

Date: 12/03/2020
To: Amy E Smith
From: Office of Research Ethics
Title: **Keepers of the Garden Phase 3: Religion and Support for Environmental Protection in Brazil**
IRB ID: 20-457
Submission Type: Initial Submission **Exemption Date:** 12/03/2020

The project referenced above has been declared exempt from most requirements of the human subject protections regulations as described in 45 CFR 46.104 or 21 CFR 56.104 because it meets the following federal requirements for exemption:

2018 - 2 (iii): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) when the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a LIMITED IRB REVIEW to [determine there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data].

The determination of exemption means that:

- **You do not need to submit an application for continuing review. Instead, you will receive a request for a brief status update every three years. The status update is intended to verify that the study is still ongoing.**
- **You must carry out the research as described in the IRB application.** Review by IRB staff is required prior to implementing modifications that may change the exempt status of the research. In general, review is required for any *modifications to the research procedures* (e.g., method of data collection, nature or scope of information to be collected, nature or duration of behavioral interventions, use of deception, etc.), any change in *privacy or confidentiality protections*, modifications that result in the *inclusion of participants from vulnerable populations*, removing plans for informing participants about the study, any *change that may increase the risk or discomfort to participants*, and/or any change such that the revised procedures do not fall into one or more of the [regulatory exemption categories](#). The purpose of review is to determine if the project still meets the federal criteria for exemption.
- All **changes to key personnel** must receive prior approval.

- **Promptly inform the IRB of any addition of or change in federal funding for this study.** Approval of the protocol referenced above applies only to funding sources that are specifically identified in the corresponding IRB application.

Detailed information about requirements for submitting modifications for exempt research can be found on our [website](#). For modifications that require prior approval, an amendment to the most recent IRB application must be submitted in IRBManager. A determination of exemption or approval from the IRB must be granted before implementing the proposed changes.

Non-exempt research is subject to many regulatory requirements that must be addressed prior to implementation of the study. Conducting non-exempt research without IRB review and approval may constitute non-compliance with federal regulations and/or academic misconduct according to ISU policy.

Additionally:

- All research involving human participants must be submitted for IRB review. **Only the IRB or its designees may make the determination of exemption**, even if you conduct a study in the future that is exactly like this study.
- **Please inform the IRB if the Principal Investigator and/or Supervising Investigator end their role or involvement with the project** with sufficient time to allow an alternate PI/Supervising Investigator to assume oversight responsibility. Projects must have an [eligible PI](#) to remain open.
- **Immediately inform the IRB of (1) all serious and/or unexpected [adverse experiences](#) involving risks to subjects or others; and (2) any other [unanticipated problems involving risks](#) to subjects or others.**
- **Approval from other entities may also be needed.** For example, access to data from private records (e.g., student, medical, or employment records, etc.) that are protected by FERPA, HIPAA or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **An IRB determination of exemption in no way implies or guarantees that permission from these other entities will be granted.**
- Your research study may be subject to [post-approval monitoring](#) by Iowa State University's Office for **Responsible Research**. In some cases, it may also be subject to formal audit or inspection by federal agencies and study sponsors.
- Upon completion of the project, transfer of IRB oversight to another IRB, or departure of the PI and/or Supervising Investigator, please initiate a Project Closure in IRBManager to officially close the project. For information on instances when a study may be closed, please refer to the [IRB Study Closure Policy](#).

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.