

Institutional Review Board (IRB)

### Research Proposal Submission Form for New Projects

Federal regulations and Landmark College policy require that all research involving human subjects be reviewed and approved by the Landmark College Institutional Review Board (IRB). External researchers seeking access to Landmark College faculty, staff, students, their families, data and/or records must have his or her project approved by the Institutional Review Board (IRB). **All external projects must be co-sponsored or facilitated by a Landmark College employee.** Furthermore, written approval from the IRB must be received before conducting research at the College. For more information, templates, and forms please go to [http://www.landmark.edu/academics/institutional-review-board](file:///C%3A%5CUsers%5CAdministrator%5CDocuments%5CGroupWise%5Cto%20http%3A%5Cwww.landmark.edu%5Cacademics%5Cinstitutional-review-board).

**Please submit the proposal and supporting documents electronically (in WORD format) to the IRB Chair** for determination regarding IRB review. If you are not able to submit your documentation with an electronic signature please mail a hard copy to the following address:

For more information on research review requirements please review the decision charts found at <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>.

**Project title:**

Researcher Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*Attach additional signature sheets as necessary

# PRINCIPAL RESEARCHER INFORMATION

**Name:**

**Position title:**

**Institutional Affiliation:**

**Mailing address:**

**Phone number:**

**Email address:**

\* Please provide the above information for each researcher involved.

# LANDMARK COLLEGE FACILITATOR (see Definition for additional information)

**Name:**

**Position title:**

**Division and/or Department:**

**Phone number:**

**Email address**

**Note: This form has been designed in accordance with the new Common Rule, which shall go into effect on July 1, 2018. If more information is needed to evaluate your study, the IRB may request an appendix with information including but not limited to: a literature review, data analysis information, a timeline, internal or external site approvals, research partner information, recruitment information, and/or research dissemination plans.**

1. PROJECT ABSTRACT

Please provide a brief overview of your research project written in everyday terms. Do not exceed 250 words.

1. **project support and funding**

Indicate all entities that are funding or otherwise supporting this research.

1. **MULTI-SITE PROJECTS AND EXTERNAL RESEARCHERS**

Please indicate if this project is part of multi-site research or if you are an external researcher. Identify participating institutions. If other institutions are partners in the research, please attach relevant IRB approval(s).

### PROJECT RATIONALE

Please describe your reason(s) for conducting this research. Include an explanation of why this research/topic is important and how the findings might be used. Possible benefits to individual research subjects should also be mentioned in this section.

### EXEMPT STATUS (Optional)

If you think your project should be exempt from IRB review, please explain how it fits one of the exemption categories outlined in 45 CFR Part 46.101, part b. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta> Decision about exempt status shall be made by the IRB.

### **RESEARCH QUESTIONS**

Please list the research question(s) that will be answered by this project.

### METHODOLOGY

In this section, please describe how you plan to answer the research question(s) that you have identified. The areas below are meant to guide your discussion.

Please describe your research design.

Please describe your recruitment plan. Include recruitment materials.

### Please describe subject selection for this study. Include the sample size needed as well as any desired student characteristics/traits.

Please describe the activities that participants will engage in as research participants. Also give an estimate of total time commitment per subject.

### Briefly describe procedures you expect to follow to obtain voluntary informed consent. Information about the research project must be presented to potential research subjects in a manner that allows them to make an informed and voluntary decision about participation. Please attach all consent forms you plan to use. For information on the required elements of a consent form please visit our website [http://www.landmark.edu/academics/institutional-review-board](file:///C%3A%5CUsers%5CAdministrator%5CDocuments%5CGroupWise%5Cto%20http%3A%5Cwww.landmark.edu%5Cacademics%5Cinstitutional-review-board)

Describe the measures you plan to take to protect the confidentiality of subjects’ data, including how long you anticipate storing the data you have collected during the study.

Please describe all the locations/settings where the research activities described above will be conducted.

Please describe any instrumentation, interview protocols, or other data collection methods that you plan to use. Please attach existing instruments and protocols to this proposal form.

Please describe the risks and benefits that this project poses to subjects as well as the steps you plan to take to minimize risks.

### K. Credentials and training

### Please summarize briefly your professional research experience.

Please confirm that you have completed the CITI training titled *Group 2 Social/Behavioral Investigators and Key Personnel.*

\_\_\_\_\_ I have completed the CITI course *Group 2 Social/Behavioral Investigators and Key Personnel.*

*\_\_\_\_\_* I have not completed *Group 2 Social/Behavioral Investigators and Key Personnel.* If you checked this option, please indicate your plans to finish the training:

Please attach the curriculum vitae (CV) and CITI completion reports for all researchers named on the study.