

Guidelines and Requirements for Human Subjects Research Projects

(Consider applying relevant advice to the rest of your project as well.)

Introduction:

Human subjects research may seem deceptively easy, but it is in fact one of the most difficult types of research to perform correctly. There are innumerable factors that affect the human condition, and taking all of them into account in a study is a daunting task at best. Improperly conducted research leads to incorrect, and sometimes harmful conclusions. Additionally, special consideration for the subjects' confidentiality, safety and other rights, must be administered. There are federal, institutional, ISEF (*International Engineering and Science Fair*), IRB (*Institutional Review Board*), SRC (*Science Review Committee*), district, and school regulations that guide this type of research. Students interested in this line of study must be aware of these requirements, since their project will be reviewed by several different committees with greater levels of scrutiny. It is for these reasons that Rio Rancho Public Schools requires a petition process for human subjects research.

Due Date:

PETITIONS need to be submitted to Mr. Keeney in ET 101 at RRHS (or Angelica Olivas in rm 3111 at CHS) by 2:45 pm by 11 Sep. Or, students may orally submit their petitions in an in-person interview with Mr. Keeney or Ms. Olivas BEFORE the due date. See your sponsor for the date or contact information. It is important to remember that the deadline is a hard deadline. Except in unusual and compelling circumstances, late petitions will not be accepted. Permission to turn in a late petition will not be granted for requests submitted after the deadline. Being absent from school on the deadline date is not an excuse to turn in a late petition.

General Advice:

Overall, the petitions will be reviewed to see if the student has a solid understanding of the procedures and requirements of proper human subjects research, and scientific research in general. Specifics are outlined in the next section. The petition must be no longer than a page, and therefore it is difficult to include all of the information listed in this document. The idea is to convey a sense of understanding of the requirements and not to try and address every point in detail. You will do this in your experimental design. Succinctness, clarity, and accuracy are important.

Points to Address in Your Written Petition:

- One page only – you should be able to convey the important points of your project within this limit. Use only Times New Roman, Arial, or other standard 12-point font, with no less than 1-inch margins. Do not include a cover sheet, folder/binder, plastic sheet protectors, or any attachments (*unless requested by the reviewer*).
- Heading – First, then last name, grade, teacher to return the petition to.
- Do not include a bibliography – you will however need a properly cited, annotated bibliography in your experimental design.
- Clear purpose – what is your objective for doing this study? What goals/conclusions do you wish to achieve?
- Sound hypothesis: This is critical! Your hypothesis is the foundation of your research, and without a solid hypothesis, the rest of your project will not come together correctly.
 - Is the hypothesis valid? The hypothesis should not be subjective, but something that can be objectively measured/determined. Does it clearly outline the aspects of the human condition you intend to investigate? Does it help to clarify your variables?
 - The hypothesis must be based on valid background research. Your own ideas, opinions of others, ideas from media or the Internet are legitimate starting points, but

you must then support these notions from established relevant scientific research. Although you are not to include a bibliography in the petition, use parenthetical citations in the justification and support of your reasoning. For example, “According to Pavlov’s theory of conditioned response, students will start packing up for the end of class when they notice other students doing so.”

- Do not use the “if, then, because” format for your hypothesis. It is better to simply state the hypothesis as your expected results. For example, “Over 50% of the subjects tested will admit to text messaging on their cell phones while driving.” The “because” portion should be replaced with supporting statements after the hypothesis, unless you intent to investigate and verify the “because/causation” aspect in your research. However, in most cases this is extremely difficult to do, and so should generally be avoided.
- Do not use the word “prove” or “proven”. Hypotheses are supported, not supported, substantiated, refuted, etc. They are never proven or disproven.
- Viabile Experimental Design
 - Can the project reasonably be conducted by a high school student, with the resources, time, supervision, or expertise available to him or her?
 - Are there operational definitions? An operational definition clearly defines what the researcher is referring to in the experiment, which removes subjective interpretation. Let’s say you wish to conduct a study of the effects of sugar on school children. What is meant by “effects”, “school children”, or “sugar”? Are effects behavioral or physical? Are students those under 18, those in high school, any school students, those between 14-18, etc? Is sugar any simple carbohydrate or just refined sugar? What quantities are we considering? In this case, valid operational definitions might be: Effects – disruptive behavior that requires attention and intervention from adult authority. School children – someone between 5-10 years of age attending 1st through 4th grade. Sugar – 50-150 grams of refined processed sugar. Notice that these definitions are quantifiable and measurable. This level of specificity is important in conducting the study, however you do not need to go into this detail in you petition. But understand the idea and process, and make sure to clarify ambiguous terms in your petition.
 - Are the independent and dependent variables clearly defined? The independent variable is the attribute or factor, that when manipulated affects the dependent variable. An example in a study of the effects of sugar on grade school children might be as follows. The independent variable is the consumption of between 50-150 grams of refined sugar within a ten-minute period by a 1st through 4th grade student, and the dependent variable is the number of times the teacher or other authority figure has to verbally or otherwise reprimand the student on his or her behavior. Notice that these are objective definitions that clearly define the data. Subjective and therefore incorrect variables might look like the following: Independent Variable – eating sugar. Dependent Variable – misbehaving.
 - Are there more than one variable/factor affecting the dependent variable? A constant is a factor which is not the independent variable, but could also potentially affect the dependent variable. These need to be held as constant as possible, hence the name. In the example of the effects of sugar on grade-school students, anything that might also affect a student’s behavior besides sugar consumption should be considered a constant. As you can see, there are considerable factors possible, most of which would be difficult to control in your experiment. If it’s not possible to hold all of these affecting factors constant (*this is often the case in human subjects research*) these influences can be diluted by larger sample sizes and/or control groups.

- Clarify your treatment. The treatment is how you intend to manipulate or observe the independent variable in order to see its effect/impact on the dependent variable. In many cases this does not need to be stated because it is obvious or clearly implied. In the “effects of sugar on behavior” study you would not be manipulating the independent variable (*in fact this would not be allowed in this study*) but simply observing the difference between those who didn’t eat a certain amount of sugar and those who did, and their disruptive behavior. However, in this case it would have to be made clear in the petition that you were not actually giving the students sugar.
- How will you collect your data? If this is obvious or implied, you do not need to address this point specifically. However, in many situations practical, logistical, confidentiality, liability, and/or safety concerns may be an issue in how the data are collected. Therefore, your intended methodology may need to be clarified in order to alleviate potential concerns by the SRC and IRB.
- How will you analyze your data? This is not something you necessarily need to address in your petition, but make sure you have a clear idea. When the reviewer reads your petition and he or she cannot infer how this could be done, the petition may be returned for revisions.
- Is there an alignment among purpose, hypothesis, and research design? What you propose to achieve (*purpose*), what you expect to find (*hypothesis*), and how you intend to go about investigating it (*research design*) need to address the same specific issues. For example, if your purpose is to investigate the impact of the Mozart Effect on learning, you would not want hypothesize that the students will have higher grades in algebra and then give a math facts test to your subjects. The Mozart Effect is believed to aid in spatial reasoning, to which math facts have little or no relation, and algebra grades are affected only minimally by a person’s spatial reasoning skills. Additionally, a single math facts test is a poor indicator of algebra grades.
- Do No Harm to Subjects! – The following only need to be addressed in the petition if there is a potential issue with them.
 - Are all safety and other physical injury concerns addressed? It is important to be cautious, but not excessive. It is both a matter of courtesy and proper research ethics to take all reasonable precautions to make sure your research is not in no way harmful.
 - Are all confidentiality issues addressed? This makes sense on several levels. Firstly, results are not going to be accurate if your subjects are not confident that any information they give will be treated with absolute confidentiality. However, most importantly, it is again a matter of courtesy and proper research ethics to protect this information. It is required by all human subjects research protocol at any level, and questions of improper confidentiality safeguards will result in rejection of the petition.
 - Are emotional or other psychological considerations addressed? The human mind is multifaceted, and what may seem harmless to one individual, may have negative effects for another. Simply the process of participating in a research activity could cause stress to some. Therefore, at the very least, all participation must be voluntary and subjects may decline to continue at any point without adverse consequences.
 - Is a system of informed consent in place? This is the purpose of the ISEF Informed Consent form. It allows a participant to know exactly what to expect before agreeing to volunteer and to know the experiment was reviewed and approved by an IRB. It also serves as documentation that the subject was informed beforehand and those under 18 had parental permission.

Good luck with your petition, and remember – submit early!