

175 Forest Street

Waltham, Massachusetts 02452

**Institutional Review Board**

**Adverse Events Report Form**

This form is for reporting any adverse consequences to human subjects participating in Bentley University related research projects. It is the responsibility of the Principal Investigator to complete this form and submit it with any related attachments to the Bentley Institutional Review Board (IRB) for any incident or outcome that has:

* Resulted in any harm to the subject;
* Affected the subject detrimentally; or
* Placed the subject at risk, whether or not the risk actually caused any harm (e.g., misplacing a subject’s research records constitutes an increased risk that should be reported).

**Project title**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator (PI)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Incident**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Report**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Description of Incident**: Please include a brief narrative of the incident, where it occurred, who was present, which subject(s) was (were) involved (age, gender, relevant characteristics), and the type of harm or risk involved.

**Describe any and all steps and actions taken in response to the incident or to resolve the issue**:

**What was the subject’s participation in the research following the incident (check all applicable categories)?**

\_\_\_\_\_ Subject stopped research participation

\_\_\_\_\_ Subject has already completed the research

\_\_\_\_\_ Subject continued research participation

\_\_\_\_\_ Subject withdrew from further participation

\_\_\_\_\_ Investigator withdrew subject from further participation

\_\_\_\_\_ Other (explain):

**Has this incident occurred previously?** Yes \_\_\_\_\_ No \_\_\_\_\_

**If yes, please describe the incident and reference any previous reports**:

**Based on the PI’s judgment, the incident was**:

Expected \_\_\_\_\_ Unexpected \_\_\_\_\_

Serious \_\_\_\_\_ Not serious \_\_\_\_\_

**Relation to stated risks**: In the PI’s judgment, was the probability, magnitude and/or reversibility of the incident consistent with the risk information provided in the research protocol, IRB application and informed consent documents previously reviewed and approved by Bentley’s IRB?

Yes \_\_\_\_\_ No \_\_\_\_\_

**Research revisions needed?** In the PI’s judgment, should the research protocol and/or consent forms be revised?

Yes \_\_\_\_\_ (Please explain all revisions to the research)

No \_\_\_\_\_ (Please explain why revisions to the research are not required)

**Notification of subjects or others?** In the PI’s judgment, should any of the following subjects, legally authorized representatives, or parents or guardians be notified? Check all that apply:

\_\_\_\_\_ New subjects

\_\_\_\_\_ Currently enrolled subjects

\_\_\_\_\_ Subjects who have completed the research

\_\_\_\_\_ None

**Impact on Research**. In the PI’s judgment, should the research:

\_\_\_\_\_ Continue as planned, with no changes to the research protocol or informed consent

\_\_\_\_\_ Continue with changes to the research protocol or informed consent as noted above

\_\_\_\_\_ Suspend any subject enrollment until the incident is further assessed

\_\_\_\_\_ Be terminated (stopped completely), with all subjects removed from the research

**Investigator Assurance**

I have reviewed the contents of this form, and any related attachments, and certify that the information provided is complete and accurate to the best of my knowledge.

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

**Principal Investigator Signature** **Date**

**For questions, please contact**:

Susan Richman

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IRB Chair

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*Last revised, Oct. 2019*