CSULB IRB SUBMISSION & REVIEW PROCESS

SPRING 2018
OVERVIEW

• CSULB IRB
• Research Regulation
• IRB Submission Process
• IRB Review Process
• Q&A
WHAT IS THE ROLE OF THE IRB?

CSULB IRB
The CSULB IRB is comprised of 13 members from various disciplines. The role of the IRB is to ensure the protection and welfare of human subjects participating in research according to the regulation by:

- Assessing the risk/benefit ratio to ensure the risks are minimized
- Ensure equitable selection of subjects
- Confirming potential subjects understand their rights
- Reviewing adequate data protection and storage measures
The IRB must review and approve all elements of the research to ensure the procedures are ethical.

Last semester an individual conducted a survey without IRB review and approval. The “research” activities alerted campus police because participants felt the survey questions were invasive and the “researcher” groped female participants.
COMPLIANCE

GREAT EXPECTATIONS
COMPLIANCE IS A TWO WAY STREET
RESEARCH COMPLIANCE

IRB

- Adheres to federal, local and local regulation
- Maintains accurate records of all research related activities
- Reviews all research with human subjects to ensure subjects are not exposed to more risk than necessary
- Reports issues of non-compliance

INVESTIGATOR

- Conducts research according to the IRB approved protocol
- Reports adverse events
- Maintains CITI training
- Avoids conflict of interests and coercion
- Complies with University research policies
RESEARCH WITH HUMAN SUBJECTS

The federal regulations consider the definition of “Research with Human Subjects” to be a systematic investigation that collects information, biospecimens or uses data derived from living individuals to draw conclusions that contribute to a knowledge base.

Collecting/using new or existing data or biospecimens from a small population to analyze and apply the results to a larger population.
BEFORE IRB SUBMISSION
TRAINING AND PROJECT FEASIBILITY
CITI TRAINING

• Online training, free of charge to CSULB affiliates
• About 2 hours to complete
• The CSULB IRB only requires completion of the Social & Behavioral Basic/Refresher Course
• Training is valid for 3 years after date of completion
• www.CITIprogram.org
From the **Main Menu** – Click on the link,  "Add a Course or Update Learner Groups"
PROJECT FEASIBILITY

• What is the goal of the project? What questions am I seeking to answer or what hypothesis am I trying to prove?
• What type of assessments (surveys, interview or focus group questions) do I need to create?
• How will I recruit participants?
• Do I need permissions from anyone?
• Will I have enough time to complete my research as planned? Account for delays or unanticipated problems because so many other entities are involved beyond yourself.
SUBMISSION PROCESS
FORMS, TEMPLATES & IRBNET
WHAT HAS CHANGED WITH THE CSULB IRB PROCESS?

• Now 3 IRB Applications based on risk level
• New category of review added, Limited Review
• Most projects that previously required expedited review now qualify for Administrative and Limited Review
• Secondary data analysis now includes prospective data
• Consent Form (“legal document”) is replaced with a Consent Notice
• Most projects no longer have an expiration date
• Revised Faculty Advisor Letter
• Federally funded projects will receive review under the pre-2018 Common Rule until July 19, 2018
SUBMISSION DECISION TREE

Is my project research with human subjects?

- **YES**, because I am collecting information through interaction with individuals OR analyzing identifiable private information (individuals can be directly or indirectly identified).
  - Submission to the **IRB is required**. Which IRB Application should I submit?
    - IRB Application for Existing and Secondary Data
      - For Projects Involving:
        * Secondary analysis of identifiable data
        * Retrospective and/or prospective secondary data analysis
    - IRB Application for Administrative and Limited Review
      - For projects involving:
        * Surveys, interviews, and focus groups (release of data will not place subjects at harm)
        * Benign behavioral interventions with adults.
        * No children or other vulnerable populations
  - IRB Application for Expedited and Standard Review
    - For projects involving:
      * Interventions and assessments (minimal and greater than minimal risk)
      * Behavioral interventions
      * Inclusion of children or other vulnerable populations
- **NO**, because I am not conducting a systematic investigation that will contribute to generalizable knowledge through interactions with individuals OR I am only analysing non-identifiable information.
  - STOP
    - No further action is required. An IRB Application is not required.
CATEGORIES OF REVIEW

• Administrative & Limited Review
  – IRB Application for Administrative & Limited Review
  – IRB Application for Existing & Secondary Data

• Expedited Review
  – IRB Application for Expedited & Standard Review

• Standard Review
  – IRB Application for Expedited & Standard Review

<table>
<thead>
<tr>
<th>Admin &amp; Limited</th>
<th>Expedited</th>
<th>Standard</th>
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</thead>
<tbody>
<tr>
<td>Less than minimal risk</td>
<td>Minimal risk</td>
<td>Greater than minimal risk</td>
</tr>
<tr>
<td>Surveys, interviews, observations, secondary data (no children or vulnerable populations)</td>
<td>Interventions, assessments, projects involving children</td>
<td>Any project that requires invasive or risky procedures. Vulnerable populations included</td>
</tr>
<tr>
<td>1 board member review</td>
<td>At least 2 board members review</td>
<td>Full IRB review</td>
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TIMELINE OF RESEARCH ACTIVITIES

Develop project ideas & methodologies

Solicit permission letters

Submit IRB Application & respond to IRB inquiries

IRB Approval

Recruit, consent and begin data collection

Submit Requests for amendments to the IRB

Publish
FORMS

TEMPLATES & OTHER APPENDICES
IRB APPLICATION FOR ADMINISTRATIVE & LIMITED REVIEW

Administrative & Limited Review Research Projects

Before proceeding to the application on the next page, please confirm that your research activities satisfy one of the following criteria. Otherwise, your project may require Expedited or Standard Review. If your project involves the use of identifiable secondary or existing data, please complete the MR Application for Expediting & Secondary Data.

You should only fill this form out if your project involves any of the following:

- Nonveteran educational practices in an educational setting. The research activities cannot adversely affect students’ opportunity to learn required educational content OR adversely affect the instruction who provides instruction.
  - Example: Comparing multi-media lesson plans in Fall Semester to paper-based lesson plans in Spring semester. The same educational material is covered, only the teaching technique varies.
- Surveys, interviews, observations: educational or behavioral interventions where the data collection is verbal, as writing or recorded (audio or video) and MUST satisfy one of the following:
  - Anonymous data collection (no links to identifiers such as names)
  - Data collected does not allow subjects to be identified as follows:
    - Data that are identifiable, but protections are provided for confidentiality
  - Data collection involving children (under 18) or other vulnerable populations requires Expedited Review and submission via the IRB Application for Expedited and Standard Reviews.
  - Example: 5: Qunatified surveys to collect data on CSUSM students’ study habits during finals for the purpose of a senior thesis, whether data are collected anonymously or confidentially.
  - Example 2: Interviews with transgender women to understand the harassment they endure in the campus. No names, employers, or company names are used. Pseudonyms used instead. Interviews will be audio recorded with permission of the consent form prior to the interview.
- Descriptive behavioral data collection involving authorized deception (subjects must consent to deception prior to the research proceeds). The use of consensual deception or manipulation requires Expedited Review and submission via the IRB Application for Expedited and Standard Reviews.
  - Example: Group activity involving a white woman in scenario 1 and a black man in scenario 2, who both demonstrate an anger problem and subjects are surveyed to determine underlying gender and racial bias. Subjects were consensual to participate in a specific competition that involved an element of deception that the PI agreed to reveal at the conclusion of the experiment.
- Public benefit and service programs that are federally funded or conducted by the federal government.
  - Example: An assessment of emergency room wait times in a Veterans Affairs Hospital.
- Taste and food quality tests involving ingredients that the FDA determines safe for consumption.
  - Example: A marketing taste test evaluation of a chocolate chip cookie compared to a variation bar flavored like a chocolate chip cookie. Participants will submit surveys to determine whether the healthy variation bar is a tasty substitute for real chocolate chip cookies.
WHEN TO SUBMIT THE IRB APPLICATION FOR ADMINISTRATIVE & LIMITED REVIEW

• Surveys, interviews, focus groups and observations that involving ADULTS
• Benign behavioral interventions
• Normal educational practices meaning, the instructional technique or pedagogy is altered but the content of instruction remains the same
• Taste tests
• Federally funded service projects
PROJECT SUMMARY

Provide the IRB with some context:

- Why is the research important?
- Is there current literature to support your hypothesis?
- Describe any program functions as necessary.
- Define any new terms

Subject characteristics such as: CSULB students 18+, majoring in Psychology and self-identify as an ethnic minority and gender fluid.
Describe how you plan to recruit subjects:

- What is your initial point of contact?
- How will you inform potential subjects of your study?
- How will potential subjects inform you that they are interested in participating?
- Will you conduct any follow-up contact?

You will need permission to conduct your research anywhere on campus, within an organization, business or club.
- Permission must be obtained prior to IRB approval
- Only list sites you have permission to include
METHODOLOGY

MOST IMPORTANT QUESTION!!

SECOND MOST IMPORTANT QUESTION!!
The primary focus of the IRB is to protect the protection of human subjects, not just through research methodologies but through protection of their data during and after the research.

### DATA ACCESS & STORAGE

#### 4. DATA ACCESS

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
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<tbody>
<tr>
<td>Who will have access to the data?</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Where will the data be stored?</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Will identifiable data be collected (names, student ID numbers, address, etc.)?</td>
<td>Yes*, No, Not Sure</td>
</tr>
<tr>
<td>*If yes, why is it necessary for identifiable data to be collected?</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Will you have access to external data i.e. medical charts, public records, proprietary information?</td>
<td>Yes*, No</td>
</tr>
<tr>
<td>*If yes, please describe the additional data you will have access to:</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Is it possible for the information collected to be traced back to identify the individual with subject master list or by other means?</td>
<td>Yes*, No</td>
</tr>
<tr>
<td>*If yes, describe the method(s) to protect subject privacy and confidentiality:</td>
<td>Click or tap here to enter text.</td>
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IRB APPLICATION FOR EXPEDITED & STANDARD REVIEW

Research Projects Qualifying for Expedited & Standard Review

Note: Before proceeding to the application on the next page, please confirm that your research activities satisfy one of the following criteria. Otherwise, your project may require approval for Administrative or Limited Review.

You should only fill this form out if your project involves any of the following:

- Clinical trial involving a medical drug or device cleared for use by the FDA.
- Collection of blood samples by finger prick or venipuncture under the following conditions:
  - Healthy, non-pregnant adults weighing at least 110 pounds. Amount of blood collected cannot exceed 550 ml with 8 weeks (no more than two blood draws per week).
  - Other adults and children (with consideration for age, weight and overall health). Amount of blood collection cannot exceed 50 ml with 8 weeks (no more than two blood draws per week).
- Prospective collection of biological samples by non-invasive means.
- Collection of data by non-invasive means in a clinical setting with the use of FDA cleared/approved medical devices (excluding X-ray).
- Identification data collection of individuals via video, audio or image recordings made for research purposes and the data collection may place subjects at increased risk.
- Research on an individual or group characteristics or behavior (perception, cognizance, motivation, identity, language, communication, cultural beliefs or practices and social behavior) that do not satisfy the Exempt category (research involving public officials, anonymous data collection or less than minimal risk posed to subjects would be considered Exempt).
- Research is greater than minimal risk, meaning the assessment or intervention involves more than what subjects would encounter in normal everyday activities or the data has the potential to pose additional physical, psychological, criminal or social harms.
- Research involving vulnerable populations (i.e., children, pregnant women, fetuses, prisoners, undocumented individuals and other populations deemed vulnerable by the IRB).
WHEN TO SUBMIT THE IRB APPLICATION FOR EXPEDITED & STANDARD REVIEW

• Project activities involve interventions or invasive assessments
• Children under 18 years old are subjects, regardless of risk level
• Inclusion of vulnerable populations such as undocumented residents, elderly, or individuals with cognitive impairments
• Federally funded (Until July 19, 2018)
• Use or collection of biospecimens
IRBNet (www.IRBNet.org) is the online submission platform for the CSULB IRB
OTHER REQUIREMENTS

• Faculty Advisor Letter (students)
• Consent Notice
• Recruitment Material
• Permission Letters
• Survey/Interview Protocol
CONSENT NOTICE

Notice of Informed Consent

Purpose & Instructions

The purpose of the Notice of Informed Consent is to provide subjects with a concise summary of the research activities, risks, benefits and rights as a research subject. The information is designed to be supplemented by the consent form and will not replace investigator-provided details. To keep the consent form concise, remember the purpose is to communicate.

Eligibility

Please use the template on the third page to create a Notice of Informed Consent. All areas of activity data from human subjects must include this document in the IRB application. Subjects cannot provide consent to participate in any study until all IRB approval(s) are in place. Therefore, it is important to submit a Notice of Informed Consent when a project is approved by the IRB. Subjects must provide consent to participate in any study until all IRB approval(s) are in place. Therefore, it is important to submit a Notice of Informed Consent when a project is approved by the IRB.

Subjects

The Notice of Informed Consent should be consistent with the data entered in the IRB application. The template does not have to be extended but the subject should be the same.

Child Subjects

For subjects under 18 years old, the child must provide consent in addition to informed consent. The child’s age should be noted in the Notice of Informed Consent. This should be noted in the Notice of Informed Consent and the subject should provide consent in addition to the child subject. The subject should be the same.

Parent Consent

Parents must provide consent to allow their child under 18 years old participate in the study. The parents should be informed of the child’s participation in the study and should provide consent. The parent should be the same.

Name of Subject

Date

Signature of Parent

Date

Notice of Informed Consent

Project Title: [Project Title]

Institution: [Institution]

PI Contact: [PI Contact]

California State University, Long Beach (CSULB)

Office of Research and Sponsored Programs

[Name]
[Signature]
[Date]

You are being asked to participate in a research study:

The purpose of this study is to determine whether the use of [the study activity] is effective in improving [the outcome]. You are free to participate in the study or not. If you choose to participate, you will be asked to [describe the procedure]. The study will start on [date]. You will be given an opportunity to ask questions about the study. You may withdraw from the study at any time without prejudice to you. Any information collected from you in this study will be stored in a secure location and will not be shared with anyone that does not have appropriate permission to access the information.

You are required to consent to participate in the study.

You understand that this information has been explained to you and you wish to participate.

Name of Subject: [Name]

Date: [Date]

Signature of Parent: [Signature]

Date: [Date]
Notice of Informed Consent

California State University, Long Beach (CSULB)
Office of University Research, CSULB - 1525 Bellflower Blvd, Long Beach, CA 90840

Project Title: How to Increase Happiness
Investigator(s): Betty Smith, M.S.

Project Contacts: Smith@csulb.edu, (562) 985-1000

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about the purpose, procedures and duration of the research activities. Additionally, you will be informed of all experimental procedures, any potential risks, and discomforts, benefits of the research and whether there are any beneficial alternatives to participating in this study. Finally, the investigator will explain how any information collected about you will be kept confidential. Remember, participation is voluntary and you should ask any questions you have before agreeing to participate. You can refuse to participate at any time without any penalty or loss of benefits.

The purpose of this study is to learn how students remain positive and happy during stressful situations. If you decide to participate you will be asked to complete a short survey which is all for research purposes. The total time of your participation is expected to last about 15 minutes. Although the risks to participating in this study are minimal, you may experience feelings of discomfort from answering questions. The investigator will make every attempt to reduce these risks by reminding you that you may ask questions or refuse to answer any question. You may not directly benefit from participating in this study. However, the results of this study may benefit other college students who can learn methods of increasing their happiness.

Any information collected from you in this study will be stored in a secure location and will not be shared with anyone who does not have appropriate provisions to access the information.

You may contact the Office of University Research at ORU@compliance@csulb.edu, if you have questions about your rights as a research participant.

Signing this document means that all information about the study has been explained to you clearly; the investigator has answered any questions you have about the study; and that you voluntarily agree to participate.

Subject Signature

Date

Subject Signature
PERMISSION LETTER

• Printed on letterhead (when applicable)
• PI’s name
• Project title
• Explain the scope of the permissions:
  – Recruitment
  – Use of facility resources
  – Conduct research activities at the site
  – Sending emails on behalf of the PI
  – Providing organization/agency data
Faculty Advisor Statement

TO: CSULB Institutional Review Board
FROM: Debbie Foxy, PhD, RN

NAME OF STUDENT: Amber Jones
TITLE OF PROJECT: Investigating Eating Behaviors Among California State University, Long Beach Veteran Students

STATEMENT OF THE ADVISOR:

I, Debbie Foxy, certify that I have reviewed and confirmed the following regarding the aforementioned project:

- The student and I have discussed and reviewed the submission for appropriateness and completeness with regard to the collection and protection of subject data.
- The research methodologies align with acceptable methodologies of this discipline.
- The risk/benefit ratio is appropriate for the project activities.
- The potential risks include: Discomfort answering questions.
- The appropriate safeguards in place to minimize the risks include: Participants can skip any question(s) they desire to not answer.
- I will continue supervision of this project and ensure the student remains compliant with CSULB research policies by meeting regularly with the student to discuss data collection and maintenance.

My signature below certifies that I as the Faculty Advisor of this research have read and approved the attached IRB Application.

[Signature]

Department of Family and Consumer Sciences 5-3147
Debbie.Foxy@calstate.edu
REVIEW PROCESS

REVIEW & APPROVAL
IRB REVIEW

Step 1: Submission
- Complete CITI training
- Upload IRB Application and all relevant attachments to IRBNet
- Sign the submission

Step 2: Pre-Review
- Confirms completeness
- Recommends revisions to improve submission

Step 3: IRB Review
- Project is assigned to the appropriate review category
- Projects assigned in order of submission
- IRB has 1 week to review project and suggest modifications

Step 4: Modifications
- Mandatory changes requested by the IRB based on ethics and compliance
- Changes must be made to secure approval
- Contest any modifications in a cover letter

Step 5: Approval
- Approval letter issued via IRBNet after modifications are adequately addressed
- Start research according to approved application
- Request Amendments
• No expiration date for less than minimal and minimal risk projects.

• Insert the header or footer “Approved [Date] by the CSULB IRB” on consent forms and flyers.

• Respond to Annual Check-In if you plan to continue the research after one year.

• Contact the IRB to report adverse events, request amendments.
Submit a Request for Amendment to an Approved Protocol form when changing or adding:

- Personnel
- Advertisements
- Study procedures
- Survey/Interview questions
- Recruitment sites
- Subject size or characteristics
FINAL TAKEAWAYS

IF YOU DON’T REMEMBER ANYTHING ELSE, REMEMBER THESE THINGS
REMEMBER...

- Complete CITI training BEFORE submitting to the IRB.
- If you are conducting a survey, interview or focus group with adults, you will need to complete the IRB Application for Administrative & Limited Review.
- The review process takes time.
- Contact the IRB first with any questions. It is easier to prevent mistakes or correct minor mistakes than it is to resolve a situation that got too far out of hand. Even then, we are still available to help.
CSULB Institutional Review Board (IRB)

ANNOUNCEMENTS

Dear IRB Applicants,

As announced in November 2017 - Effective January 31, 2018 the CSULB IRB will no longer accept versions of IRB forms dated prior to 1/2/2018 as indicated in the header of each form.

The IRB revised all forms and templates according to changes in research regulation and CSULB IRB policy. Please read the cover page of each form prior to completing it to ensure you are using the appropriate form for your submission. All forms and templates on this site and in the Documents Library on IRBNet contain links to the new 1/2/2018 versions of the forms and templates. Any forms or templates submitted on outdated versions will require resubmission.

Click HERE for more information about how the changes will affect your research submissions.
Questions?
Email: IRB@csulb.edu

Phone: (562) 985-8147 (Ask for the IRB)

Location: Bldg. FO5, Rm. 111

Website: http://web.csulb.edu/divisions/aa/research/compliance/humans/

OR

Visit www.csulb.edu, type “IRB” in the search bar and click the first link
Thank you