

Human Subjects Research Parent Information Form – 2019 Student Research Expo

Dear parents and guardians:

Your son or daughter is planning on submitting paperwork to the RRPS Science Review Committee (SRC) that involves research on human subjects. This paper is designed to inform you of the procedures and requirements they will need to complete. Because of many considerations involved in this type of research, there are more steps and scrutiny they must undergo before they can be approved to begin their project. Specifically **the project needs review and approval by an external Institutional Review Board (IRB) after approval by the SRC and Pre-IRB.** These protocols are adaptations of standard practices in institutional research on human subjects and are designed to insure safe, ethical, and confidential participation of the subjects, as well as expose students to the protocol of higher-level research. RRPS’s Student Research Expo feeds directly into the regional level of the International Science and Engineering Fair (ISEF) and therefore we follow their requirements for research approval. The steps are outlined below.

Steps for Approval:

1. **BEGIN EARLY!** Below are the deadlines. These are the latest the steps can be met, NOT the recommended start times. It is in the best interest of the student to be well ahead of these dates.
2. The student needs to write a 1-page proposal petition to **Mr. Keeney at RRHS by 11 September**, 2018, 2:45 pm in ET 101 (or **Ms. Olivas** at CHS in Rm 3111). Only one petition per group is needed if the project is a team effort. Or BOTH students may discuss their proposal IN PERSON with Mr. Keeney or Ms. Olivas BEFORE 11 September by visiting them in their office. No appointment necessary; just come by when the door is open. No paper submission is required in this instance. **Only students whose petitions or interview are approved are permitted to proceed further in the process.**
3. Parents/guardians and student read and sign this form and submit it to Mr. Keeney by **11 September**, 2018, 2:45 pm in ET 101 (or **Ms. Olivas for CHS in Rm 3111**). One form for each student is needed if the project is a team effort.
4. Submit SRC paperwork to Mr. Keeney (RRHS) or Ms. Olivas (CHS) by 2:45 pm on **16 October**, 2018. Besides the normal requirements for SRC submission, human subjects paperwork needs to:
 - a. attach the approved petition from step 2, including all submissions if revisions were required, feedback forms, and comments from the pre-IRB. This is not required if the petition was done as an interview.
 - b. address specific questions and concerns outlined in the Human Subjects Experimental Design Checklist.
 - c. include a properly completed Form 4. Requirements and guidelines are outlined in the Form 4 Checklist.
 - d. if the project involves physical activities or potentially risky activities, a designated supervisor and a form 3 are needed. A designated supervisor is a responsible supervising adult. Coaches, parents, trainers, teachers, or medical personnel are common choices.
 - e. if the project involves any consumption (*to include tasting, ingestion, smelling, or skin contact*), a qualified scientist (*usually a medical professional*) and a form 2 are also required in addition to the designated supervisor.
5. Once the project is approved by the SRC it needs to be sent to the IRB. Approvals usually take several submissions. Don’t worry – this is normal! The IRB consists of licensed psychologists and medical professionals with extensive experience in human subjects research and additional training in ISEF and district regulations. The SRC will take care of sending the packet. This process can take a week or two. Often the IRB will have additional recommendations, and these need to be met before the IRB will approve the project. Feedback will be in the form of attached comments that will be stapled to the front of the returned paperwork.
6. Once the project is approved by the IRB, the paperwork will be returned to the SRC and the approval process is complete. The SRC will register the project for the Expo, and experimentation can begin. **Please make sure that no data collection begins before then.**
7. When the original Form 4 is returned with the approved project, it will include a signature from an IRB member, the Chair of the SRC, and a RRPS administrator. The approved Informed Consent then needs to be copied, one for each subject, and each subject needs to complete one of these copies before experimentation begins. This is the only acceptable way to meet the “Informed Consent” requirement that is standard protocol for human subjects research.

Please sign below that you have read the above information. If you have any further questions, please contact Mr. Keeney or Ms. Olivas. Good luck with the project, and please remember: Begin Early!

Parent/Guardian’s Printed Name:	Signature:	Date:
Student’s Printed Name:	Signature:	Date:
Sponsoring Teacher’s Printed Name:	Rob Keeney – SRC Chair, RRHS 962-9303 (office and voicemail) rob.keeney@rrps.net	