



## Application Guidance

This document goes through each question on the Human Subjects Application Form and provides some additional guidance for those people looking for a little bit more information.

All of our documents are updated on a regular basis, so please always check back for the latest information.

If you see a mistake, feel free to let us know.

### Application Signatures

This is like a contract. The PI signs to document that they are responsible for the ethical conduct of the research. If the PI is a student, a Faculty Advisor signs to demonstrate that they are providing support and taking partial responsibility for the conduct of the research. The Department chair signs to demonstrate that there are adequate resources for the research.

There are only 3 fields on this page where you can type text – you can only type names of each person. We did this on purpose, because of the requirements around the possible methods for signing the application.

*Why can't you type your name for the signature?*

There's no way to ensure that a typed name is a valid signature. Anyone could type your name.

There are two ways you can have this page signed:

1. An "ink signature"  
This is where you print and sign the form. The final form with all the signatures is scanned and attached to your application submission or submitted in person or via campus mail.
2. A valid digital signature  
Some people have Adobe Signature or DocuSign, which allows them to legally give their digital signature on PDF documents.

If you are stuck in a scenario where getting an ink signature or a valid digital signature isn't possible, just ask a Research Compliance Officer. We can figure something out.

*Can I attach the signature page separately from the application form?*

Yes, absolutely. When submitting your application you can attach separate documents to the email. This is likely necessary for the signature page.

*What if you are both the PI and the Department Chair?*

In the place of the Department Chair signature, you'll need to get the signature of the person who is the next level higher – like the Dean, for example.

### **1.1. Principal Investigator**

*Why is there only space for one PI?*

We ask for one PI for several reasons. First, it helps keep lines of approval and communication clear. It mucks up the process when we receive emails from several people submitting information about the same protocol. When one person submits information, we can clearly keep track of the communication. Second, it prevents any possibility for confusion between co-investigators. When one person is designated as having responsibility for the application, it ensures that all changes are reviewed and approved by the PI. If there's a problem later on, there's no chance of co-investigators looking at each other saying "well I didn't approve that change" or "I didn't know that was modified". Third, it ensures that there is one person who will be overseeing the ethical conduct of the research.

Keep in mind that the PI designation on an IRB application has no bearing on manuscript authorship or other "ownership" considerations. For compliance applications, this is purely administrative. For example, you could not be listed on the IRB application, but you are Co-PI and therefore a co-author on future publications.

*But I want to list all my Co-investigators!*

We understand wanting to give "credit" to your other co-PIs. If you are applying for a grant to go along with the research it will feel counter-intuitive to not include them on the application. Keep in mind that this process is ensuring compliance with regulations – not giving credit for research.

Remember that this procedure benefits you. It prevents "nuisance" modifications, where you have to add and remove people from your research application.

*What is the Home Institution?*

Home institution is referring to the university or organization with which you are affiliated. Likely this will be Western Washington University.

### **1.2. Faculty Advisor**

*Who should my Faculty Advisor be?*

We allow any Western affiliated faculty member to be a faculty advisor. The faculty advisor should be someone familiar with human subjects research or willing to learn. They must also be ready to take on the responsibilities of a faculty advisor.

*What does the Faculty Advisor/Student PI collaboration look like?*

We never make assumptions about how faculty advisors and student work together. In some cases this partnership is very collaborative and every change and consideration is carefully pored over by the faculty advisor and student PI. In other cases, the advisor is just there for questions every once and awhile, but the student is doing everything else independently. There have been some misunderstandings where researchers were frustrated with the IRB for not understanding the particular partnership of an advisor and student. That's why we need your help to understand your particular partnership.

Our office will direct all conversation to the PI, or PI proxy. We make every effort to cc Faculty Advisors on communication and approval documentation. Other than that, we are expecting the PI (the student) to loop in their faculty advisor as much or as little as needed. If you have a particularly collaborative partnership, and you prefer to have only conference calls or meetings, please plan for this with the IRB. Faculty Advisors, please also let your student PIs know if you prefer this to be the case, so that if a Research Compliance calls them with advice, then the student can be sure the pause the conversation until the Faculty Advisor is present. For example, the IRB likes to reach out to people by phone to help clear up small details or talk about the study. If the IRB reaches out to a student PI by phone, and the student PI knows that they are working very closely with their Faculty Advisor, the student can ask to set up a conference call with all parties at a later time.

*What is the Home Institution?*

Home institution is referring to the university or organization with which you are affiliated. Likely this will be Western Washington University.

**1.3. PI Proxy**

A PI Proxy is a person who is delegated by the PI to manage IRB stuff. This doesn't mean that the PI is no longer able to converse with the IRB, it's only saying that someone else is authorized to submit things on the PIs behalf. Otherwise, we need all submissions of applications, modifications, or other paperwork to come from the PI.

Please don't use this option to try to circumvent our request for having one person responsible for lines of communication with the IRB. We'll notice. We ask for one person to be the line of communication, because it helps our office and improves compliance. We're asking for your help here, even if it may be less convenient for the team.

**2.**

**2.1. Study Title**

This is an administrative title for the IRB. You don't need to use the same title as your grant application, thesis proposal, poster title, etc. You aren't limited for study title length. We ask for a short study title, because it's easier for us (and easier on our documentation systems).

## **2.2. Anticipated Determination**

This is an optional question, but we recommend going through the process of using the online guidance tool. Even if you think you know the category from prior experience, it may be that your research will be categorized under one of our newer categories.

For example, I've heard of investigators who are pretty sure that their application would be expedited, but they went through the online guidance tool and were surprised that it could be eligible for exemption. That saved those investigators a fair amount of time and effort.

## **2.3. Funding**

We need to know the study funding, because it can change what rules apply to your research. Federally funded projects have to meet more requirements.

If you are planning to submit for funding at a later time, you can say "No" on the application form and submit a modification later when you receive the funding. Receiving funding could change what rules apply to your research. If you are planning to apply for federal funding, you should let the IRB know, so that we can apply federal requirements to your research at the beginning and save you the trouble of a modification.

## **2.4. Other Universities**

Each University will have their own procedures for research compliance and approval. Sometimes, instead of having the researcher get IRB approval at both universities, one university IRB will choose to defer to the review and approval of another IRB. We prefer that deferrals happen as much as possible, because there is rarely a point to duplicating IRB reviews. That said, each deferral is reviewed on a case by case basis, so you need to get in touch with us.

## **2.5. Research Location**

We ask this question to get a general idea of where the research is occurring, so that we can determine if any location-specific compliance requirements are involved. For example, if you are conducting research at WWU, that's different than if your research is happening on another university's campus, or online, or in schools, or in other organizations, or in other states or countries.

There has been a bit of confusion about this question. For example, some researchers thought we needed to know the location of the research for ADA accessibility concerns. ADA accessibility isn't in our jurisdiction, though we encourage researcher to consider accessibility for all eligible participants. It could be that this confusion stemmed from providing an example of listing particular classrooms for study locations. It depends on your study about how specific you might want to be.

We encourage you to give yourself flexibility here. If it's important to list a specific location, then definitely do so, otherwise you may be accidentally cornering yourself.

For example, if a researcher wants to conduct research in math classes, these are all the different ways that they could list their research location(s):

- A. MATH102
- B. WWU math classes
- C. Pacific northwest college level math classes.

All of these are valid ways. Option A is the most limiting. If it's important that the IRB knows that the location is MATH102, then by all means list that. For example, if this is important for risk determinations or compensation. If you ever plan on conducting the research in other classes though you would need to submit a modification. Option B has a lot more flexibility, but importantly specifies WWU, so that we know only WWU's policies and procedures apply. Option C is quite general, but will require more work, since there are more protections needed when you're working in multiple colleges. You would need to contact each of the colleges' research compliance departments to ensure that you are following their policies and procedures. You would also need to consider more screening procedures to make sure that participants under 18 years old are screened out. We don't have a preference for your answer. We look at what you say you want to do and then make sure all the compliance policies and procedures are taken into account.

### **3.**

#### **3.1. Purpose**

You can keep this short and to the point. For exempt studies usually one paragraph with 1-4 sentences is sufficient. For expedited studies or full board studies you may need several paragraphs.

#### **3.2. Design**

Only answer this question if your study is not eligible for an exemption. That means expedited and full board studies will answer this question. This is where you describe why you are using this study design and any other background information for your research.

#### **3.3. Additional Application Instructions**

##### **3.3.1. Research on Students Populations**

If this applies, read the guidance and follow the instructions on how to write your application for this type of research.

##### **3.3.2. Collection of Existing Data**

If this applies, read the guidance and follow the instructions on how to write your application for this type of research.

##### **3.3.3. International Research**

If this applies, read the guidance and follow the instructions on how to write your application for this type of research

This even if applies if only some of your participants are from another country. For example, if you have any survey that might include people from Canada.

#### **3.3.4. Use of radiation**

You need separate review and approval from the Biosafety Office. We'll continue forward with your application, because that's not our jurisdiction, but make sure you're attending to those procedures at the same time.

### **4.**

#### **4.1. Participants with special considerations**

##### **4.1.1. Non-English Speaking Populations or Use of Non-English Materials**

Use this supplement if you are working with a population speaking a language other than English, or if you would like to use non-English materials. For example, if you are conducting research in Latin American countries and using Spanish materials.

##### **4.1.2. American Indian/Native American or indigenous populations**

Use this supplement if you are targeting or working with any of these populations. For example, if you plan to interview Lummi Tribe members or send an online survey to a listserv of Native American individuals.

##### **4.1.3. Prisoners**

If you plan to work with prisoners I would recommend getting in touch with a research compliance officer, in addition to completing this supplement. We don't see much prisoner research at Western, so we'll need to talk about this on a case by case basis.

##### **4.1.4. People with Impaired Decision Making**

This is a tough category because people are often on a spectrum of ability. For example, someone with Asperger's may have impaired decision making depending on their condition. Someone in the early stages of dementia may be perfectly fine at making decisions when the study starts, but their condition progresses over time to the point where their ability is impaired. If there is any chance, just complete the supplement.

#### **4.2. Adults or minors**

There are different protections for minors in research. The "age of majority" is when a person has attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

A majority of the states in the United States share the age of majority as 18 years old. Currently, the age of majority in Alabama and Nebraska is 19 years old, while Mississippi is 21 years old. These laws may change over time, so we recommend checking for your states in question.

Many other countries share the age of majority as 18 years old, such as the United Kingdom. In some countries this age may be younger (for example: Saudi Arabia, Iran, Indonesia, or Cuba) or older (for example: some Canadian provinces like British Columbia, Honduras, or Thailand). We recommend starting with a google search for the country or state in question, using the term “age of majority”. If you have trouble finding the answer, contact a Research Compliance Officer.

To clarify, it’s not considered a “problem” to have minors involved in your research. Many researchers tip-toe around this and kind of cower when they ask the IRB about working with minors. Don’t think of it that way. It’s okay to work with minors as long as we have ensured that the right protections are in place.

If minors are not supposed to be enrolled, then there needs to be method of making sure they don’t participate.

If your subjects are only WWU enrolled students, your research is not federally funded, and does not involve FERPA considerations, you can select “18+” and check that “Population” will be the method used to screen for minors.

If your subjects are not all WWU enrolled students, your research is federally funded, or there is any involvement of student education records, we cannot apply this “mature minors” procedure. You must include a method for screening out participants under 18 years old, or follow the procedures for recruiting minors in research.

If your country has a different age of majority, then your answer to question 4.2 will look similar to the example below. In the scenario below, the investigator is recruiting only adults (19+) from British Columbia and intending to both screen them over the phone and have a statement about the age requirement in the consent form.

**4.2. Adults or Minors:** Will you recruit subjects under 18 years old, over 18, or both?

<18 → Read our guidelines on research with minors and complete the [Minors in Research Supplement](#)

18+ → Select a method (or methods) for ensuring that subjects are 18 years old or older:

**Population:** The nature of your population naturally excludes participants under 18 (Ex. senior citizens). This option is possible for WWU students for non-federally funded research as the IRB considers WWU students to be mature minors. If checked, please describe the nature of the population in question 4.2.

**Screening:** Participants will be asked for their age during screening. If checked, explain this process in your answer to question 5.2.

**Consent:** A statement is included in the consent form indicating that by signing the form the participant is confirming that they are at least 18 years old.

Other age of consent → If the age of majority to participate in research for your population is different (which may be possible in some states and international research), please specify the age of majority in the box to the right. Then check one of the boxes above (<18 or 18+) as if you are answering for the age of majority for your research subjects. *For example, if your research is conducted on adults in Alabama, you would type “19” in the box to the right and then select the “18+” box and indicate your method for screening.*

19

### 4.3. Inclusion/Exclusion Criteria

If you think about answering “NA” to this question, pause for a minute to consider if you are intending to recruit a certain group. We see a lot of people accidentally answering “NA” when they actually do have some criteria. In fact, most studies have some criteria that would make someone eligible (inclusion criteria) or ineligible (exclusion criteria).

Here are some example answers for this question:

- A. NA (where question 4.2 about Minors vs Adults has been answered as only recruiting 18+ and that’s the only criteria for participating)
- B. Only participants ages 50 – 80 will be enrolled
- C. Inclusion criteria: Graduate Students in the <Whatever> Department
- D. Case inclusion criteria: An ankle sprain within the past 6 months  
Control inclusion criteria: No history of ankle sprains within the past 6 months  
Case and control exclusion criteria: (for females) Pregnancy; any chronic pain lasting 3 months or more; any other lower limb injury in the past 6 months

In Option A, the study has no additional criteria that would include or exclude someone other than being over 18 years old, which was answered in question 4.2, so the researcher can indicate “NA” for question 4.3. In Option B, the study is actually trying to recruit that specific age range, so they need to specify that in addition to answer question 4.2. In Option C, the researcher is intending only to include graduate students from a particular department. Notice that in both Option B and C, the researcher writing the application make sure to have some indication that the criteria they are referencing in an inclusion criteria. Otherwise, the IRB would want to clarify whether it was an inclusion or exclusion criteria. Option D shows how you can list criteria for studies that require more complex screenings.

#### **4.4. Number of Subjects**

Unless your study is likely full board, meaning the risk is higher, estimate high. Having to submit a modification to increase your numbers by 5 people on a minimal risk expedited application is a bummer.

### **5.**

#### **5.1. Recruitment methods**

Be flexible when describing your recruitment methods.

Here are three example descriptions:

- A. Participants will be recruited through an announcement in Professor <whoever>’s class.
- B. Participants will be recruited through announcements in WWU classrooms where the professor has agreed to allow the announcement.
- C. Participants will be recruited through announcements in WWU classrooms (where the professor has agreed to the announcement), fliers posted around Bellingham, and social media posts.

All of the three examples are valid ways to describe your recruitment method(s). Option A is the most limiting. If you get approved for Option A, the IRB expects that you will only give an announcement in that one classroom. If you ever wanted to recruit elsewhere, you would need to

submit a modification. Option B is pretty good – it incorporates more flexibility because it allows you to recruit in multiple classrooms. Option C gives the researcher multiple options. Notice that you don't need to be overly specific about where fliers are posted. You also don't need to be overly specific about what you mean by social media.

If you include multiple recruitment options, and you end up not doing one recruitment component, that is okay. It's only bad if you do something beyond what you are approved for.

There are very few times that the IRB needs to moderate recruitment methods. If you are recruiting from special groups or organizations then we want to know that you have permission to recruit from there. If you are accessing contact information without people knowing about it, then you'll need to have a justification and likely permission for this use.

**The biggest issue that we see with recruitment relates to FERPA considerations. FERPA is not the IRB's jurisdiction, so in this case we are just a conduit for information. Be careful if you are using an institutionally maintained email list to send information about research. You need to read more about this to understand the complexities. The IRB will approve you, but that doesn't mean you can't get in trouble with FERPA later on.**

## 5.2. Screening

A lot of studies have screening procedures, but don't recognize it.

Here are a few different examples of screening procedures:

- A. A researcher stands on a corner and asks people passing by "Would you like to participate in research?" When people stop the researcher first asks "Are you 18 years old or older?" to weed out minors. After screening for adults only, the researcher continues with informed consent and the research procedures.
- B. A researcher in the Psychology Department includes a question on the SONA questionnaire to screening for participants who are interested in social justice. Participants who say yes, are shown your study, because they were determined to be eligible.
- C. A researcher creates an online screening survey for a complex physical fitness study. Interested participants enter the online survey and answer questions about their health and wellness. Only participants who are eligible for the study are contacted by the researchers to talk further about the study and go through the process of informed consent.

In all of these cases, information is obtained from the participant in order to determine if they might be eligible to participate. None of the participants have been consented at the point that this information is collected.

Let the IRB know what you want to do, so that we have an understanding of the process.

## 6.

### 6.1. Consent type

When you select an option here you are confirming that you're following the directions in our Research Compliance Manual for the method selected. That means you really do have to read the guidance on consent types. Know what you're agreeing to!

Even if your application is eligible for exemption – meaning you don't need to submit your consent form(s) for review – you can still ask for our office's help. We are happy to look over consent forms and provide suggestions, even for exempt applications.

## **6.2. Consent process**

If your study involves an in-person visit, such as physical exercise studies, we recommend that the consent form be distributed prior to the visit. If your study is complex in nature we also recommend distributing the consent form ahead of time.

For more minimal risk studies or online surveys it's okay that the consent form is received right before participating.

We ask that you confirm that participants are given an opportunity to ask questions to emphasize that consent should be process.

It's a federal requirement that participants be given a copy of the consent form. This can look different depending on the study. If you have an online survey, it's sufficient to put a reminder in the consent form that they should print a copy of this consent form for their records. For in-person studies it's as easy as handing them an unsigned copy of the form.

We've seen some researchers choose to have a "participant copy" and "researcher copy". We recommend that you **do not do this** unless you feel incredibly strong about it. It's more work than required, doubles consent paperwork, makes modifications more cumbersome, and opens you up to accidental non-compliance if there's a mix-up with the forms.

## **6.3. Influence & Coercion**

If history has shown anything, it's that there may always be some level of influence and coercion in research. Studies have shown that if someone in a lab coat tells you that you need to continue, that you will feel compelled to follow authority. Many things have changed and we have lots of protections now, but influence and coercion is still something that we deal with on a regular basis, especially on university campuses.

If you are a professor conducting research with students, we expect you to answer this question as Yes. Then talk about the methods you have in place to prevent even the possibility of appearance of influence or coercion.

There are lots of ways to prevent influence and coercion.

1. Having someone other than the professor present the research
2. Having someone other than the professor consent the students

3. Keeping signed consent forms sealed, not to be looked at by the professor/researcher, until grades have been submitted to the Registrar's Office
4. Reminding your students that participation is voluntary and will not affect their grade
5. Structuring your study so that you obtain consent for coursework after it's all been completed, so that students can think about what they feel comfortable submitting for the research component
6. Turning a paper survey into an online survey, so that students can complete it at home

#### 6.4. Deception or Incomplete disclosure

A lot of researchers make a mistake on this question because they see "deception" and don't consider the second part of the question about "incomplete disclosure". Many studies involve incomplete disclosure, because they need to be purposefully vague about the goals of the research in order to prevent a response bias.

Some researchers have mistaken our reasoning for asking this question. The misperception is that the question implies that our office is planning to prevent this research technique. That's **not true**. We ask because they are important parts of the research. We need to know when they are happening and understand how the usage is necessary. These practices may also affect the category of research. For example, an application may be eligible for exemption if it has deception, but only if the subjects prospectively agree to the deception.

Here are some examples of incomplete disclosure:

- A. A researcher wants to know whether or not certain color schemes on marketing materials make participants more or less interested in the product. The researcher plans on telling participants that the purpose of the study is to investigate marketing preferences. That statement is technically true, but doesn't disclose that participants will be randomly assigned to different color schemes to test whether color has an effect.
- B. A researcher wants to know whether holding warm beverages influences people's perceptions of likeability. They will have participants look at pictures of people's faces and rate their likeability while holding hot, cold, and neutral beverages. Participants are told that the purpose of the study is to investigate how likeability is affected by beverages. That statement is true, but it doesn't disclose that one of the variables is how hot the beverage is and how the study is looking at that factor.
- C. A researcher wants to know whether people remember details from scary movies better than they do from funny movies. They will have participants watch a scary movie and a funny movie and test them on how well they remember the movie details. Participants will be told that the purpose of the study is to test memory recall of movies. That's a true statement, but it doesn't disclose that the true purpose of the research is to see whether memories made during scary movies are more detailed than memories made during funny movies.

In all of these examples, the incomplete disclosure was necessary and justified. The participants aren't lied to. They just aren't told key details about the purpose of the research.

Deception is fairly well understood. It's when you tell the participants one thing, but it's actually something else entirely. For example, if you tell subjects that they are being video recorded to make them feel nervous, when actually you're not video recording them. This would be necessary if part of the study purpose was to research how nerves affects ability. Again, deception can be necessary and justifiable – we just need to be informed about it.

The will want to know if you plan to debrief subjects afterwards. Depending on the study this could be unnecessary or undesired. We want to hear those reasons, so that we can understand your thought process. This is essentially a continuation of the consent process, where you continue to provide information.

## **7.**

### **7.1. Procedures**

Typically, this is where the most text is in your application.

If your application is as simple as an exempt eligible online survey, you may only need one line to describe this. For all other studies we want to know as much detail as possible about your research procedures that relate to your participants.

Some researchers misinterpret this question and include things like data analysis here. If we need to know things like that about your research methods, then you'll be asked about it later. Otherwise, don't add steps like that here unless they are part of the procedures. For example if part of your procedures is to randomly assign subjects based on some analysis.

Describe any devices that are study specific or not commonly known. We know about smartphones, but assume that the IRB doesn't know about that special VR headset that you plan on using. We know about exercise bikes, but we may not know the details about a fancy kinesiology piece of equipment that measures other things during cycling.

Include data collected. For example, if you are requesting data from student education records, then tells us the pieces of data that you plan to request.

Tips:

- We like lists or bulleted formats! It's easy on the eyes and makes it possible to browse your application.
- Please try not to repeat yourself tons of times here. I know it's tempted because it feels like you're "covering all your bases", but resist that impulse. Not only does it get a bit confusing for us when information is repeated, but it can actually create more screening questions if we can't figure it out.
- Keep your activities in order. If you describe things out of order, we'll likely have to clarify because the IRB can't just assume things. We could make the wrong assumption and then there are two different ideas floating out there about the protocol. Assumptions = sadness and potential noncompliance.

For example, if the researcher writes: Subjects are brought in and the process is explained. They complete a 10 minute questionnaire. The researcher will ask if subjects have any questions to help with their decision. Subjects participate in a focus group that is estimated be about 1 hour.

The problem here is that it sounds like consent is happening twice. Once when the “process is explained” and again when subjects are asked if they have questions. The researcher \*could\* have meant that consent actually happens when the process is explained and the second question portion is just a check in, but the IRB has no way of knowing that. Then we’re not sure if the questionnaire was completed with consent or not. If in the consent section of the application there are two consent types marked then there’s a chance we could figure it out that there are actually two consent processes, but that would only work if you had different consent methods for each portion. It’s not like these options would be a “problem” to fix – it’s that the IRB need to have a clear understanding of what you mean.

- Word choice is important. Sometimes the words you use have different meanings to the IRB and it can create confusion. For example, here are a few commonly confusing words or sentences and what the IRB will think you mean:

- **An IRB:** This is the Institutional Review Board. A lot of people use “an IRB” to refer to an approved research protocol, but that’s not technically correct. We’ll know what you mean usually, but you’ll get a gold star if you call it a “protocol” or “application”.
- **Focus group:** A bunch of people sit around together with a facilitator and talk about something based on a topic or set of questions
- **Interview:** Someone, usually just one person unless otherwise specified, is asked questions by the researcher
- **Informed Consent:** Let’s say it all together – informed consent is a process! Here are sentences or phrases that put up red flags for the IRB:
  - “Researchers will get consent.” – this one isn’t so bad, but it can sound like you’re assuming the person will consent
  - “Participants are asked to signed the form.” – this sounds like you’re just telling people to sign the form and consent.

You could be thinking that these are just fussy things that the IRB worries about when we should just assume that you meant you would go through a process of informed consent. But we can’t assume. Consent is one of the most important things that we consider. If someone isn’t using the right words to describe what they’re doing it’s a cause for concerns because maybe it’s because they really don’t understand.

Impress the IRB with your word choice. Gold star if you use “informed” in addition to “consent”.

- **Confidential**

This doesn't mean anything specific to the IRB. That's why we're going to rely on you to explain what it means.

Now, you might be from a department at Western or a field of research that has a *\*very\** clear idea of how this is intended. That's super, for your department or field. The IRB reviews research from all departments and fields though and this just isn't standardized.

For example, if I told you "Your data will be kept confidential" that could mean:

- This data is intended to be kept secret.
- This data will be kept private between the PI and the researchers on this application.
- This data will be kept private between the PI, the researchers on this application, the sponsor of the research, and other participating institutions – because this is a study with several sites!
- This data will not be linked to identifying information directly, but instead the data is labeled with an ID number and your name is stored separately. Your data itself is actually going to be aggregated and made public.

Just like any other term that may have different interpretations, we ask that you briefly clarify what you mean. Use whatever additional words you like.

○ **Anonymous**

This is the same story as above with confidential.

For example, if I just gave you a blanket statement "This study is anonymous", what do you think that means? Here's what it could mean:

- The researcher has no possible way of knowing who you are. They never see you face to face and there's no way to ever link the data back to you.
- A twist on the example above: the researcher will never see you face to face and the data they receive technically doesn't have a link to your identifying information, but actually the software that was used to conduct the study has a back-end link to your personal identifying information that could actually be used to connect data and identifiers.
- The researcher is actually going to see you face to face for the study so they might remember your responses, but the responses themselves won't ever be linked to information that could identify you.
- The researcher isn't technically collecting your name and contact information, but there's enough information out there in the world to link you back up of the investigator really wanted to, but they're promising you that they won't do that.

Describing these possible scenarios isn't a judgement about the scenario themselves. This is illustrating the various things that the IRB could think. With enough supporting information the IRB may be able to piece together what you mean, but if there's not enough information, then we won't assume, we'll have you clarify.

- **De-identified**

This is a very specific method of removing all identifiers from data so that there is absolutely no way to link the data back to identifying information. In comparison “coded” is when you pull identifiers into a separate place but they still link up to the data.

## **8.**

### **8.1. Identifiers**

Researchers seem to feel hesitant to put down that they are collecting identifiers. They look at this question like a trick, but it’s not. It’s not an issue to collect identifiers. It’s only a consideration.

If you’re looking at email addresses to recruit people, that’s collecting an identifier (email addresses). If you’re audio recording interviews, that’s collecting an identifier. If you’re accessing Western ID numbers, that’s accessing identifiers.

As much as it’s okay to collect identifiers, here are our preferences:

1. If possible, don’t collect identifiers. It makes things easier. If you don’t need them, you don’t need to worry about keeping them secure.
2. If you do need identifiers, can you keep them separate from (or not linked to) data? For example, if you are conducting an online survey and you want to collect contact information to distribute an incentive or to initiate contact for a future study, you can accomplish that by having the first survey link to a second survey. The second survey collects the identifiers and keeps them separate from the data in the first survey.
3. If you do need to collect identifiers, and they do need to be linked to data, then try to find ways to store identifiers and data separately.
4. If you do need to collect identifiers, and they do need to be linked to data, and there isn’t a great way to keep them separate from data, then make sure that your participants know that this is the case and take care with your security measures.

In all these cases, try and delete identifiers as soon as possible.

Remember that audio is an identifier, so you need to consider how to de-identify it. One method is to transcribe the audio, de-identify the transcript, and delete the raw audio. Another is to use software to alter the audio and black out any identifying words that were used.

As far as deletion of identifiers, you would ideally balance the considerations of trying to delete them asap because it’s better for participant security, and the benefit of having some flexibility in your protocol. For example, if you say that you’ll delete identifiers 24 hours after the data is collected, that’s incredibly specific.

### **8.2. Data Identifiability**

The IRB understands that data Identifiability can change over time. For example, you might have a direct link between data and identifiers for a short time, but then you code the data. That's fine – but this question isn't about what happens later on. This question is about how data is initially collected.

For example, if you have audio then you need to mark that your data is linked directly, even if you plan to transcribe, de-identify, and delete the audio later.

We are asking specifically about the beginning because that's the part that will affect our review. The IRB makes every effort possible to only ask questions that are important for the review and approval of your study. For example, some exemption criteria require considering this link when data is first collected. It doesn't matter for the exemption determination if that link is severed at a later point.

For example, say you were trying to receive an exempt determination for category 2, but you planned on asking questions about illicit drug use which could potentially affect a subject's employability. If you audio record the interview, then you're not eligible for exemption, even if you planned to completed de-identify the audio later. The exemption criteria is very specific about how the information obtained is "recorded" in related to identifiers.

Question 8.1 captures what happens to identifiers in the long run, so that covers the other important component of data identifiability.

### **8.3. Methods of Data Protection**

Even if your study is exempt, so you're not required to answer this question, we recommend just taking a look at the guidelines to get an idea of how to keep data safe.

### **8.4. Withdrawal**

The last piece of important information is what happens to data if someone decides to withdraw from the study. It's part of the rights of human subjects.

You might have a study where it's actually not possible to withdraw. For example, subjects complete an online survey that doesn't ask for identifying information. If the subject completes the survey they actually can't withdraw at a later time because the researcher has no idea whose data is whose.

If there is a link between data and identifying information then it is possible to withdraw, if only for some period of time. You may have a study where you are planning to delete identifying information at some point, so subjects only have a window of time where they could withdraw their data.

The point is just to be truthful and clear about what is possible. You wouldn't want to tell you subjects that they can withdraw their data at any time, but someone contacts you after identifiers are deleted and the person finds out that they actually don't have that right.

## 9.

### 9.1. Incentives

There's a lot of guidance about this available, so there are very few tips to add other than to say – read the guidance.

Know what you're responsible for when it comes to incentives, like documentation.

### 9.2. Incentives Type & Amount

Some may not be sure what “pro-rated means”. This is when you plan to give compensation for certain tasks. If someone drops out of the study early, they receive compensation for what they completed.

### 9.3. If Course Credit or Extra Credit Incentives Are Used

The IRB is ideally trying to maintain a standard alternative to research between departments. The current standard that has been approved for other departments is that for every 1 hour of participation, the alternative is a 2-3 page pass/fail paper on a topic of choice within a scope of provided options.

By saying this that doesn't mean we'll absolutely require this standard, but because a few departments have this standard, we'll be looking for a good reason why your students should do more than that. If they would be asked to do less than this standard that would be perfectly fine.

### 9.4. If Requesting Cash or Physical Gift Cards AND Research is Funded

We want every person requesting a different method to have a thorough understanding of what they're signing on to. Be a model researcher if you are approved for a different method, so that we can keep these alternative methods alive. There are been issues in the past with researchers not properly accounting for cash or physical gift card incentives and that almost spoiled it for everyone.

## 10.

### 10.1. Anticipated Risks

**Do not say “There are no risks”. You'll be required to change this language.** All research is assumed to inherently have the potential for risk, though very minimal in many cases.

If you say “There are no anticipated risks” that's the closest we'll allow. It's not a blanket statement that risk does not exist.

On this question just be honest. If there is a risk that someone would be uncomfortable with the questions, then include that in the consent form. It's preferable to have a fully informed subject than to have someone triggered by questions that you said weren't uncomfortable.

### 10.2. Benefits

Compensation cannot be listed as a benefit if your study is FDA regulated. Even if your research is not regulated by the FDA, don't include that information here.

It's okay to say that there are no benefits to subjects. That's okay.