



Office of Sponsored Programs
and Research Integrity

UNIVERSITY OF COLORADO **COLORADO SPRINGS**

Student Guide for IRB Submission

2020

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How to Use This Guide


The goal of this guide is to help new student researchers navigate through the IRB process. Submitting an application for a study to the IRB can be intimidating. There are a lot of things to consider while designing your study materials. You also need to follow the rules after approval.

Even after reviewing this guide, it is important to read the official [UCCS Researcher Manual](#). It includes the material in this guide as well as more in-depth information. The Researcher Manual is a great resource to visit. **Be sure to also work closely with your faculty advisor during all stages of your research.** And, of course, you can always email irb@uccs.edu if you have questions about the IRB or the IRB process.


This guide is divided into five color-coded sections. Skip to different sections or read through the entire guide, whichever works best to help you submit your application.




Introduction—This section includes background information about the IRB and its processes.




Preparing—This section breaks down a few of the most important materials you might need to submit with your IRB application.



Submitting—This section looks at the process of submitting your application, the types of review you might encounter, and what to do if you must revise your application.



After Approval—This section looks at your responsibilities after you get IRB approval as well as some of the things you may need to do in the course of your research.



Additional Information—This section has links to other guides and important resources available to you.

What is the IRB?

The Institutional Review Board (IRB) is charged with ensuring the rights and welfare of human subjects in a research setting. IRBs help to make sure that research institutions are following the federal regulations. This helps protect not only research participants, but also researchers and their institutions.

The IRB is responsible for reviewing all “human subjects research.” **Human subjects** are any living individual from whom an investigator obtains data through an intervention or interaction. How you get information can vary, such as by direct interviews, observation, biospecimens, and information from a secondary source. These activities, among others, involve “human subjects.” **Research** is gathering and/or analyzing information to develop or contribute to “generalizable knowledge.” Any project that intends to apply results to a group other than the people in the study counts as research. The full definitions of **human subjects** and **research** can be found in our [SOPs](#), available on the [IRB's website](#).

Ethical Principles of Human Subjects Research

The IRB's ethical considerations are based on three principles outlined in the [Belmont Report](#). Investigators and IRBs should always abide by these principles.

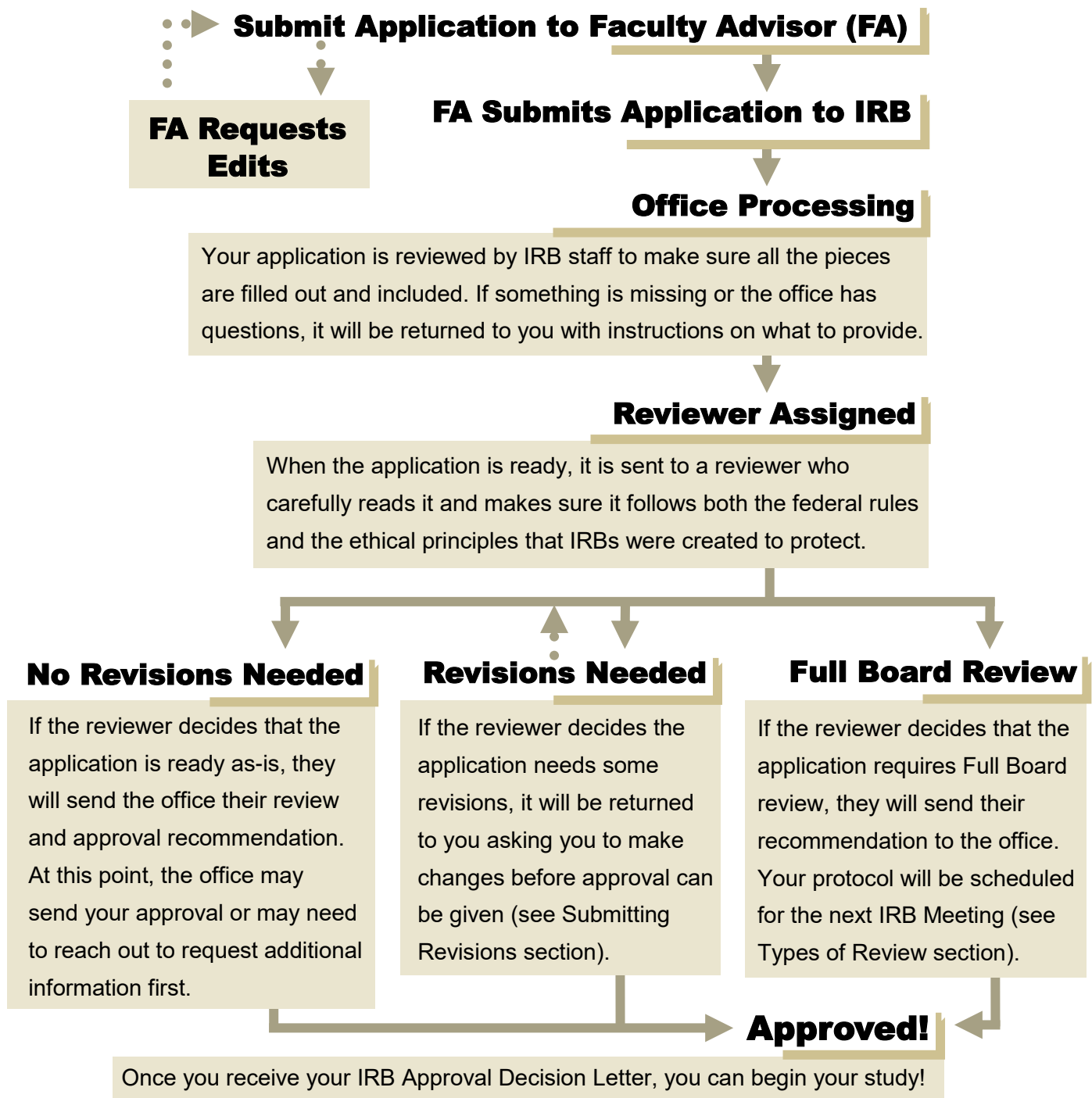
Respect: Respect means supporting people's right to make decisions for themselves. This means that individuals should participate in research voluntarily and be given enough information to make an informed decision about whether to participate. The Belmont Report also states that we should protect people with diminished autonomy, like children or people with cognitive impairments. We practice respect through the informed consent process.

Beneficence: Beneficence means protecting individuals from harm and also making efforts to secure their well-being. IRB review includes examining benefits and risks of the research. Risk is determined by considering how likely AND how damaging harm might be. Harm can take a variety of forms (e.g., psychological, physical, social). On the other hand, benefit is the anticipated positive effects of the research. Benefit might be for the participant directly or for society, such as gains in knowledge. We practice beneficence through risk-benefit analysis.

Justice: Justice means that the benefits and burdens of the research are fairly distributed. It is a violation of the principle of justice to select a class of participants (e.g., welfare recipients, an ethnic minority, institutionalized persons) simply because they are easy to find or recruit rather than for reasons directly related to the questions being studied. We practice justice by making sure we select participants fairly.

The IRB Process

The IRB process can seem like a black box, but it's pretty straight-forward once it's broken down. Knowing the stages your application will go through, from beginning to end, helps you understand what you can do to get your application approved with minimal snags. A full flowchart of the IRB's process is available online on the [IRB's Guidance Resources](#) page, as well as in the [Researcher Manual](#).



When to Submit

The IRB is federally and institutionally obligated to review all research that involves human subjects. Failing to get IRB approval not only puts YOU at risk but also puts ALL research at UCCS at risk. Additionally, the IRB is not able to review projects that have already begun. Therefore, it's important to remember: **when in doubt, submit.**

It's best to submit as soon as possible once you know how your study will be conducted and have developed your materials. Approval can take anywhere from a few days to a few months. It depends on a few critical factors: Clarity, Preparedness, and Level of Review.

Clarity

Make sure your application is written as clearly as possible. Everything in your protocol should be written as though you were explaining it to a stranger on the street.

Preparedness

One of the biggest hold-ups for applications is not having all your materials double-checked and ready to go. Every time an application is sent back for revisions, you and the reviewer need to look at the materials again. Revisions cost time. Preparedness is key.

Level of Review

The IRB determines your protocol's level of review, which may affect how long it takes to get approval. Full Board reviews take the longest. If you'll be working with pregnant women, children, prisoners, or international populations OR if you think your research risks are greater than what people might encounter in daily life, plan to submit a couple of months early. That way, if you end up in Full Board review, your timeline won't be busted.

REMEMBER...

When in doubt, submit... and submit early! Work with your FA to decide if you need to get IRB approval. The IRB cannot issue approval after a study starts, so get approval first.

Training Requirements

Federal regulations require training for everyone who participates in human subjects research. This includes not only researchers working directly with participants, but also researchers who are only analyzing data. In addition, UCCS requires training for all Faculty Advisors who oversee students doing research. Unfortunately, the IRB can't approve protocols until the *entire* research team has completed training. So, getting a jump-start on training is very important.

Training is completed through the Collaborative Institutional Training Initiative (**CITI**) and must be updated every three years. You should expect to take 2-3 hours to thoroughly complete the training. The good news is you'll only need to do this every few years, and it's easy to get started. For more help, a [Quick Start Guide to CITI training](#) is available online.

Be sure to select **University of Colorado Colorado Springs** as your Organizational Affiliation, and use your UCCS email.

These options will guide you to the **human subjects research** training the IRB requires.

1. Visit CITI at <http://www.citiprogram.org>
2. Click on the **Register** button at the top of the screen and follow the directions to set up your account.
3. Select the **Ethical Conduct of Research with Human Subjects** option as your curriculum.
4. Select "I need to enroll in a basic human research course."
5. Select "Social and Behavioral Research."

Funded Studies

Some types of funded studies require special or advanced training. For example, the National Institutes of Health (**NIH**) requires researchers to complete Good Clinical Practice (**GCP**) training for clinical trials. Many institutions require Conflict of Interest (**COI**) and/or Responsible Conduct of Research (**RCR**) training. These requirements can be hard to keep straight, but the Office of Sponsored Programs and Research Integrity (OSPRI) will help you determine what additional training you need during your grant proposal process.

Informed Consent

From an ethics point of view, the informed consent is one of the most important documents participants will see. The informed consent document is designed to let participants know about your study as well as their rights as a study participant. But informed consent is also a process. Participants *always* have the right to withdraw from your study, no matter when and no matter the reason.

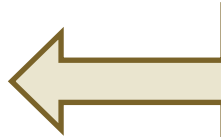
The IRB strongly advises you use one of the informed consent templates on our website because they already include all the elements required by the regulations. There are several consent documents, including a standard informed consent and a child assent form for studies with children. If you need help determining which form is appropriate for your study, reach out to the IRB.

This section offers tips for each piece of a standard informed consent, but the IRB website also has a document that will help you figure out [language for more uncommon situations](#).

Title:

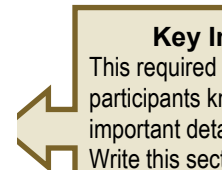
Principal Investigator:

Funding Source:



Title, PI, and Funding Source
 The basics. You will most likely be the Principle Investigator (PI), though you may have a Co-PI. If you're not sure, talk with your faculty advisor about the information that should be included here.

Key Information « As part of the revised Common Rule, there is the requirement that the document begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not participate in the research study. It must be organized and presented in a way that facilitates comprehension. Include a BRIEF summary of the protocol, including the following: 1. Consent is being requested and participation is voluntary; 2. The purpose of the research, expected time commitment, and procedures to be followed; 3. reasonably foreseeable risks or discomforts; 4. Benefits to the participant and others; and 5. Appropriate alternative procedures, if any. »



Key Information
 This required section lets your participants know ALL the important details of your study. Write this section as though your participants won't read anything else (though they should!)

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. A member of the research team will describe this study to you and answer any questions. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you.
- Please ask questions about anything that is not clear.

Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.



Introduction
 The Introduction reminds participants about some of their rights and the purpose of the informed consent. You should not have to change or add anything in this section.

Study Overview This study plans to learn more about... « Describe why you are conducting the study. Make sure to provide potential participants with a clear and accurate description of the purpose and objectives of the research. »

Ultimately, this research may be... « published in a journal, as part of a book, presented at a conference, etc. »

Study Overview

Include the background information about your study (such as the topic or purpose) here, including whether you're planning to publish. Remember to write it as simply and clearly as possible.

Procedures You are being asked to be in this research study because... « Include information the location of and what will happen during the study and information regarding the approximate amount of time required to participate in the study. If participants will be screened, describe screening procedures and major inclusion/exclusion criteria. All experimental procedures must be identified as such. »

Procedure

While writing your procedures, imagine you participated in your study. What exactly did you do? Where were you? How long did it take? This is also where screening and inclusion/exclusion criteria go.

Other people in this study: Up to « indicate number » people will participate in this study.

Other people

In total, how many people will participate?

Risks and Discomforts « Provide possible examples of the risks and discomforts that may be associated in the research. Even if the study is of minimal risk, a risk must be specified. If there are no known risks, then use the following suggested statement in this section: "We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study. Also, consider a breach of confidentiality." Describe how you will minimize the risks that the subject might face and how you will deal with the risks if they occur during the study. »

Risks and Discomforts

All research has some risks, even if it's just frustration or inconvenience. Carefully consider the risks (physical, social, psychological, economic, legal), and do not understate them.

Benefits This study is designed for the researcher to learn more about... « Discuss benefits of the study. First describe any direct benefits to the subject, then any benefits to others. There may not be any benefits for the subjects participating in the study, and if so this needs to be stated clearly. Even if the participant will not profit, there must be a benefit stated such as the greater good for society or knowledge development. »

Benefits

Include the benefits that your participants or anyone else might get from your research. If your participants won't directly benefit, tell them that.

Compensation « Provide the exact amount of compensation here (i.e. \$10, 1 point of extra credit, or clearly state if no compensation is provided). Also indicate how they will receive payment and if they will receive payment if they do not complete the study. »

Compensation

If you're planning on compensating your participants (see Compensating Participants section), explain how here.

Confidentiality

«Provide how you as the researcher/PI will protect the confidentiality of the research study and research subjects(i.e. data is deidentified, secured, etc.). »

Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

Certain offices and people other than the researchers may have access to study records. Government agencies and UCCS employees overseeing proper study conduct may look at your study records. These offices include the UCCS Institutional Review Board, and the UCCS Office of Sponsored Programs and Research Integrity. UCCS will keep any research records confidential to the extent allowed by law. A study number rather than your name will be used on study records wherever possible. Study records may be subject to disclosure pursuant to a court order, subpoena, law or regulation.

«Use the most appropriate statement and delete the other»

Your de-identified data collected during this study could be used for future research studies without additional consent.

Your de-identified data collected during this study will not be used for future research studies.

Confidentiality

Explain how you plan to keep your participants' data safe. This includes details like plans to de-identify data (remove any personally identifying information) or who will have access to the data. A lot of this section includes legal language that you shouldn't have to change. But don't forget to choose one of the highlighted statements about future research.



Voluntary Participation and Withdrawal from the Study

Taking part in this study is voluntary. You have the right to leave a study at any time without penalty. Withdrawal will not interfere with your future care or services at UCCS. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you withdraw from the study, you may request that your research information not be used by contacting the Principal Investigator listed above and below.

« Studies involving students should provide information on what alternative activity they could do in lieu of participation. A study that requires testing a novel therapy to improve a particular health aspect of the subject should provide information on an alternative therapy in case the person decides not to participate. The alternative therapy would be a standard therapy, which would have to be specified as well as where the person can obtain the standard therapy. »

Withdrawal

Participation for your study is voluntary, and this section lets participants know that. It also lets them know other available activities or treatments if they don't want to participate.



Contact Information

Contact (PI's info): « Your UCCS email address is preferred. »

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research, or
- if you would like information about the survey results when they are prepared.

Contact the Research Compliance Program Director at 719-255-3903 or via email at irb@uccs.edu:

- if you have questions about your rights as a research participant, or
- if you have questions, concerns or complaints about the research.

Contact Information

Let participants know how to contact you. Make sure not to change or remove the contact information for the IRB. Participants need to know who to contact if they have questions about their rights.



Consent

A copy of this consent form will be provided to you.

« If you have any inclination about wanting to contact study participants in the future, you should include the following statement. "Are you interested in being contacted about future research I may conduct? Yes or No." »

I understand the above information and voluntarily consent to participate in the research. By signing this consent, I am confirming that I am 18 years of age or older.

Signature of Participant _____ Date _____

Consent

Participants can sign the informed consent if you're meeting with them in person. If you're doing your study online, the IRB has an electronic consent that lets participants consent by pressing a "next" button or something similar. Make sure the form says what participants are actually seeing (e.g., sign, "Next," "Agree," arrow).

Important note: Consent received online is technically a waiver of documentation of consent, so make sure you select that option in your application.



Compensating Participants

Some researchers opt to compensate participants, but compensating participants with money, food, or anything else is not required. If you *want* to compensate participants, though, there are a few things to keep in mind.

The goal of compensation is to account for the costs (e.g., time and effort) of participating in your study. While it's nice to be paid for your time and effort, compensation can create coercive situations or undue influence.

Undue Influence: Whatever you offer participants in your study, it should not encourage them to participate against their better judgement. If your compensation is too good to pass up, then it creates undue influence.

Coercion: It can be challenging to compensate certain groups of people without creating a situation where someone feels like they **have** to participate. One of the most prominent examples of a coercive situation is paying someone for the participation of another person they have authority over (e.g., parents and children). In general, this compensation strategy is not a good idea.

Thinking About Compensation Strategies

There are a few guidelines when you're trying to figure out how to compensate participants. Remember, the IRB can help you develop a compensation strategy. Just reach out!

Take On Your Participants' Perspective

\$20 looks very different to a 12-year-old than it does to a 40-year-old. It looks different to someone who is unemployed than it does to someone who makes six figures. It's **critical** to take the perspective of your participants while making decisions about compensation.

Consider Prorating

Sometimes, it makes sense to pay participants for the amount of time they participate. If your study is three hours long, consider paying by the hour. Similarly, if your study has different sessions, consider paying for each individual session rather than in one lump sum.

Don't Draw Attention

A surefire way to have your application sent back for revisions is to highlight or exaggerate your compensation in your advertisements. Don't make it bigger or a different color or anything else that makes it more obvious. Doing this draws potential participants' eyes to the compensation and away from the important details of your study.

Developing Advertisements

Advertisements help alert participants to your study. There are some things your advertisement needs to include, but there's also a lot of freedom when it comes to design. The IRB sees a wide range of creativity in study advertisements. Regardless of if or how you design your ad, be sure to include:

- How long participation will take
- Who can participate (inclusion or exclusion criteria)
- Any risks and benefits (but **do not emphasize any compensation!**)
- A statement that it is research
- Your contact information
- A basic summary of what your study is about

Above all, make sure your advertisement is consistent with your application details. Below are some tips and suggestions to keep in mind while creating your ad.

The advertisement shown is for a study titled "The Cupcake Controversy" with IRB number 29-087. The main text asks for help determining the ultimate cupcake flavor. It provides contact information for Jane Doe at research@example.com and lists participation criteria: 18 years or older, no allergies, blind taste test of four samples, 30-minute duration, and a reward of an extra cupcake. The ad includes a graphic of two cupcake liners.

Callout boxes provide the following tips:

- Everything is spelled correctly and the grammar is appropriate. The size of the font is large and clear enough to read easily.** (Points to the title and subtext)
- Your IRB number lets participants know what project to reference if they contact the IRB and also that you have approval.** (Points to IRB 29-087)
- Contact information, including the name of the PI, is featured prominently so participants know exactly who to contact and how.** (Points to the contact email)
- Stating your inclusion/exclusion criteria prevents participants from wasting their time contacting you if they can't participate.** (Points to the participation criteria text)
- Summary includes enough information to decide if they're interested—what they'll have to do, where they'll have to go, and how long the whole thing will take.** (Points to the study description text)
- Pictures, if present, look professional and aren't blurry or pixelated.** (Points to the cupcake graphic)
- Compensation is the same size and font as everything else.** (Points to the reward text)

Getting Site Permission

Imagine you've spent weeks making sure your whole study is perfectly polished only to find out that you can't get permission to do your study where you had planned. Site permission is often required when you're doing research. If your research is not occurring in a public place* or on the UCCS campus, the IRB might ask for a **Letter of Access**. A letter of access shows that your planned location knows about and allows you to use their location or access their population. Often, the IRB can't approve your research until you've provided this documentation, so getting permission before submitting your application will save time.

Businesses

Privately-owned establishments and businesses sometimes *seem* public, but they're not. The owners still have the right to ask you to leave. It's usually best to get permission first, even if they're generally open to the public.

Online

Check the Terms of Service for any website or social media platform before using it for research purposes. Look for explicit statements of whether research is allowed. Also look for rules that potential researchers should follow. While some websites are "public" and don't require permission, not everything online is. If you have to log in or set up an account to access a website, it's a good bet that the website is not public. You should get permission from moderators or website owners to use these kinds of sites.

Schools

School districts often have people or departments in charge of deciding if and how research can be performed in their schools. The IRB has collected the [contact information for most of the local school districts](#) on our website. Remember that you should also get permission from colleges to access their student population.

Organizations

Organizations can offer access to specialized populations that often have special risks and issues to consider. Many organizations are responsible for protecting the safety and privacy of their populations. They'll want to make sure your study doesn't pose any unnecessary dangers. **However, contact the IRB if access to populations or data requires you to sign something.** Only certain people on campus have this authority.

UCCS Campus

Most research done on campus doesn't require special permission. However, some kinds of data DO. For example, if your research needs [FERPA](#) data (e.g., student emails, enrollment status, class schedules, grades, etc.) or [HIPAA](#) protected data (e.g., medical or health information), you need to get special permission from the UCCS Registrar or Privacy Board, respectively.

*A Note About "Public Places"

Some places, both online and in real life, may seem "public" but aren't. It's important to investigate your potential research locations carefully. You might accidentally violate someone's privacy (and put them at risk) if you assume information is public when it's not.

Using the Internet for Research

If you're planning on using internet sources, such as social media, websites, forums, chatrooms, online games, and LISTSERVs, you'll want to know if the source is **public** or **private**. You'll also need to be aware if your research is **active** or **passive**. Regardless, it's important to make sure that the research you're planning on doing is allowed by the site's Terms of Service, Policies, or Terms of Access (see Getting Site Permission).

Public vs. Private Online Sites

	Private	Public
How to Identify	May have restricted access or sign-ins; may have higher expectation of privacy	Generally freely accessible and have limited expectation of privacy... but check the site culture!
Guidelines For Research	<ul style="list-style-type: none"> Follow the terms of service Check permissions Get permission from site administrator Acquire consent from your participants 	<ul style="list-style-type: none"> Follow the terms of service De-identify participant data (paraphrase, no direct quotes, no screen prints, and no names, screennames, monikers, avatars, etc.) If identification is necessary, explain why

Active vs. Passive Research

	Active Research	Passive Research
How to Identify	Generally involves things like engaging the community or manipulating the environment	Generally more observational and does not involve interacting with the community or environment
Guidelines When Applying to IRB	<ul style="list-style-type: none"> Clearly indicate consent procedure Explain how you will handle privacy/confidentiality issues Ensure permission is granted by administrators or website Terms of Service Indicate potential interaction with vulnerable populations Indicate any potential increases to harm or risk Mitigate confidentiality/anonymity risks Check and explain the expectation of privacy 	<ul style="list-style-type: none"> Ensure the site is public and has no expectation of privacy If using a private site, get permission first Explain measures to protect anonymity and confidentiality of human subjects If using automated data collection techniques, make sure they are allowed by the site's terms of access and explain how and why they'll be used

Recruiting Participants

If you're recruiting participants using social media or another online source, make sure:

- Participants know data collection won't happen until after they've been enrolled.
- The consent process is separate from the recruitment process.
- Your inclusion/exclusion criteria are very clear.
- You are able to screen for children and other vulnerable populations.

Tips for a Smooth Application

Before you submit your IRB application, there are a few things to check. These tips will help your application be as successful as possible.

Before You Begin Your Application

- 1 Ensure all of your research team has finished CITI training in the past three years.
- 2 Make sure all the elements of consent are present and clear. The language should be appropriate for your demographic. For adults, aim for an 8th grade reading level. That means short words and sentences. Do not remove anything already on the UCCS template except the instructions in the grayed-out sections.
- 3 Make sure your ads include: that people are being asked to participate in research, your name and institution, the purpose of the research, inclusion or exclusion criteria, a brief statement of the procedures, time commitment, compensation, location of research, and contact number or UCCS email. Additionally, do not emphasize (bold, underline, etc.) any benefit or compensation.
- 4 Make sure you submit a Letter of Access if you have one. If your site wants an IRB approval before they'll give you permission, let us know in your application.

While Completing Your Application

- 1 Read and follow the directions on the application.
- 2 Make sure your procedures are crystal clear. Write as though you were explaining your study to a stranger on the street.
- 3 Explain any jargon or acronyms that you use.
- 4 State risks and benefits to the participants. **Do not understate risks.**
- 5 Make sure your numbers (e.g., sample size, compensation, time commitment) are consistent across all of your documents.
- 6 Make sure all your surveys or questionnaires are uploaded in the application.
- 7 Re-read the application to make sure everything is completed.


How to Use IRBManager

All forms and applications are submitted to the IRB through IRBManager. IRBManager uses a Smart Form. You'll only see and fill out sections that are important for your study.

This section provides a jump-start on using IRBManager, as well as common mistakes and things that you, as a student, need to know. The IRB has also issued guides for using IRBManager and a detailed walkthrough for filling out IRBManager forms. You should review those documents (see the Additional Information section) if you run into issues.

Getting Started

1. Click the button on the [IRB's website](#) (or visit <https://uccs.my.irbmanager.com/>)



IRBManager Online IRB Application

ONLINE IRB APPLICATION

2. Sign in using your UCCS credentials.



UCCS University of Colorado Colorado Springs

UCCS affiliated personnel (Faculty, Staff, Students) can use UCCS username and password to login [click here](#)

3. Start a new application by clicking “New Request for IRB Review Form”

Power View (left side)

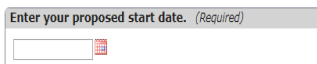
xForms
Click Here to Start a New Request for IRB Review Form

Bubble View (near top)

Click Here to Start a New Request for IRB Review Form

Tips for Students

- Make sure your proposed start date is a reasonable time in the future.
- If you enter a member of your research team and no name comes up, they probably haven't signed into IRBManager yet. Ask them to sign in and try again.
- You must have a Faculty Advisor (FA). If they aren't in IRBManager, ask them to sign in and try again.
- Remember that online studies technically require a waiver of **documented** consent (because they can't physically sign it), so make sure you select that option on your application. Your study will still need a consent form, though, and participants will need to see it.
- Make sure you hit save when you add people, populations... any table with a “Save” button!
- Online websites (such as social media or survey sites) count as additional sites.
- Hover above “Show Help” or question marks to get more information about some prompts.
- Clicking “Submit” will send your application to your FA for them to review. Your FA needs to approve your application before it is sent to the IRB. If they approve it, it will be sent to the IRB. Otherwise, they may send it back for you to make some changes.



Enter your proposed start date. (Required)

Types of Review

There are three main types of IRB Reviews: Exempt, Expedited, and Full Board.

Exempt and Expedited Reviews

Most studies at UCCS are reviewed as Exempt or Expedited. This means they have a series of federally defined characteristics and are allowed to be reviewed by a single reviewer. Your reviewer will determine whether your study is exempt or expedited by examining your study for those [characteristics](#).

There are many important differences between Exempt and Expedited studies. For you, the primary difference will be how often you will need to check-in. **Exempt** studies check-in every three years. **Expedited** studies check-in annually.

The IRB may also decide that your study falls outside the IRB's purview. If that happens, you'll get back a letter stating that your study is **Non-Human Subjects** research. These letters can be especially useful if, for instance, you decide to publish in a journal that requires IRB review.

Full Board Review

Sometimes, a study will require a Full Board review. A Full Board review is most likely to occur when a study is working with vulnerable populations (children, pregnant women or neonates, or prisoners) or if the likelihood or magnitude of risk to the participants is greater than minimal.

A Full Board review can be intimidating, but it's important to remember that the IRB's goal is to protect both research subjects and you, the researcher. If your protocol is on the agenda for an IRB meeting, you'll be informed ahead of time. The IRB encourages you to attend this meeting, though you don't have to. Before the meeting date, you'll receive a **primary review**, which includes issues that your primary reviewer would like you to address before they can approve your protocol. At the meeting, the IRB committee will discuss any concerns that they have.

During a Full Board review meeting, the committee will ask questions to clarify parts of your protocol. They'll likely focus on areas that are confusing to them or aspects that might pose extra risk to research participants. That means the best thing you can do to help a Full Board review go smoothly is to **be prepared**. Afterward, you'll get a final list of revisions, if any.

Submitting Revisions

After you submit your application, the reviewer carefully reads your application and materials. They may require additional information or changes before approving your protocol. Regardless of whether the revisions requested are substantial or seem trivial, the main goals of the reviewer are to 1) make sure participants are adequately informed and protected and 2) uphold the image and reputation of the university. Below are some examples of changes a reviewer may ask you to make.

Vague Procedures

If the reviewer can't understand what will happen to participants in your study, they won't be able to determine risk. Make sure your procedures are clear.

Missing Documentation

The reviewer needs to review everything that a participant will see, including things like emails you'll send and surveys you'll distribute. If you'll be doing interviews or recruiting over the phone or in person, the reviewer may also want to see written recruitment scripts or outlines of your interview questions.

Grammatical or Spelling Errors

The reviewer may request corrections for grammatical or spelling errors. These kinds of errors affect clarity and can cause confusion for your reviewer and participants. They also reflect on the professionalism and reputation of UCCS.

Contact Information

Study participants should know how to contact you if they have concerns or questions. Make sure your contact information is clearly presented and consistent in all your documents.


Consistency

The reviewer will check if the information in your application is the same throughout. They'll also check that information in your application is consistent with attached documents. Make sure your application and attached documents (like consent forms, recruitment emails, or advertisements) are consistent.

Data Protection

Protecting your collected data is one of the primary steps towards protecting the privacy of your participants. The reviewer will check your data protection plan, so make sure you have one and that it's explained clearly.

A Note About Revising Attached Documents

If your reviewer asks you to change a document attached to your application, make sure you use the "Replace" button  rather than uploading the revised document as a new attachment. The "Replace" button will delete the old document and make it clear for the reviewer which document is correct.

What Are Your Responsibilities

When you receive your approval, you're agreeing to several statements about what you'll do while your research is ongoing. Read your approval letter carefully and ask questions if you're unsure what something means. In some cases, failure to follow these rules can prevent you from using your data or even shut down your study entirely. **After you get approval, you should...**

... Get permission **BEFORE** changing your study.

Changing aspects of a study is very common, but you should work with your faculty advisor to submit a Request for Change form **BEFORE** making changes. This includes changes to things such as:

- Your procedures
- Anything your participants see (recruitment materials, advertisements, etc.)
- Informed consent forms
- The people who are working on your study
- How many people you want to recruit

... Report any problems within 24 hours.

If someone gets hurt, complains, or experiences unexpected consequences by participating in your study, you should work with your faculty advisor to submit an Unexpected Events/Deviations form as soon as possible. Researchers are sometimes nervous or worried about reporting these events. It's important to remember that no matter how serious your unanticipated event is, failure to report puts you, your participants, and the university at more risk.

... Report any deviations as soon as you discover them.

If something happens that is not in your application or in any changes you've had approved, work with your faculty advisor to report the deviation to the IRB as soon as possible. Report deviations regardless of whether they are accidental or on purpose.

... Renew, Check-In, or notify when your study is complete.

If your study has an expiration date, you should submit a Request for Continuing Review at least 10 business days before it expires. The IRB will send reminders, but, ultimately, it is **your** responsibility to submit a renewal/check-in on-time. The IRB may close your study if you don't.

If your study doesn't have an expiration date, you'll be asked to check-in with the IRB occasionally through IRBManager. Checking-in is a simple process that only takes a few minutes and lets the IRB know everything is going to plan. This is a great opportunity for you to take stock of your study and ensure nothing has fallen through the cracks.

Once you're done with your study (including analyzing your data), let the IRB know with a quick email so that we can close it.

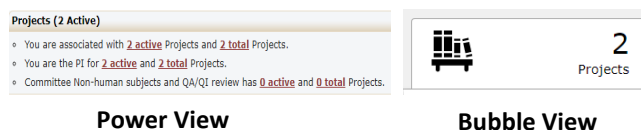
Submitting a Request for Change

Once you have approval for your study, everything you do should exactly match what you said you'd do in your application. However, sometimes, you'll have to make changes. Work with your faculty advisor to submit a Request for Change (ROC). An ROC should be submitted if you want to make any changes to your study AFTER you've already gotten approval. Remember that you **should not make any changes to your study until your request has been reviewed and approved by an IRB reviewer**. Things that need a Request for Change include, but are not limited to:

- Adding new measures, surveys, or survey questions
- Changing how your study will be performed
- Adding new research personnel, changing your faculty advisor, PI, or adding a Co-PI
- Changing your flyers or recruitment materials
- Changing compensation
- Recruiting more participants than originally approved

Starting a Request for Change

1. Find the study you want to change in IRBManager under your project tab (in Bubble view) or projects section (in Power view).



2. Begin and fill out a “Request for Change” xForm by clicking on “Start xForm” on your study’s Project page. You’ll find this link on the left-hand side.



Tips for Students

1. Ensure that all of your changed materials are uploaded!
2. Consider highlighting the things in your materials that you've changed. This will make the changes easier for your reviewers to find.
3. If you want to change things like compensation or procedures, consider explaining why the changes are necessary. Often, this will help your reviewer understand why any changes to risk might be acceptable.

Unexpected Events and Deviations

Things happen in research. Someone might complain or accidentally get hurt. You might deviate from your protocol or accidentally lose your data. If anything unexpected happens or you didn't follow the protocol you outlined for the IRB, **immediately stop your study** (if it's safe to do so) and work with your faculty advisor to submit an Unexpected Events and Deviations (UED) form. The main purpose of the UED is to let the IRB evaluate whether an event has increased or changed risk to your participants. Don't let worry or fear stop you from reporting a UED. The process ultimately protects you, your participants, and UCCS.

Starting a UED

1. Find the study in question in IRBManager.
2. Find the "Unanticipated Event/Deviation Form" xForm by clicking "Start xForm" on the study's Project page.



Tips for Filling Out a UED

1. Report the event or deviation as soon as possible or as soon as you discover that it's happened. If safe, **immediately stop your research** until you hear from the IRB about next steps.
2. Be as honest and thorough as possible when filling out the details of the event. This will help the IRB chair determine if risk is increased or harm has occurred. It will also help them determine if appropriate steps have been taken to mitigate any risk or harm or what steps can be taken.

What Happens Now?

After submitting a UED, the IRB chair will review the report details and make a determination.

- **No Noncompliance and No Harm:** If this determination is made, you will be informed. That's it!
- **"Not Serious" Noncompliance or Harm:** You and your faculty advisor will likely be asked to discuss the event's details with the IRB chair. In most cases, they will work with you to determine how to best mitigate any harm or risk caused, as well as prevent any future issues. Rarely, you may be required to delete some of your data or stop your study permanently. Often, a plan can be worked out without any drastic measures.
- **Serious or Continuing Noncompliance:** Your case will likely be referred to the Research Integrity Office. At that point, refer to the "[Noncompliance SOP](#)" document online.

Renewing or Checking-In

Depending on your level of review and certain other factors, your study might have an expiration date and need renewal, or you might just need to check-in. The main purpose of both renewals and check-ins is to make sure everything is going to plan. It also helps remind you to close your protocol, request changes, or report deviations to the IRB. Whether you need to renew or check-in, the IRB will email you to let you know. Remembering to renew is your responsibility. If your approval letter has an expiration date, submit a Continuing Review form **at least 10 business days** beforehand. If you don't, the IRB may close your study. Work with your faculty advisor to submit renewals/check-ins.

Starting a Request for Continuing Review

1. If you received a reminder email, start your Continuing Review by clicking on the link provided and signing into IRBManager.

As indicated in the PI Responsibilities section of your IRB Approval Letter, you are required to submit applications to renew protocols at least 10 business days prior to expiration and to notify the IRB if the project is complete. If you're continuing to collect and/or analyze data (this applies to all types of research), please submit a Request for Continuing Review/Renewal as soon as possible. If you are continuing to collect or analyze data then your protocol MUST remain active.

To complete a Continuing Review/Renewal application [Request for Continuing Review](#)

Please note that if your protocol was previously approved at the full level, it is possible that your renewal will need to be reviewed at the full level by the IRB board during a regularly scheduled meeting. A determination will be made when the renewal is submitted.

If your protocol expires, all research activities must be terminated. A new application

Please direct any questions to irb@uic.edu

PLEASE NOTE: All investigators submitting new and continuing protocols, as well as their to www.cllprogram.org and register for the course.

[Request for Continuing Review](#)


2. If you don't get or can't find your reminder email, start a "Request for Continuing Review" xForm from your study's page.

- First, find the study you want to renew in IRBManager.

Projects (2 Active)

- You are associated with **2 active** Projects and **2 total** Projects.
- You are the PI for **2 active** and **2 total** Projects.
- Committee Non-human subjects and QA/QI review has **0 active** and **0 total** Projects.

Power View

 **2**
Projects

Bubble View

- Then, find the "Request for Continuing Review" xForm by clicking on "Start xForm" on your study's Project page.

Actions

Send EMail

Start xForm

xForms (0)

Done

➔ [Request for Continuing Review](#)

Starting a Check-In

1. If you received a reminder email, start your check-in by clicking on the link provided and signing into IRBManager.
2. If you don't get or can't find your reminder email, start a "Exempt and Non-Expiring Check-In" xForm from your study's page. You'll find that form in the same place as your "Request for Continuing Review" forms (see above). ➔ [Exempt and Non-Expiring Check-In 2.0](#)

Where to Learn More

Manuals and Guides: Your Official Resources

[Standard Operating Procedures of the UCCS IRB](#)

The guidelines, rules, and policies that the IRB sets for itself and researchers

[Researcher Manual for IRB Submission](#)

Detailed guidance into many topics surrounding research and the IRB

[IRBManager User Manual](#)

Invaluable resource that will walk you through the IRBManager application

Additional Resource Documents: Help! I...

[... am doing qualitative research!](#)

[... am using Qualtrics!](#)

[... need to secure my research data!](#)

[... am doing a classroom project!](#)

[... am doing research in the EU!](#)

(All of these additional resource documents and others are available online at <http://www.uccs.edu.osp/research-involving-human-subjects-irb>)

Websites: UCCS and Outside Resources

[The Official IRB Page](#)

[Office of Sponsored Programs and Research Integrity](#)

[Office of Research](#)

[U.S. Department of Health and Human Services](#)

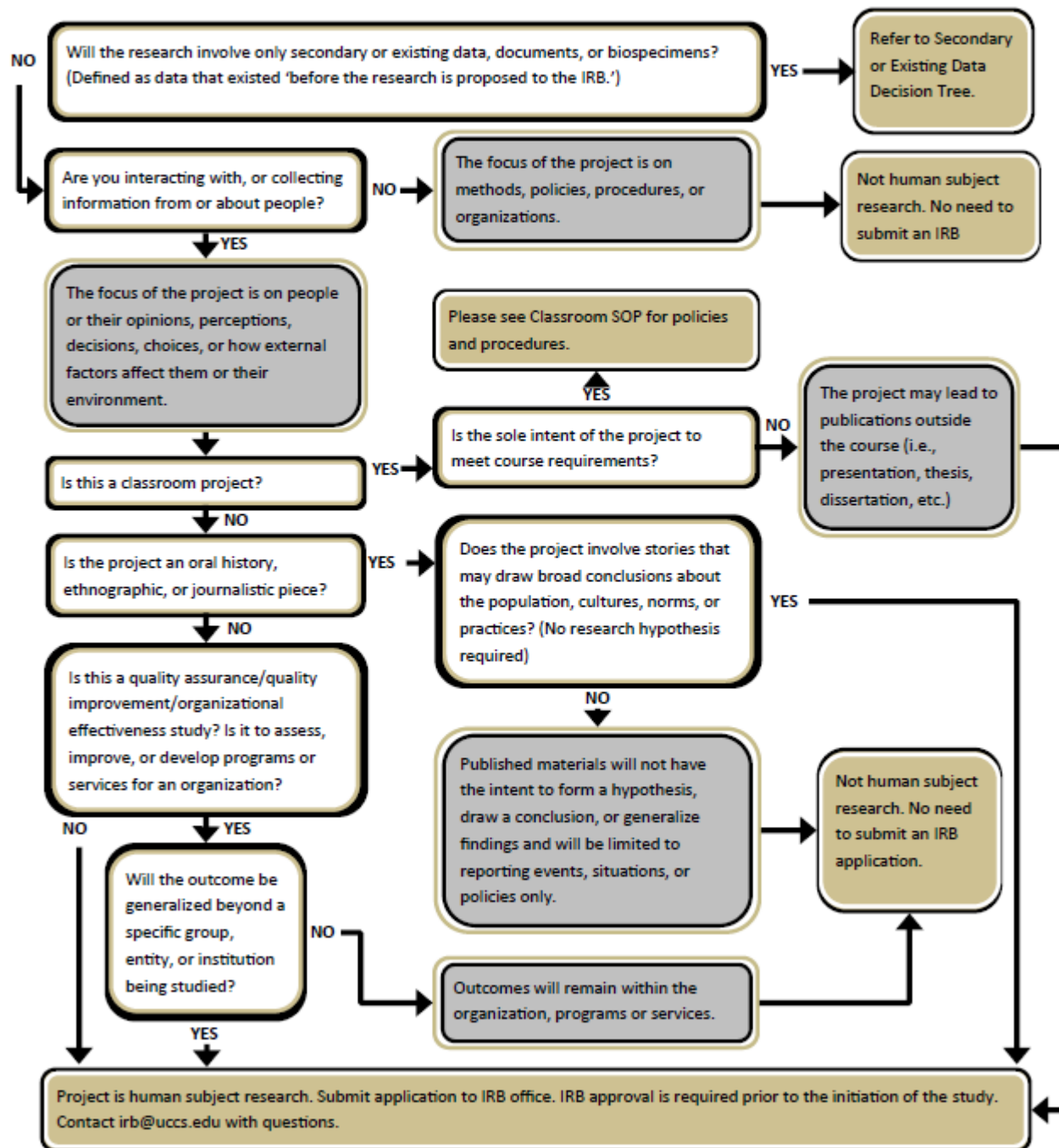
Decision and Flowcharts: Does Your Project Require a UCCS New IRB Application?



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Does Your Project Require a UCCS New IRB Application?

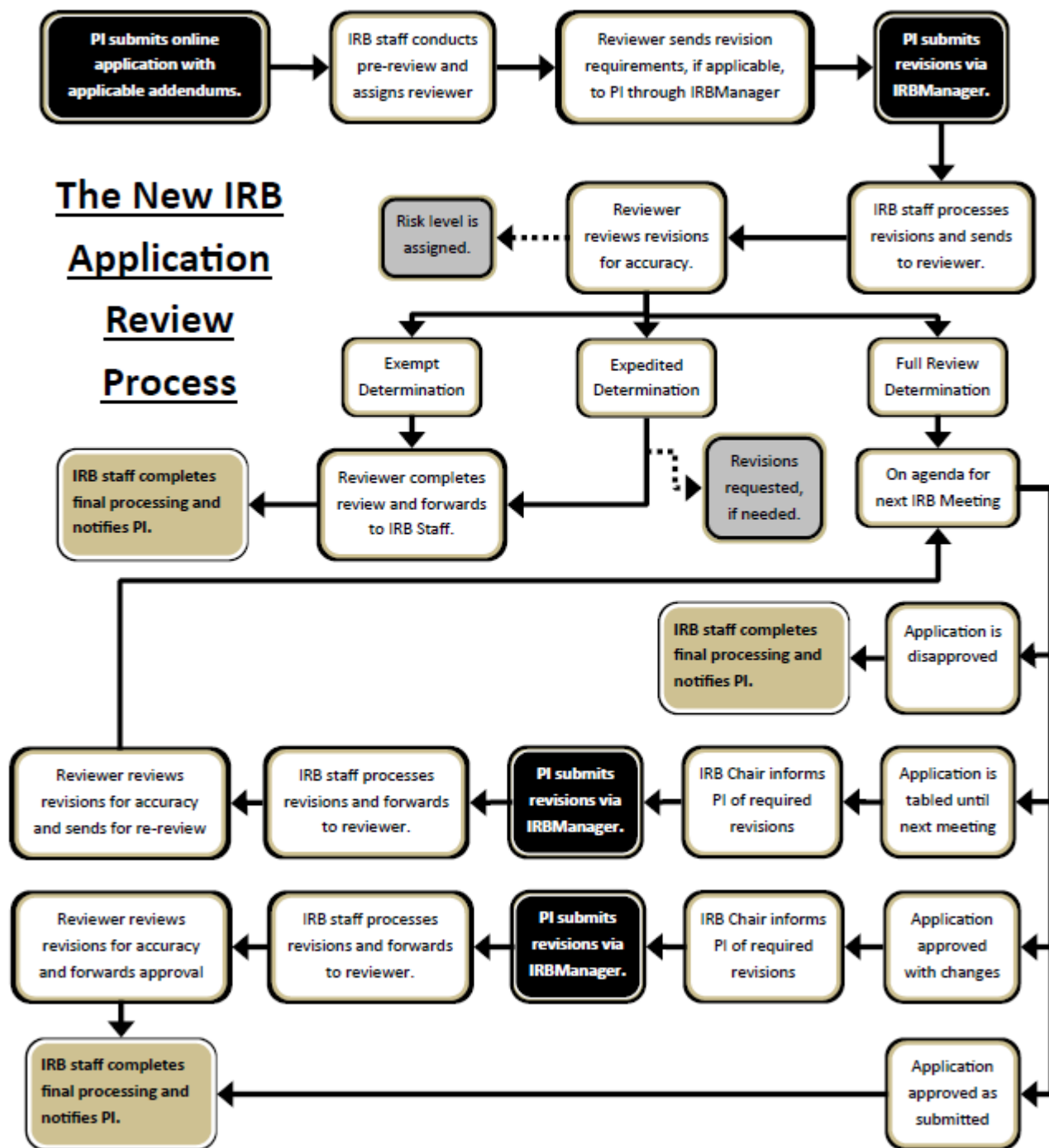


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t 719-255-3321 • f 719-255-3706

Additional Information: Requires IRB Review

Decision and Flowcharts: The New IRB Application Review Process

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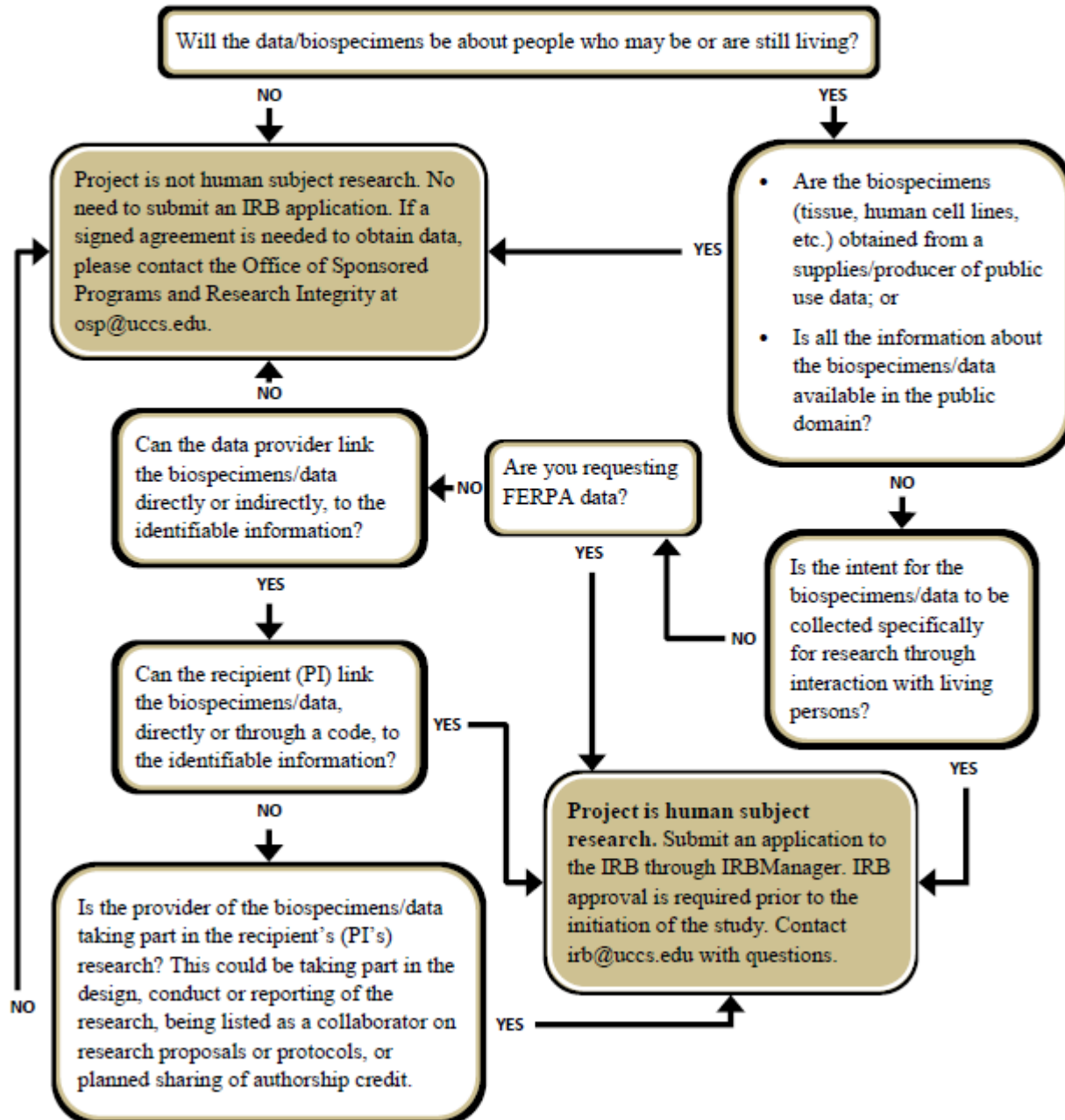
Decision and Flowcharts: Secondary or Existing Data Flowchart



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Secondary or Existing Data Flowchart



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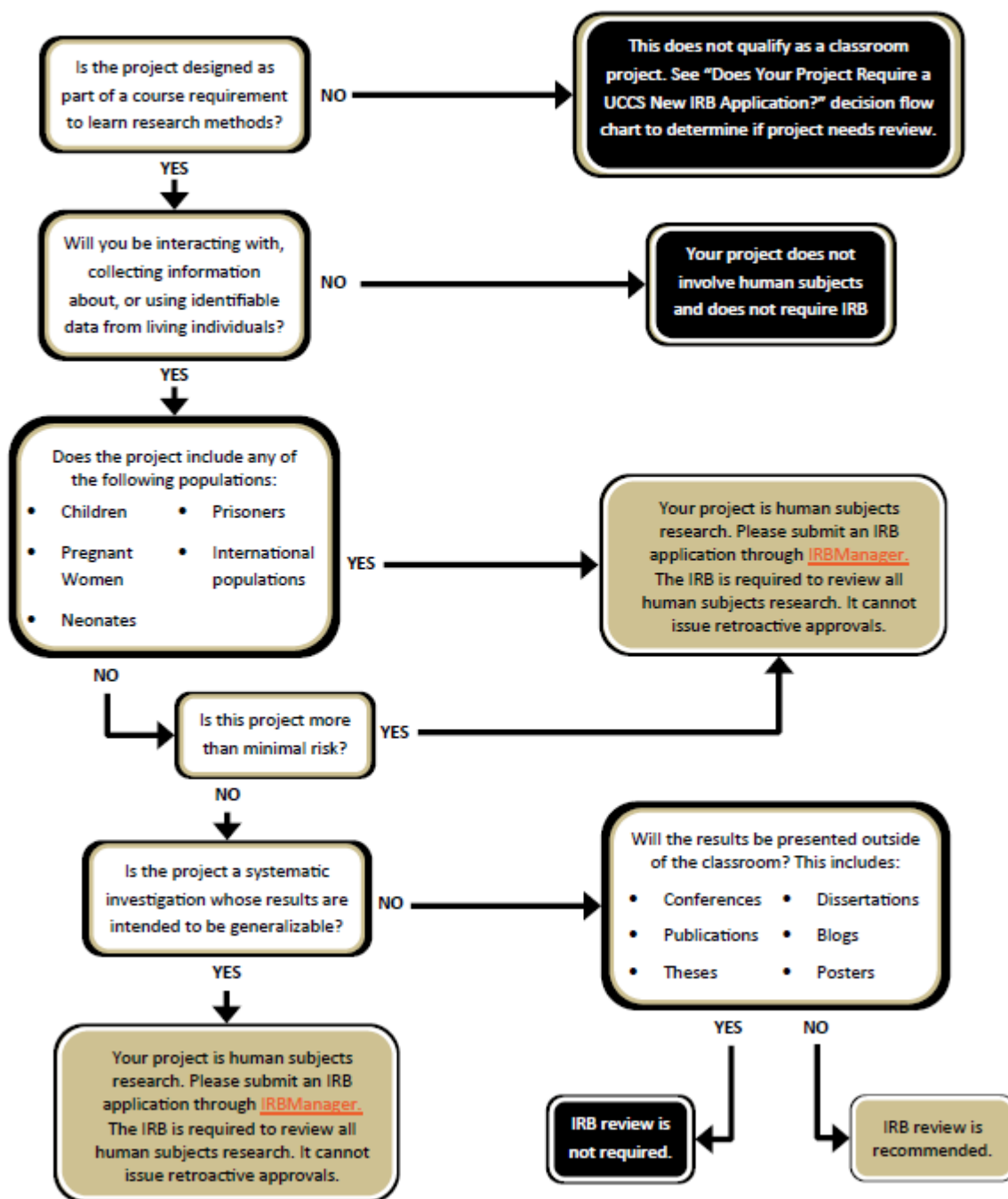
Decision and Flowcharts: Classroom Project Decision Flowchart



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Classroom Project or Research? Decision Flow Chart



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