Informed Consent/Human Subjects Checklist

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

General

- ❑ RETYPE the Informed Consent Form on a separate sheet paper. Do not just fill in the template form.
- ❑ Include ALL of the bolded subtitled sections, signature lines, and other information from the Informed Consent Template. (except instructions to student and the footing information at the bottom) Get the template from your sponsor or RRPS Expo website.
- ❑ Have "Human Participants Informed Consent" at the top of your form. Your name and title of your project should then come right below.
- ❑ Think "user friendly" as you write your Informed Consent. Keep the language simple, direct, and well-organized.
- ❑ In your EXPERIMENTAL DESIGN, you need to include enough information so that the reader can readily visualize the entire process that involves the participants, from start to finish. In your EXPERIMETNAL DESIGN, you want to be very elaborate and detailed.
- ❑ Keep your information succinct. Do not over-elaborate or include unnecessary information.
- ❑ Use correct grammar and spelling. Have someone proofread what you have written.
- ❑ Do not include another section's information in the wrong subheading.
- ❑ All information on the Informed Consent must be typed.
- ❑ Do not use a font size any smaller than 12 on the form itself, or on any attachments. Use Times New Roman or Arial font only.
- ❑ Multiple pages are ok, but if that is the case, be sure to have "Page 1 of 2" or "Page 2 of 2" or whatever is appropriate at the bottom right hand corner of each page. Double-siding is also ok, but be sure to have, "See other side" at the bottom right hand corner of the front page.
- ❑ No participants/human subjects or anyone else may sign the Consent Form until it has been reviewed and approved by the IRB.
- ❑ Write "Do not write your name anywhere on this sheet", for any surveys or other written response forms.
- ❑ All surveys, song titles, lyrics, movies and their rating and summaries, TV shows and summaries, video game names, ratings and summaries must be included in the experimental design (and maybe in the Informed Consent form as well).

Purpose and Procedure

- ❑ You must include the purpose. What is the objective you wish to achieve?
- ❑ All of the research procedures in which the subject is involved must be included.
- ❑ Include only 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 included. Do not include the length of the entire project that you will be involved in, but rather only how long the subject may be participating in your process.
- ❑ BRIEFLY describe the environment and location of where the experiment(s) will take place.

Risks

- ❑ Include the statement: "Subjects may feel uncomfortable with participating in the procedure." as written. NEVER say there are 'no risks'.
- ❑ Any other reasonable potential risks must be listed. This includes discomfort with sharing personal information if applicable. It does not include paper cuts or accidentally poking oneself in the eye with a pencil. The IRB is looking for anything related to psychological, legal, social, and/or physical injuries, discomforts, or conflicts that may result in subject participation.
- ❑ If your study requires subjects to eat, smell, or come in contact with any substances, you must include a comprehensive ingredients list.
- ❑ If your study requires subjects to eat, smell, or come in contact with any substances, you must include the statement, "I have read the attached ingredients for the substances 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.
- ❑ For subjects doing physical activities, all risks of physical injuries must be addressed, such as muscle strain, overexertion, twisted ankles, and falls. Students doing physical activities MUST not engage in any activities beyond what they normally encounter.
- ❑ Quick communication to emergency personnel (usually a phone is sufficient) is 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.
- ❑ 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. No R-rated movies or M-rated video games are allowed in any studies.
- ❑ Blood pressure cannot be taken more than three times within an hour.
- ❑ Under no circumstances may a student researcher draw a subject's blood other than his/her own. This may only be done by qualified medical personnel.
- ❑ All safety precautions must be addressed. If you highlighted a risk, you must address how you will minimize the risk.

Benefits

- ❑ Don't leave this section blank and don't say that there are no benefits. There is always the benefit that you as the researcher will become more familiar with research procedures with human subjects. There may also be the added benefit that the subjects may learn something about themselves.

Confidentiality

- ❑ Include the statement: "All documents containing subjects' names, or other identifying information, including all Informed Consent Forms will be kept confidential in a locked cabinet (or however you are doing it) and shredded at the conclusion of the study." as written.
- ❑ Include the statement: "No personal information beyond what is necessary to conduct the study will be collected." exactly as written.
- ❑ Include the statement: "Any results of this study will be presented in aggregate form only, and no identifying information about participants will be displayed in the presentation nor retained beyond the data analysis." exactly as written.
- ❑ Include any needed additional information and safeguards for confidentiality that are not included in the above three statements.