permission of each child's parents or legally authorized representative. [45 CFR 46.408(b)]

   **Research Meeting Categories 45 CFR 46.404 or 46.405:**
   Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk.

   **Research Meeting Categories 45 CFR 46.406 or 46.407:**

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4 "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
Where parental permission is to be obtained, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

**Waiver of Parental or Guardian Permission [45 CFR 46.408(c)]**

If parental or LAR permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), the investigator may request that the IRB waive the consent requirements described above, provided both (i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and (ii) the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

**D. Documentation of Consent**

Permission by parents or guardians shall be documented in the same manner as required for other subjects. When the IRB determines that assent of a child is required, it shall also determine whether and how assent must be documented.

**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 46.406 or 46.407 (see A.3 and A.4 above) 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.

**Pregnant Women and Fetuses**

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

**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 only if these special provisions are met.
A. **Special Definitions Pertaining to Research Involving Prisoners**

(1) **Minimal Risk**
For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk used for other populations. The definition for prisoners includes reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons.  

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

B. **When Subjects Become Prisoners During the Course of the Research**
If a subject becomes a prisoner after enrollment in research, the investigator is responsible for reporting in writing this situation to the IRB immediately. Upon its review, the IRB can either:

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

C. **Specific Findings of IRB Required to Approve Research**
When the IRB is reviewing a protocol in which a prisoner is a subject, the IRB Committee must make seven findings as follows:

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

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

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

**D. Permitted Research Involving Prisoners.**
For research conducted or supported by HHS to involve prisoners, two actions must occur:
(i) the IRB must certify to OHRP that it has reviewed and approved the research under the federal regulations; and
(ii) OHRP must determine that the proposed research falls within one of the categories of permissible research described above.

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

**E. 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.

**F. 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.
Special Categories of Research

Internet Research & Use of Email

The growing popularity of the Internet has given researchers yet another medium in which to interact with subjects. Internet research does pose challenges in the application of traditional human subject regulations. The following is offered as guidance when undertaking research on the Internet:

- If documentation of consent can be waived, portals can be used to require consent (i.e., an introductory web page advising participants of the nature of the study and their rights with a button to click before allowing further access). If signed consent is required, a form must be signed and returned before access to the website is allowed.
- Participation by minors is discouraged, due to difficulties obtaining and verifying parental permission. There are several programs (e.g. Adult Check systems and Internet Monitoring software) that may be used as an aid to screen out minors.
- A variety of concerns about the ability to protect confidentiality arise:
  - Could there be inadvertent disclosure if someone mistakenly hits the “reply to all” button when utilizing email?
  - Is information stored on a web server?
  - Are “cookies” used?
  - Is this information vulnerable where hackers may deliberately access it?

These issues become particularly important when sensitive data are being collected. Depending on the sensitivity of the information being gathered, it may not be possible to sufficiently minimize risks when using the Internet. In such cases, the Internet may not be an appropriate medium to use to conduct the research. When using electronic correspondence (email), subjects should be informed of confidentiality issues specific to email.

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. In areas where government-issued research visas are required, a copy of the visa should be submitted.
- Information about the investigator’s knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator’s personal experience conducting research (or studying or residing) in the region.
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.
The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how they will be minimized.

 Copies of the translated informed consent documents and instruments, including verification of the accuracy of the translation(s).

 If the research is federally funded, information about the status of the assurance for the performance site, where applicable.

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).

Research Conducted on American Indian Reservations

Researchers working on American Indian reservations should be aware local requirements for the conduct of research and should demonstrate to the IRB that all required local approvals have been acquired prior to submitting a protocol to the IRB. This approval may vary depending on the tribe or nation on whose territory the research will be conducted. In some cases, a letter from the tribal council may be sufficient. In others, the approval of a tribal IRB may be required (in which case, the researcher should provide the SBS-IRB with copies of all materials submitted to the tribal IRB). The Navajo Nation IRB, for example, meets once per month to consider research on Navajo Nation territories and requires a multi-stage application for research approval. As a number of other Indian Nations have or are in the process of establishing IRBs (including the Cherokee, Navajo, and Ho-Chunk Nations), researchers should contact the communities in which the proposed research will be conducted to determine the appropriate form of local review.

Researchers should also be aware that the federal Indian Health Service (IHS) has an established IRB system that is responsible for reviewing research conducted on or through IHS clinics on and off reservation territories. The IHS also provides training and information materials for researchers working on reservation lands for the first time. If IHS IRB approval is required for a project, a copy of the IHS IRB submission and approval documentation should be submitted to the IRB.

Proposals for research on American Indian reservations should demonstrate that research procedures are appropriate given the culture, mores, and laws of the communities in which the research will be conducted. Researchers are further encouraged to incorporate the concerns, needs, and expertise of the local community into their research design and practice. As many tribes require that research conducted on reservation lands have direct benefits to local communities and that data and findings are made available to the tribe or Nation, the SBS IRB
encourages researchers to detail steps taken to meet these requirements in their protocol submissions.\(^6\)

**Audits and Monitoring**

To help ensure compliance with federal regulations and local 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.

**Unanticipated Problems, Study Complaints, and Allegations of Noncompliance**

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.

\(^6\) The Navajo Nation IRB, for example, requires that all proposals for research on tribal lands provide direct tangible benefits to the Navajo Nation, make use of local expertise when hiring research staff, and make findings and data available to the Nation for its archives. The Canadian “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans” (2003) suggests similar actions among its “best practices” for research involving indigenous peoples (§6B).
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.

Complaints or allegations of noncompliance with human research protections may arise from a variety of sources or individuals. Examples include, but are not limited to:

- Verbal or written complaints from subjects in research
- Reports that an investigator is not following the protocol as approved by the IRB
- Repeated failure of the Principal Investigator to report required or requested information to the IRB
- Research publication written by research for which there is not an approved protocol
- Whistleblower information

Every complaint or comment should be addressed in a consistent, professional and prompt manner through a qualified individual (IRB Director, IRB Chair, or IRB delegated individual). No complaint should be dismissed or viewed as unimportant. However, each instance need not be subjected to the same level of scrutiny.
Every noncompliance report or complaint about human research protections is taken seriously by the University. Any allegation or complaint received the University will be referred to the appropriate IRB for initial assessment and follow up. Complaints or reports of potential noncompliance that are received by Principal Investigators must be disclosed to the IRB. Each report is initially evaluated by the appropriate IRB Chair or designee and IRB administrative staff and the follow up will be documented. The IRB is responsible for assuring that the complaint or report of noncompliance is investigated appropriately relative to its level of seriousness, taking special steps to assure that problems involving risks to health and well being of subjects have first priority. The IRB shall move quickly to suspend or terminate approval of research that is suspected of causing serious to subjects at the University of Chicago. A PI may voluntarily elect to suspend subject accrual to a protocol which an allegation of noncompliance or a complaint is investigated.

If non-compliance is alleged, the IRB Chair will initiate an investigation. The researcher will be informed of the allegations and given ample time to respond. The IRB Chair will then review the relevant information and make a Report to the Institutional Official, including recommendations. Non-compliance can have serious consequences for both the researcher and the University: approval for the project may be terminated and the University could be placed at risk of losing Federal or other funding related to research activities. The IRB Chair is required to report cases of non-compliance directly to the appropriate Dean, with a copy to the Institutional Official who has executive responsibility for enforcement of the University’s FWA. If the Institutional Official determines the non-compliance to be either serious or continuing, it must be reported to OHRP and if sponsored, to the sponsoring agency.

The IRB is responsible for carrying out an initial inquiry and reporting the outcome of that inquiry as detailed below.

**Determine If It is Necessary to Suspend the Study**

The IRB will determine if immediate suspension of the participant enrollment is required for the protocol in question as well as for other protocols with the same PI. This initial decision will be made by the IRB Chair or Vice Chair in consultation with the IRB Director and other institutional officials as may be appropriate. The decision will be based on preliminary information and the seriousness of the situation. The length of the suspension (no further participant enrollment) will be determined by continuing consultation and/or receipt of further information in conjunction with the protocol(s) in question.

The initial inquiry will examine information such as the nature of the study or whether or not the consent form contained inappropriate information. From this inquiry, a determination shall be made about whether continued inquiry (including suspension) is merited.

**When Suspension is Not Necessary**

If the IRB Chair and/or Vice Chair in consultation with the IRB Director determine the situation does not merit suspension, a report of the situation and factors considered will be prepared. The Report must include the date and signatures of the IRB officials who made the determination, with a statement of their conclusion and the subsequent actions to be taken are documented. All communication and ultimate resolution of the situation will be documented and maintained in the IRB protocol file.

**When Suspension is Necessary**
If the report indicates that suspension of the research study is merited, further steps are required:

1. Notice of suspension effective immediately will be sent to the PI, co-Investigators, department Chair, appropriate grants administration office, institutional official, and IRB Chair. The notification includes the requirement to halt further participant enrollment. When the PI voluntarily elects to suspend a study while an investigation of noncompliance or a complaint is undertaken, the IRB must notify the Institutional Official that a voluntary suspension is in place, identifying the PI, the protocol and a preliminary indication of the situation.

2. Within two working days, the IRB Chair, Vice Chair, IRB Director, PI and other parties as may be appropriate given the circumstances, shall meet to discuss the nature of the situation and to determine if the situation merits a designation of serious or continuing noncompliance.

3. Further study of the situation including an examination of consent forms, all data related to the study, IRB protocol documentation, etc. may be necessary to determine whether a designation of serious or continuing noncompliance is warranted. The PI is required to produce whatever records are called for by the IRB and University. The IRB may take what steps are considered appropriate and necessary to carry out its initial investigation, including the use of outside experts. Any involvement of investigation where outside expertise is solicited should not be undertaken without the knowledge and concurrence of the Institutional Office.

Study Suspended: Determine if the Event is Serious or Continuing

The results of the review of protocol and study records and discussions with the PI will determine whether the situation is of non-serious and non-continuing nature.

- Non-serious and Non-continuing: If the incident appears to be isolated and, for example, a miscommunication or misunderstanding of a non-serious and non-continuing nature, the incident will remain internal to the University and the documentation will remain with the IRB. A letter from the IRB office to the PI describing a summary of the investigation of the allegation or complaint will be written. A response from the PI describing corrective actions is also required. IRB Chair/Vice Chair acceptance of the PI response and corrective action will constitute closure to the incident. Suspension of subject enrollment will be lifted.

- If the IRB determines that the investigation (or audit of protocol records, consent forms, data, etc.) indicates that the situation should be considered serious or continuing, the IRB must notify the University Institutional Official including a copy of the investigative report no later than 48 hours after the determination of Serious or Continuing is made, no matter whether the project is externally funded or not. If the research is not federally funded the IRB may make a recommendation as to whether the noncompliance should be reported to OHRP, recognizing that the University’s Federalwide Assurance requires federally-funded serious and continuing noncompliance to the reported to OHRP and other federal agencies as may be necessary.*

- The institutional official coordinates review of the IRB’s investigation of a situation determined to be serious or continuing with appropriate institutional officials including the Office of General Counsel and the Office of the Provost. It is the responsibility of the institutional official to notify OHRP when the University is required to make this disclosure or elects to self-report.
• The institutional official will notify OHRP of the incident of serious, continuing noncompliance. The notification letter to OHRP (and other sponsor organization) will briefly describe the incident, the preliminary steps, and an indication of the time frame for full audit and full report to follow, including corrective actions for this specific incident as well as for the research program to ensure incidents will not occur again.

• The institutional official and the IRB Chair and IRB Director will assure that all documentation supporting the audit of the incident, any additional audits of other research conducted by the PI in question, and all communication with internal offices and other regulatory bodies at the University of Chicago as may be required are completed. It is the responsibility of the IRB to maintain all audit records of the investigation and to assure that all corrective action requirements made by the IRB and/or the University are implemented.

Corrective Action Steps

In the course of investigation of allegations of noncompliance or complaints, corrective actions plans may be stipulated to assure that the situations giving rise to the investigation do occur again. Examples of corrective action plans that may be initiated by the PI or imposed by the IRB and/or the University include, but are not limited to:

• Suspend the research until certain conditions are met
• Terminate the research
• Require additional training for research staff
• Impose other sanctions, such as limiting the number of subjects to be enrolled
• Require modifications/amendments to the protocol

* Under the Terms and Conditions of the University of Chicago Federalwide Assurance, the University is obligated to report to [the federal Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) serious or material unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval for Federally-supported research.
SOCIAL AND BEHAVIORAL SCIENCES IRB
THREE-YEAR APPROVAL POLICY

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

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

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

AND

- Not subject to federal funding/oversight

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

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

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

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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.