

Notes from the IRB – Form 4 Requirements and Guidelines

*****Please read the following carefully. Adhering to the requirements and advice listed below can significantly help your chances of being approved by the IRB.*****

Form 4 is required when anyone does research that involves human participants. There are two primary purposes for the Form:

1. To show your potential participants that the IRB has reviewed your study design and assured that it is minimizes potential harm to subjects. This is accomplished by having the authorizing signatures appear on the Form itself.
2. To clearly inform participants of what they will be asked to do (the information in Section 1), what risks to their well-being may occur (Section 2 information), and what steps you are taking to minimize their exposure to those risks (Section 3 information).

Meeting the second objective of Form 4, and increasing your odds of approval on your first submission, requires the following:

1. **All information on the Form must be typed.** If you cannot do this directly on the form itself, neatly print “*See attached Form 4 content*” on the form and then attach the typed content. Do not use a font size any smaller than 12 on the form itself, or on any attachments.
2. **At the top of the typed attachment, include the following:**
 - a. the words: “Form 4 Content.”
 - b. your name
 - c. the date
 - d. the study title
3. **Think “user friendly” as you type your Form 4.** Keep the language simple, direct, and well-organized. You are asking your potential participants to do you a favor by helping with your study. Make it easy for them to feel good about you by making sure it easy for them to understand what you are asking and what steps you are taking to protect their well-being.
4. **In Section 1 of the Form, include only that information that is directly relevant to the participant.** In other words, tell him/her what s/he will be asked to do, or have done to her/him. Do not include your hypothesis, your planned data analyses, the demographics of your target sample, or anything else that does not affect the participant.

Example	
<i>Clean Section 1</i>	<i>Cluttered Section 1</i>
<p>This study investigates the effects of swimsuit color on swimming speed. Participants will be assigned one of three suit colors (blue, red, or yellow) to wear during a timed two-lap swim at Haynes Park swimming pool. Suits will be given to participants the day prior to the swim so they can change in the privacy of their own homes. There will be two observers timing the swim and no other swimmers will be in the pool while the participant is being timed. At the end of the timed trial, the participant will have access to a private changing room to dress in his/her own clothing and then return the swimsuit to the experimenter. The entire procedure should take no more than 30 minutes.</p>	<p>This study tests the hypothesis that red swimsuits enhance swimming speed over that of blue or red suits. Participants will be between the ages of 11 and 87 and be assigned one of three suit colors (blue, red, or yellow) to wear during a timed two-lap swim at Haynes Park swimming pool. Two experimenters will time each trial using Timex watches that have second hands on them. Upon hearing the starting whistle, blown by one of the experimenters, subjects will begin swimming as fast as they can for the two laps. At the end of the laps, their times will be recorded on a data form. Swimsuits will be given to participants the day prior to the swim so they can change in the privacy of their own homes. There will be no other swimmers in the pool while the participant is being timed. At the end of the timed trial, the participant will have access to a private changing room to dress in his/her own clothing and then return the swimsuit to the experimenter. The entire procedure should take no more than 30 minutes. The data will then be tabulated in columns according to swimsuit color (red versus other) and an independent samples t-test used to compare the mean times. Blah blah blah.</p>

5. In designing your **methodology**, give very careful consideration to subjects’ **confidentiality**. Unless you absolutely must have names or other identifying information as part of your data, do not collect it.
 - If you only meet with your subjects once, you can easily use subject numbers to distinguish data points without including names, etc. Clearly mark data collection forms or questionnaires/surveys with the words “**Do not write your name on this form.**”
 - If your design calls for repeated contacts with participants, keep a master list that connects names with subject numbers and then explain in Section 3 of Form 4 how this list will be kept secure and when/how destroyed.

6. **Section 2** of the Form must list all the potential risks to the subject (so there's no need to also list them in Section 1). In addition to the general risks of the subject experiencing discomfort due to non-specific causes, there may be some very real risks associated with a particular study. Make sure these are appropriately addressed in this section, and then proper precautions are taken and listed in section 3. However, if a risk is not reasonable, (e.g. ink poisoning from using a pen or being hit by a meteor) then don't list it.
- If your study requires subjects to eat, smell, or rub on their skins any substances, you must take the extra step of attaching an ingredients list to the Form. This list will be referenced in Section 2. Then, in Section 3 you will have the participant, or his/her legal guardian, initial that s/has read the list and affirms s/he knows of no reasons that would make it unsafe for her/him to participate.
 - Any substance consumption or contact also requires that you have a **qualified scientist** (medical professional with B.S. or higher and relevant experience), a completed **Form 2**, a **designated supervisor** (parents/guardians are usually fine), and a completed **Form 3**.

Example	
<i>Clean Section 2</i>	<i>Cluttered Section 2</i>
Participants may feel self-conscious in the assigned swimsuit or while being timed during their swim. They may also become fatigued or experience other distress during the swim up to and possibly including the risk of drowning.	Participants may feel self-conscious in the assigned swimsuit because the color does not complement their skin-tone, or while being timed during their swim because they think they should be able to swim faster. They may also become fatigued or have muscle cramps or become short of breath or swallow water or possibly risk drowning. They may also be cold when they get out of the pool.

7. **Section 3** of the Form should specify the relevant precautions you are taking to minimize risk to your participants. The following four generic statements should always be included:
- 1) All subjects must sign this Human Subjects Form 4 indicating informed consent, and those under the age of 18 years must also obtain consent and signatures on this Form from their legal guardians.
 - 2) Participants may stop at any time for any reason without adverse consequences.
 - 3) Results of this study will be presented in aggregate form only, and no identifying information about participants will be retained beyond the data analysis.
 - 4) All documents containing subjects' names, or other identifying information, will be kept confidential (*in a locked cabinet or however you are doing it*) and shredded at the conclusion of the study. (*Make sure to keep all Form 4's until ALL competition with that year's project is over.*)

If your study involves exposing subjects to substances they will ingest, smell, or rub on their skin, or engaging in potentially risky activities such as swimming, running, playing with fire, robbing convenience stores, etc., Section 3 must also specify what precautions are in place to minimize the associated risks. In the case of substance use that triggered the need for an ingredients list in Section 2, add a statement to Section 3 that asserts the participant or her/his legal guardian has read the list and affirms there are no contraindications to participation. Write the statement as follows:

I have read the attached ingredients for the beverages to be used in this study and my initials here indicate that I (my child/ward) have no known allergies to these substances. _____ (initial here)

Example	
<i>Clean Section 3</i>	<i>Cluttered Section 3</i>
All subjects must sign this Human Subjects Form 4 indicating informed consent, and those under the age of 18 years must also obtain consent and signatures on this Form from their legal guardians. Participants may stop at any time for any reason without adverse consequences. Results of this study will be presented in aggregate form only, and no identifying information about participants will be retained beyond the conclusion data analysis. A Red-cross certified lifeguard will be present at the swimming pool for the entire time the subject is in the water and a phone will be available to contact emergency personnel if needed.	All subjects must sign this Human Subjects Form 4 indicating informed consent, and those under the age of 18 years must also obtain consent and signatures on this Form from their legal guardians. Participants may stop at any time if they get tired or have cramps or for any other any reason without adverse consequences. Results of this study will be presented in aggregate form only, and no identifying information about participants will be retained beyond the conclusion data analysis. A Red-cross certified lifeguard will be present at the swimming pool for the entire time the subject is in the water. The lifeguard will be seated on the edge of the pool and will be paying close attention. In case there is an accident, or for some other reason emergency personnel need to be called, the designated supervisor, who will be my mom, will immediately call 911 and alert the appropriate response group to the nature of the situation and have them arrive as quickly as possible.