



THE UNIVERSITY OF  
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Social & Behavioral Sciences  
Institutional Review Board

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# SBS Research Quarterly

News for and by the IRB and Research Community at the University of Chicago, for Those  
Conducting Social and Behavioral Research

## IRB NEWS



### Welcome To The First Edition of the SBS Research Quarterly

*Michael Silverstein*  
**Charles F. Grey Distinguished Service  
Professor,  
Anthropology, Linguistics, Psychology;  
Chair, SBS IRB**

The University of Chicago, Social and Behavioral Sciences (SBS) Institutional Review Board (IRB) feels that the distribution of information to research professionals is important, and imperative for the promotion of quality research in the Social and Behavioral Sciences and the pursuance of effective research within the University of Chicago. It is for this purpose that the SBS IRB has created the Research Quarterly Newsletter. This newsletter will be published in March, June, October, and December of each year to promote and enhance the education and knowledge base of faculty, principal investigators, student researchers and other research personnel.

The IRB would like to invite faculty, principal investigators, student investigators, and other research personnel to submit ideas, articles, research tidbits, and updates to Mary Barnhart, Director, SBS IRB at [mbarnhart@uchicago.edu](mailto:mbarnhart@uchicago.edu) or by fax to (773) 834-8700.

This is a newsletter by and for our faculty and student researchers. If you have an area of interest, exciting study developments, a need for specific research information, or would like to share research updates, please feel free to submit an article for publication.

We hope this publication will provide you with guidance and the tools to assist you in the research process and help make the University of Chicago and SBS IRB a trendsetter in the research community. Your feedback and contributions will be greatly appreciated. We look forward to our partnership with you the faculty, the researchers and the University of Chicago.



### IRB Wise: On-Line Protocol Submission System

IRB Wise, the University of Chicago's online protocol submission and review system, is available for all researchers submitting through the SBS IRB. Access the system at:

<http://sbsirbwise.uchicago.edu/>

The SBS IRB no longer accepts paper submissions. All SBS IRB protocol, amendment, and continuing review requests must be submitted through IRB Wise. All currently active protocols are available in IRB Wise.

An account is required in order to access IRB Wise and IRB protocols. IRB Wise accounts generally use CNET ids and passwords, but these must be activated in IRB Wise by the IRB Staff prior to an individual's first use of the system. If you will be using IRB Wise for the first time, please send a message to the IRB Staff requesting activation of your account. Please include your name, department, University position, and CNET ID in this message.

If you have any questions about the IRB Wise system, or encounter difficulties while accessing it, please contact the SBS IRB staff at (773) 834-7835 or [sbsirbwise@listhost.uchicago.edu](mailto:sbsirbwise@listhost.uchicago.edu).

### Help Using IRB Wise

The SBS IRB staff is prepared to answer any questions about the IRB Wise system and the IRB review process. If you have questions, please call the SBS IRB Office, 834-7835 or email [sbsirbwise@listhost.uchicago.edu](mailto:sbsirbwise@listhost.uchicago.edu). IRB Wise also includes a user manual in the application (a link appears at the top of every page in the application).

### Feedback

The SBS IRB welcomes your comments on IRB Wise and the IRB review process. Please send any questions, problems, complaints, or suggestions to [sbsirbwise@listhost.uchicago.edu](mailto:sbsirbwise@listhost.uchicago.edu).

## SBS NEWS AND TIDBITS



We would like to welcome our new SBS IRB Director, Mary Barnhart. Mary comes to us from Detroit, Michigan where she has spent the last 11 years working with community hospital IRBs as well as with the hospital clinical ethics committees. We are looking forward to her input and feedback in the coming months. She can be contacted for IRB questions and information at [mbarnhart@uchicago.edu](mailto:mbarnhart@uchicago.edu) or by telephone at (773) 702-5064.

We would also like to thank Grace Kim, Julie Zaura, and Regina Meeks for working together and keeping the SBS IRB Office running smoothly and efficiently during the absence of a director. We, the

SBS IRB, faculty, and student researchers appreciate your dedication and hard work.

In conclusion, we would like to thank the IRB Chair, and the IRB Members who work so diligently on a volunteer basis to review the SBS research. Your dedication and expertise are greatly appreciated.

## IRB INFORMATION CORNER



### What is an IRB and Why Do We Need One?

The status of all research involving human subjects (as defined below), regardless of sponsorship or funding, must be determined by the Institution's IRB. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB determined the status of the research. It is the responsibility of the IRB to determine whether a project is "research" or involves "human subjects."

If faculty and researchers are unsure whether a project needs to be submitted to the IRB, please call the IRB Offices at 773-834-7835 or email the [sbsirbwise@listhost.uchicago.edu](mailto:sbsirbwise@listhost.uchicago.edu) for assistance.

The IRB's primary purpose and responsibility is to protect the rights and welfare of human subjects. The IRB reviews and oversees such research to ensure that it meets well-established ethical principles and complies with federal regulations (45 CFR 46) that pertain to human subject protection, as well as any other pertinent regulations and guidelines.

### A. What Needs IRB Review?

According to federal regulations any activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual, must be reviewed by the IRB. Specific activities that require IRB review include, but are not limited to the following:

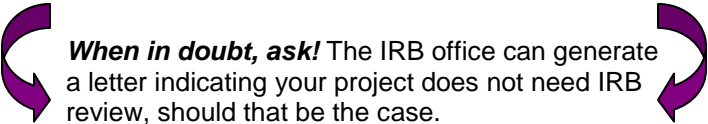
- In general, studies that involve data gathered solely for internal, on-going campus use (e.g. course evaluation or institutional program development), or are part of classroom

projects that will not be presented outside the classroom do not need to be reviewed by the IRB. If results of these studies will be disseminated publically in any way (e.g., conference presentation, publication), then the study is considered to constitute “research”. If no dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, the researcher is advised to submit the project for IRB determination of status, before initiating the research.

### **B. Failure to Submit a Project for IRB Review**

Unless IRB approval has been obtained *prior* to collecting data, results of non-approved studies may not be presented in any public forum (including scientific meetings), used to satisfy thesis or dissertation requirements, or published.

If an investigator begins a project and later realizes that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the investigator should submit a proposal to the IRB for review as soon as possible. Approval must be given for the data to be used.



***When in doubt, ask!*** The IRB office can generate a letter indicating your project does not need IRB review, should that be the case.

### **C. Assurance of Independence**

The IRB is mandated to act as an independent entity within the structure of the University of Chicago (U of C). All decisions by the Board are binding. The IRB and the University of Chicago take their responsibility seriously and make every effort for encourage responsible research. The actions of the IRB, its chairperson, members and administrative staff in matters of human subject protection derive from the authority granted under federal regulations, separate and distinct from the U of C. It is the responsibility of our Institutional Official (IO), to maintain and enforce the independent nature of the relationship between the IRB and the U of C.

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#### ***IRB Policy on Investigator Responsibility***

Investigators have the responsibility to provide safe and viable research to the human subjects enrolled in their project(s). Subject safety is the responsibility of the investigator and of the IRB. The investigator’s responsibility is as follows:

**Purpose and Objectives:** Each investigator is responsible for taking action to promote and protect the research subject’s rights and safety. The investigator assumes the responsibility for compliance with all Federal, State, and institutional rules and regulations related to research involving human subjects. The investigator may not initiate any research involving human subjects without IRB review and approval.

**Policy Statement:** The promotion and protection of research subjects’ rights and safety consistent with Federal and State Law and regulations is the primary responsibility of each investigator in the conduct of his/her research study.

**Procedure:** The IRB holds the principal investigator responsible for the following:

#### Protection of Human Subjects

1. To ensure the risks to the involved research subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the subjects to risk;
2. To ensure that risks to the subjects are reasonable in relation to the anticipated benefits (if any) to the individual and the importance of the knowledge that may be expected to result;
3. To ensure that subject selection is equitable;
4. To ensure in the event of an unexpected event (UE), every reasonable effort is made to provide the involved subjects, as soon as possible, with adequate care to correct or alleviate the consequences of the unexpected event to the extent possible;
5. To ensure the subjects are informed of any new information that may affect their willingness to stay in the study;
6. To notify the IRB of any on-site serious adverse events (SAE) or unexpected event within 7 days of becoming aware of it.

#### Informed Consent Content

1. To ensure that subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each subject or his/her legally authorized representative, in accordance with IRB policy and Federal regulations;

2. To obtain informed consent prior to research participation, to appropriately document said consent, and to provide a signed copy of the consent to the research subject in a timely manner;
3. To ensure, where appropriate, that routine monitoring of data collection is in place for the safety of subjects;
4. To ensure the privacy of subjects is protected and confidentiality is maintained as agreed by the subject in the informed consent, and consistent with Federal and State Law and regulations affecting the privacy interests of research subjects; and
5. To ensure that appropriate additional safeguards are included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (i.e., children, prisoners, pregnant women, mentally disabled persons and economically or educationally disadvantaged persons).

#### Investigator Interaction with the IRB

1. To ensure a prompt response is provided to all requests for information or materials from the IRB Office, including the timely submission of protocols for re-approval;
2. To ensure that data is not collected nor enrollment of subjects begun or continued:
  - a. Until such study is approved in writing by the IRB,
  - b. During periods wherein the IRB or sponsor/principal investigator has suspended study activities, or
  - c. Following IRB-, sponsor-, or principal investigator-directed study termination;
3. To ensure prompt reporting to the IRB, sponsor, and government agencies (if applicable), any serious or unexpected AE that is observed in the study or any significant changes to the risk/benefit ratio. To ensure that such reporting is consistent with IRB policy and procedure;
4. To ensure that IRB relevant recommendations and approvals are maintained with the study records.

#### Guidance on IRB Review of Research Involving Existing Data Sets

The IRB recognizes that some research involving existing data sets and archives may not meet the definition of “human subjects” research requiring IRB review; some may meet definitions of research that is exempt from the HHS regulations at 45 CFR 46; and some may require IRB review. This section is intended to provide guidance on IRB review policies and review procedures and to reduce burdens associated with IRB review for investigators whose research involves only the analysis of existing data sets and archives.

The IRB considers most research involving existing data sets and archives to fall within the following categories:

- Analysis of de-identified, publicly available data
- Analysis of non-publicly available data with restricted access to participant identifiers (coded private information)
- Analysis of publicly available data with private identifiable information or of non-publicly available data with private identifiable information where researchers will not record individual identifiers
- Analysis of non-publicly available data containing private identifiable information

Because the information accessed in these forms of analysis varies, the IRB has instituted review procedures that reflect differences among data sources. Investigators conducting research involving existing data sources are encouraged to consider these review procedures (below) when preparing their studies for possible review by the IRB.

#### **Analysis of de-identified, publicly available data**

The IRB recognizes that the analysis of de-identified, publicly available data does not constitute human subjects research as defined at 45 CFR 46.102 and that it does not require IRB review. Many studies utilize data made available through large data consolidation bureaus and

consortiums. To reduce burdens on investigators, the IRB maintains a list of data holders whose archives include only publicly available, de-identified data. The IRB has reviewed the data use procedures of these data holders and recognizes that the data that they provide for analysis does not constitute “human subjects” information as defined at 45 CFR 46.102 or in the SBS IRB’s policies and procedures.

1. Inter-University Consortium for Political and Social Research (ICPSR)
2. U.S. Bureau of the Census
3. National Center for Health Statistics
4. National Center for Education Statistics
5. National Election Studies

Accordingly, research projects that are limited to the analysis of data held by these organizations do not require IRB review. **The IRB no longer requires the registration or review of studies involving the analysis of data held by these organizations unless a project merges multiple data sets and in so doing enables the identification of individuals whose data is analyzed.**

Additional data sets and archives may qualify for inclusion on this list. Investigators who wish to have a specific data set or data archive considered for inclusion on this list should submit the following information to the IRB:

1. The name of data set or data archive; and
2. The URL for the data set/archive or other specific information on how to obtain the data set; and
3. An abstract that describes the content and potential uses of the data set/archive.

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**Analysis of non-publicly available data with restricted access to participant identifiers (coded private information)**

The IRB recognizes that increasing numbers of studies involve the analysis of non-publicly available datasets that include coded private

information or that are provided to researchers after the removal of identifying information. Further, a number of data holding organizations (e.g., Bureau of Labor Statistics, Centers for Disease Control, etc.) provide statistical analysis services for investigators that generate aggregated data from data sets with private identifying information. Many of these studies do not involve human subjects. Data use permissions vary widely across data sets and holders; as such, the IRB requests that investigators conducting studies using coded private information or contracting data holders for statistical analyses of data sets involving private information seek a determination from the IRB as to whether the study constitutes human subjects research. This request is made in accordance with guidance from the Office of Human Subjects Research Protections (OHRP) concerning research involving coded private information.

For studies involving the analysis of coded private information or the analysis of private information by a third party on behalf of a research team, the IRB requests that investigators submit the following information to the IRB by email:

1. Researcher's name, title, and department; and
2. Title and brief description of the research study; and
3. Name of data set/archive that will be used; and
4. Description of the data access or security plan to be implemented or required by the data holder

If the IRB determines that the project does not constitute human subjects research a message outlining this determination will be sent to the investigator. If the IRB determines that the project does involve human subjects research the investigator will be asked to submit a protocol for consideration by the IRB.

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**Analysis of publicly available data with private identifiable information or of non-publicly available data with private identifiable information where researchers will not record individual identifiers**

Research involving the analysis of publicly available data containing private identifiable information or the analysis of non-publicly available data that will not be recorded by the investigator in a manner that allows the direct or indirect identification of individuals is exempt from IRB review (45CFR46.101(b)4). University and SBS IRB policies identify the IRB as the unit responsible for determining exemption from IRB review. As such, research involving these analyses requires the submission of a protocol for consideration by the IRB.

Investigators submitting protocols involving these research procedures are asked to provide the following information in their protocol submissions to aid the IRB in making a determination of exemption.

1. Description of data set and availability; and
2. Description of data to be accessed for analysis; and
3. Copies of data use agreements required by data holder.

#### **Analysis of non-publicly available data containing private identifiable information**

Research involving the analysis of non-publicly available data that contains private identifiable information about living individuals is considered by the IRB to constitute human subjects research that is not exempt from 45 CFR 46 and University review requirements. Studies involving analysis of this form of data require review by the IRB. This review is conducted under expedited or full board review procedures in accordance with the IRB's review policies.

Investigators submitting protocols involving these research procedures are asked to include the following information in their protocol submissions to aid the IRB in its review.

1. Description of data set(s) to be analyzed; and
2. Copies of data use or security agreements required by data holder; and

3. Description of data security and access procedures.

The IRB Staff is available to answer any questions regarding this guidance by phone (773-834-7835) or email.



### **A CALL FOR ARTICLES**

If you are interested in partnering with the SBS IRB, please send an article about your research to Mary Barnhart at [mbarnhart@uchicago.edu](mailto:mbarnhart@uchicago.edu). We would appreciate your input and research news.

Our next Research Quarterly will be available in June 2009. The deadline for articles on exciting research findings, new research or any article of interest such as awards, accolades, informational articles, etc. is due by **May 15, 2009**.

#### **SBS IRB Office Information**

##### Hours of Operation:

Mondays through Fridays, 7:30 AM – 4:30 PM

##### SBS IRB Office Contact Telephone #:

773-834-7835

##### SBS IRB Email:

[sbsirbwise@listhost.uchicago.edu](mailto:sbsirbwise@listhost.uchicago.edu)

##### SBS IRB Fax Number:

773-834-8700

##### SBS homepage:

<http://humansubjects.uchicago.edu/sbsirb/>