

23-010
Full Board
Tasha Yar Signed 04/10/2023 4:28 PM PDT

Jean-Luc Picard 03/29/2023
Accepted 04/10/2023 4:33 PM PDT

Wesley Crusher 03/29/2023
Accepted
Interdisciplinary Sas
Full Board Review Requested

04/10/2023

Tasha Yar

Interdisciplinary Sciences

Ta - Pi

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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Yes

No

Starfleet Academy

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:

Online

SJSU campus

External site

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

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 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. to all ~~Ms~~

Yes

No



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~~an appropriate and cultural~~

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.

C S

Hobbits are an appropriate population for the training intervention because they have unique physical and cultural characteristics that



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).

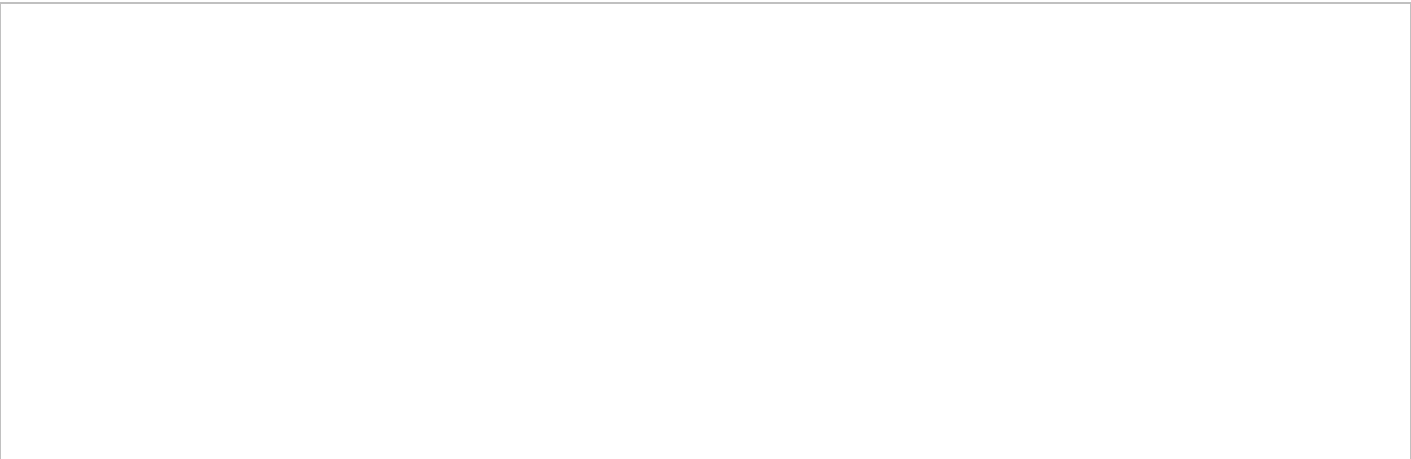
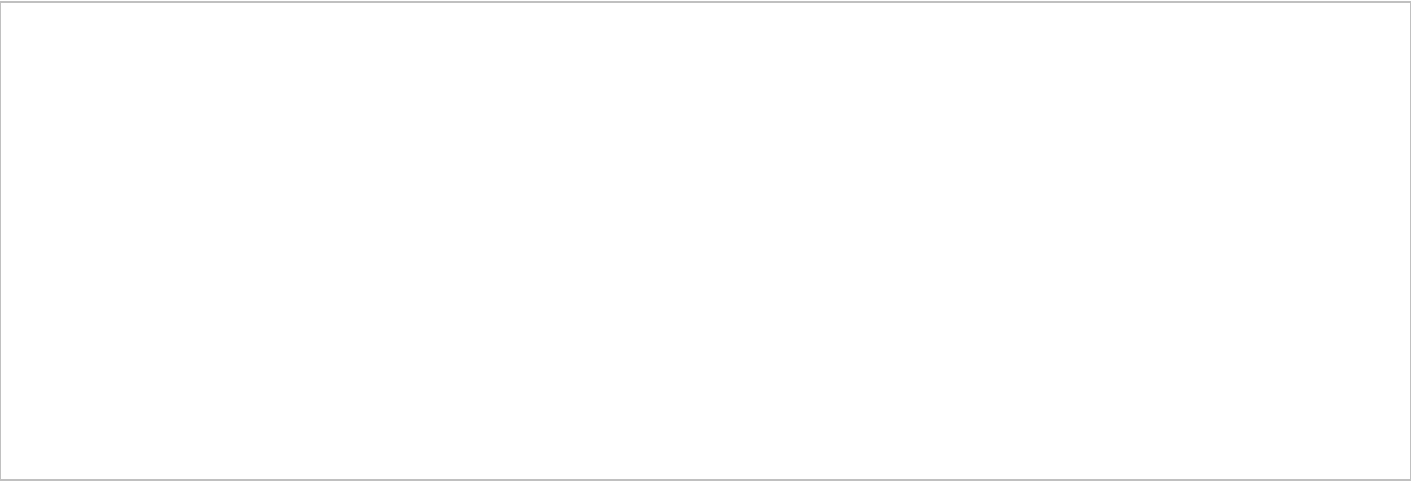
Note: this option should not be checked if you are using a consent notice. This option is typically used for research that qualifies for exemption.

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Yes
No



Observational Notes
Other
No study instruments will be used

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

- 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)

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Check all boxes that apply and answer any accompanying questions.

- 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

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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?

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.

- Yes
- No

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.

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- Yes
- No



Three years after completion of the research.

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.

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.

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

Tasha Yar

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).

Yes

No

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.

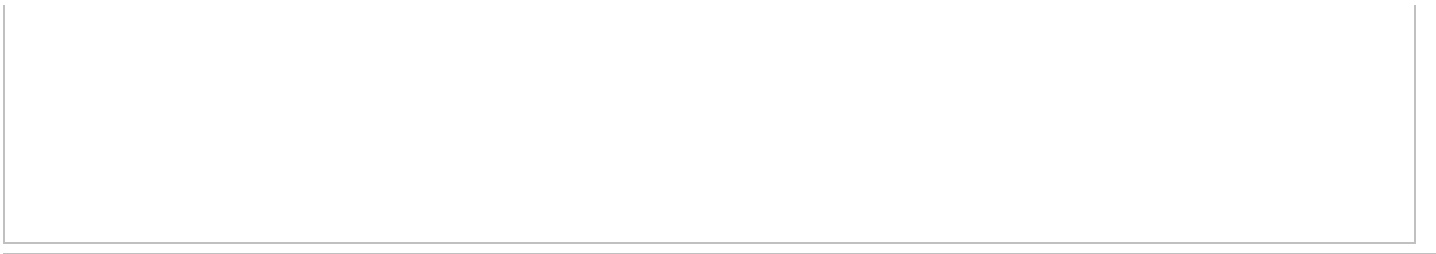
Describe special safety procedures, as needed, to avoid harm to participants. List any psychological and/or medical help available in the event of harm. For example, if the risk of emotional discomfort is high, the investigator should provide the participants with a list of referrals for counseling and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

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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