CSULB IRB SUBMISSION & REVIEW PROCESS

SPRING 2018

JASON WANG
MARY WALKER
TIFFANY ROSE

RESEARCH COMPLIANCE STAFF

OVERVIEW

- CSULB IRB
- Research Regulation
- IRB Submission Process
- IRB Review Process
- Q&A

WHAT IS THE ROLE OF THE IRB?

CSULB IRB

IRB COMMITTEE

The CSULB IRB is comprised of 13 members from various disciplines. The role of the IRB is 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

ETHICS

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

FEDERAL REGULATION

COMMON RULE VS. FINAL RULE

RESEARCH WITH HUMAN SUBJECTS

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

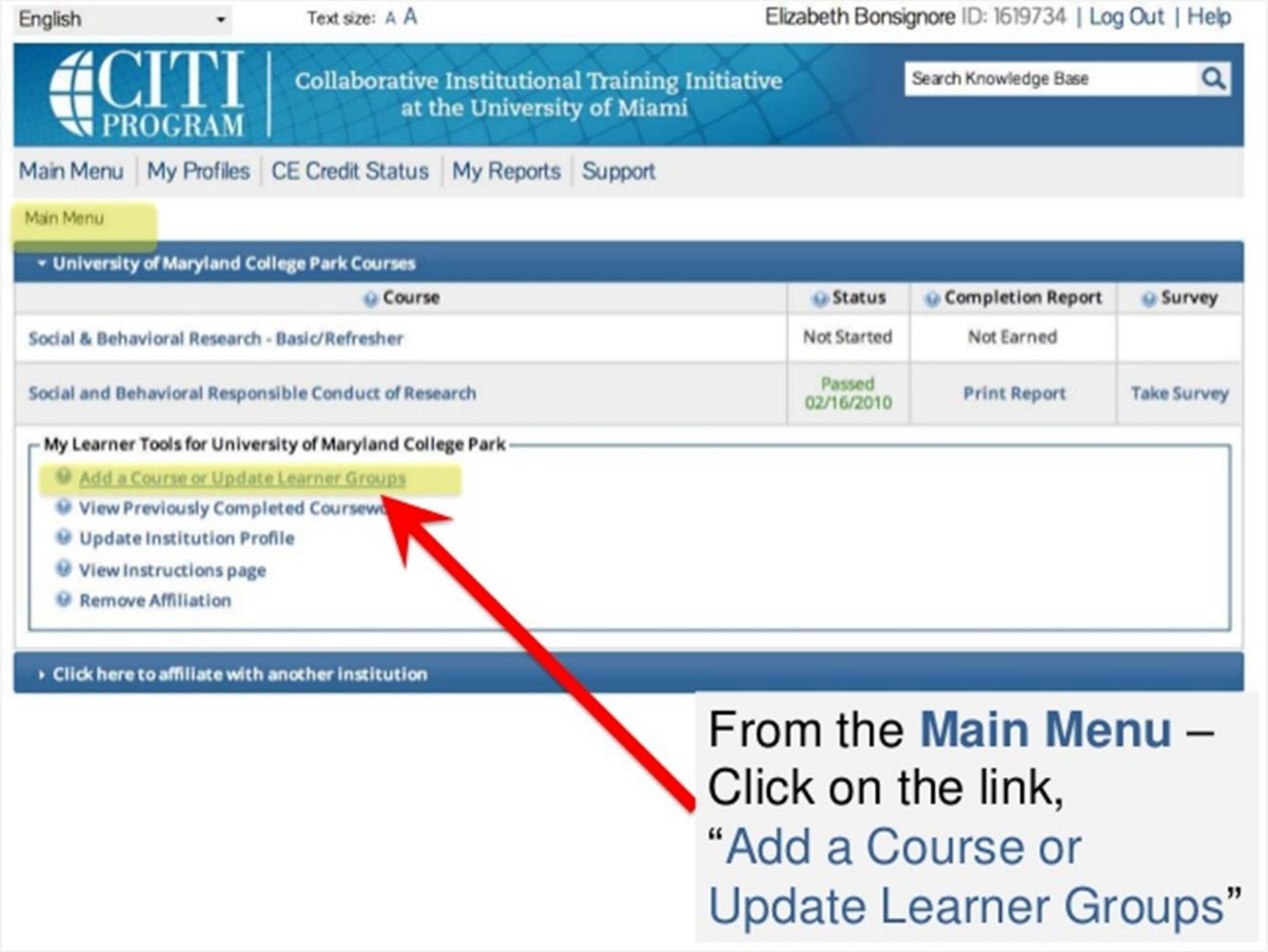
Collecting/using new or existing data or biospecimens from a small population to analyze and apply the results to a larger population.

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


English
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CITI PROGRAM
Collaborative Institutional Training Initiative at the University of Miami
Search Knowledge Base
Main Menu | My Profiles | CE Credit Status | My Reports | Support
Main Menu
University of Maryland College Park Courses
Course
Status
Completion Report
Survey
Social & Behavioral Research - Basic/Refresher
Not Started
Not Earned
Social and Behavioral Responsible Conduct of Research
Passed 02/16/2010
Print Report
Take Survey
My Learner Tools for University of Maryland College Park
Add a Course or Update Learner Groups
View Previously Completed Coursew
Update Institution Profile
View Instructions page
Remove Affiliation
Click here to affiliate with another institution
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.

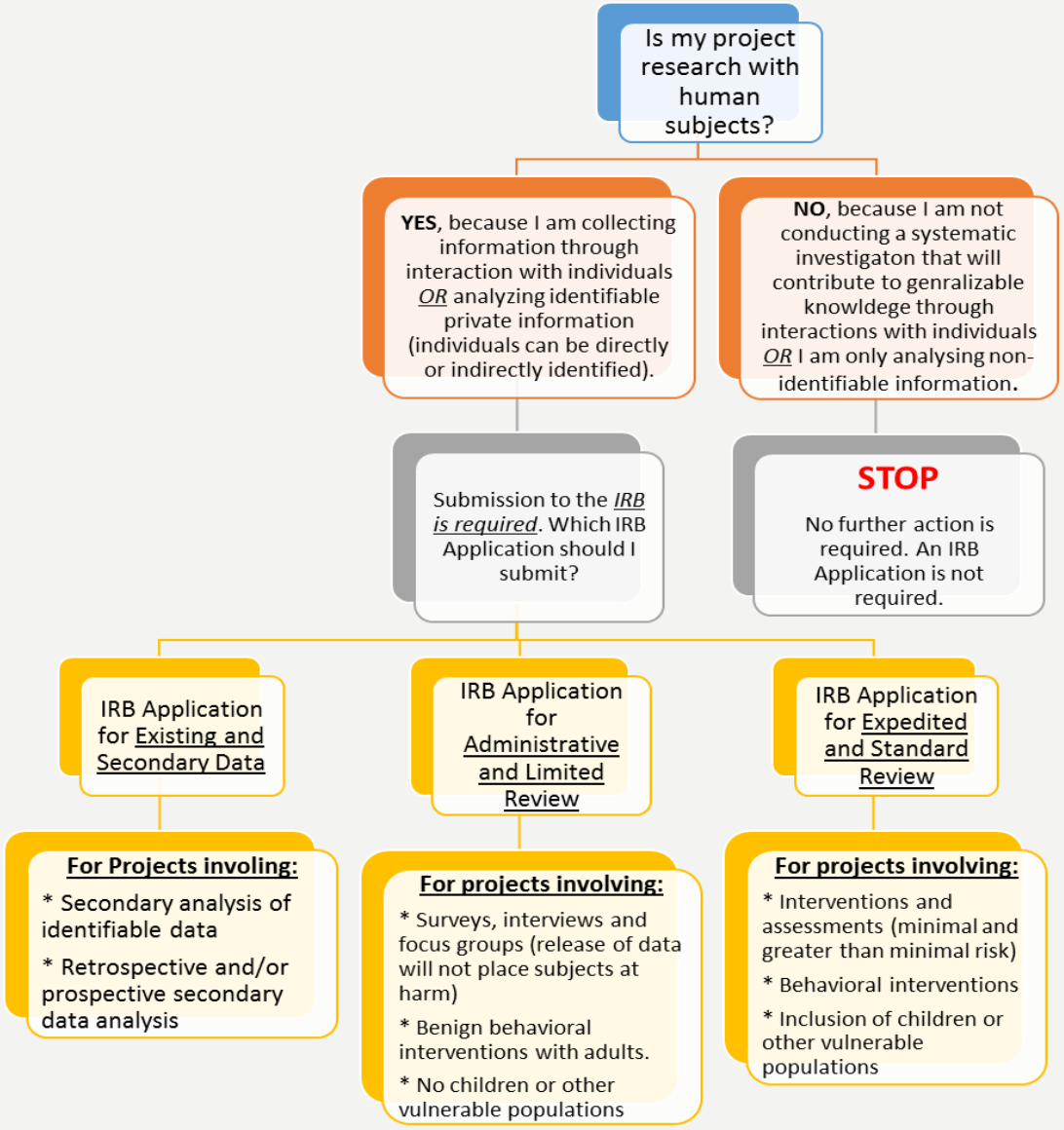
SUBMISSION PROCESS

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

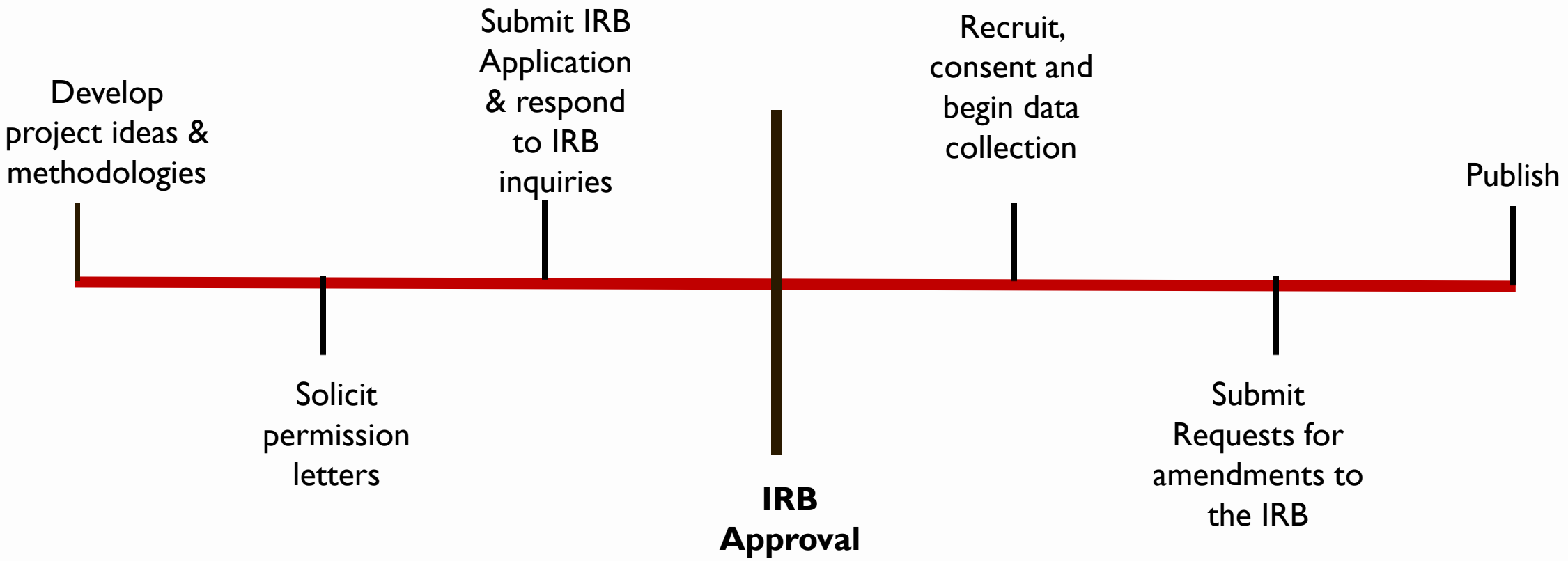


CATEGORIES OF REVIEW

- 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

Admin & Limited	Expedited	Standard
Less than minimal risk	Minimal risk	Greater than minimal risk
Surveys, interviews, observations, secondary data (no children or vulnerable populations)	Interventions, assessments, projects involving children	Any project that requires invasive or risky procedures. Vulnerable populations included
1 board member review	At least 2 board members review	Full IRB review

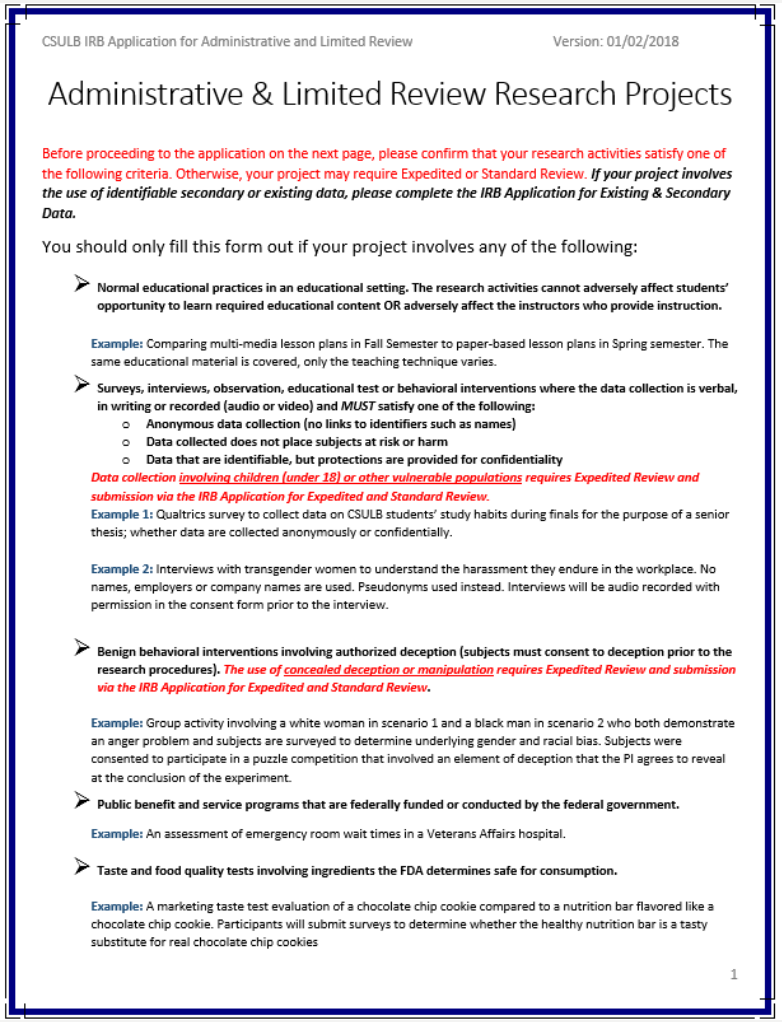
TIMELINE OF RESEARCH ACTIVITIES



FORMS

TEMPLATES & OTHER APPENDICES

IRB APPLICATION FOR ADMINISTRATIVE & LIMITED REVIEW



CSULB IRB Application for Administrative and Limited Review Version: 01/02/2018

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 IRB Application for Existing & Secondary Data.***

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

- **Normal educational practices in an educational setting. The research activities cannot adversely affect students' opportunity to learn required educational content OR adversely affect the instructors who provide 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, observation, educational test or behavioral interventions where the data collection is verbal, in 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 place subjects at risk or harm**
  - **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 Review.

  Example 1: Qualtrics survey to collect data on CSULB 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 workplace. No names, employers or company names are used. Pseudonyms used instead. Interviews will be audio recorded with permission in the consent form prior to the interview.

- **Benign behavioral interventions involving authorized deception (subjects must consent to deception prior to the research procedures).** ***The use of concealed deception or manipulation requires Expedited Review and submission via the IRB Application for Expedited and Standard Review*.**

  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 consented to participate in a puzzle competition that involved an element of deception that the PI agrees 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 the FDA determines safe for consumption.**

  Example: A marketing taste test evaluation of a chocolate chip cookie compared to a nutrition bar flavored like a chocolate chip cookie. Participants will submit surveys to determine whether the healthy nutrition bar is a tasty substitute for real chocolate chip cookies

1

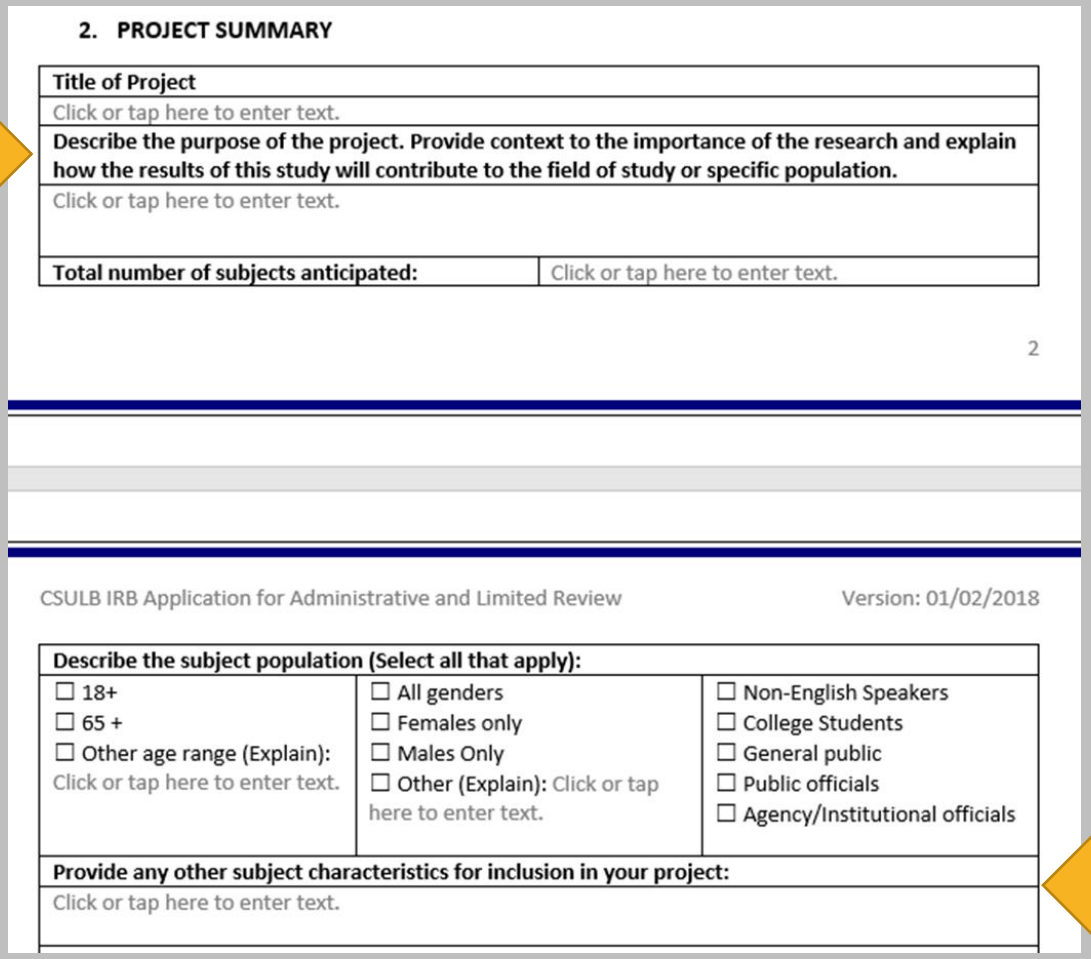
WHEN TO SUBMIT THE IRB APPLICATION FOR ADMINISTRATIVE & LIMITED REVIEW

- 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



2. **PROJECT SUMMARY**

Title of Project
Click or tap here to enter text.
Describe the purpose of the project. Provide context to the importance of the research and explain how the results of this study will contribute to the field of study or specific population.
Click or tap here to enter text.
Total number of subjects anticipated: Click or tap here to enter text.

2

CSULB IRB Application for Administrative and Limited Review Version: 01/02/2018

Describe the subject population (Select all that apply):		
☐ 18+ ☐ 65 + ☐ Other age range (Explain): Click or tap here to enter text.	☐ All genders ☐ Females only ☐ Males Only ☐ Other (Explain): Click or tap here to enter text.	☐ Non-English Speakers ☐ College Students ☐ General public ☐ Public officials ☐ Agency/Institutional officials
Provide any other subject characteristics for inclusion in your project:		
Click or tap here to enter text.		

Subject characteristics such as: CSULB students 18+, majoring in Psychology and self-identify as an ethnic minority and gender fluid

SUBJECT RECRUITMENT

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?

List all methods of subject recruitment (Select all that apply):

☐ Flyers/letters ☐ Emails ☐ Telephone ☐ In-class announcement	☐ Subject pool ☐ Tabling in public ☐ Personal network/Snowball sampling	☐ Passive recruitment ☐ Social media post ☐ Other (Explain): Click or tap here to enter text.

Describe the step-by-step recruitment methods for each subject group (do not include any other project procedures in this section):

Click or tap here to enter text.

List the setting(s) of the research activities (Select all that apply):

☐ CSULB (in class) ☐ CSULB (out of class) ☐ CSULB (online) ☐ Other College Campus ☐ K-12 School ☐ Lab	☐ Public setting ☐Nonprofit or Other Agency ☐ Government Facility ☐ Foreign Country ☐ Subject's work/home ☐ Prison/Jail	☐ Telephone ☐ Email ☐ Social media ☐ Amazon mTurk ☐ Online (general public) ☐ Other

List the location of the research activities (Agency/school names, city, county or social media site):

Click or tap here to enter text.

Do you have permission from the facility, institution or director of the organization to conduct your project? **** If yes, please attach signed permission letter or data sharing agreement to this package.***

☐ Yes* ☐ No ☐ In Progress

Is the project primarily for training purposes?

☐ Yes ☐ No ☐ Other (Explain): Click or tap here to enter text.

List all methods of data collection (Select all that apply):

☐ Surveys/Questionnaires ☐ Focus Groups ☐ Educational Tests/Assessments ☐ Accessing Public Records ☐ Observation ☐ Audio recording ☐ Video recording	☐One-on-One interviews ☐ Data Mining ☐ Digital media (videos, pictures, simulation) ☐ Access to medical/academic records ☐ Biospecimen Analysis ☐ Experimental Controls ☐ Other (Explain) Click or tap here to enter text.

- 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!!!

Describe the step-by-step procedures of your project beginning with the informed consent process and continuing with all other project activities (all project activities must occur *AFTER* IRB approval):

Click or tap here to enter text.

Will subjects be compensated for their participation? If monetary compensation is to be provided, please specify the amount and provide a justification for that amount that avoids potential coercion.

☐ No
☐ Yes (Complete below):
Mode of compensation (Check one): ☐Cash ☐ Gift Card ☐ Course credit ☐ Other (Explain):
Click or tap here to enter text.
Total Amount per Subject: Click or tap here to enter text.
Justification (Explain): Click or tap here to enter text.

3. RISKS AND MITIGATIONS

Describe any reasonable risks subjects may experience participating in this project (Ex. Risk #1: Loss of confidentiality, Risk #2: Discomfort answering questions, Risk #3: etc...):

Click or tap here to enter text.

Provide a reasonable mitigation to reduce each potential risk listed above. Each mitigation should directly correspond to each risk (Mitigation for Risk #1, Mitigation for Risk #2, etc.):

Click or tap here to enter text.

SECOND MOST IMPORTANT QUESTION!!

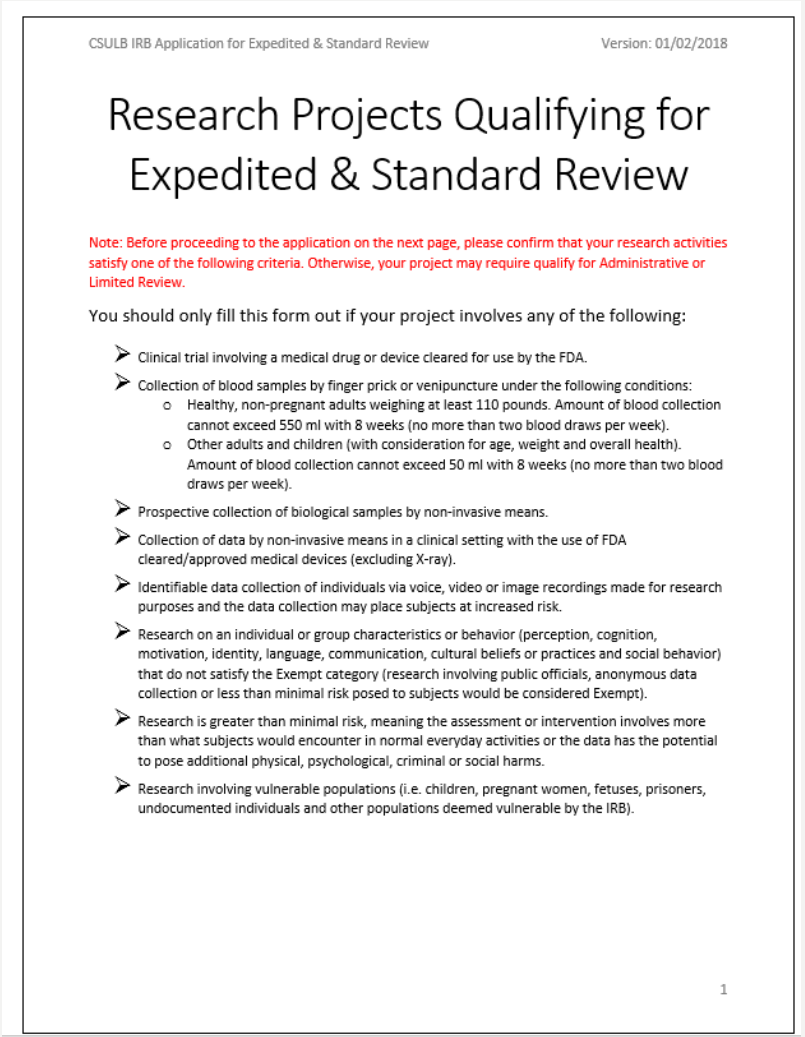
DATA ACCESS & STORAGE

4. DATA ACCESS

Who will have access to the data?	Click or tap here to enter text.
Where will the data be stored?	Click or tap here to enter text.
Will identifiable data be collected (names, student ID numbers, address, etc.)?	☐ Yes* ☐ No ☐ Not Sure
***If yes*, why is it necessary for identifiable data to be collected?**	Click or tap here to enter text.
Will you have access to external data i.e. medical charts, public records, proprietary information?	☐ Yes* ☐ No
***If yes, please describe the additional data you will have access to:**	
Click or tap here to enter text.	
Is it possible for the information collected to be traced back to identify the individual with subject master list or by other means?	☐ Yes* ☐ No
*If yes, describe the method(s) to protect subject privacy and confidentiality:	
Click or tap here to enter text.	

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.

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 qualify for Administrative or Limited Review.

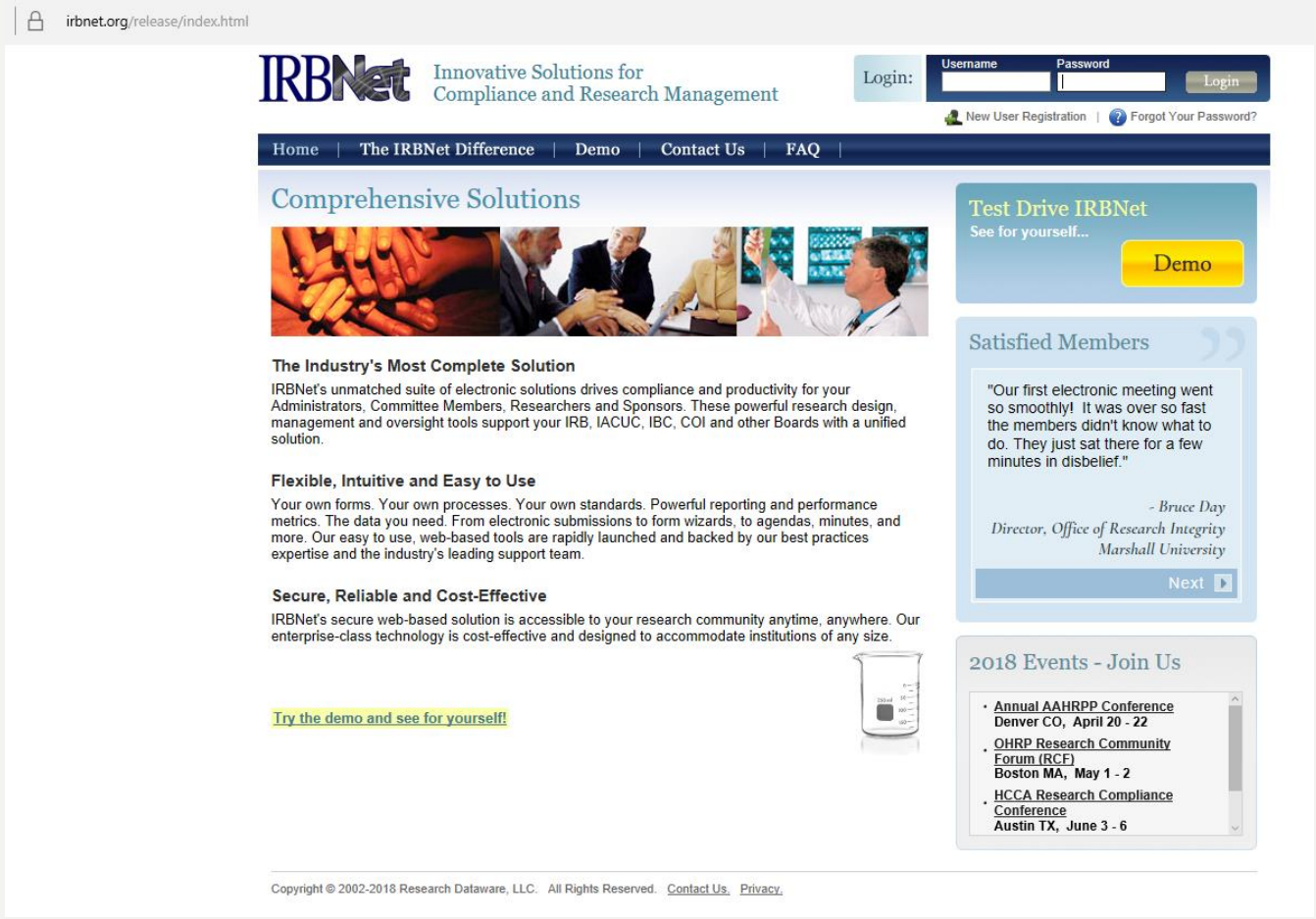
You should only fill this form out if your project involves any of the following:

- 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 collection 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).
- Identifiable data collection of individuals via voice, video 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, cognition, 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

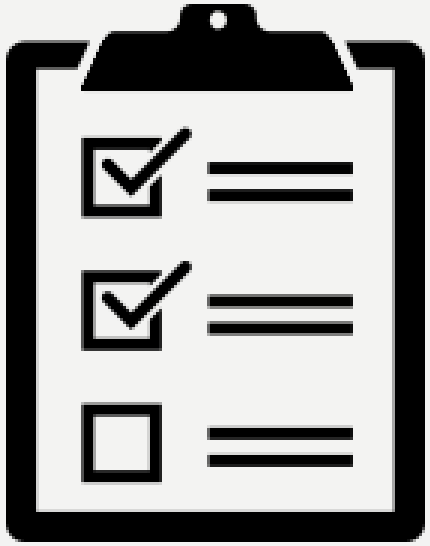
IRBNET



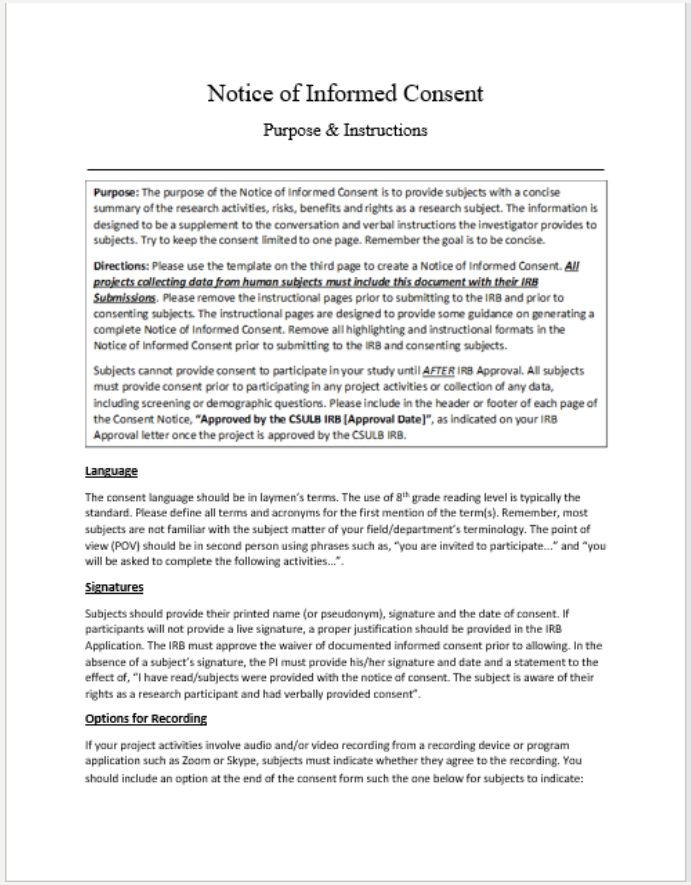
IRBNet (www.IRBNet.org) is the online submission platform for the CSULB IRB

OTHER REQUIREMENTS

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



CONSENT NOTICE



Notice of Informed Consent

Purpose & Instructions

Purpose: 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 a supplement to the conversation and verbal instructions the investigator provides to subjects. Try to keep the consent limited to one page. Remember the goal is to be concise.

Directions: Please use the template on the third page to create a Notice of Informed Consent. ***All projects collecting data from human subjects must include this document with their IRB Submissions***. Please remove the instructional pages prior to submitting to the IRB and prior to consenting subjects. The instructional pages are designed to provide some guidance on generating a complete Notice of Informed Consent. Remove all highlighting and instructional formats in the Notice of Informed Consent prior to submitting to the IRB and consenting subjects.

Subjects cannot provide consent to participate in your study until *AFTER* IRB Approval. All subjects must provide consent prior to participating in any project activities or collection of any data, including screening or demographic questions. Please include in the header or footer of each page of the Consent Notice, **"Approved by the CSULB IRB [Approval Date]"**, as indicated on your IRB Approval letter once the project is approved by the CSULB IRB.

Language

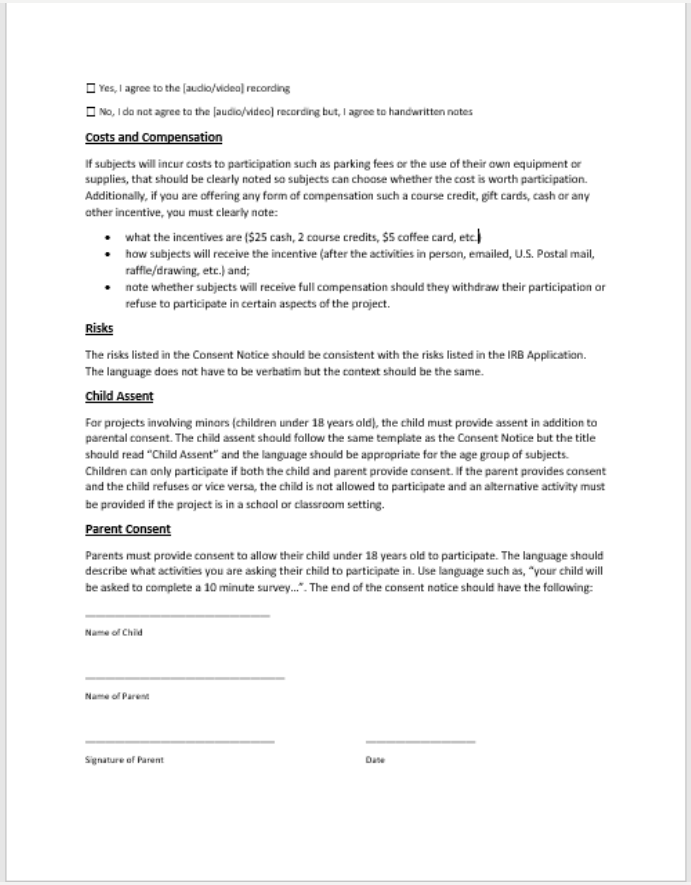
The consent language should be in laymen's terms. The use of 8th grade reading level is typically the standard. Please define all terms and acronyms for the first mention of the term(s). Remember, most subjects are not familiar with the subject matter of your field/department's terminology. The point of view (POV) should be in second person using phrases such as, "you are invited to participate…" and "you will be asked to complete the following activities…".

Signatures

Subjects should provide their printed name (or pseudonym), signature and the date of consent. If participants will not provide a live signature, a proper justification should be provided in the IRB Application. The IRB must approve the waiver of documented informed consent prior to allowing. In the absence of a subject's signature, the PI must provide his/her signature and date and a statement to the effect of, "I have read/subjects were provided with the notice of consent. The subject is aware of their rights as a research participant and had verbally provided consent".

Options for Recording

If your project activities involve audio and/or video recording from a recording device or program application such as Zoom or Skype, subjects must indicate whether they agree to the recording. You should include an option at the end of the consent form such the one below for subjects to indicate:



☐ Yes, I agree to the [audio/video] recording

☐ No, I do not agree to the [audio/video] recording but, I agree to handwritten notes

Costs and Compensation

If subjects will incur costs to participation such as parking fees or the use of their own equipment or supplies, that should be clearly noted so subjects can choose whether the cost is worth participation. Additionally, if you are offering any form of compensation such a course credit, gift cards, cash or any other incentive, you must clearly note:

- what the incentives are ($25 cash, 2 course credits, $5 coffee card, etc.)
- how subjects will receive the incentive (after the activities in person, emailed, U.S. Postal mail, raffle/drawing, etc.) and;
- note whether subjects will receive full compensation should they withdraw their participation or refuse to participate in certain aspects of the project.

Risks

The risks listed in the Consent Notice should be consistent with the risks listed in the IRB Application. The language does not have to be verbatim but the context should be the same.

Child Assent

For projects involving minors (children under 18 years old), the child must provide assent in addition to parental consent. The child assent should follow the same template as the Consent Notice but the title should read "Child Assent" and the language should be appropriate for the age group of subjects. Children can only participate if both the child and parent provide consent. If the parent provides consent and the child refuses or vice versa, the child is not allowed to participate and an alternative activity must be provided if the project is in a school or classroom setting.

Parent Consent

Parents must provide consent to allow their child under 18 years old to participate. The language should describe what activities you are asking their child to participate in. Use language such as, "your child will be asked to complete a 10 minute survey…". The end of the consent notice should have the following:

_____

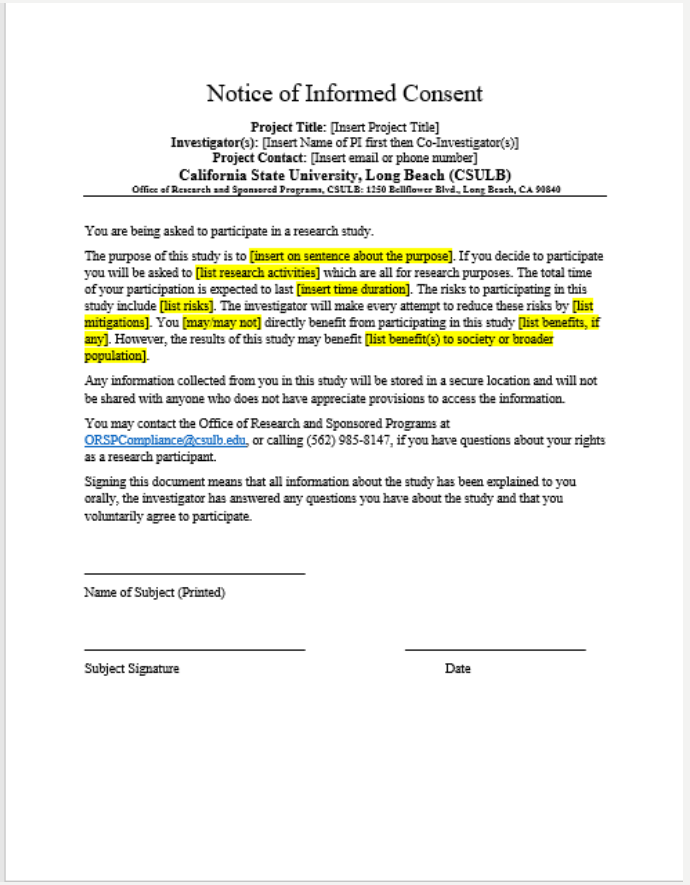
Name of Child

_____

Name of Parent

_____ _____

Signature of Parent Date



Notice of Informed Consent

Project Title: [Insert Project Title]
Investigator(s): [Insert Name of PI first then Co-Investigator(s)]
Project Contact: [Insert email or phone number]
California State University, Long Beach (CSULB)
Office of Research and Sponsored Programs, CSULB: 1250 Bellflower Blvd., Long Beach, CA 90840

You are being asked to participate in a research study.

The purpose of this study is to [insert on sentence about the purpose]. If you decide to participate you will be asked to [list research activities] which are all for research purposes. The total time of your participation is expected to last [insert time duration]. The risks to participating in this study include [list risks]. The investigator will make every attempt to reduce these risks by [list mitigations]. You [may/may not] directly benefit from participating in this study [list benefits, if any]. However, the results of this study may benefit [list benefit(s) to society or broader population].

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 appreciate provisions to access the information.

You may contact the Office of Research and Sponsored Programs at ORSPCompliance@csulb.edu, or calling (562) 985-8147, 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 orally, the investigator has answered any questions you have about the study and that you voluntarily agree to participate.

_____

Name of Subject (Printed)

_____ _____

Subject Signature Date

Notice of Informed Consent

California State University, Long Beach (CSULB)

Office of University Research, CSULB: 1250 Bellflower Blvd., Long Beach, CA 90840

Project Title: How to Increase Happiness

Investigator(s): Betty Smith, M.S.

Project Contact: Smiles@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 skip 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 appreciate provisions to access the information.

You may contact the Office of University Research at ORSPCompliance@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 orally, the investigator has answered any questions you have about the study and that you voluntarily agree to participate.

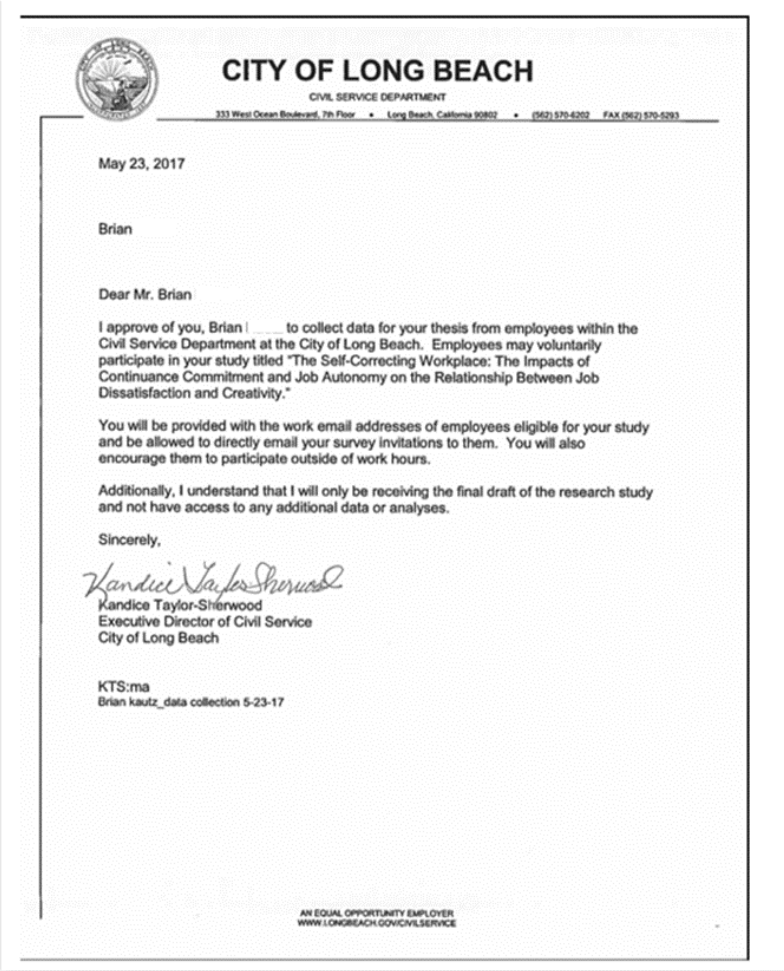
_____ _____

Subject Signature Date

_____

Subject Signature

PERMISSION LETTER



CITY OF LONG BEACH

CIVIL SERVICE DEPARTMENT

333 West Ocean Boulevard, 7th Floor • Long Beach, California 90802 • (562) 570-6202 FAX (562) 570-5293

May 23, 2017

Brian

Dear Mr. Brian

I approve of you, Brian [redacted] to collect data for your thesis from employees within the Civil Service Department at the City of Long Beach. Employees may voluntarily participate in your study titled "The Self-Correcting Workplace: The Impacts of Continuance Commitment and Job Autonomy on the Relationship Between Job Dissatisfaction and Creativity."

You will be provided with the work email addresses of employees eligible for your study and be allowed to directly email your survey invitations to them. You will also encourage them to participate outside of work hours.

Additionally, I understand that I will only be receiving the final draft of the research study and not have access to any additional data or analyses.

Sincerely,

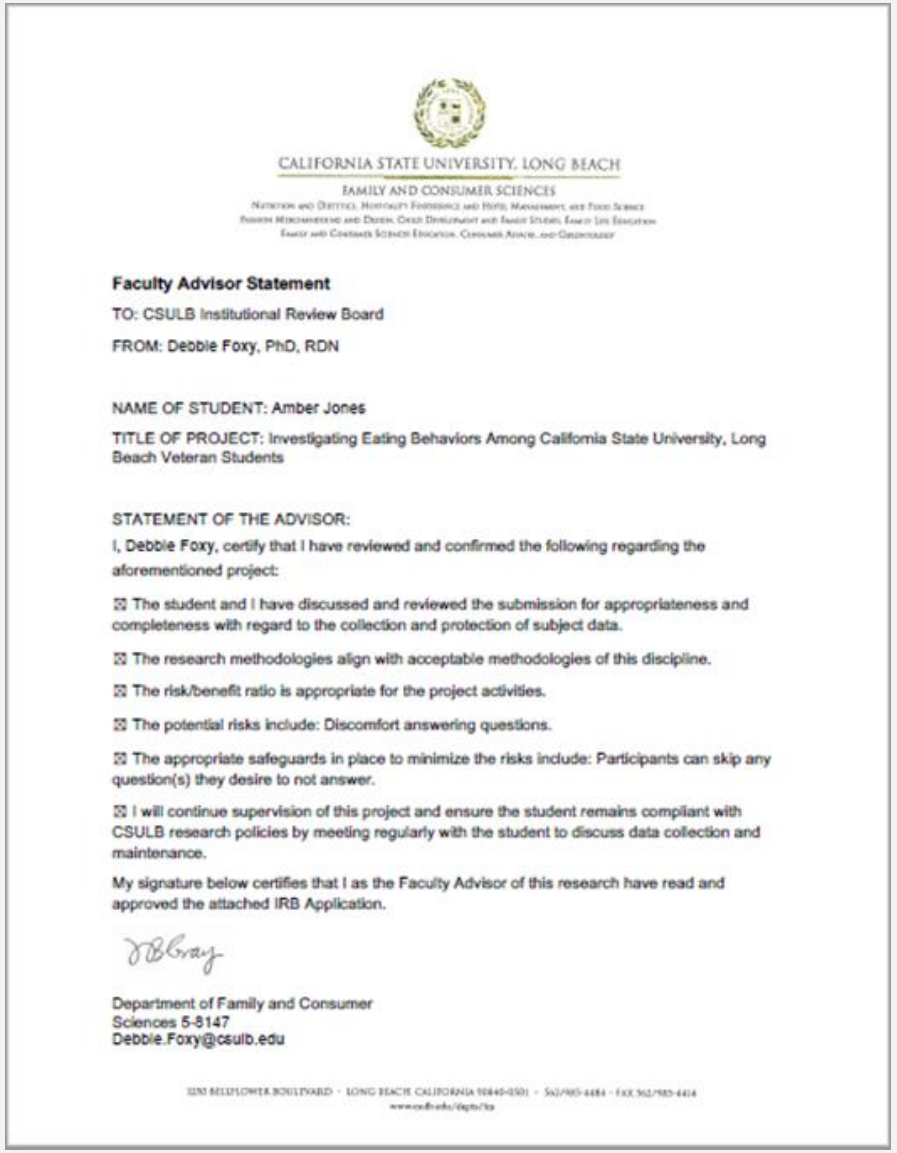
Kandice Taylor-Sherwood
Executive Director of Civil Service
City of Long Beach

KTS:ma
Brian kautz_data collection 5-23-17

AN EQUAL OPPORTUNITY EMPLOYER
WWW.LONGBEACH.GOV/CIVILSERVICE

- 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 LETTER



CALIFORNIA STATE UNIVERSITY, LONG BEACH

FAMILY AND CONSUMER SCIENCES

Faculty Advisor Statement

TO: CSULB Institutional Review Board

FROM: Debbie Foxy, PhD, RDN

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.

Department of Family and Consumer Sciences 5-8147
Debbie.Foxy@csulb.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

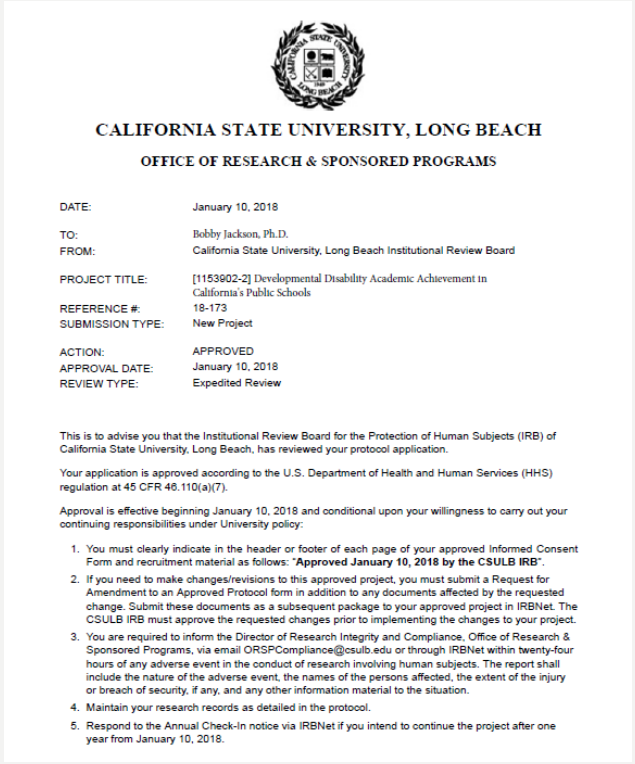
- Mandatory changes requested by the IRB based on ethics and compliance
- Changes must made to secure approval
- Contest any modifications in a cover letter

Step 5:

Approval

- Approval letter issued via IRBNet after modifications are adequately addressed
- Start research according to approved application
- Request Amendments

APPROVAL LETTERS



CALIFORNIA STATE UNIVERSITY, LONG BEACH

OFFICE OF RESEARCH & SPONSORED PROGRAMS

DATE: January 10, 2018

TO: Bobby Jackson, Ph.D.
FROM: California State University, Long Beach Institutional Review Board

PROJECT TITLE: [1153902-2] Developmental Disability Academic Achievement in California's Public Schools
REFERENCE #: 18-173
SUBMISSION TYPE: New Project

ACTION: APPROVED
APPROVAL DATE: January 10, 2018
REVIEW TYPE: Expedited Review

This is to advise you that the Institutional Review Board for the Protection of Human Subjects (IRB) of California State University, Long Beach, has reviewed your protocol application.

Your application is approved according to the U.S. Department of Health and Human Services (HHS) regulation at 45 CFR 46.110(a)(7).

Approval is effective beginning January 10, 2018 and conditional upon your willingness to carry out your continuing responsibilities under University policy:

1. You must clearly indicate in the header or footer of each page of your approved Informed Consent Form and recruitment material as follows: "**Approved January 10, 2018 by the CSULB IRB**".
2. If you need to make changes/revisions to this approved project, you must submit a Request for Amendment to an Approved Protocol form in addition to any documents affected by the requested change. Submit these documents as a subsequent package to your approved project in IRBNet. The CSULB IRB must approve the requested changes prior to implementing the changes to your project.
3. You are required to inform the Director of Research Integrity and Compliance, Office of Research & Sponsored Programs, via email ORSPCompliance@csulb.edu or through IRBNet within twenty-four hours of any adverse event in the conduct of research involving human subjects. The report shall include the nature of the adverse event, the names of the persons affected, the extent of the injury or breach of security, if any, and any other information material to the situation.
4. Maintain your research records as detailed in the protocol.
5. Respond to the Annual Check-In notice via IRBNet if you intend to continue the project after one year from January 10, 2018.

- 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.

AMENDMENTS TO APPROVED PROJECTS

Submit a Request for Amendment to an Approved Protocol form when changing or adding:

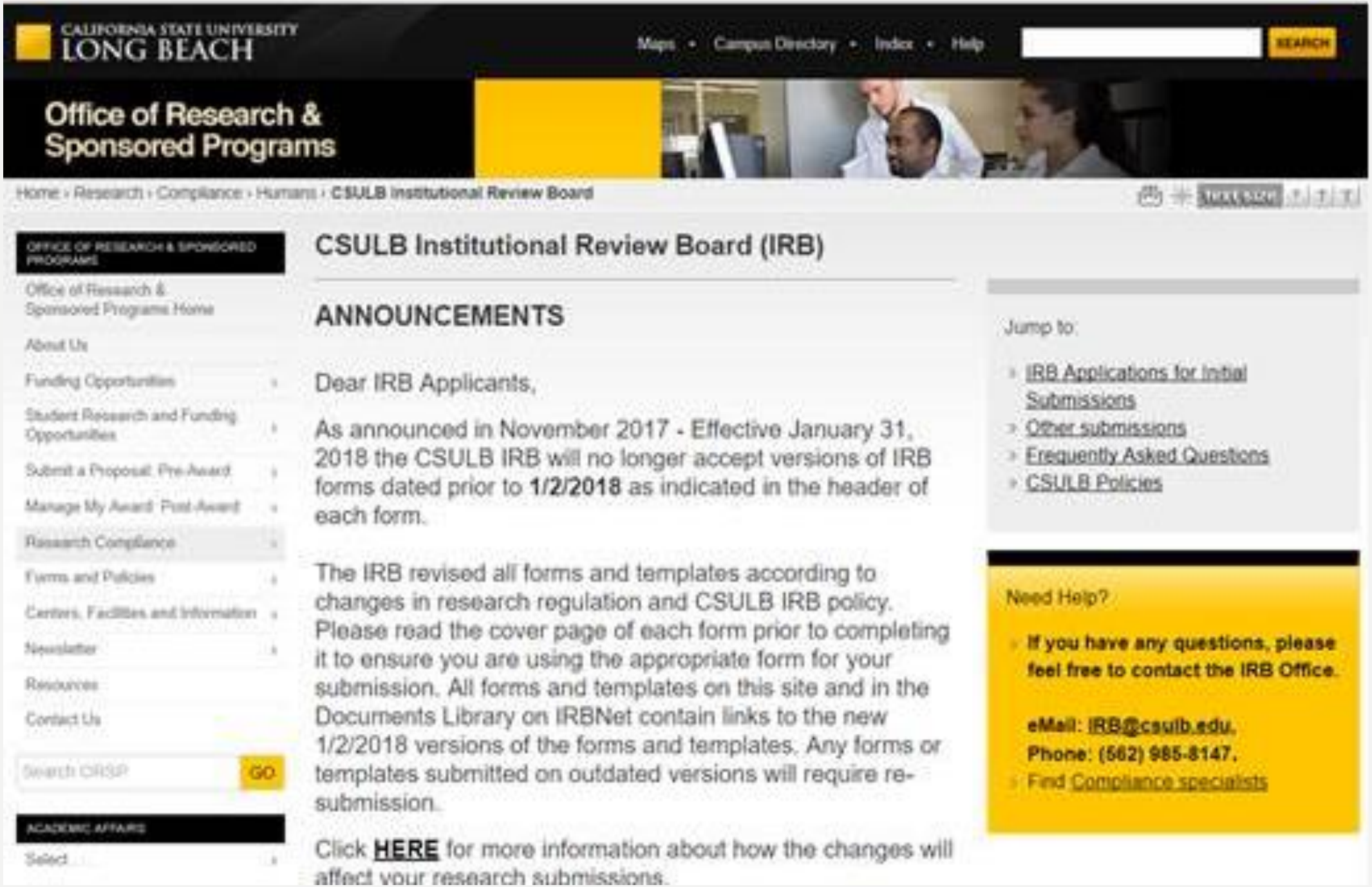
- Personnel
- Advertisements
- Study procedures
- Survey/Interview questions
- Recruitment sites
- Subject size or characteristics

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.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Manage My Award: Post-Award
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Contact Us
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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 re-submission.
Click HERE for more information about how the changes will affect your research submissions.
Jump to:
IRB Applications for Initial Submissions
Other submissions
Frequently Asked Questions
CSULB Policies
Need Help?
If you have any questions, please feel free to contact the IRB Office.
eMail: IRB@csulb.edu,
Phone: (562) 985-8147,
Find Compliance specialists


Questions?

CONTACT THE IRB

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