

Human Subjects Research Form 4 Checklist

****Include this checklist in any resubmissions****

General

- 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 helping by insuring that it is easy for them to understand what you are asking and what steps you are taking to protect their well-being.
- Keep your information succinct. Do not over-elaborate or include unnecessary information.
- Use correct grammar and spelling. Have someone proofread.
- Do not include another section’s information in the wrong section.
- All information on the Form 4 sections 1, 2, and 3 must be typed. Other info should be typed if possible, or neatly and clearly written if not. (*Participants may of course hand-write their information and signature afterwards.*)
- Do not use a font size any smaller than 12 on the form itself, or on any attachments. Use Times New Roman or Arial.
- You cannot type sections 1, 2, and 3 directly onto the form. It is impossible given the limited space and font restrictions. Therefore, type or neatly print “*See attached Form 4 content*” in section 1 and attach the typed content sheet behind Form 4.
- At the top of the typed Form 4 attachment, include the following:
 - the words: “Form 4 Content.”
 - your full name
 - the date you wrote the form
 - the study title in full
- The current year’s forms must be used.
- Complete name and title must be entered in the sections at the top of the form.
- Adult sponsor and contact info (*phone number and email address*) are required in the part below section 3).
- Any section within the boxed-in area must be left blank before approval.
- The “To be completed by Human Subject:” and “To be completed by Parent/Guardian:” sections need to be filled in after the paperwork is accepted. Students need to copy the signed Form (4) (*with those sections left blank*) and have each subject sign their own copy. Subjects under 18 also need their parent’s/guardian’s signature.
- A completed and intact Form (4) is the only allowed informed consent document.

Section 1)

- Must include the purpose.
- All of the research procedures in which the subject is involved must be included. Include ONLY what involves the subject.
- Include only that information 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, sample size, or anything else that does not directly affect the participant.
- The estimated duration of subject’s involvement must be listed. Do not include the length of the entire project, but rather only how long the subject may be participating.
- Briefly describe the environment and location of where the experiment(s) will take place.

Section 2)

- Include the statement: “*Subject may feel uncomfortable with participating in the procedure.*” exactly as written.
- Any other reasonable potential risks must be listed. This includes discomfort with sharing personal information. It does not include paper cuts or accidentally poking oneself in the eye with a pencil. The IRB is looking for anything from psychological, legal, social, and/or physical injuries to just discomforts or conflicts that may result in subject participation. **NEVER say there are ‘no risks’.**
- If your study requires subjects to eat, smell, or come in contact with any substances, you must attach a comprehensive ingredients list to the Form 4. Make sure to specifically reference this list in section 2). See additional section 3) requirements.
- For subjects doing physical activities, all risks of physical injuries must be addressed, from simple muscle strain, to more extreme injuries and falls.

Section 3)

- Include the statement: “*All subjects will 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.*” exactly as written.
- Include the statement: “*Participants may stop at any time for any reason without adverse consequences.*” exactly as written.
- Include the statement: “*Results of this study will be presented in aggregate form only, and no identifying information about participants will be retained beyond the data analysis.*” exactly as written.
- Include the statement: “*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.*” as written.
- All safety precautions must be address. If you highlighted a risk in section 2), you must address it in this section.
- If your study requires subjects to eat, smell, or contact any substances, you must include the statement, “*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)*” exactly as written within section 3).
- PG and PG-13 rated movies and T rated games are only allowed for subjects 13 and older, can only be viewed/played off campus, and must have parental consent for subjects from 13-18 years old. This must be specifically written in this section.
- Quick communication to emergency personnel (*phones*) are required for any physical activities.
- Physical activities that will increase the heart rate require prior stretching, water, and a cool-down period.
- You are required to have qualified medical personnel and first-aid kits on hand for strenuous or risky activities.
- Exposure of the skin to the sun for longer than 20 minutes requires sunscreen.
- Blood pressure cannot be taken more than three times within an hour.
- Under no circumstances may a student researcher draw a subject’s blood. This may only be done by qualified medical personnel.