

# Hobbits in Space

## Admin

Protocol ID	23-010
Panel	Full Board
Student Investigator	Tasha Yar Signed 04/10/2023 4:28 PM PDT
PI Type	Student
Faculty Supervisor	Jean-Luc Picard 03/29/2023
Faculty Supervisor Acceptance Status	Accepted 04/10/2023 4:33 PM PDT
Co-I's	Wesley Crusher 03/29/2023
Review Type	Full Board Review
Approval Status	Full Board Review Requested
Submitted By	Tasha Yar
Date Received	04/10/2023
Date of Completion	04/10/2023
Final Approval Date	
Date Closed	
Is this a multi-institutional, collaborative study?	Yes
Department	Interdisciplinary Engineering - College of Engineering

<b>Recruitment Materials</b>	04/10/2023 Screening Survey - Training Intervention .pdf 04/10/2023 Email Script - Training Intervention.pdf 04/10/2023 Email Script - Youth Survey.pdf 04/10/2023 Flyer - Training Intervention.pdf 04/10/2023 Flyer - Youth Survey.pdf 04/10/2023 Web Content - Training Intervention.pdf 04/10/2023 Web Content - Youth Survey.pdf 04/10/2023 Study Sign-up Form - Summer Youth Space Camp.pdf
<b>Consent Documents</b>	04/10/2023 Consent Form - Training Intervention.pdf 04/10/2023 Parent Permission Form - Youth Survey.pdf 04/10/2023 Consent/Assent Notice - Youth Survey.pdf
<b>Assent Documents</b>	04/10/2023 Assent Notice.pdf
<b>Data Instruments</b>	04/10/2023 Pre and Post Survey - Training Intervention.pdf 04/10/2023 Pre and Post Survey - Summer Youth Space Camp.pdf
<b>Additional Documentation</b>	04/10/2023 One Ring Schematic and Technical Details.pdf 04/10/2023 Hobbit Training Intervention Daily Schedule.pdf 04/10/2023 Letter of Support - HBAC.pdf 04/10/2023 List of References.pdf
<b>Notifications</b>	04/10/2023 SJSU IRB: Full Review Selected - 23-010.pdf

## STUDY PERSONNEL

### PI

Tasha Yar (03/29/2023)

### PI Documents

- IRB Human Subjects Training Certification

File

– no entries found –

### Department

**Answer:** Interdisciplinary Sciences

03/30/2023 11:43 AM PDT

### Qualifications

*Describe any relevant expertise or experience as it relates to this study which prepares this study team member to conduct research with the subject population(s) identified in this submission. Also describe any specialized knowledge of local community attitudes, cultural norms, and the cultural sensitivities necessary to carry out the research, if applicable.*

**Answer:**

1. Prior coursework and experience in the fields of education, psychology, and space science.
2. Familiarity with research methodologies and data analysis techniques used in experimental studies.

3. Four years of experience serving as a security officer for hobbits of the Shire. During this time, I was immersed in the hobbit community and carried out an in-depth study of hobbit culture, with specific emphasis on their often overlooked contributions to science. This work has resulted in a published article in the Journal of Hobbit Affairs.

04/10/2023 2:07 PM PDT

**List the study activities to be carried out by this investigator (e.g., research design, recruitment/enrollment of subjects, obtaining consent, collecting data, analysis of data).**

**Answer:**

Research design, obtaining consent, carrying out the intervention with the help of the other personnel listed in this application, and collecting and analyzing the data.

03/30/2023 11:43 AM PDT

## Faculty Supervisor

Jean-Luc Picard

### PI Documents

- IRB Human Subjects Training Certification

File

– no entries found –

### Department

**Answer:** Interdisciplinary Engineering

03/30/2023 11:47 AM PDT

### Qualifications

*Describe any relevant expertise or experience as it relates to this study which prepares this study team member to conduct research with the subject population(s) identified in this submission. Also describe any specialized knowledge of local community attitudes, cultural norms, and the cultural sensitivities necessary to carry out the research, if applicable.*

**Answer:**

1. Extensive experience in space exploration and the Starfleet Academy, with a deep understanding of the technical and scientific aspects of space travel.
2. Strong leadership and communication skills to effectively manage a team of researchers and communicate with colleagues, study participants, and research sponsors.
3. Familiarity with ethical guidelines for research involving human subjects, as well as experience obtaining IRB approval for studies involving human participants.
4. A strong background in experimental design and data analysis, including experience with statistical analysis methods commonly used in research studies.
5. Excellent problem-solving and critical thinking skills to identify potential challenges and develop creative solutions.
6. A commitment to advancing the field of space exploration through rigorous and innovative research, with a passion for discovery and exploration.
7. A record of publishing research findings in high-impact journals and presenting research findings at academic conferences, demonstrating expertise in the field of space exploration and research.

04/10/2023 2:08 PM PDT

**List the study activities to be carried out by this investigator (e.g., research design, recruitment/enrollment of subjects, obtaining consent, collecting data, analysis of data).**

**Answer:**

Overseeing all aspects of study activities to be carried out by the student investigator; coordinating high level communication between the participating institution and organization.

03/30/2023 11:50 AM PDT

## Co-I's

Wesley Crusher (03/29/2023)

No Allow Edit

### PI Documents

- IRB Human Subjects Training Certification

File

– no entries found –

**Department**

**Answer:** Engineering

**Qualifications**

*Describe any relevant expertise or experience as it relates to this study which prepares this study team member to conduct research with the subject population(s) identified in this submission. Also describe any specialized knowledge of local community attitudes, cultural norms, and the cultural sensitivities necessary to carry out the research, if applicable.*

**Answer:**

1. Prior coursework and experience in the fields of education, psychology, and space science.
2. Familiarity with research methodologies and data analysis techniques used in experimental studies.

04/10/2023 2:08 PM PDT

**List the study activities to be carried out by this investigator (e.g., research design, recruitment/enrollment of subjects, obtaining consent, collecting data, analysis of data).**

**Answer:**

Helping with intervention activities, and data analysis.

04/10/2023 2:08 PM PDT

**External Study Personnel**

**List the names, affiliations, roles, and study activities of any external study personnel.**

**Answer:**

Mr. Gollum Smeagol, chair of the Hobbit Community Advisory Board (HCAB), will assist in advertising the study to participants in the Summer Youth Space Camp Program by sending out recruitment flyers to the space camp mailing list. Mr. Smeagol will also coordinate the resources of the HBAC to ensure that the dietary needs of hobbits in the training intervention will be fulfilled. Lastly, Mr. Smeagol will serve as the point person for coordinating responses to any questions that research personnel may have related to hobbit cultural traditions and practices.

04/11/2023 11:48 AM PDT

**If you have human subjects research training certificates for external personnel, please upload the document(s) here.**

*Note: SJSU does not provide access to its CITI training subscription to external investigators.*

**Answer:****STUDY TIMING AND FUNDING****Anticipated Start Date**

**Please indicate your anticipated start date, making sure that it is not retroactive and allows enough time for review and approval of your protocol submission.**

***Important Note:** The SJSU IRB does not review or approve studies retroactively. You are required to make sure your timeline is reasonable prior to submitting your protocol or submitting requested revisions to your protocol. Refer to our [website for information regarding review timelines for various types of research](#). Submissions with retroactive start dates will be withdrawn from consideration.*

**Answer:** 03/01/2024

**Funding**

**Is the study currently funded?**

**Answer:**  Yes

No

**Please list the funding source(s).**

Starfleet Academy RSCA grant

**OTHER INSTITUTIONS****Names and roles of participating institutions**

*List any participating institutions that will be engaged in the research. Include specific information about the institution's role in the research.*

**Answer:**

Starfleet Academy: source of contact information and performance records for hobbits on Space Station 5; study sponsor.

The Hobbit Community Advisory Board (HCAB): providing cultural advisory support as well as personnel and resources to ensure hobbits

who participate in the training intervention study are comfortable and have all their unique nutritional needs met. HCAB is also involved in organizing the annual Summer Youth Space Camp Program in the Shire and will assist in advertising the study to prospective participants and their parents.

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**Besides SJSU, do any of the participating institutions listed have their own IRB committee?**

**Answer:**  Yes

No

**List the names of the participating institutions which have their own IRB.**

Starfleet Academy

**Is the PI requesting that SJSU serve as the IRB of record/reviewing IRB for one or more of the participating institutions?**

**Answer:**  Yes

No, each institution will conduct its own IRB review.

No, an external IRB will be the IRB of record/reviewing IRB.

03/30/2023 2:52 PM PDT

*Note: if an SJSU PI wishes to add investigators and research personnel from other institutions to the SJSU IRB, those institutions must either contact the SJSU IRB and request to establish a reliance agreement with SJSU to rely on our IRB review instead of conducting their own review or they must conduct their own, separate review. Outside institutions may use their own reliance agreement document or they may request to use the standard SJSU reliance agreement document, which can be provided upon request. The SJSU PI is responsible for:*

- *Providing the currently approved documents and the approval letter to relying external investigators so that they can contact their IRB to initiate a reliance agreement.*
- *Submitting modification requests to the SJSU IRB for any modifications to the approved study procedures at the external site.*
- *Submitting reportable events from relying sites to the SJSU IRB.*
- *Communicating to relying investigators that they must also submit reportable events to their local IRB following local IRB reporting requirements.*

*Reliance agreements can usually be initiated after the reviewing IRB (in this case, SJSU) has approved the study. **However, external investigators who may have been listed in the previous section of this application are not covered under the SJSU IRB's approval of this study unless a reliance agreement is established.** An executed reliance agreement must be in place before SJSU can serve as the reviewing IRB for participating institutions. If the participating institution does not wish to engage in a reliance agreement, the external personnel listed in this application must pursue their own approval via their institution's IRB (though you may still list them in this application).*

*Turnaround time can vary due to the negotiation process and the possible involvement of legal counsel or procurement. The responsiveness of the participating institution may also affect the turnaround time. Agreements can take a few weeks to several months to be fully executed.*

*For more information, please contact the [SJSU IRB Office](#).*

**Provide information on whether and how SJSU will be involved as a campus in this multi-institutional, collaborative study (e.g., as a source of recruitment for subjects, as a source of secondary data, as a source of research personnel).**

**Answer:**

SJSU is the source of the research personnel, including the student investigator and faculty supervisor who will be responsible for carrying out all aspects of the study. All study activities will occur off-campus, either on Space Station 5 or in the Shire.

03/30/2023 2:55 PM PDT

## STUDY LOCATION

**Where will the study be conducted?** *Select all that apply.*

**Answer:**  Online

SJSU campus

External site

**Name the external study location(s) where recruitment/enrollment, data collection, and other study procedures will take place.**

**Answer:**

Space Station 5, in a galaxy far far away.

The Shire.

03/30/2023 2:58 PM PDT

**Investigator(s) affiliation.**

*Disclose any affiliation that you or other investigators have with each external study site (e.g., employee, intern, collaborator, client, contractor) or state that you have no affiliation.*

**Answer:**

All SJSU investigators have served on Space Station 5 in previous assignments but currently do not have any affiliations with the external site.

Tasha Yar has served as a security officer for the Shire in the past but has no current affiliation.

03/30/2023 3:02 PM PDT

**External site engagement: Are personnel from external sites conducting any of the following procedures for this research while being overseen by the SJSU PI? Select all that apply.**

**Answer:**

- Obtaining research consent
- ✓Collecting information from individuals
- ✓Handling private, identifiable information
- Not applicable

**Describe any applicable site, location, or regional specific regulations, policies, or customs affecting the research at this external site:**

Space station 5 is managed by Starfleet Academy. All Starfleet policies are applicable and will be observed by affiliated and non-affiliated personnel. Hobbits have special nutritional needs and must eat at least 6 meals a day (typically: breakfast, second breakfast, elevensies, luncheon, afternoon tea, dinner and supper). The Hobbit Community Advisory Board (HCAB) has provided guidance and support to the research team in order to ensure that the nutritional needs of hobbits enrolled in the intervention study are met. The research team has consulted with hobbit community members and stakeholders in the design and conduct of the study to ensure that the intervention component of the study is culturally appropriate.

04/11/2023 11:49 AM PDT

**STUDY DESIGN**

**Study Purpose**

*Provide an explanation of the purpose of the proposed research, written for a general audience. Include a concise statement of your research questions or hypotheses.*

**Answer:**

The purpose of this study is to investigate the effectiveness of a training intervention designed specifically for hobbits in preparing them for deep space exploration at the Starfleet Academy Deep Space Program on Space Station 5. This study aims to determine whether the hobbit-specific training program results in improved adaptability of space-faring hobbits and whether hobbits' performance and behavioral outcomes in space are any different compared to the standard treatment group.

A second component of the study will be conducted with hobbit adolescents who are interested in exploring the wider world beyond their community. The purpose is to see if the Summer Youth Space Camp Program conducted in the Shire increases young hobbits' interest in space exploration.

04/10/2023 2:24 PM PDT

**Study Background**

*Include a brief (1-2 paragraphs) review of any relevant and current scholarly literature that supports the purpose of the research or that led to the formulation of the study. Include citations and include a list of references, if applicable.*

**Answer:**

The literature review suggests that training programs tailored to the needs of specific populations can significantly improve their performance outcomes in the context of space exploration. For example, a study conducted by Smith et al. (2018) found that a training program specifically designed for individuals with disabilities resulted in improved performance outcomes in space missions compared to standard training programs. Similarly, a study by Brown et al. (2019) demonstrated that a training program for individuals from diverse cultural backgrounds resulted in better performance outcomes in space missions than a standard training program. Furthermore, research by Baggins et al. (2020) found that tailoring enrichment programs to underserved youth led to their greater interest in space exploration and a higher likelihood that they will pursue space exploration as a career.

In light of these findings, it is important to investigate whether a hobbit-specific training program can better serve the needs of hobbits in the context of deep space exploration as well as motivating young hobbits to pursue careers in space. This study has the potential to contribute to our understanding of the effectiveness of training programs for diverse populations in the context of space exploration, and to inform the development of future training programs that can better meet the needs of hobbits.

A list of references is attached under the Other Study Attachments section of this application.

04/10/2023 2:26 PM PDT

**Research Summary**

Provide a brief outline of how you will achieve the study objectives and answer your research questions in the following ways:

**Research design (experimental, descriptive, correlational, etc.).**

**Answer:**

Experimental: adult participants will be randomly assigned to either the hobbit training program designed by the research team or the standard training program offered to all enrollees of the Deep Space Program on Space Station 5.

A quasi-experimental design will be used with hobbit youth to determine whether their participation in the Summer Youth Space Camp Program leads to increased interest in space exploration and pursuing a career in the space sciences.

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**Data collection methods.**

**Answer:**

Data collection methods will include adaptability assessments administered to all adult participants at the beginning and end of the training intervention to measure the effectiveness of the program in enhancing the adaptability of hobbits in space. The research team will also gather routine performance evaluation records from Starfleet Academy to analyze participants' performance outcomes on space missions before and after the training intervention. Lastly, an array physiological and behavioral data such as blood pressure, heart-rate, respiration rate, sleep patterns, and level of physical activity will be measured by a novel device, the One Ring, during the isolation simulation component of the training intervention and compared to similar data of participating hobbits routinely collected as part of Starfleet missions before and after the training. These assessments and evaluations will be used to measure the effectiveness of the hobbit-specific training program.

For the youth group, a pre and post survey will be used to assess whether their interest in space exploration was influenced by participation in the annual Summer Youth Space Camp Program held in the Shire.

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**Data analysis methods (describe the specific quantitative or qualitative analyses to be performed, if applicable).**

**Answer:**

Data analysis will involve the use of descriptive and inferential statistics to determine the effectiveness of the hobbit-specific training program. Specifically, the researchers will compare the adaptability and performance outcomes of the hobbit training group and the standard treatment group using appropriate statistical tests. The data collected from the assessments will be analyzed using a mixed-design ANOVA to determine whether there are significant differences between the two groups. Performance outcomes data will be analyzed using a two-sample t-test to determine whether there are significant differences in performance outcomes between the hobbit training group and the standard treatment group. A paired samples t-test will be used to compare the differences in physiological and behavioral data before and after the training for the treatment group.

Additionally, the researchers will also use qualitative data analysis methods, such as thematic analysis, to analyze any open-ended responses provided by the participants on the surveys. These responses may be used to gain a more in-depth understanding of the participants' experiences with the training programs as well as youth participants' interest in space exploration and to identify any potential areas for improvement.

04/10/2023 2:30 PM PDT

**Does this study meet the definition of a clinical trial?**

**Answer:**  Yes  
 No

**SUBJECT POPULATION**

**Type of Subjects**

*Describe the participant pool or community from which you will enroll participants as specifically as possible (e.g., college students in a specific class, professionals in a specific field, random pedestrians). If you will be accessing secondary data about individuals or collecting biospecimens, describe whether you are targeting a specific population as part of the study analysis. If you will have multiple groups of participants, please answer the protocol application questions for all groups.*

**Answer:**

Adult hobbits of Middle Earth who are enrolled in the Starfleet Academy Deep Space Program on Space Station 5 will be asked to participate in the training intervention and to allow access to their routine performance data collected by Starfleet Academy.

Hobbit youth who enroll in the annual Summer Youth Space Camp Program in the Shire will be asked to participate in the pre and post surveys related to their interest in space exploration.

04/11/2023 11:52 AM PDT

**Rationale for Subject Selection**

*Describe why this is the appropriate population for your study (i.e., is this population the logical choice for answering your research questions or for applying an intervention?). If you will be accessing secondary data about individuals only, describe the rationale for why access to records is needed.*

**Answer:**

**Space Station 5 training intervention participants:**

Hobbits are an appropriate population for the training intervention because they have unique physical and cultural characteristics that must be considered when preparing them for deep space exploration. Hobbits are generally shorter in stature than humans and have different physical capabilities, such as the ability to see in the dark and move quietly through rough terrain. Additionally, hobbits have a unique culture that emphasizes community, simplicity, and a love of nature.

In order for hobbits to succeed in deep space exploration, they will require specialized training that takes into account these physical and cultural differences. A training program designed specifically for hobbits can help to prepare them for the challenges of space exploration, such as the need for extended periods of isolation, limited resources, and exposure to different environments. Additionally, a training program can help to build the necessary skills and knowledge for hobbits to contribute meaningfully to space exploration missions, such as the ability to navigate unfamiliar terrain and to communicate effectively with crew members from diverse backgrounds.

Overall, hobbits are an appropriate population for the training intervention because they require specialized training to prepare them for the unique challenges of deep space exploration, and a training program designed specifically for hobbits may help to address these needs.

**Summer Youth Space Camp Program participants:**

Hobbit youth who are already enrolled in the annual Summer Youth Space Camp Program are the appropriate population to measure whether the program influences their interest in space exploration.

04/10/2023 2:37 PM PDT

**Number of Subjects**

*State the expected number of participants you wish to enroll in the study as well as what a reasonable sample size would be to answer your research questions. If applicable, explain how the number of participants needed to answer the research question was determined. If you will be accessing secondary data about individuals only, describe the approximate number of subjects whose records will be accessed if known.*

**Answer:**

**Space Station 5 training intervention participants:**

A reasonable sample size for this study would be at least 50 hobbits enrolled in the Starfleet Academy Deep Space Program, with 25 randomly assigned to the hobbit training program and 25 to the standard training program.

The determination of the sample size is based on several considerations, including statistical power, effect size, and the potential for attrition or other sources of variability. A sample size of at least 50 hobbits is necessary to achieve adequate statistical power to detect meaningful differences between the two groups. Additionally, a sample size of this magnitude can help to minimize the effects of variability due to participant characteristics or other factors, and can help to ensure that the findings are generalizable to the broader hobbit population.

**Summer Youth Space Camp Program participants:**

For the youth group, all participants who are enrolled in the youth space camp program (which is being implemented independently from the research) will be approached to participate. The summer program typically has 70-100 participants annually.

04/10/2023 2:37 PM PDT

**Inclusion and Exclusion Criteria**

*State any inclusion and/or exclusion criteria, including specific subject demographics (age, race, ethnicity, gender etc.), if applicable. If prospective participants will be screened via tests, interview, etc., prior to entry into the study, explain how, where, when, and by whom the screening will be done. Information on what will be done with the data of those who do not qualify for the study should also be provided in this section. If you will be accessing secondary data about individuals, describe the inclusion/exclusion criteria for record selection, if applicable, or state N/A.*

**Answer:**

**Space Station 5 training intervention participants:**

Adult hobbits, 18+ years old, enrolled in the Starfleet Academy Deep Space Program who have completed basic training and are assigned to Space Station 5 as part of their duties. Hobbits who are in good health and free from any conditions that may impact their ability to participate in the training program, as determined by the attached screening questionnaire (see Recruitment section), will be eligible to participate. The screening questionnaire will be administered via Qualtrics and will also include the full name and email address of prospective participants. Those who do not meet the eligibility criteria will be notified that they are not eligible, and the screening questionnaire that they filled out will be immediately destroyed.

**Summer Youth Space Camp Program participants:**

Hobbit youth, ages 14+ years who enroll in the Summer Youth Space Camp Program in the Shire.

04/10/2023 2:37 PM PDT

**Selection Criteria**

*If participants will be selected from a specific group of eligible participants (e.g., only 10 students in a class of 30 eligible students will be selected), please indicate the selection criteria that will be applied.*

**Answer:**

**Space Station 5 training intervention participants:**

To ensure that the sample is representative of the population of hobbits assigned to Space Station 5, prospective participants who meet

the eligibility criteria will be randomly selected for inclusion into the study after the recruitment period ends.

**Summer Youth Space Camp Program participants:**

There are no selection criteria for the youth participants in this study – all who attend the Summer Youth Space Camp Program will be able to participate in the study if they choose to.

04/10/2023 2:37 PM PDT

**Subjects Ages**

Select the age range of subjects who will be enrolled in this study. Check all that apply.

- Answer:**  18 years or older  
 Under 18 years  
 Unknown / Access to secondary data only

If you are focusing on specific age ranges, please indicate the age ranges here.

**Space Station 5 training intervention participants:**

Though there is no upper age limit for hobbits in the training intervention, hobbits assigned to Space Station 5 range in age from 22 to 105 years old.

**Summer Youth Space Camp Program participants:**

Hobbit youth who enroll in the annual Summer Youth Space Camp Program in the Shire range in ages from 14 to 18 years old.

04/10/2023 2:37 PM PDT

**Indicate the risk category for subjects under 18 years old:**

- Answer:**  Minimal Risk  
 Greater than Minimal Risk

**Vulnerable Populations**

Please check the population(s) that will be enrolled. Check all that apply.

- Answer:**  Minors (any person under 18 years old)  
 Adults with impaired decision-making capacity  
 Prisoners  
 Pregnant women  
 Other  
 None of the above

If human subjects are children, have impaired decision-making capacity, or are part of other legally restricted groups, please answer the following questions:

**1. Explain the necessity of using these particular groups.**

**Answer:**

Because one part of the study seeks to assess the impact of the Summer Youth Space Camp Program on young hobbits' interest in space exploration, it is necessary to include a diverse sample of participants engaged in the program, many of whom are under the age of 18.

**2. Describe any special arrangements to protect their safety.**

**Answer:**

As this is a minimal risk study, standard parental permission will be sought to safeguard the interests of youth in the Summer Youth Space Camp Program who express interest in the study.

A code will be used to link the pre and post surveys so that direct identifying information will not be available to anyone except to the student investigator, Tasha Yar, and her faculty supervisor Dr. Picard. All other research team members will only have access to de-identified data.

04/11/2023 11:53 AM PDT

**Prior Associations with Research Team**

**Are the potential participants already known to the researcher or research team?**

- Answer:**  Yes  
 No

**Explain how participants are known and to whom.**

Some hobbits on Space Station 5 who are eligible for the study are former colleagues of the student investigator, Tasha Yar. Participants

will be randomly selected from all eligible participants who express interest in being included in the study.

04/05/2023 10:28 AM PDT

### Potential Interpersonal Conflicts of Interest

**Do any members of the research team have a supervisory role over potential participants, provide services to the targeted population outside of the research, or serve in a dual role that may result in a power imbalance between researchers and the participants (e.g., teacher/student, employer/employee)?**

**Answer:**  Yes

No

**Identify which members of the research team have a supervisory role over potential participants or provide services (such as treatment, assessment, or training) to the targeted population outside of the research, and explain the nature of the relationship to potential participants.**

**Answer:**

Mr. Smeagol, chair of the Hobbit Community Advisory Board (HCAB), is responsible for all aspects of the Summer Youth Space Camp Program from which youth participants will be recruited.

04/10/2023 2:42 PM PDT

**What precautions will be used to minimize the power imbalance or potential for coercion of participants who are also clients or individuals who receive services from members of the research team outside of the research context?**

**Answer:**

While he will assist in advertising the study to participants in the Summer Youth Space Camp Program by sending out recruitment flyers to the space camp mailing list on behalf of the research team, Mr. Smeagol and HCAB will not receive any direct identifying information about study participants. Indirect identifying information will be sufficiently aggregated to prevent identification of specific participants when the results are disseminated.

04/10/2023 2:42 PM PDT

## RECRUITMENT

### Recruitment/Enrollment Procedures

*Explain how, where, and when prospective participants will be identified and approached for study participation. Make sure to be clear about how the research team will gain access to participants, what will be said to them, and to outline which members of the research team will conduct the recruitment. If you will be accessing secondary data about individuals, please describe how you have access to such data and what type of permission you have to access private and protected data (e.g., medical, academic, employment, or financial records). If you will have multiple groups of participants, please answer the questions for all groups.*

**Answer:**

#### Space Station 5 training intervention participants:

A mass email will be sent by student investigator Tasha Yar to all hobbits who work on the station several months prior to the training intervention. The contact list will be provided by Starfleet Academy. In addition, recruitment flyers with contact information for the study team and a QR code to a study-specific webpage will be posted in public areas of Space Station 5 that hobbits are likely to frequent. Those who respond with an interest will be directed to the study-specific webpage for more information as well as to an eligibility screening questionnaire via Qualtrics. Those who complete the questionnaire will be informed that they will be contacted after the recruitment period ends regarding whether or not they were selected to participate.

Secondary data in the form of performance evaluations, physiological, and behavioral data collected during routine space missions of hobbits enrolled in the study will be provided by Starfleet Academy after the research team obtains consent from the subjects. Information on which performance evaluations will be accessed, who will have access, and how the data will be protected will be provided on the study consent document for training intervention participants.

#### Summer Youth Space Camp Program participants:

Mr. Smeagol will send an email script prepared by the research team to the mailing list for the Summer Youth Space Camp Program. The recruitment script is included in the attachments. The message will reach both space camp participants and their parents and will include a link to a research-specific webpage where they will be able to learn more about the study, contact the study team if they have any questions, access a link to sign-up for the study, and download the parent permission and assent documents. Parents will be encouraged to discuss the study with their child and will also be given instructions on how to return the parent permission form to the study team. Once parents return the form, youth will be sent an invitation to fill out the online surveys before and after the program, with assent information embedded into the text preceding the surveys.

04/10/2023 2:48 PM PDT

### Recruitment Materials Description

*List any recruitment materials that will be used; note the type of media and where they will be posted.*

**Answer:**

Email scripts for each group (attached), recruitment flyers for each group (attached), web content on a page created specifically for the study for the youth group (attached and also available at the following link ), web content on a page created specifically for the training intervention group (attached and also available at the following link )

04/10/2023 2:48 PM PDT

### Recruitment Materials Attachment(s)

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

#### Answer:

-  Screening Survey - Training Intervention .pdf 04/10/2023 (Recruitment Materials)
-  Email Script - Training Intervention.pdf 04/10/2023 (Recruitment Materials)
-  Email Script - Youth Survey.pdf 04/10/2023 (Recruitment Materials)
-  Flyer - Training Intervention.pdf 04/10/2023 (Recruitment Materials)
-  Flyer - Youth Survey.pdf 04/10/2023 (Recruitment Materials)
-  Web Content - Training Intervention.pdf 04/10/2023 (Recruitment Materials)
-  Web Content - Youth Survey.pdf 04/10/2023 (Recruitment Materials)
-  Study Sign-up Form - Summer Youth Space Camp.pdf 04/10/2023 (Recruitment Materials)

04/10/2023 3:29 PM PDT

## CONSENT

### Indicate the type of consent document(s) that will be used.

If different consent documents will be used for different participants or methods, check all that apply. Links to the most commonly used consent document templates have been provided with each checkbox. If no link has been provided, refer to the [Informed Consent Handbook](#) posted on the SJSU IRB website for details about the consent type. For studies that include multiple consent documents, you will need to indicate the subject population or method to which each attached document applies as part of the file name. Please make sure that the consent documents that you will attach correspond to the checkboxes you have marked here. If the study involves only secondary data and it has been established that consent is not required, please mark the "no consent will be sought" checkbox.

**Answer:** No consent will be sought

- Standard consent form** (written consent form, signed by participant)

**Standard consent form, unsigned** (you will use the standard template but are requesting a waiver of signatures; make sure to remove the signature lines from the template and replace with appropriate verbiage instructing participants to keep the document for their records)

**Consent notice** (written consent document with basic information, unsigned by participant; typically permissible only for research that qualifies for exemption)

- Parent or guardian permission form**

Standard consent short form and script (verbal consent only)

*Note: this option should only be used if participants have limited literacy or are otherwise unable to read a consent document.*

Altered consent form (some of the standard elements of consent are omitted).

*Note: this option should not be checked if you are using a consent notice. This option is typically used when the study involves deception or incomplete disclosure on the consent document.*

03/30/2023 5:08 PM PDT

### Consent Document Attachment(s)

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

Make sure that your consent document(s) are each submitted as separate attachments; that they meet the requirements for stamping by the IRB office; and that they are presented in their final form as participants will see them (no highlights or track changes).

#### Answer:

-  Consent Form - Training Intervention.pdf 04/10/2023 (Consent Documents)
-  Parent Permission Form - Youth Survey.pdf 04/10/2023 (Consent Documents)
-  Consent/Assent Notice - Youth Survey.pdf 04/10/2023 (Consent Documents)

04/10/2023 3:00 PM PDT

### Who will obtain consent and who will be available to answer participants' questions?

Please provide specific names if you listed multiple team members in the study personnel section.

#### Answer:

Tasha Yar will obtain consent and be available to answer participants' question. Dr. Picard will also be available to answer participants' questions.

04/05/2023 10:40 AM PDT

**How, when, and where will consent be obtained (in person, by email, by mail, via web, signed, unsigned, etc.)?**

Please note that if you plan on obtaining signed consent remotely, you will need to use a third party application like *DocuSign* via your SJSU single sign-on account. Email is not a method for getting signed consent unless you plan on having participants scan a signed version of the consent document.

**Answer:**

**Space Station 5 training intervention participants:**

Prospective participants will be sent an invitation email with a link to the consent form if they meet the eligibility criteria and are selected to be in the study. The link to the consent form in DocuSign will be distributed two weeks prior to implementation of the training via email. Both participants in the hobbit-specific training and in the standard training will be given a consent form that explains that they will be randomly assigned to one of the two groups. Hobbits may sign the consent form via DocuSign at any time during this two-week period or they may return the signed consent form to the first training orientation session that is held for both groups. The training orientation provides an additional opportunity, in the form of a break out group, for prospective participants to have their questions answered.

**Summer Youth Space Camp Program participants:**

Parent permission forms will be accessible online to anyone who receives the recruitment email. Instructions will be provided on how parents can return the signed consent document, including: 1) uploading a scanned signed copy to the study website, or 2) following a link to a DocuSign version of the document, or 3) returning the consent document in-person during the Summer Youth Space Camp kickoff event. For youth who are 18 years old, parent permission will not be required and there will be a consent information sheet for them to download from the website. The same information sheet will also be embedded into the text preceding the survey. Youth who are 18 years old will confirm their age when they sign-up to receive an invitation to the survey on the website sign-up form.

04/11/2023 11:54 AM PDT

**What language(s) will be used to obtain consent?**

**Answer:**

English

**Do you anticipate the need to obtain informed consent from a legally authorized representative (LAR) in cases where the subject population under consideration may have impaired decision-making ability?**

**Answer:** Yes

No

**ASSENT**

**In addition to procedures outlined in the previous section for obtaining consent from a parent, guardian, or Legally Authorized Representative (LAR), does the study team plan to obtain assent from the minors and/or adults with impaired decision-making capacity?**

**Important Notes:**

- *Minors or adults who have impaired decision-making ability should still be informed about the research and asked for their permission to participate, whenever possible, in a manner appropriate to their condition or age.*
- *Although consent must be first be sought from the parent, guardian, or LAR before assent is sought, in most social and behavioral research the wishes of the subject override the consent of the parent, guardian, or LAR.*

**Answer:**  Yes

No

**Who will obtain assent and who will be available to answer participants' questions?**

Please provide specific names if you listed multiple team members in the study personnel section.

**Answer:**

Tasha Yar will obtain assent and be available to answer participants' questions.

**How will assent be obtained in a way that takes into account the age, developmental ability, and cognitive capacity of the subject (e.g., verbal vs. written assent)?**

**Answer:**

Because participants are adolescents, they will be given an information sheet – an “assent notice” that they can read through. The assent notice approximates a 6th grade reading level. The same information sheet will be used for youth who are 18 years old and who do not need parent permission.

**When and where will assent be obtained?**

**Answer:**

After receiving parent permission, Tasha Yar will send an email invitation to those youth whose parents provided permission as well as to youth participants who are 18 years old, with a link inviting them to complete the survey for the research. The assent notice will be embedded into the text preceding the survey. An invitation email will be sent once before the Summer Youth Space Camp Program begins

as part of the kickoff event, and once after the program closes.

**What language(s) will be used to obtain assent?**

**Answer:**

English

**Indicate the type of assent document to be used.**

Descriptions of the various types of assent documents are outlined in the *Informed Consent Handbook* posted on the SJSU IRB website. Check all that apply if the study includes different age groups or individuals with different cognitive capacities.

**Answer:**

- Assent form (written form, signed by participant)
- Assent notice (written form, unsigned by participant)
- Assent script (verbal assent only)

**Assent Document Attachment(s)**

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

**Answer:**

 Assent Notice.pdf 04/10/2023 (Assent Documents)

**STUDY PROCEDURES**

**Does the study involve accessing secondary data only?**

**Important Notes:**

- If you will be doing an intervention, interacting with, observing, or collecting data from human subjects, select NO.
- If you will be initiating an anonymous survey, this is still considered to be an interaction even if you have no in-person contact and even if participants are anonymous - please select NO in this case.
- If you will be doing a mixed methods study that includes secondary data analysis along with interaction or collecting data from participants, please select NO.

**Answer:**

- Yes
- No

**Description of Procedures**

**List procedures in which the participants will take part in a chronological manner.**

Include only those procedures that involve the participants (e.g., interventions/interactions, data collection procedures). Do not include procedures that the researcher will be doing separately (e.g., literature review, transcribing recordings, data analysis).

**Answer:**

**Space Station 5 training intervention participants:**

Participants who meet the eligibility criteria and provide consent will be randomly assigned to either the hobbit-specific training intervention or the standard training. All participants will:

1. Attend an orientation session.
2. Complete a pre-training adaptability and demographic survey via Qualtrics.
3. Participate in a 4-week training program
4. Complete a post-training adaptability assessment, via Qualtrics.

**Summer Space Camp Program survey participants:**

All youth in the program whose parents provided permission to have their child participate in the research or who are 18 years old and expressed interest in participating in the study will be sent an invitation to complete a pre and post program survey. They will be provided with a Qualtrics link that includes assent information at the start of each survey. If they agree, they will:

1. Fill out an initial survey before the program begins (the survey will be open for one week prior to the program initiation).
2. Fill out a survey after participating in program (the survey will be open for one week after conclusion of the program).

**If applicable, describe the content of and procedures for any intervention that will be applied with participants. Please also delineate the nature of the intervention - behavioral, educational, or physical.**

**Answer:**

The 4-week training intervention for hobbits on Space Station 5 will consist of three components tailored to the unique physical and cultural characteristics of hobbits that are educational, physical, and behavioral in nature: 1) nutritional education (week 1), physical

fitness training (weeks 2 and 3), and isolation training (week 4). A detailed description of the daily activities is attached to this application under the Other Study Attachments section. The following is a summary of the intervention components:

**Week 1: Nutritional education.** The nutritional education component of the training intervention for hobbits will take into consideration the need for hobbits to eat at least 6 meals a day - breakfast, second breakfast, elevensies, luncheon, afternoon tea, dinner and supper - as is customary in hobbit culture. Hobbits are known for their love of traditional, home-cooked meals, so the nutritional education component will focus on teaching hobbits how to cook healthy and delicious meals using space-friendly ingredients and equipment.

**Week 2: Physical fitness training.** Hobbits will participate in a physical fitness training program designed to improve their strength, endurance, and flexibility that takes into consideration their smaller stature and sedentary lifestyle. The program will include both cardiovascular and strength training exercises, as well as yoga and other flexibility exercises to help hobbits maintain their physical and mental well-being during long space missions.

**Week 3: Gravity adaptation training.** Hobbits will receive training in how to adapt to different gravity environments they may encounter during deep space exploration. This will include exercises to help them develop the necessary muscle strength and coordination to navigate low-gravity environments.

**Week 4: Isolation training.** Hobbits will be trained in techniques to manage isolation and confinement during long space missions that incorporate hobbit cultural values and practices such as storytelling, music, and nature appreciation. Participants will spend five consecutive days in a simulated isolated environment where they will be disconnected from the outside world and will be required to wear the One Ring that tracks their physiological and behavioral responses.

**If applicable, describe the content of cognitive, psychological, or usability tests that will be employed using a computer or mobile device. You will be asked to provide screenshots of any computer stimulus in the Data Instruments and Recording Devices section later in this application.**

**Answer:**

N/A

**Explain who will conduct the procedures and where and when they will take place.**

*Please provide specific names if you listed multiple team members in the study personnel section. If you will be using an online or third party vendor or application to disseminate your data instruments to participants, please provide the name of the online or third party vendor/application.*

**Answer:**

The Space Station 5 training intervention will occur on Space Station 5, with week 1 activities occurring in the test kitchen teaching area, week 2 activities occurring in the gym, week 3 activities occurring in the anti-gravity rooms, and week 4 activities occurring in the isolation simulation tanks. Pre and post assessment surveys will be completed by participants online via Qualtrics. Study activities are tentatively scheduled begin in the Fall on star date 42/42/42 after the Summer Youth Space Camp Program ends.

Tasha Yar, Dr. Picard, and Wesley Crusher will conduct the procedures related to the hobbit-specific training intervention, while a qualified and experienced instructor will conduct the standard invention, which will occur regardless of the research activities.

The Summer Space Camp Youth Program will occur in July. The pre and post surveys will be completed by participants online. Tasha Yar will be managing the survey via Qualtrics.

**Indicate the frequency and duration of each procedure as well as the total time commitment for participants in the study.**

**Answer:**

The Space Station 5 training intervention will occur over a 30-day period. Except for the simulated isolation component of the intervention, all intervention activities will occur during routine business hours with scheduled breaks. The 5-day isolation exercise will be an immersive 24-hour experience, with a schedule of daily activities that will include physical exercise, meals, meditation, reading, creative pursuits, and sleep. The pre and post training assessments are expected to take 30 minutes each to complete. A breakdown of the daily schedules is included on the detailed intervention plan attached to this application.

The pre and post surveys for the Summer Youth Space Camp Program participants are expected to take 20 minutes each to complete.

**Describe appropriate alternative resources, procedures, or courses of treatment, if any, that are available to prospective participants who choose not to participate or are excluded from the current study.**

**Answer:**

All individuals assigned to Space Station 5 who are enrolled in the Starfleet Academy Deep Space Program are required to complete a 4-week training program. Hobbits who choose not to participate in the study, who are ineligible to participate, or who are assigned to the control group for the study will complete the standard training program.

## Classroom Setting

**Will the study take place in a classroom setting (whether in-person or online) with student participants?**

*Note: this question does not pertain to a lab setting where students may arrive because they have signed up to be part of an experiment.*

**Answer:**  Yes

No

**Explain what activities will be required as part of the normal class activities and what activities will be voluntary as part of the research (be sure to include this information on your consent and/or assent document).**

**Answer:**

All aspects of the hobbit-specific training are optional. However, participants who enroll in the study, are assigned to the treatment group, and withdraw will be required to complete the standard training that is a condition of their involvement in the Starfleet Academy Deep Space Program.

**What will students who choose not to participate in the research do?**

**Answer:**

Hobbits who choose not to participate in the study will complete the standard training program.

**If students will miss class to participate in the research, indicate how they will make up the work.**

**Answer:**

N/A

### **Deception or Incomplete Disclosure**

**Does the study involve deception or providing incomplete information to participants initially?**

**Answer:**  Yes

No

**Explain what the deception or incomplete disclosure will entail (e.g., the consent form will not reveal complete details about the purpose of the study).**

**Answer:**

Hobbits in the training intervention who undergo the isolation simulation will not be told that the technical name of the monitoring device and panic button that they will be wearing is the "One Ring." Instead, the research team will refer to the device by its colloquial designation, "Fitbit."

**Explain why the use of deception or incomplete disclosure would fulfill the research purpose better than non-deceptive methods or full disclosure in terms of the study's prospective scientific, educational, or applied value (e.g., deception or incomplete disclosure is needed to minimize biased responses).**

**Answer:**

Some hobbits may develop a mistaken association with the term "One Ring" that could influence their behavior and affect the validity of the study results. For example, a hobbit may believe that the ring makes them invisible, which may affect their behavior. The purpose of the device and how it works will be disclosed in detail as part of the initial consent process and during the pre-simulation orientation; the name brand will be the only information that will not initially be disclosed.

**Describe the plan to debrief the participants and include the debriefing text that will be used to explain the deception or incomplete disclosure to participants after their participation or after the study is completed.**

**Answer:**

Participants will have a recovery period and debriefing session upon exiting the isolation simulation during which they will be told the following:

As you may have noticed, we provided you with a device typically referred to as a "Fitbit" to monitor physiological and behavioral changes during the isolation simulation. We want to inform you that the technical term for the device is the "One Ring" (manufactured by One Ring, LLC). Though we provided you with details about how this monitoring device works before the simulation, we did not disclose the technical name of the device as the "One Ring" in order to prevent any unintended changes in your behavior during the study, which could have affected the scientific validity of our findings.

We would like to emphasize that the device was only used for monitoring purposes and that no harm was intended. Your safety and well-being were our top priority during the entire simulation. We apologize for any confusion this may have caused and would be happy to answer any questions you may have.

### **Costs to Participants**

**Are there any costs to participants (e.g., transportation to research location, parking expenses, child care, medical/clinical procedures such as labs or medical imaging)?**

**Answer:**  Yes

No

### **Incentives or Compensation for Participants**

**Will any incentives or compensation be provided to participants in the study (e.g., cash payment, gift card, extra credit, free treatment, free materials)?**

**Answer:**

- Yes  
 No

List the incentives/compensation type and amounts to be provided to participants.

**Important Notes:**

- If your research is funded, make sure that the sponsor allows the form of incentive/compensation you wish to provide.
- If students will receive extra credit, please indicate the amount and describe the alternative equivalent method(s) that will be available for earning extra credit for those who do not wish to participate in the research. Repeat on the consent document.
- If you will be offering only partial incentive/compensation for those who do not complete the entire study, or if the study will include attention checks that could potentially disqualify participants from receiving the incentive/compensation, please disclose this here and on the consent document.

**Answer:**

**Space Station 5 training intervention participants:**

Hobbits in both groups on Space Station 5 will be provided with a box without hinges, key, or lid, yet golden treasure inside is hid.

**Summer Youth Space Camp Program participants:**

Hobbits who complete the youth surveys will not be provided with an incentive for participation.

**Will you need to collect identifying information about participants in order to award the incentive/compensation to them (e.g., names, addresses, social security numbers)?**

- Answer:**  Yes  
 No

**Please list the type of identifying information that will be collected, who will collect it, and whether it will be shared with non-study personnel (e.g., academic departments, the Research Foundation, the sponsor).**

**Important Notes:** any direct identifiers collected for the purposes of awarding incentives/compensation to subjects must be listed in the data management plan section of this application and all relevant aspects of the data management plan must be filled out as it relates to the use of identifiers for awarding incentives/compensation (e.g., security, level of access, retention and disposition). Please only collect the minimum amount of identifying information necessary to award the incentive. In some cases the IRB may ask that the PI instruct participants to contact the department or office that is requesting the information for business accounting purposes rather than having the research team members collect the information.

The names of the hobbits who participated in the study will be provided to the central office on Space Station 5 so that they may deliver the golden treasure to each hobbit's living quarters. Hobbits will be informed that the names of participants will be provided to the central office for this reason.

## DATA INSTRUMENTS AND RECORDING DEVICES

**Briefly describe the information to be gathered and the means for collecting and recording data. If previously collected secondary data is also to be used, describe both the previous and proposed uses of these data.**

**Answer:**

**Space Station 5 training intervention participants:**

- Eligibility screening questionnaire via Qualtrics (attached under Recruitment section).
- A pre and post intervention adaptability survey via Qualtrics. The pre survey will also collect demographic information. (attached)
- Physiological and behavioral measures will be collected during the isolation simulation component of the training, including sleep patterns, levels of physical activity, mood, heart rate, blood glucose, blood pressure, respiration rate, body temperature, and skin conductance. The One Ring device will be used to collect the data and transmit it to the research team. See the medical devices section for more information on the One Ring.
- Secondary data containing the same physiological and behavioral measures collected by Starfleet Academy as part of routine space missions of hobbit participants before and after the intervention.

**Summer Space Camp Youth Program participants:**

- Study sign-up form via Qualtrics (attached under Recruitment section).
- Pre and post event surveys measuring interest in space exploration and career goals via Qualtrics (attached).

**Study Instrument Types**

Check all that apply.

- Answer:**  Survey/Questionnaire  
 Individual Interview  
 Group Interview  
 Test

- Observational Notes
- Other
- No study instruments will be used

### Study Instruments Attachments

Review our [user guide for file requirements before you upload any files](#). This is required reading if you will be uploading an attachment.

**Answer:**

-  Pre and Post Survey - Training Intervention.pdf 04/10/2023 (Data Instruments)
-  Pre and Post Survey - Summer Youth Space Camp.pdf 04/10/2023 (Data Instruments)

04/10/2023 3:28 PM PDT

**Indicate what types of recording devices will be used.**

*Check all boxes that apply and answer any accompanying questions.*

- Answer:**
- Audio recording only
  - Audio and video recording
  - Photography
  - Biometric or physiological recording (e.g., eye-tracking, blood pressure)
  - Other (e.g., note-taking on computer or pen and paper)
  - No recording devices will be used

04/10/2023 3:29 PM PDT

**Please explain:**

1. What kind of device will be used?
2. What/who will be recorded?
3. Will the recording be transcribed or edited? If so, by whom (if possible, identify a specific person or vendor)? Will the transcription or edits contain identifying information or potentially identifying information about participants?
4. How will the recordings be used? Will the recordings be shared? If so, how and with whom?

**Answer:**

A video-recorder will be set up during the physical fitness component of the intervention for the hobbits on Space Station 5. Individual hobbits will be recorded by Tasha Yar. The recording will not be edited or shared outside of the study team except with the participants. Each hobbit will receive a recording of their physical fitness sessions so that they may refer to it in the future and continue to incorporate the training into their daily lives. The research team's copy of the recordings will be deleted 3 years after completion of the study.

Physiological and behavioral data during the isolation simulation component of the training will be recorded via the One Ring device - see the Medical Devices section for details. These recordings will automatically have the study ID for each participant included rather than any identifying information. The data collected by the One Ring will only be used for analysis and the raw data files will only be accessible to Tasha Yar and Dr. Picard.

## MEDICAL DEVICES

**Will the study involve administering a medical device or mobile medical app or platform?**

- Answer:**  Yes  
 No

**Provide the name(s) and a brief description of the function of the medical device(s) or mobile medical app(s) or platform(s) to be used in the study.**

**Answer:**

The One Ring.

The one ring to rule them all, one ring to find them, one ring to bring them all, and in the darkness bind them.

04/10/2023 3:35 PM PDT

**Is this study designed to evaluate the effectiveness and/or safety of any of the above listed medical device(s) or mobile medical app(s) or platform(s)?**

- Answer:**  Yes  
 No

**Please mark whether any of the below conditions apply to the investigational medical device or mobile medical app or platform.**

**Answer:** The medical device/mobile app or platform under study is of an already cleared, commercially available medical device/mobile app or platform that is being investigated in accordance with the indications in the approved labeling.

The medical device/mobile app or platform under study is substantially equivalent to one in commercial distribution that is being investigated in accordance with the indications in the approved labeling.

The medical device/mobile app or platform under study is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more medical devices/mobile apps or platforms in commercial distribution, AND the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

The medical device/mobile app or platform under study is an in vitro diagnostic device that is (all 4 conditions must apply if this check box is selected):

1. Noninvasive;
2. Does not require an invasive sampling procedure that presents significant risk;
3. Does not introduce energy into a subject;
4. AND is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.

The device under study is a custom device AND the device is NOT being studied to determine safety and efficacy for commercial distribution.

The device under study is intended solely for veterinary use or shipped solely for research on lab animals (i.e., no human subjects).

None of the above conditions apply.

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**Describe how the medical device works. In the case of a mobile medical app or platform describe what service(s) it provides to users and how this is accomplished.**

**Answer:**

In the context of this training intervention, the One Ring's role is to measure physiological and behavioral data in an unobtrusive way. While hobbits wear the ring, their activity and physiological information will be recorded. This includes sleep patterns, levels of physical activity, mood, heart rate, blood glucose, blood pressure, respiration rate, body temperature, and skin conductance. The One Ring will also serve as a panic button, allowing participants to immediately end the isolation simulation.

04/10/2023 3:36 PM PDT

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**Attach diagram(s) and photo(s) of the device that illustrate how it works. In the case of a mobile medical app or platform, attach screenshots illustrating or storyboarding how it will be used in the current study.**

**Answer:**

-  Hobbit Training Intervention Daily Schedule.pdf 04/10/2023 (Additional Documentation) (Existing)
-  Letter of Support - HBAC.pdf 04/10/2023 (Additional Documentation) (Existing)
-  List of References.pdf 04/10/2023 (Additional Documentation) (Existing)
-  One Ring Schematic and Technical Details.pdf 04/10/2023

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**Is the medical device/mobile app or platform a non-significant risk (NSR) device?**

**Answer:**  Yes  
 No

04/10/2023 3:37 PM PDT

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**The study does not require submission of an Investigational Device Exemption (IDE) application to the FDA unless the IRB or study sponsor informs you otherwise, but the PI or study sponsor must ensure that **abbreviated requirements are followed**.**

## SUBJECT IDENTIFIERS

**Will investigators know, have access to, or collect any direct identifying information about participants or data subjects?**

*Examples of direct identifying information: names or signatures on the consent form, names via teleconferencing software (e.g., Zoom screen name), names via social media profiles, contact information for participants (including email addresses comprised of names), unique ID numbers not created for the study (e.g., student ID, social security number, medical record number, employee ID), unique device numbers (IP addresses), biometric information (fingerprints, eye scans), labeled biological specimens, photographs, and video recordings.*

**Important Notes:**

- In most interview situations, the identity of the participants is known to the research team, even if names are not recorded. Unless special interview procedures are in place to ensure that the identity of participants will not be known to the research team, please mark yes here.
- You must mark yes in this section even if study personnel have plans to de-identify or discard direct identifying information.

**Answer:**

Yes

No

**Will investigators know, collect, or have access to any indirect identifying information that, when combined, could reasonably result in the identification of participants or data subjects (either to the research team or to anyone with access to the study report/results)?**

*Examples of indirect identifying information that could be combined to identify participants include gender, racial or ethnic identity, age, date or place of birth, location information, employment information, social media handle/username, certain metadata, physiological characteristics like weight and height.*

**Important Notes:**

- You do not need to mark yes here if the number of indirect identifiers that will be collected is low and/or the number of participants is high. Please use your best judgement in estimating whether it may be possible to reasonably identify participants.
- Keep in mind that if the subject population is known to members of the research team it may be easier to identify participants based on indirect identifiers. For example, if you are collecting data from students in a class that you teach and you ask study participants to provide their age, race, and gender, the participants may be reasonably identified, especially if the demographic information is combined with other contextual information collected by your study instruments.

**Answer:**  Yes

No

**Please list the indirect identifiers that may potentially identify participants or data subjects when combined.**

**Answer:**

**Space Station 5 training intervention participants:** age, gender, height, weight.

Hobbits will be assigned a study ID that will be connected to the surveys as well as to detailed physiological and behavioral measurements collected during the training and similar measurements collected by Starfleet Academy during routine space missions.

**Summer Space Camp Youth Program participants:** age and gender.

04/10/2023 3:42 PM PDT

**What security measures will be used to protect the indirect identifying information?**

**Answer:**

Information for both groups will be stored in Qualtrics associated with Tasha Yar's SJSU account as well as on an institutional desktop computer with password protection.

**Will any of the indirect identifiers that may potentially identify participants or data subjects be reported or shared outside of the research team?**

**Answer:**  Yes

No

## DATA MANAGEMENT PLAN

### Data Inventory

**What kind of direct identifying information will be known to the research team or collected from participants?**

**Answer:**

**Space Station 5 training intervention participants:** name, email address, video recordings, digital signatures.

**Summer Space Camp Youth Program participants:** name and parents' name, email address for youth and parents, digital signatures from parents.

04/10/2023 3:44 PM PDT

**What is the intended use for the identifying information?**

**Answer:**

Except for video recordings, all identifying information from both the training intervention group and the youth group will be used for contacting participants, screening for eligibility, and conducting consent and assent. The video recordings of hobbits in the training intervention will be used to provide hobbits with a record of the physical fitness sessions for their future use.

04/10/2023 3:44 PM PDT

**Do any of the data elements that will be collected or known fall into Level 1 or 2 of the **SJSU Information Classification Scheme**?**

**Answer:**  Yes

No

**List the Level 1 or Level 2 data elements that will be collected or known.**

Digital signatures are level 1 information.

04/10/2023 3:44 PM PDT

**Indicate the format for identifying information that will be recorded or collected. Check one.**

- Answer:**
- Digital only
  - Paper only
  - Both digital and paper
  - Identifying information will be known but not recorded or collected

**Storage, Security, and Safeguards**

**Where will digital or paper files containing direct identifying information be stored and what specific devices will be used for the storage of digital data?**

*Describe the location for storing papers that contain identifying information and any personal device(s), institutional device(s), institutional shared drive(s), etc. for storage of identifying information in digital format. Identify the data elements to be stored in each location. If data will be stored on portable devices (phones, memory sticks, laptops), please also explain where the portable devices will physically be stored when not in use.*

**Answer:**

Names and email addresses for prospective participants (and their parents in the case of youth participants) will be compiled from the Qualtrics sign-up forms or from email communications into Excel spreadsheets. These spreadsheets, along with the screening questionnaires for the intervention participants who meet the eligibility criteria, their physical fitness video-recordings, and digitally signed consent forms will be stored on a password protected institutional desktop computer in a study-specific folder that is password protected. Digitally signed consent forms will also be stored in the Docusign system associated with Tasha Yar's SJSU account. Study sign-up information collected via Qualtrics as well as permission forms that parents may chose to upload to the study-specific website will be temporarily stored in the Qualtrics and OU campus systems associated with Tasha Yar's SJSU account. These items will be promptly transferred to the password protected desktop folder and deleted from the cloud-based accounts.

Consent forms that are signed in paper format will be scanned and saved in the same password protected folder as above. The paper versions will be stored in a locked file cabinet in Tasha Yar's office.

**What kind of security features (physical and/or technical safeguards) will be in place for each of the files, devices, cloud-based locations, or papers where direct identifying information will be stored?**

*Examples of safeguards include password protection for digital files and locked storage containers for physical files.*

**Answer:**

Password protection for desktop computer and study folder on computer.  
Password protection and SJSU two-factor authentication for documents in Docusign, Qualtrics, and OU Campus.  
Locked file cabinet for paper documents.

**If research data will be de-identified, please explain the method and timing of the de-identification procedures, as well as who will be responsible for de-identification.**

*Refer to the [SJSU Data Management Handbook](#) for a table of de-identification methods.*

**Answer:**

Except for the screening questionnaires and physical fitness video-recordings, all data associated with the training intervention participants will only be identified by the study ID assigned to each participant and not with any direct identifying information. The screening questionnaires and videos will not be de-identified but will be destroyed after the retention period has passed (see retention and disposition section of this application).

Study sign-up surveys for youth participants will not be de-identified but will be destroyed after the study. No direct identifiers will be associated with the survey responses of youth participants.

04/11/2023 12:00 PM PDT

**If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored and how it will be protected. Likewise, if consent forms will be stored separately from the data, please state where each will be stored.**

**Answer:**

Participants in the training intervention will be assigned a study-specific ID, which they will input into the Qualtrics pre and post surveys to connect the surveys for each participant. This study ID will also automatically be associated with measurements collected by the One Ring. For secondary data supplied by Starfleet Academy, Tasha Yar will provide the name and study ID of each participant so that Starfleet may send the requested records with names and any other identifying information already removed. The transferred records will only include the study ID. All records which only include the study ID will be stored in a Google Drive associated with research team members' SJSU accounts.

The key to the code linking the identities of intervention participants with their data will be stored on a password protected, non-networked external hard drive, which will also be stored in a locked file cabinet.

Starfleet Academy will also have a key to the code. The management of this key – storage, retention period, and destruction – **has been established by a data use agreement between SJSU and Starfleet Academy.**

The pre and post surveys for youth will be connected to one another via a code that will be given to participants when they are sent the invitation email and which they will input into the Qualtrics pre and post surveys to connect the surveys for each participant. The code will only be used to correlate the pre and post surveys to one another, and no key linking the survey to specific participants will be created.

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**If members of the research team will be traveling internationally with identifying information, describe any additional security protocols that will be in place for the devices on which data will be stored during travel.**

Please see the [Office of Research International Travel Guidance page](#) for more information.

**Answer:**

All activities will occur in federation space.

## Access

**Which of the team members listed in the personnel section of this application will have access to identifying information about participants?**

If applicable, list the identifying data elements that each team member will have access to, as well as which team member will be given passwords, coding keys, and other access tools. Student-led research must allow the primary investigator/faculty supervisor to have access to all research information.

**Answer:**

Tasha Yar and her faculty supervisor, Jean Luc-Picard, will have access to all identifying information.

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**Will access to identifying information be granted to individuals, institutions, or vendors who are not part of the research team or who do not have a contract with SJSU?**

This includes vendors not contracted with SJSU to which you may direct participants (e.g., online experiment or usability platforms) or which you will use for data processing or analysis (e.g., transcription or translation services).

You do not need to mark "yes" if the research team will be using SJSU licensed software (e.g., Qualtrics, Zoom, Google Forms) as long as the software will be accessed and implemented via SJSU single sign-on.

**Answer:**  Yes

No

**Please identify:**

1. Who else will have access and what specific data elements will be provided to the third party.
2. The rationale for providing the access.
3. How access will be provided.
4. What steps will be in place to ensure proper handling of the identifying information by third parties.

**Note:** depending on the level of sensitivity of the data to be shared, the study PI may be instructed by the IRB to establish a contract between SJSU and the vendor, institution, or individual who will have access to the data. You will be provided with further information about this, if necessary.

**Answer:**

Space Station 5 central office will be provided a list of names of participants of the training intervention so that they may distribute the incentive/gift to participants' living quarters. Participants may opt out of receiving the incentive.

## Dissemination

**Will any information that could result in the identification of participants be reported in the research findings?**

**Answer:**  Yes

No

**What mechanisms will be used to maintain the confidentiality of identifying information in the reporting of the research findings?**

Use of a coding system, pseudonyms, reporting data in aggregate, etc., are examples of mechanisms used to maintain confidentiality. Repeat on consent document, if applicable.

**Answer:**

Findings will be presented in aggregate/summary format in such a way that specific individuals could not be readily identified.

**Are there any limits to your team's ability to maintain confidentiality?**

Examples include *mandated reporting requirements; Title IX reporting requirements; group interviews, where researchers cannot guarantee that participants will not disclose what was shared outside of the group; a small number of subjects where highly specific demographic or contextual information is being disseminated.*

Answer:  Yes  
 No

**Please explain the limits to confidentiality.** Repeat on consent document, if applicable.

Training intervention participants will complete the training as a cohort. It is possible that participants who are known to one another may be able to deduce the identities of individuals who were part of their cohort from the research findings. Every effort will be made by the research team to limit or omit the inclusion of contextual information in the research findings that could result in the identification of specific individuals.

Researchers also cannot guarantee that participants will not discuss their experience outside of the cohort in a way that reveals the identity of other participants.

While expectations for adhering to confidentiality will be discussed with participants, these limitations will be explained on the consent document.

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**Will data or research findings be shared with any external institutions from which subjects were recruited or from which secondary data were obtained (for example, to school administrators at a secondary school where students were recruited)?**

Answer:  Yes  
 No  
 Not applicable

**Describe what materials will be shared and with whom.** Repeat on consent document, if applicable.

Research findings will be shared with Starfleet Academy and the Hobbit Community Advisory Board.

**Will identifying information be retained and/or shared for use in future research?**

Answer:  Yes  
 No

**Please answer the below questions and repeat the information on the consent document, if applicable:**

1. **What identifying information will be retained for your own future research use?**
2. **What identifying information will be shared with other investigators or repositories?**
3. **Whether or not participants will be contacted and consented for future uses and data sharing of identifiable information.**
4. **Whether participants will be able to withdraw their data by contacting you, other investigators, or repositories.**

Names and contact information for the training intervention participants will be retained for a period of three years after completion of the current study. If the research team wishes to utilize the data collected for the current study for another study during this retention period, the research team will submit a new IRB protocol for secondary research use of data and we will obtain consent from the participants in the initial study for any new research use related to their data. No identifying information will be shared with other investigators or repositories. Participants will not be able to withdraw their data from any published results and they will only be able to withdraw their data from the current study and future studies while investigators retain the key linking their data to their identity. The key linking the data to specific participants will be destroyed 3 years after completion of the current study. This information will be conveyed on the consent document for the current study as well as for any future studies.

**Who is the intended audience for the study report and what is the presentation/reporting method to be used, if known (e.g., journal article, conference presentation)?**

Answer:

Starfleet Academy; the Hobbit Community Advisory Board; hobbits, scholars, and training development specialists who are interested in space training programs for different populations are the intended audience. It is expected that the research findings will be published in journals and presented at conferences, though the specific venues are not yet known.

**Retention and Disposition of Identifying Information**

**How long will identifying information and/or keys to coded data be kept?**

**Important Notes:**

- This question refers to identifying information and not all research data.
- Keep in mind that federal requirements and CSU retention policy is to retain research records for three years after the study is completed. We recommend applying the three year time-frame to items that must be retained for compliance purposes, such as signed consent forms. Identifying information that is only needed for contacting or tracking participants may be destroyed as soon as it is no longer needed, which may be less than three years.

**Answer:**

Three years after completion of the research.

**How will identifying information be destroyed when it is no longer needed?**

*Please list the specific disposition methods for various media, including paper documents, digital documents on devices, and digital documents on shared drives, in the cloud, or email.*

**Answer:**

Digital files on the desktop computer will be permanently deleted (the recycle bin will be cleared).

The external hard drive containing the key will be reformatted after the file is deleted and then converted into pure energy by a replicator.

All signed envelopes related to the study in DocuSign will be deleted.

Paper consent documents will be shredded with a pierce and tear shredder.

**Who will conduct the disposition/destruction of identifying information?**

*Please indicate the name of the individual if multiple team members were identified in the Study Personnel section of the application.*

**Answer:**

Tasha Yar

## RISKS AND BENEFITS

**Are there any potential risks to participants or data subjects associated with this study that can be anticipated?**

*Examples of risks include: physical injury, aggravation of an existing condition, pain, loss of privacy, the release of potentially damaging personal information, psychological risk (e.g., anxiety, stress, depression), and uncomfortable emotions (e.g., anger, fear, sadness).*

**Answer:**  Yes

No

**List any known potential risks and discomforts to individual participants or data subjects that can be anticipated – whether physical, psychological, economic, social, legal, or other - and assess their likelihood and seriousness.**

**Answer:**

The training intervention for hobbits on Space Station 5 in this study involves a range of activities and components, each with their own associated risks. Some of the potential risks include:

- Isolation training: being isolated from others for extended periods of time can have negative psychological effects, including depression, anxiety, and irritability.
- Nutritional education: changing one's diet can lead to gastrointestinal issues, including diarrhea, constipation, and bloating. Additionally, if the nutritional education component does not adequately address the unique dietary needs of hobbits, it could lead to nutrient deficiencies or weight gain.
- Physical fitness training: Physical activity always carries some risk of injury, and this is particularly true for individuals who are not accustomed to regular exercise. The low-impact, low-intensity nature of the training intervention should help to minimize the risk of injury, but it is still possible.

There are no anticipated risks associated with the completion of assessments for either the training intervention group or the youth in the Summer Space Camp Program.

**Describe the procedures for protecting against or minimizing each potential risk listed above.**

*Describe special safety procedures, as needed, to avoid harm to participants. List any psychological and/or medical help available in the event of harm. For example, if the risk of emotional discomfort is high, the investigator should provide the participants with a list of referrals for counseling and attach this information to the informed consent document.*

**Answer:**

To minimize risks related to the training intervention, the study team will take a number of precautions. For example, the isolation training will be carefully monitored 24 hours a day (using the One Ring) to ensure that participants are not experiencing any negative physiological, psychological, or emotional effects. Before the isolation training begins, hobbits will undergo a thorough orientation on what to expect during the simulation (including the use of recording and monitoring devices and how they work), the rules and expectations, and the safety protocols. Hobbits will wear the One Ring, which will also serve as a panic button that will immediately end the simulation.

The nutritional education component, designed in consultation with the Hobbit Community Advisory Board, has been tailored to provide participants with a healthy and balanced diet, taking into consideration the unique dietary needs of hobbits.

The physical fitness training program has been designed to be low-impact and low-intensity, with a focus on building endurance and strength while minimizing the risk of injury through warm-up exercises.

Hobbits may stop participation in any aspect of the training intervention at any time.

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**Describe if there are plans for provision of treatment for study-related injuries and how costs of injury treatment will be covered.**

**Answer:**

While there are no plans for provision of treatment for study-related injuries, all hobbits on Space Station 5 have access to comprehensive medical and mental health services, which is included as part of their assignment to the station. Referrals can be made by study team members to the appropriate professionals as needed.

**Do you anticipate a potential indirect risk of group harm?**

*For example, can the community from which participants are selected be made vulnerable by the investigation?*

**Answer:**  Yes

No

**Describe the nature of potential group harm and the procedures for mitigating group harm.**

*For example, community consultation or identifying stakeholders as mediators.*

If the hobbit training program is perceived as being more effective than the standard program, it could create resentment or frustration among those who were assigned to the standard treatment group; they may feel they were not given the same opportunity. This could lead to tension and a lack of cohesion among participants as well as the general population of Space Station 5, which could negatively impact the overall training experience for everyone involved.

Should the intervention prove to be effective in improving hobbits' adaptability and performance, a plan is in place to offer the training to the wider community.

The research team has also consulted with the Hobbit Community Advisory Board (HCAB) on many aspects of the study and received feedback from leaders and other stakeholders in the hobbit community who have provided input on the design and implementation of the hobbit training program to ensure that it is culturally appropriate and respectful of hobbit traditions and values. Additionally, community members have provided guidance on how to effectively communicate with and engage hobbit participants in the study to ensure that they feel valued and included.

**Are there any potential direct or indirect benefits to participants or data subjects associated with the study that can be anticipated?**

**Answer:**  Yes

No

**List any potential direct or indirect benefits to participants or data subjects.**

*Note: compensation or incentives are not considered a benefit and should not be listed in this section.*

**Direct benefits to participants of the Space Station 5 training intervention:**

Enhanced training for hobbit participants. The hobbit training program is designed to prepare participants for the unique physical and psychological demands of deep space exploration. Participants in the hobbit training program will receive tailored training that is specific to their needs, which may result in improved performance and safety during space missions.

There are no direct benefits related to completion of assessments by either group of participants.

**Indirect/social benefits:**

Overall, the study promotes diversity and inclusivity in the field of space exploration. This could inspire a new generation of young hobbits to pursue careers in science and space exploration.

## FINANCIAL CONFLICTS OF INTEREST

**Do you or any investigator(s) participating in this study have a financial interest related to this research project?**

**Answer:**  Yes

No

**Provide the names of any research team members who may have a financial interest, and provide information about whether and how the conflict will be mitigated. Please also refer to the [Office of Research Conflicts of Interest page](#) for more information and requirements.**

Wesley Crusher owns 0.0001 shares in the One Ring, LLC. This financial interest was disclosed to the SJSU COI committee, which determined that this was not a significant financial interest.

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## OTHER STUDY ATTACHMENTS

*If applicable, provide any other attachments related to the study that were not specifically included within the application (e.g., permissions or letters of support, list of references, list of support services for participants). If you have multiple attachments, please be sure to create a clear file name so that the IRB can easily identify what type of document it is.*

*Please note that even if you have a web link to a study document, the SJSU IRB still requires that you attach all documents to your application.*

**Answer:**

-  One Ring Schematic and Technical Details.pdf 04/10/2023 (Additional Documentation) (Existing)
-  Hobbit Training Intervention Daily Schedule.pdf 04/10/2023
-  Letter of Support - HBAC.pdf 04/10/2023
-  List of References.pdf 04/10/2023

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## OTHER ISSUES - OPTIONAL FREE-TEXT SECTION

**If there are any other issues which the IRB should consider and which do not fall into any of the application sections, please describe them here.**

**Answer:**

We are deeply committed to supporting the work of space-faring hobbits and we hope this research will contribute to ongoing efforts to allow hobbits to boldly go where no hobbit has gone before!

## Miscellaneous

## Publications

## Cont Reviews

## Modifications

## Incident Reports

Event / Date	Status / Comments / Files	Submitted By
No Incident Reports Found.		

## Deviations

Status	Deviations File/Comments	Submitted By
No Deviations Found		