# Basic Information

1. **\*** Title of Study: Low Cost Telescopes
2. **\*** Principal Investigator: Robin Allen
3. Does the Principial Investigator have a financial interest related to this research?

[ ] Yes [X] No

1. The Principal Investigator will receive all communications related to this project. Select one or more persons to receive the same communications or to have read access to the project even if they are not study team members (e.g., a project coordinator.)

Nandana Weliweriya

David Seiden

1. a. Are you requesting determination if your project meets the definition of human subjects research?

[ ] Yes [X ] No

b. Are you requesting determination if your project meets the criteria for developmental review?

[ ] Yes [ X] No

c. Will an external IRB act as the IRB of record for this study?

[ ] Yes [X ] No

# ~~For Non-human subjects only (yes to 5a)~~

## ~~Determination of non-human subjects~~

1. ~~Is the activity a systematic investigation?~~

~~[ ] Yes [ ] No~~

1. ~~Is the activity designed to develop or contribute to generalizable knowledge~~

~~[ ] Yes [ ] No~~

1. ~~Does the activity involve an individual as a recipient of any test article (i.e., drug, biologic, or medical device) or as a control?~~

~~[ ] Yes [ ] No~~

1. ~~Does the activity involve an individual on whose specimen a medical device will be used (21 CFR 812.3(p)) (i.e., in vitro diagnostic [IVD] device)?~~

~~[ ] Yes [ ] No~~

1. ~~Will you interact or intervene with a living person to collect information about, or biological samples from, the person OR Receive or obtain information about, or biological samples from, a living person (from any source or already in your possession)?~~

~~[ ] Yes [ ] No~~

1. ~~Is the information that will be obtained about the individual (i.e., his/her own personal thoughts, opinions, attitudes, and/or perceptions) and not on policies, practices, and/or procedures that this person is familiar with?~~

~~[ ] Yes [ ] No~~

1. ~~Will the information that will be obtained or received be considered private (e.g., an educational or medical record)?~~

~~[ ] Yes [ ] No~~

1. ~~Will the information that will be obtained or received contain direct identifiers?~~

~~[ ] Yes [ ] No~~

1. ~~Will the information that will be obtained or received contain indirect identifiers (e.g., codes) such that a key exists that would allow the data/specimens to be linked to the individuals who provided these?~~

~~[ ] Yes [ ] No~~

1. ~~Is/are the investigator(s) unable to readily ascertain the identity of the individuals who provided the information/specimens because the holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased? Attach the agreement in Q12~~

~~[ ] Yes [ ] No~~

~~Is/are the investigator(s) unable to readily ascertain the identity of the individuals who provided the information/specimens because the investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased? Attach the agreement in Q12.~~

~~[ ] Yes [ ] No~~

## ~~Not Human Subjects Research Activity Information (only if project is not human subjects research; Question 5a)~~

~~1.Describe the study objectives and rationale:~~

~~2. Provide a brief description of the study procedures.~~

~~3.Describe the subject population, and the type of data/specimens to be studied:~~

~~4. Identify the source of data/specimens (i.e., from whom/where these will be obtained):~~

~~5. Describe how data/specimens were collected:~~

~~6. Were the data/specimens originally collected solely for research purposes?~~

~~[ ] Yes [ ] No~~

# Project Funding (complete for all proposals)

1. Is the work described in this protocol, or the work described in the overarching project, funded by an external source:

[ x] Yes [ ] No

1. Compare the scope of the Human Subjects Activities included in the overall project to the activities described in this protocol submission:

[x] They are the same: All human subjects activities in the overall project are included in this protocol submission:

[]They are different: Human subjects activities included in the overall project but not part of this protocol submission have already been included in a separate pending or approved protocol submission:

[ ] Human Subjects Activities included in the overall project but not in this IRB Submission are intended to be included in a future UGA IRB Submission:

[ ] Human Subjects Activities included in the overall project but not in this IRB Submission have already been included in a separate pending or approved IRB Submission to an external institution/entity:

[ ]Human Subjects Activities included in the overall project but not in this IRB Submission are intended to be included in a future IRB Submission to an external institution/entity:

# Study Team Members

Identify each UGA faculty, staff, or student who will be engaged in the conduct of human research. Do not select the PI again

David Seiden

Inseok Song

Nandana Weliweriya

Identify non-UGA collaborators\* who will be engaged in the conduct of human research.
*\*Submit an Individual Investigator Agreement for all study personnel with an institution that does not have an assurance with the Office for Human Research Protections or OHRP (typically, local schools, private doctors, clinics).*
*\*For study personnel who are affiliated with an institution that has an assurance (has its own IRB), do not submit an Individual Investigator Agreement. Instead indicate that you have an External Site on the Study Scope page.*
*\*If the submission is for reliance on an External IRB, do not list study team personnel at non-UGA sites.*

# Study Scope (if selected human subjects research)

1. Will you recruit or conduct the study at a non-UGA agency/institution/facility (i.e., referred to as an External Site) where you do not normally have research privileges?

[ ] Yes [X ] No

1. Check the methods/procedures that are used:

|  |  |
| --- | --- |
| X | Project is Exempt |
|   | Blood Sampling/Collection |
|   | HIPAA (Protected Health Information) |
|   | Deception, concealment, or incomplete disclosure |
|   | Internet Research |
|   | Research activities are limited to analysis of data |
|   | Genetic Analysis |
|   | DXA/X-Ray |
|   | More than moderate Exercise |
|   | Electrical Stimulation |
|   | Data/Tissue Repository |
|   | ClinicalTrials.gov Registration |
|   | Use of Drugs/Biologics, Dietary Supplements or Devices |

1. Does the study use any of the following test articles? Check all that apply.

|  |  |
| --- | --- |
|  | Dietary Supplements used for a therapeutic purpose - See Help |
|   | Food that is not used primarily for its taste, aroma, or nutritive value but for a therapeutic purpose or to affect the structure/function of the body - See Help |
|   | Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - See Help |
|   | Device Software Functions and Mobile Medical Applications - See Help |
|   | Medical Devices |
|   | Drugs or Biological Products |

1. ClinicalTrials.gov Registration and Results Submission. Check all the requirements that apply (see Help):

|  |  |
| --- | --- |
|  | This is an Interventional Clinical Trial that will be published in an ICMJE journal. |
|   | This is an Applicable Clinical Trial per FDAAA 801. |
|   | This is a study with direct funding from NIH (wholly or partially) that meets the definition of a Clinical Trial. |
|   | Others. |

1. Will the project require use of the CTRU Unit?

[ ] Yes [ X] No

1. Will the project require use of the CTRU personnel?

[ ] Yes [X ] No

# Exempt Categories (if selected Project is exempt)

If your study has federal funding, only the six categories in Q1 may be used. For all other projects, review the first six; If none apply, review the Q2-FLEX categories below. Please review the Policy and Procedure: Exempt Research for additional guidance. It is located in the Click IRB Library under SOPs.

1. Education Research

[X ] Yes [ ] No

DHHS - Exempt 1): Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Check the box below to indicate that you will comply with the requirement to obtain External Site Authorization. Please complete the External site page accordingly. For more information on doing research at external sites, see our policy at:<https://research.uga.edu/docs/policies/compliance/hso/PP-Use-External-Sites-Research.pdf>

EXTERNAL SITE AUTHORIZATION: I must obtain site authorization that indicates the procedures are normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.

[ X] Yes [ ] No

If the project involves access to or use of educational records, check the box below to acknowledge FERPA requirements. For more information about FERPA, see our policy at: <https://research.uga.edu/docs/policies/compliance/hso/PP_FERPA.pdf> FERPA: I must obtain documented parental permission or adult student consent as required by FERPA unless the site authorization describes that my project meets criteria for exception to this requirement.

[X ] Yes [ ] No

1. Exempt 2. SURVEYS, INTERVIEWS, OBSERVATION OF ADULTS

[X ] Yes [ ] No

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

Check one of the following criteria i-iii:

i. DATA ARE NOT IDENTIFIABLE: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects (no a/v recording);

**ii. IDENTIFIABLE BUT NO RISK:** Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

iii. IDENTIFIABLE SENSITIVE DATA: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

1. Exempt 3: BENIGN BEHAVIORAL INTERVENTIONS WITH ADULTS [ ] Yes [ ] No

(DHHS - Exempt 3(i)): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

Check one of the following criteria A-C.

A. DATA ARE NOT IDENTIFIABLE: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

B. IDENTIFIABLE BUT NO RISK: Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

C. IDENTIFIABLE SENSITIVE DATA: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

4. Exempt 4: Secondary Data Analysis [ ] Yes [x ] No

Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met (check all that apply):

PUBLICLY AVAILABLE: The identifiable private information or identifiable biospecimens are publicly available;

INVESTIGATOR WILL NOT RECORD (KEEP) IDENTIFIERS: Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

PROJECT IS HIPAA REGULATED: The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA for the purposes of ‘‘health care operations’’ or ‘‘research’’; or

FEDERAL AGENCY PROJECT USING FEDERAL DATA - Call UGA Human Subjects Office before choosing this option: The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002.

# Human Research Participants

1. Targeted Populations - Click "Add" to provide a general description of the targeted participants. See Help text on the right for definition of human subject.

Students enrolled in ASTR 3010 at the University of Georgia in Fall 2024

1. Inclusion Criteria - if there are multiple targeted populations, identity the criteria for each:

Not Applicable

1. Exclusion Criteria - if there are multiple targeted populations, identity the criteria for each

Not Applicable

1. Eligibility Criteria - Describe how potential participants will be initially identified and how eligibility will be determined:

Participants will be selected based on their enrollment in ASTR 3010

1. Exclusion Justification - If the research will exclude a particular gender or minority group, provide justification:

Not Applicable

1. Incentive Description - Describe any incentive/compensation for participation:

Not Applicable

# Vulnerable and Special Populations

1. Special populations – check any that apply:

|  |  |
| --- | --- |
|  | Pregnant women, neonates, or fetuses.  |
|   | Prisoners  |
|   | Minors  |
|   | Mentally-disabled/cognitively-impaired/severe psychological disorders  |
|   | Physically-disabled  |
|   | Terminally ill  |
|   | Economically/educationally disadvantaged  |
|   | A specific group based on religion, race, ethnicity, immigration status, language, or sexual orientation  |
|  X | Students/Employees  |
|   | Other (please describe) |

1. Provide justification for including the group(s) checked above in this particular study:

The study is about developing and using 3D tools to use in astronomy courses at UGA and thus could not be reasonably conducted without collecting data from instructors.

1. Describe the working relationship between any researchers and the participants, as applicable:

PI Song is the instructor of the ASTR 3010 course.

1. Describe the safeguards to protect the rights and welfare of these participants and to minimize any possible coercion or undue influence:

The instructor of the course will not be given access to any data prior to the end of the course. Those not involved with the course will lead data collection.

# Recruitment Methods and Materials

1. Will you recruit individuals to take part in the study

[X ] Yes [ ] No

1. Describe when, where, and how participants will be initially contacted

A member of the research team will speak to students in the course to introduce the study.

1. Describe any follow-up recruitment (e.g. multiple attempts/contacts for the purpose of inviting someone to participate):

Following initial contact with potential subjects PI will follow-up by email.

# Consent Process and Materials

1. Select the applicable option(s) below to describe the consent process/es for this study:

|  |  |  |
| --- | --- | --- |
|  | Option | Description |
|  X | Informed consent will be obtained and documented  | The consent process includes all elements of consent and participants will sign a consent document.  |
|   | Signatures will not be obtained on consent documents  | Participants will not physically sign a document as part of the consent process.  |
|   | Informed consent will not be obtained or some or all elements will be waived or altered  | There will not be a consent process or the consent process will not include all elements of informed consent. |

1. Describe how, where and when informed consent will be obtained from research participants:

For the survey, participants indicate their consent with a question before the rest of the survey starts. For the interview, participants will be given the consent form and the opportunity to read it and ask questions prior to the interview beginning.

1. Consent forms: **Important Note:** The IRB strongly recommends the use of consent templates that are available on the consent materials page to ensure that all the elements of informed consent are included (per 45 CFR 116). Add attachments below. If more than one consent document will be used, please name each accordingly.

# Research Design, Methods, and Procedures

1. Brief Description

As an active learning intervention, a class set of low cost telescopes are being implemented in ASTR3010: Observational Astronomy, with a semester-long project utilizing the telescopes. We will collect survey data measuring the student experience and conduct several rounds of interviews with volunteers to gain feedback about the project and measure the impact of the intervention.

1. Describe the overall research design and method(s) of data collection. Also, identify specific factors or variables and, if applicable, treatment and control conditions or groups

Survey collection via Google Forms with the Undergraduate Research Student Self Assessment (URSSA), measuring identity and attitudes. Interviews will occur face-to-face and be audio recorded.

1. Describe the time commitment per activity per individual subject and provide the estimated total duration of participation. If known, also describe the anticipated duration to enroll all study subjects and the estimated time until completion of primary analyses.

Individuals who participate in the study will be committing approximately an hour of their time. This time will be broken into three sections:

1. Pre-survey (15-20 minutes)

2. Multiple rounds of interviews (10-15 minutes each round): participants can participate in up to 2 interviews.

3. Post –semester survey (15-20 minutes)

1. Describe in detail, and in sequence, all study procedures from the perspective of the participant. Begin with any procedure that involves interaction or collection of data to determine eligibility, if applicable. Separate any procedures that are part of regular practice from procedures that are specific to this research study. If procedures are long and complicated, use a table, flowchart or diagram to outline the study procedures.

For individuals participating in the study, they will take a survey provided by the instructor. They will then have the option to volunteer for an interview, which would last approximately 15 minutes. If needed, multiple interviews may take place. At the end of the semester, students take the end-of-semester survey.

1. Describe the data analysis plan, including any statistical procedures. For qualitative studies, specify the proposed analytic approaches.

Participants will be audio recorded during the interview. Survey data and interview data will be analyzed for common themes and emerging results, such as feedback on how to improve the project or implement more support, as well as common themes such as equipment struggles.

# Data Collection Materials

1. Upload data collection materials: Data Collection Materials may include, but are not limited to: surveys, interview guides/questions, questionnaires, focus group guides/questions, observation guides, bio-metric measure recording sheets. Do not list equipment such as audio/video-recording devices, EKG, Ultrasound.

Interview Guide Attached.

# Risks and Benefits

1. If there is collection of information that could place a participant at risk of criminal or civil liability or damage a participant's financial standing, employability, or reputation, mark any box(es) that apply below. If information to be collected is not sensitive, do not mark any. The list below is not exhaustive but represents common elements or procedures in research where the primary risk is potential harm associated with breach of confidentiality

|  |  |
| --- | --- |
|  | Collection of sensitive information in surveys or interviews.  |
|   | Collection of information that may cause embarrassment or may be associated with stigmatization.  |
|   | Collection of information that may be considered an invasion of privacy of the subject or the subject's family |

1. Describe in detail the nature and degree of risk associated with participation. Address any items marked above in detail. Include risks associated with physical procedures/interventions and procedures and interventions that may cause psychological harm

There is minimal risk in participation. The instructor may learn of participant involvement.

1. Describe the measures that will be taken to minimize each of the potential risks/harms identified in questions 1 and 2

The risk will be mitigated by removing the course instructor from any data collection and analysis. They will not have access to any results before the end of the course.

1. Describe any anticipated direct benefits to participants. If there are none, please state so:

Individuals will not benefit directly.

1. Describe any anticipated benefits to others (e.g., societal) that may result from the research. Describe the generalizable or transferable knowledge that may result

Future students in astronomy courses may benefit from the developments active learning interventions.

# Confidentiality and Privacy

1. Will the researchers collect or record any direct identifiers with the data (e.g., names, addresses, telephone numbers)?

[ X] Yes [ ] No

1. Will the researchers use a coding system and/or will the data be collected via the Internet?

[X ] Yes [ ] No

1. Will the link/indirect identifier be retained after data collection is complete?

[X ] Yes [ ] No

1. Is it reasonable foreseeable that the study will collect or be privy to information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse) or ethically might require action by the research (e.g., suicidal ideation, intent to hurt self or others)? If "Yes", this must be described in the the consent documents

[ ] Yes [X ] No

# ~~(Complete only for developmental proposals) Investigator Assurance Seeking Release of Funds for Preliminary Activities from Non-federal Source~~

~~Account numbers are assigned by Sponsored Projects Administration once all award and compliance documents are obtained. Some contracts and awards may involve a period of development for which funds are needed to support activities preliminary to the research involving human subjects. If your non-federal award has been received but the account number cannot be assigned without IRB approval, and you cannot seek IRB approval until the preliminary activities are completed, you can provide an assurance and notification to the IRB that you are setting up a developmental period. This automated process will result in documentation pertaining to IRB review that your SPA representative will add to your project record. Complete the following questions to begin the process:~~

1. ~~Describe use of funds that are necessary and/or the activities that must be completed before the project can be submitted for IRB review:~~
2. ~~Indicate the anticipated date for submission of the human research project for IRB review:~~
3. ~~Indicate the anticipated date when human subjects research will begin:~~
4. ~~Does the project involve collaboration with non-UGA institutions?~~

~~[ ] Yes [ ] No~~