

**RESEARCH REVIEW FORM**

Principal Investigators (PIs) are responsible for providing acopy of the following documentation for all research involving human subjects to the Bentley University Institutional Review Board (IRB) for review and approval *prior to* conducting the research with human subjects.

**Project Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Academic Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Department: \_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Work Phone:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Campus Address/Code** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **E-mail:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Projected Dates of Data Collection and Analysis:** Beginning Date: \_\_\_\_\_\_\_\_\_\_\_ End Date: \_\_\_\_\_\_

**Requested Review Type:** a. Exempt: **⬜**  b. Expedited: **⬜**  c. Full Committee Review: **⬜**

 **[**If “Exempt” or “Expedited,” briefly explain *why,* citing appropriate regulatory details.**]**

**Funding Status:** a.. Not Funded **⬜**  b. Bentley Funded **⬜**

 c. Externally Funded (or Pending) **⬜**  d. Funding Source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RESEARCH PROTOCOL**

1. **Purpose of the Study** [1-2 paragraphs providing an overview of the study, including the expected benefits from the research, including a statement about the likelihood of these benefits for the subjects.]

1. **Study Design** [1-2 paragraphs outlining the study design, including, as needed, a discussion of the appropriateness of research methods and description of procedures to be performed.]
2. **Subject Characteristics and Involvement** [Including any inclusion/exclusion criteria (e.g., on the basis of ethnicity, gender, occupation, industry). If any special or vulnerable population is involved (e.g., children, decisionally-impaired individuals), the inclusion of these subjects must be explained and justified.]

**Subjects to be Recruited** (Check all that apply):

a. Adults (18 years or older **⬜**  b. Children and Minors (under 18) **⬜**

c. Cognitively Impaired Persons **⬜**  d. Prisoners **⬜**

e. Elderly/Aged Persons **⬜**  f. Minorities **⬜**

g. Students **⬜**

h. Others (describe) **⬜** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 i. Using existing data, no subjects will be recruited **⬜**

**Anticipated Number of Subjects: \_\_\_\_\_\_\_\_\_\_\_\_**

**Method of Recruiting: [**Please describe and include a copy of any recruiting materials if available**]**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Will Subject be involved in:**

a. An Intervention or Manipulation? Yes **⬜**  No **⬜**  [If yes, briefly describe]

b. Deception? Yes **⬜**  No **⬜** [If yes, briefly describe]

**Informed Consent [**Briefly describe plans for obtaining informed consent, including circumstances surrounding consent procedure (e.g. setting, subject autonomy concerns, special considerations for vulnerable and/or non-English-speaking populations). Also include procedures to be followed for documentation of informed consent, including any procedures for obtaining parental consent and child assent when subjects are minors, using witnesses or translators, plans for document storage, and provisions for protecting subject’s privacy. Also include the proposed informed consent document (following guidelines stipulated in 45 CFR 46; see Informed Consent Guidelines and Template).**]**

4. **Study Data**

**Data will include** (check all that apply):

a. Names of people **⬜**  b. Income **⬜**  c. Age **⬜**

d. Social security number **⬜** e. Phone numbers **⬜**  f. Address **⬜**

g. Job title **⬜** h. Employer name **⬜** i. Gender **⬜**

j. Ethnicity **⬜** k. Marital status **⬜**

l. Other unique information (specify) **⬜**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Are codes used to link data to subject?** Yes \_\_\_ No \_\_\_

 **[**If Yes, please indicate how the codes will be maintained**]**

**Instruments** (check all that apply):

a. Standardized tests **⬜**  b. Written notes **⬜**  c. Observation (group) **⬜**

d. Questionnaire **⬜**  e. Audio tape **⬜**  f. Observation (individual) **⬜**

g. Evaluation **⬜**  h. Interview **⬜**  i. Video tape/film **⬜**

j. Needs assessment **⬜**  k. Photograph **⬜** l. Other (specify) **⬜** \_\_\_\_\_\_\_\_\_\_\_\_

**[**Please attach copies of surveys, questionnaires, interview guides, tests, or other instruments to be utilized in the research.**]**

 **Data Storage**: **[**Please specify where and how all data will be stored, and who will have access to

the data.**]**

 **Confidentiality: [**Please describe the procedures for assuring confidentiality of the data.**]**

5. **Potential Risk Exposure [**Please check all that apply.**]**

Physical **⬜**  Psychological **⬜**  Economic **⬜** Legal **⬜**  Social **⬜**

**[**Briefly discuss potential risks, including an assessment of the likelihood of their occurrence and provisions for managing adverse reactions. This section should also include any anticipated costs to subjects for their participation in the research.**]**

6**. Is Compensation Offered?** Yes **⬜**  No **⬜**

**[**If Yes, please describe the compensation offered**]**

7. **Follow-Up Documentation [**Please submit the following as appropriate.**]**

* Grant proposals
* Any revisions, amendments, and/or addenda to approved protocol and/or attachments related to human subjects. All changes must be approved by the IRB prior to implementation.
* Timely (within 72 hours) reports of unexpected adverse events.
* Annual progress reports, or as required by the IRB.
* Final report, indicating date of research completion and plans for data storage and/or destruction.

8. I have completed the [Collaborative Institutional Training Initiative (CITI) Program](https://www.citiprogram.org/)’s online training course on human research subjects protection. My certificate of completion is included.

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Signature*

Bentley IRB Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Signature*

For questions, please contact:

Susan Richman

IRB Chair

Director, Sponsored Programs

AAC 160B

781.891.2660

GA\_IRB@bentley.edu

*Last revised: Oct. 2019*