

HUMAN SUBJECTS RESEARCH PROCEDURES AND REQUEST FORM

The Galileo School for Gifted Learning is pleased to partner with researchers wishing to conduct human subjects research that is *mutually beneficial* to both the researcher and the Galileo School for Gifted Learning. The general guidelines and procedures for review of human subjects research are described herein.

Researchers interested in conducting human subjects research must electronically submit to debbie.hahs-vaughn@galileogiftedschool.org the following:

- **Galileo human subjects research request form**
- **IRB approval letter and all approved protocol and related instruments and materials submitted to and approved by an institution that adheres to Federal Policy for human subjects research** (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>)

Questions about conducting research at the Galileo School can be directed to debbie.hahs-vaughn@galileogiftedschool.org.

Please note: Research at the Galileo School will not be considered unless and until it has received approval from an institution that adheres to Federal Policy (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) (most colleges and universities, such as UCF, which receive federal funding adhere to this federal policy; if the researcher is not working through an institution that adheres to Federal Policy, there are also private organizations through which human subjects research can be reviewed, such as New England IRB, www.NEIRB.com). Please include a copy of the IRB approval letter or indicate when the research was submitted for approval.

Review Procedures

Information about procedures concerning class protocols and general review procedures are included below. Researchers may not begin recruitment, enrollment of subjects, or data collection until they have received approval from an institution that adheres to Federal Policy (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) (most colleges and universities, such as UCF, which receive federal funding adhere to this federal policy) and approval from the Galileo School Principal.

General Procedures

- a. Applications are submitted electronically to debbie.hahs-vaughn@galileogiftedschool.org. Requests for research will reviewed on a rolling basis.
- b. Applications for human subjects research will be reviewed on a rolling basis by the Galileo Principal and a designated member of the Board of Directors or another designated individual. Questions may be directed from Galileo to the researcher(s) to ensure transparency and clarity in the application. Applications will not be reviewed unless and until all requested materials are received and any questions effectively responded.
- c. The final decision on applications for human subjects research at Galileo will be made by the Galileo Principal in consultation with Galileo staff and Board as deemed relevant given the scope and topic of investigation. Researchers will receive a response from the Board of Directors in writing (email or letter). This may indicate approval as written, approval with stipulations, deferment/tabling the project, or disapproval/removal of ongoing approval. The response from the Board of Directors will include details of any modifications requested and reasons for the committee's decision. Researchers can usually expect a decision on the status of their research within three weeks from the date of submission.

Amended Protocols

Should the researcher amend their IRB protocol with the institution at which the initial IRB was submitted, the approved amendment must also be submitted to Galileo *prior* to enacting the amended process. If the outside IRB requires further changes in the project and/or the consent form, the amended documents must be filed with Galileo.

Adverse Events

An adverse event is defined as any undesirable and unintended, although not necessarily unexpected impact on a subject, as a result of therapy or other intervention. Researchers must report in writing to Galileo School all adverse events, including isolated incidents of unanticipated adverse reactions. Should the institution at which the initial IRB was submitted require the research to be modified, this information must also be submitted to Galileo prior to enacting the modification process. Should the institution at which the initial IRB was submitted require the research to be ceased, this information must be submitted to Galileo immediately.

Researcher Responsibilities

Individuals who propose to undertake research involving human subjects acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects. They also must comply with all applicable provisions outlined in this document and any documents and/or requirements issued by the institution that adheres to Federal Policy for human subjects research which approved the human subjects research. Research investigators involving human subjects also shall be responsible for complying with all human subjects research decisions, conditions, and requirements set forth by Galileo. Investigators will promptly report to the School Principal (or designee) and Board of Directors anticipated changes they may propose or that may be imposed by an external IRB for previously approved human subject research activities. Researchers will not initiate any changes without review and approval by the School Principal except where necessary to eliminate apparent immediate hazard to subjects. Researchers will report promptly to the School Principal (or designee) and Board of Directors any injuries or unanticipated problems involving risk to research subjects or others.

Galileo Student Human Subjects Research

Galileo School teachers assigning their students to conduct research projects involving human subjects must take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of applications for human subjects research approval. Teachers shall take an active role in ensuring that the conduct of the research meets the highest ethical standards. Teachers shall ensure that their student researchers:

- a. understand the elements of the consent process
- b. develop a readable consent form
- c. plan and accomplish appropriate recruitment strategies for identifying subjects, and
- d. establish and maintain strict guidelines for protecting anonymity, where names are not known or recorded and thus cannot be disclosed, or confidentiality, where names are known/recorded but will not be disclosed.

Galileo teachers must submit the application for human subjects research. The signature of the teacher is required on the human research subjects application form, providing documentation that these aspects of research have been addressed, and that the Teacher is ultimately responsible for the protection of human subjects in student research.

Please note: Should classroom research conducted by Galileo School students be conducted for purposes of dissemination (i.e., publication or presentation), the research must be approved by an institution that adheres to Federal Policy for human subjects research

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) (most colleges and universities, such as UCF, which receive federal funding adhere to this federal policy; if the teacher is not working through an institution that adheres to Federal Policy, there are also private organizations through which human subjects research can be reviewed, such as New England IRB, www.NEIRB.com) as well as the Galileo School Principal, in conjunction with staff and the Board of Directors as deemed relevant given the scope and topic of investigation.

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Please Note: Depending on the nature of your research, certain sections below may not be applicable. Indicate this as appropriate.

GENERAL INFORMATION	
Protocol Title	
Primary investigator and affiliation	
Email address of primary investigator	
Phone number of primary investigator	
Co-investigator(s) and affiliations	
Objectives of the research	
Resources available to conduct the human research	
SETTING OF THE HUMAN RESEARCH	
Number and type (e.g., grade level) of teacher participants desired (if a specific grade level is desired, please indicate)	
Number and type (e.g., 3 rd grade only) of student participants desired	
Anticipated class time required (if multiple dosages are required, indicate the number of days and amount of class time per day)	

<p>School facilities needed (<i>briefly list space, materials, equipment, etc. necessary for the proposed research, indicating those that the researcher will be providing—also list the purpose or use intended for each item listed</i>)</p>	
<p>Cost to participants</p>	
<p>Sharing of results with participants and/or the Galileo School</p>	
<p>Any and all research conducted at the Galileo School must be mutually beneficial. <i>Please indicate what the Galileo School will be provided in return for conducting research at the school (e.g., no-cost teacher professional development, classroom resources, no-cost programs for students, monetary donation to the school).</i></p>	
<p>Please indicate the institution at which your research been approved by IRB (e.g., UCF or other college or university). <i>Please include a copy of the approval letter along with the approved protocol, consent, and all instruments or other materials that will be used as part of the research. Research at the Galileo School will NOT be considered unless and until it has received approval from an institution that adheres to federal policy regarding the protection of human subjects research.</i></p>	

Applicant Assurances

Submitting the Human Research Request Form indicates that you agree to the following statements and will adhere to Galileo policies:

1. I understand that contact with schools/departments and/or potential participants is considered a research activity and cannot occur until approval is received by the Galileo School.
2. The information available through Galileo is, by federal and state law, confidential and shall be used only for the authorized purposes. Under no circumstances shall records and reports be released by Galileo to any party unless such release is in strict accordance with the provisions, and to the entities identified in, the Family Educational Rights and Privacy Act (FERPA) 20 U.S.C. §1232g; 34 CFR Part 99, chapter 119 and section 1002.22, Florida Statutes.
3. Any data or information gathered for this research project will be used solely for the project outlined above; I understand that additional research projects using this data and/or information will need to be approved in advance by the Galileo School
4. The party receiving data acknowledges its separate obligations in accordance with the requirements of these provisions by establishing duties of confidentiality, privacy, and nondisclosure.
5. Deliberate or accidental misuse of information may result in loss of access, disciplinary action, dismissal or prosecution under the scope of all applicable federal and state laws and regulations.
6. After approval of your research application, each researcher or research team member who interacts in-person with Galileo staff, students, or families on site at Galileo, during school-related events, or otherwise must follow school protocol required for campus visitors or volunteers. This includes: checking in and out of the front office daily, wearing an ID badge, and being screened as a Dividend for short-term projects or paying for, submitting fingerprints, and passing a background check for extended projects.
7. Staff/Student/Family Involvement. I understand that consent forms and student assent is required for research involving Galileo staff, students, or families and I must adhere to the protocol and consent process as approved by the IRB.
8. I understand that approval does not constitute an endorsement for the research project. Approval reflects only permission to request the voluntary cooperation of Galileo staff.

9. I understand that every researcher or research team member requesting in-person access to Galileo faculty/staff, students or their families on site at Galileo or at Galileo-hosted events must have a volunteer badge, which requires fingerprinting and a background check before engaging in research activities. I understand that I will be responsible for the costs involved in the badging process. This requirement applies to all researchers and members of the research team (the applicant, research assistants, collaborators, etc.) who interact in-person with Galileo staff, students or families site at Galileo, during events or otherwise.
10. I understand I must obtain permission to use the Galileo school name, or names of any personnel in research findings prior to dissertation or prospectus defense, publication, presentation, and/or any correspondence regarding this research project. An email requesting permission may be sent to debbie.hahs-vaughn@galileogiftedschool.org. Otherwise, the Galileo school name and/or or names of any personnel in research findings should not be included in any written or oral communication or publication regarding this research.
11. Galileo may request one complete copy of each report or product developed as a part or outcome of the research project. No charge will be made of Galileo for any of these reports, copies, or products; and all will be provided within 45 calendar days of the development of the report or product, or within 45 calendar days of the end of the study, whichever comes first.
12. I understand that Galileo requires an Executive Summary or abstract to be submitted within 45 calendar days of completion of expiration of this human subjects research, and that Galileo may post the required Executive Summary or Abstract on their website.
13. I understand that I will have 12 months from the date of approval to complete this research project; if additional time is needed, I will need to request additional time in writing to Galileo for an extension.
14. I understand that I am obligated to report unanticipated problems or adverse events related to subject participation that occur in the context of an ongoing or closed Galileo-approved research project. If there are any unanticipated problems or adverse events, I will notify the Galileo Principal immediately via email or phone.