|  |  |  |  |
| --- | --- | --- | --- |
| Submission Type | **INITIAL APPLICATION** | | |
| Study Title | Fire Safety Study | | |
| Principal Investigator | Lynn Grennough | Appointment Type[[1]](#footnote-1) | Non Teaching administrative |
| Email Address | lynn.greenough@oregonstate.edu | Telephone No. | 541-737-3811 |
| College or Administrative Office | NA | | |
| School | NA | | |
| Department, Program, Unit, Center, or Institute | Technology Across the Curriculum | | |

1. **In one paragraph, state your primary research question or purpose:** For this project, we define “Fire Safety” as the set of behaviors to have and not have in case of fire in a residence hall. The goal of this project is to assess the current state of knowledge on “Fire Safety” for students living in OSU residence hall.
2. **Anticipated Level of Review –** *If uncertain, complete the Review Level Determination form*

Exempt  Expedited  Full Board

1. **Funding**

External funding  Internal funding  Unfunded

1. **Ethics and Compliance Training**

All study team members involved in this project must complete training in the ethical use of human participants in research prior to submitting an IRB application. Please refer to the Education Requirement Policy on the IRB website. If you have additional study team members, please submit the information on a separate sheet.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study Team Member(s) | Role in Project | **OSU Email Address** | **Copy on Correspondence** | **Ethics Training Completed** | **Student-driven** (e.g., for thesis or dissertation) |
| Lynn Greenough | Principal Investigator | lynn.greenough@oregonstate.edu |  | YesNo |  |
| Jon Dorbolo |  | jon.dorbolo@oregonstate.edu | YesNo | YesNo | YesNo |
| Beatrice Moissinac |  | beatrice.moissinac@oregonstate.edu | YesNo | YesNo | YesNo |
|  |  |  | YesNo | YesNo | YesNo |
|  |  |  | YesNo | YesNo | YesNo |

1. **Risk/Benefit Assessment for adults and/or children**

*Minimal risk:* The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

|  |  |
| --- | --- |
| **Adults**  Not enrolling adults  Minimal risk  Greater than minimal risk | **Children**  Not enrolling children  Minimal risk  Greater than minimal risk, but holds prospect of direct benefit to subjects  Greater than minimal risk; no prospect of direct benefit to subjects but likely to yield generalizable knowledge about the subject’s disorder or condition  Research not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the subjects |

1. **Maximum number of subjects** (*not a range*) that will be enrolled over the course of the study: 100

*Enrollment must not exceed this number without prior IRB approval.*

*See Protocol Template for additional details.*

1. **Participant age range** (check all that apply):

0-7: include parental consent form (unless seeking waiver) and description of verbal assent process

8-17:include parental consent form and assent form for children (unless seeking waiver)

**≥**18: include consent form or verbal consent guide (unless seeking waiver)

1. **Target population(s)**

| **Populations** | **Excluded** | **Permitted** | **Targeted** |
| --- | --- | --- | --- |
| Adults lacking capacity to consent |  |  | *Note: Protocol must include*  *additional safeguards* |
| Children in foster care or wards of the state |  |  | *Note: There are additional safeguards that may need to be in place when children in foster care or wards of the state will be enrolled. If research poses greater than minimal risk to subjects, see the IRB website for guidance on children.* |
| Prisoners |  |  | *Note: Will be reviewed at the full board level. If the correctional facility is under the purview of the Oregon Department of Corrections (DOC), complete the DOC application and consult with them regarding feasibility before submitting an application to the OSU IRB. See IRB website for the DOC application.* |
| Pregnant women |  |  | *Note: Please explain in the risks section of the protocol whether there are any additional risks to pregnant women and/or fetuses. If excluding, please provide justification in the protocol.* |
| OSU Students or employees |  |  | *See IRB website for guidance on enrolling students and employees.* |
| Non-English speakers |  |  | *Note: Protocol must include qualifications of the translator(s) and of the study team members if obtaining consent in a language other than English. All written information to be seen by subjects must be translated and submitted with the application.* |
| American Indians and/or  Alaska Natives |  |  | *See IRB website for guidance on   enrolling tribal populations. If excluding please provide justification in the protocol.* |

1. **If the research involves any of the following, check the appropriate box**

|  |  |  |
| --- | --- | --- |
|  | Deception | *See policy on IRB website* |
|  | Audio or video recording | *Consent document must indicate whether recording is optional or a required study activity. If optional, include an opt-in/opt-out section for subjects to initial* |
|  | Drugs, devices, biologics, or supplements | *Complete relevant sections of the protocol template* |
|  | Radiation | *Complete Radiation Use Form*  *IRB will forward submission to Radiation Safety* |
|  | Human biological materials | *Complete Biological Materials Form*  *IRB will forward submission to Biosafety*  *Attach CLIA lab certification, if applicable* |
|  | Microorganisms orRecombinant DNA | *IRB will forward submission to Biosafety* |
| *Complete Attachment A* | Sending or receiving biological materials | *Contact the Office for Commercialization and Corporate Development regarding the potential need for a Material Transfer Agreement (541) 737-4437* |
|  | Using Chemical Carcinogens | *List of applicable chemicals:* [*http://oregonstate.edu/ehs/carclist*](http://oregonstate.edu/ehs/carclist)  *IRB will forward to Chemical Safety* |
|  | Waiver of parental consent/permission | *If you do not think that the requirement for obtaining parental consent/permission for children under 18 is appropriate for this study, include justification in consent section of protocol* |
|  | Waiver of documentation (signature) of informed consent | *If you do not think that the requirement for a signed consent document is appropriate for this study, include justification in consent section of protocol. See IRB website for guidance on a verbal or alternative consent process* |
|  | Waiver of informed consent | *The required elements of consent are listed here:* [*http://www.hhs.gov/ohrp/policy/consentckls.html*](http://www.hhs.gov/ohrp/policy/consentckls.html)  *If you do not think that the requirement for obtaining consent to participate in research is appropriate for this study, or if you plan to omit or alter any of the required elements of consent, include justification in consent section of protocol* |
|  | Translated documents | *Include material in English and translated into a language spoken by participants* |
|  | Multi-center study | *Complete relevant section of the protocol* |
|  | External research or recruitment sites | *Complete relevant section of the protocol* |

1. **Attachments** *(check all that apply)*:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Protocol**  *Required* |  | **Attachment A: Radiation**  *Required if participants will be exposed to radiation* |
|  | **Consent Document(s)**   * Consent Form(s)   *Required if adults, unless consent or signatures will not be sought* |  | **Attachment B: Human Materials**  *Required if study involves the collection or receipt of any biological materials* |
|  | * Verbal Consent Guide(s) and/or * Explanation of Research Handout   *Required if no signatures will be obtained* |  | **Material(s) in Other Languages**  *Required for study documents that will be seen by non-English speakers* |
|  | **External IRB Approval(s)**  *Submit if available. If there are external collaborators who do not yet have IRB approval, contact the OSU IRB Office for additional guidance* |
|  | * Assent Form(s)   *Required if minors, unless assent will not be sought* |
|  | * Parental Consent Form(s)   *May be required if minors. Please see our guidance for more information: http://oregonstate.edu/research/irb/ obtaining-parental-permission* |  | **CLIA Lab Certification**  *Required if results of lab tests will be disclosed to research participants, including urine pregnancy tests and glucose tests. For more information, please see the* [*OSU Guidance for CLIA Certification*](http://research.oregonstate.edu/irb/clia-certification-guidance)*.* |
|  | **Recruiting Tools**  *Required to submit final content if using emails, social media posts, flyers, letters, blackboard, verbal recruitment guide, SONA, MTurk, etc. See additional guidance at http://oregonstate.edu/ research/irb/recruitment-research-participants* |  | **Letters of Support from External Research Sites**  *If research will be conducted in schools, hospitals, or similar settings; or will be conducted internationally and/or with a vulnerable population, a letter of support may be required.* |
|  | **Test Instruments**  *Required to submit if using questionnaires, surveys, interview guides, focus group guides, etc.* |  | **Individual Investigator Agreements**  *May be required if external collaborators will not be covered under an external IRB. Contact the IRB Office for more information* |
|  | **Grant Application or Funding Contract** *Required if research has pending or awarded funding; other examples may include applications for student research scholarships, URISC, URAP, etc.* |  | **Other:**        *e.g., agendas for professional development workshops that are a research intervention; VO2 Max Exercise Test Supervision Competency Forms; Material Transfer Agreement; audio, video, or image files if included in the intervention; etc.* |

1. **Does the study need to be registered with ClinicalTrials.gov?**

**Yes** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[[2]](#footnote-2)

For more information, please see the [NIH Clinical Trials webpage](http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials).

**No**

1. **Conflict of Interest**

Federal Guidelines require assurances that there are no conflicts of interest in research projects that could affect the welfare of human subjects. If this study presents a potential conflict of interest, additional information will need to be provided to the IRB.

Examples of potential conflicts of interest in research involving human subjects may include, but are not limited to:

* An investigator or family member participates in research on a technology, process or product owned by a business in which the faculty member holds a financial interest. Any interest should be disclosed to the IRB, regardless of whether it meets the threshold of a “significant financial interest,” as defined by the Public Health Service (PHS).
* An investigator or family member has a financial or other business interest in an entity that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
* An investigator or family member serves on the Board of Directors of a business that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
* An investigator receives consulting income from an entity that is funding the current research project.
* An investigator participates in research on a technology, process or product developed for which the investigator has intellectual property rights (e.g., copyrights, trademarks, patents, or trade secrets) or receives royalties.

**Do any members of the study team, or any of their family members, have a financial or other non-research interest in the source(s) of funding, materials, equipment, data, research subjects, or site of research related to this study?**

No

Yes – Please describe:

**PRINCIPAL INVESTIGATOR’S ASSURANCE STATEMENT**

I understand Oregon State University’s policies concerning research involving human subjects and I attest:

that the information contained in this application is accurate and complete;

that research involving humans, including recruitment, will not begin until IRB approval has been granted;

to the scientific merit and importance of this study;

to the competency and availability of the study team member(s) to conduct the project;

that facilities, equipment, and personnel are adequate to conduct the research.

Furthermore, I agree to:

comply with all IRB policies, decisions, conditions, and requirements;

accept responsibility for every aspect of the conduct of this study;

obtain prior approval from the IRB before amending or altering the study and/or study documents;

report to the IRB in accord with current policy, any adverse event(s) and/or unanticipated problem(s);

inform the IRB if one or more of my study team members leaves OSU;

complete and submit continuing review documentation or a final report prior to the expiration date;

notify the IRB immediately of the development of any potential conflict of interest not already disclosed.

|  |  |
| --- | --- |
| Study Title: | Fire Safety Study |
| Principal Investigator: | Lynn Greenough |
| Date: | February 9th, 2015 |

**Applications will only be accepted if submitted by the Principal Investigator**

**Email completed application and all relevant attachments to** [**IRB@oregonstate.edu**](mailto:IRB@oregonstate.edu)

* File names for all attachments should include the last name of the Principal Investigator, document title, and version date. For example: Smith\_Protocol\_10272014.doc
* All attachments should include the last name of the Principal Investigator, document title, version date, and page numbers.

1. Please see the [FAQ on who may be a Principal Investigator](http://research.oregonstate.edu/irb/who-can-be-principal-investigator-pi) [↑](#footnote-ref-1)
2. National Institute of Health. 2014. [↑](#footnote-ref-2)