Southern California
Brainspotting Institute

Principal Investigator Handbook

Southern California Brainspotting Institute
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INTRODUCTION

This handbook describes procedures implemented at the Southern California Brainspotting Institute to protect human subjects involved in research. It is intended to ensure all research at SBCI complies with 45 CFR 46, the federal statute regulating human subjects research.

IRB Administrator

The IRB Administrator is your main point of contact for the IRB. The IRB Administrator saves all relevant files to ensure that the official record regarding research activities is complete at all times.

You may contact them at IRB@SoCalBrainspotting.org

Your legal protections

If you are a Principal Investigator (PI) affiliated with SCBI, your operations are legally considered part of that of SBCI, provided the SBCI IRB approved your research activities, you are following the approved protocol, and you are working within the scope of the approved provisions. If you don't meet these conditions, you will not be considered to be operating as PI performing research under SBCI with human subjects, and will be solely responsible for any legal concerns regarding your research.

Safety considerations

Southern California Brainspotting Institute is dedicated to providing comprehensive attention to the safety of its human subjects. As such, the IRB uses a robust system of considerations when approving research proposals and assigning continuing review types.

These considerations, in the form of checklists and worksheets, are available to both the IRB and prospective applicants at SoCalBrainspotting.org in the IRB section under "Submissions." Before submitting an RP Form 1 – Proposal Factsheet, applicants should carefully review the checklists pertinent to their projects. Please consult the Research Proposal Considerations Worksheet to see which checklists will be used in considering your application.

PRINCIPAL INVESTIGATOR ROLES AND RESPONSIBILITIES

As a Principal Investigator (PI), you have a number of responsibilities:

- Receive IRB approval before beginning any research on human subjects
- Complete Human Subjects Protections training with passing scores and renew the training every three years
- Adhere to the three fundamental principles of Respect for Persons, Beneficence, and Justice
- Follow all policies and procedures described in this handbook, and in the federal Revised Common Rule that was implemented in January 2019
- Make sure that your subjects' decisions to participate meet the standards of informed consent;
- Make sure the selection of research subjects is fair — subjects for potentially beneficial research shouldn't be chosen based on favoritism, and subjects for risky research shouldn't be targeted because they lack social or political power
- Ensure recruiting procedures are reasonable and that subjects aren't coerced or unduly enticed to participate
- Minimize all risks and ensure they are justified by the anticipated benefits to the subject or society
- Protect research subjects' privacy and the confidentiality of identifiable information
- If you're working with other institutions or researchers outside of SBCI, ensure that human subjects receive all protections required by the SBCI IRB
- Complete application renewals, continuing review reports and submitting other updates or modifications if needed
- Periodically review results to ensure that no harm has occurred to subjects and that the protocol is producing adequate results to justify any potential risks
- Report any unanticipated problems or other issues to the IRB in a timely manner
- Retain all research documents, including signed consent forms, for a minimum of three years after the end of the project.

***Belmont Report* fundamental principles**

More detailed information on human research subject protections are outlined in the *Belmont Report*, which is publicly accessible and is the national standard on the subject. Here is a brief review.

Respect for persons — People must be treated as autonomous agents who enter into research voluntarily and with adequate information about the purpose and procedures of the research. Anyone with diminished autonomy (e.g., children, prisoners, those who are incapacitated in some way) has a right to be protected.

Beneficence — You're obligated to secure the well-being of your subjects. Possible benefits to participants should be maximized for each subject; potential risks should be minimized.

Justice — The risks and benefits of research should be distributed equally across groups. The burden of participating in research should not fall largely on certain groups, such as the poor or prisoners, while other groups primarily benefit from the results.

Informed consent procedures

As a PI it is your job to create an informed consent. You may download and modify templates for informed consent off the Southern California Brainspotting Institute website.

All participants in your study must give informed consent. This doesn't just mean that they agree to take part; their agreement to participate must meet several criteria.

First, it must be voluntary. Subjects can't be compelled to take part. And rewards or inducements to participate can't be so large that they might unduly affect a person's decision; this is particularly important if you're working with groups (e.g., the homeless, low-income individuals) who may be more vulnerable to such persuasion.

Second, you must fully disclose all information that a person would reasonably need to make an informed decision about whether or not to participate. This includes any potential risks, the amount of time participation will take, any discomfort they might experience, and so on.

Third, the person must be able to comprehend the information provided

And finally, if your study involves children who are old enough to assent to participate, you generally must get their assent even if their parents have already given permission.

SUBMISSION PROTOCOLS

Submitting a research proposal

For anyone interested in conducting research as a part of SBCI, a RP Form 1 – Proposal Factsheet must be submitted. This form is available online at SocalBrainspotting.org in the IRB section. You will receive confirmation of your submission within 3 business days.

At this time, you will be notified of additional materials needed and of when the next IRB meeting date is scheduled. Your proposal will be discussed by the board and you will be notified by the results of the approval decision within 3 business days of the meeting date.

Determining when to submit a proposal

For the purposes of the IRB, research is a systematic, intentional, formalized plan of investigation designed to develop or contribute to generalizable knowledge. Research includes studies in which any substance or stimulus is administered to a human subject; studies that involve changes to a person's physical or psychological state or environment, or major changes to diet; interviews, surveys, tests, observations, or inquiries designed to elicit or obtain non-public information about individuals or groups; or studies of existing records or biospecimens if people can be individually identified.

To determine if a project classifies as research, consider the following:

1. Data are geared for scholars, practitioners, and/or researchers
2. The results will (or may) be shared through presentations and/or publications in order to help illuminate a topic or issue
3. The results may be applied to a larger human population beyond the sample in the study
4. The results can be replicated
5. The results will provide input into some field of study.

If your project does not fall into the any of the following, it is not research. The following also do not count as research:

1. Routine course, workshop, or curriculum development using accepted educational practices, including evaluation of participant or student satisfaction, attitude changes, and/or knowledge gained
2. Aid or services provided to clients that are consistent with accepted and established practice and interested only to meet the client's own personal needs;
3. Surveys, questionnaires, and interviews that are not supported by federal funds and are designed only for internal management and operations at SBCI, as long as the data and results aren't intended for publication or presentation outside the institution.

4. Projects completed by students as part of research methods or data analysis courses, as long as the projects will not be published or presented outside the course
5. Journalistic or historic case studies that focus directly on a specific individual and are not intended to provide any knowledge that can be generalized beyond that specific case.

Even if your project is meant only for internal assessment (e.g., determining if a learning technique was effective in class or if a student services program improved retention), think carefully about whether you would ever want to publish or present any of the data you gathered. Sometimes evaluations meant only for internal purposes lead to interesting findings, and you may want to share the results. If there's any chance this might occur, get IRB approval in advance so you'll be free to share the results in conference presentations or academic publications.

Human research

Will you be collecting or obtaining information about a living human being? If so, then congratulations, you're doing research on human subjects! The information doesn't have to be from those participants to qualify as human subjects research; you may get information about them from a third party. But you still have to ensure you aren't putting human subjects at risk.

A person is a human subject if you obtain information through interaction or intervention with the person or if you access existing information that can be linked to specific, identifiable people.

Interacting with a person doesn't always make them a human subject. For instance, a person providing strictly factual information about organizations or other groups isn't a subject (e.g., if you ask a state employee for basic information about how to apply for a government program or how many people participate per year). But if you ask that person how they feel about or perceive the organization or group (say, if you ask the state employee if they think the program should continue or be eliminated), then they are subjects.

Surveys, including online surveys, generally constitute interaction or intervention and are considered human subjects research. If your research plan includes surveys or interviews, you'll most likely need IRB approval. However, if you are conducting secondary data analysis of existing and publicly-available datasets, such as Census data or the Youth Risk Behavior Surveillance System (YRBSS), and the dataset doesn't include any information that allows you to identify specific individuals, your project isn't human subject research and you don't need IRB approval.

REVIEW, COMPLIANCE AND MODIFICATIONS

This section will cover continuing review, compliance and proposal modification procedures.

In short, after approval, one of three types of review will be assigned to the project. Continuing review ensures that the IRB is maintaining oversight into the research conducted and assuring that all aspects of the study are complying to the outlined parameters for the whole length of the study.

Types of approval

If your research is approved, you will receive a notice and an outline of the continuing review process. Your approval period will be outlined in your notice. If research continues past this time, you will need to submit another application for renewal.

It is helpful to review these as a sort of "stoplight" with Exempt being green, as in "go ahead," Expedited being yellow as in "go ahead, but with caution" and Full being red, with a policy of "there are some serious concerns to consider during research."

Exempt

This research shows minimal risk to participants, and the institute has no reason to believe it will bring harm upon the subjects. Only very basic procedures and auditing will be in place.

These can involve basic interviews, surveys and questionnaires about topics that are not sensitive or private, or able to damage them legally, financially or their reputation. The information is not able to be immediately linked back to the subjects by malicious third parties. Children and at-risk populations are not involved.

Examples: archival research (reviewing existing data), asking people to taste different types of soda, doing a questionnaire on social media preferences, interviewing subjects about feelings of safety in their community, recording subjects with their consent as they try to solve a puzzle while looking in a mirror.

Expedited

In this circumstance, the risk to the subjects again remains minimal but may involve greater privacy risks than Exempted research. This is more common in medical research but in behavioral if the information gathered (such as video recordings) can easily identify the subject and may be of a topic sensitive in nature (albeit not endangering them financially, socially or their reputation).

This research level requires a greater degree of accountability than Exempted review, especially in research methods and its auditing plan.

Examples: having subjects talk about experiences in their life, a survey on subject's sexual relationships with their partners, extended behavioral analysis of a subject

Full

This research requires in-depth and stringent auditing measures and must be carefully reviewed and safeguarded. This is automatically the ruling for any research involving people under the ages of 18, prisoners or other at risk populations (including people with impaired decision-making capacity). This also includes research that contains private or sensitive information that may be damaging to a subject if it is released, research on illegal activities, or research that may pose a risk physical or emotional harm to subjects.

Auditing measures on this research will be thorough and assure at every step of the way there is not risk of harm to subjects or their privacy.

Examples: testing how subjects react thinking they are in life or death situations, studying the behavior of children, gathering information about subject's illicit drug use, interviewing victims about past sexual abuse.

The Layfette College IRB site has a very useful, technical breakdown of requirements for the differing levels of approval here.

Continuing Review

For research projects that are given expedited or full review status, you will be provided with an outline of auditing measures and their frequency. You will need to fill out the forms provided and submit any documents outlined in your Continuing Review Outline that will be provided with your approval.

Corrective action

The IRB will review all compliance materials submitted on a continuing basis. In the event that there is a breach of protocol, violation of compliance or any other issues that endangers the safety of the study

and its human participants and their privacy as decided by the discretion of the board, you will be delivered a notice of corrective action.

This will outline changes that need to be made, the time schedule they need to be made in, and an explanation of why they are necessary. In the event that the violations of compliance continue, the IRB may choose to terminate approval of the research altogether.

Modifications of research

Any type of research including Exempt proposals may require a modification application in some circumstances. A request to modify a project is required if:

- A change in plans is made so that human subjects will be used
- The research methods or techniques are significantly different
- The informed consent document or process would change
- New hazards are evident
- Adverse events have created problems in the research, beyond your control or otherwise

Anything that alters the risk/benefit balance of a project or modifies informed consent in any way requires approval. The changes must be approved before you implement them. Minor modifications that don't alter the risk to participants don't require IRB approval.

To make modifications, submit the Modification Request form and a copy of the current or proposed informed consent document. The IRB will notify you within 3 business days that your proposal has been received and notify you of the timeline of approval and when it will be considered by the board.

The IRB has the authority to audit projects if there is reason to believe that significant changes may have occurred without IRB approval.

COLLABORATION AND RELIANCE

Working with outside institutions/reliance basics

If you are a PI who is not a member of SBCI, you may request to recruit members of SBCI to be participants in your study. To do so, you must have IRB approval from your home institution. The degree of collaboration and sharing of responsibility between the organizations is referred to as "Reliance."

The SBCI IRB will then decide with the external organization's IRB to determine which institution will be the Institution of Record (holding responsibility for documentation of compliance measures). SBCI will further need to review and approve the study protocols approved by the external IRB. SBCI will require a Memorandum of Understanding (MOU) or other agreement with your institution before we accept your IRB approval.

The administrator responsible for the SBCI population you hope to recruit as participants must give consent to allow the study to go forward, and any members who will be assisting with the study must be identified in the proposal, which must be approved before the collaboration may begin. If the IRB protocol is consistent with SBCI's own policies, it will be approved. The SBCI IRB retains the right to require a full application for the project if it determines that the approved protocol is not consistent with its policies or requirements.

In order to request a project that involves reliance, please submit a RP Form 1 – Proposal Factsheet and attach all relevant documents from the outside organization to the proposal.

Graduate students

If you are a graduate student, you will likely have to get IRB approval through that institution, even if you are a member of SBCI. Graduate programs generally require graduate students to receive IRB approval through them, with a faculty advisor overseeing the project. Failing to inform your advisor or receive your graduate institution's IRB approval can be a serious breach of their research procedures.

Even if you are an active member of SBCI, if you are enrolled in a graduate program, we strongly encourage you to speak to your advisor to determine the proper avenue for seeking IRB approval for any projects.