Bentley IRB Policy

Bentley University has an organizational subscription to CITI program, the leading provider of research ethics, compliance, and professional development education. Effective **January 1 2017**, the IRB will only accept applications from faculty, student, and administrative researchers who have successfully completed the Collaborative Institutional Training Initiative (CITI) Program online training course on human research subjects protection. Faculty sponsors of student researchers must also complete the relevant CITI Program course. **All researchers and sponsors are asked to include a copy of the completion report for their course when submitting their first application on or after January 1, 2017**.

The definitions of research and of human subject used at Bentley University are:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Activities that meet the definition of research constitute research for purposes of this policy whether or not they will be conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Federal regulations that govern the participation of human subjects in research draw on standards published in an earlier document entitled “Ethical Principles — Guidelines for the Protection of Human Subjects of Research.” Implications of three ethical principles are discussed in the Belmont Report. Briefly: Applying respect for persons means that, to the degree they are capable, subjects will be given the opportunity to choose what will or will not happen to them, through the researcher’s use of adequate standards for obtaining informed consent. Applying beneficence requires that research will be justified on the basis of a favorable risk/benefit assessment, in which “risk” is considered as the possibility that harm may occur and “benefit” is used to refer to something of positive value related to health or welfare. The risks and benefits affecting the immediate research subjects will normally carry special weight in the consideration of the IRB, although on some occasions interests other than those of the immediate subjects may be considered sufficient to justify the risks to which those subjects will be exposed. The application of justice, the third principle, requires researchers to exhibit fairness in determining which individuals will be selected to take part in potentially beneficial research and which will take part in risky research.

The extent to which, and the manner in which, IRB oversight of a particular project is required by federal law depends on an assessment of risks to the immediate human

subjects. Assessment is the responsibility of the appropriate IRB(s). If a project falls into one of a number of exemptible categories (listed in the Common Rule), an appropriate member of the IRB will determine that the project will be exempted from further IRB oversight during a defined period of time. If the initial assessment is that the project involves only minimum risk to subjects, and only certain types of activities (listed in the Common Rule) will take place, for which expedited review is permissible, then the review of the project may be performed by the IRB chair, or one or more experienced reviewers designated by the chair, acting alone to exercise all the authorities of the IRB except for disapproval. Expedited review also is permitted when the chair or an experienced reviewer determines that changes planned in previously approved research, during the period for which approval was authorized, will be minor.

For other projects (including all of those involving more than minimum risk to subjects) federal regulations specify that the project will be reviewed by the full board. Explanations of the criteria that must be satisfied during the review are presented in the Common Rule. Briefly, these focus on whether risks will be appropriately minimized; on determining that the extent of anticipated risks versus the extent of anticipated benefits will be in acceptable measure; on whether subjects will be selected in an equitable fashion; and on determining that subjects will be appropriately informed about the research, will be capable of giving informed consent, and that this will be documented. As appropriate, the IRB also may determine that the data will be monitored in order to ensure the safety of subjects and/or to protect their privacy and confidentiality in the way the data is used.

Appointments

The Vice President for Academic Affairs shall appoint individuals to be members of the board. Appointments are for three-year terms and may be renewed. The Vice President for Academic Affairs shall appoint individuals to be voting members of the board on a temporary basis whenever action by the board is required but a quorum cannot be obtained.

The Vice President for Academic Affairs shall appoint one member to act as the chairperson. The chairperson shall appoint another committee member to act as chairperson in his or her absence. Guided by time limits established below, if the chairperson is not available to appoint another committee member to act as chairperson in his or her absence, the Vice President for Academic Affairs or other senior administrator in Academic Affairs shall appoint another committee member to act as the temporary chairperson.

At all times, the committee shall consist of at least five individuals including (1) at least three members of the faculty from diverse disciplines, at least one of which whose primary concerns are in scientific area and at least one of which whose primary concerns are in a nonscientific area, (2) at least one member of the staff able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice, and (3) at least one member who is not otherwise affiliated with Bentley University and who is not part of the immediate family of a person affiliated with the University.

Bentley shall ensure that members of the IRB are extensively knowledgeable of the local research context and are sensitive to issues such as community attitudes. For projects involving special categories of individuals such as children, prisoners, pregnant women, or handicapped or disabled persons, consideration shall be given to including one or more individuals knowledgeable about and experienced in working with these subjects. Should Bentley employees begin on a regular basis to engage in research involving one of these vulnerable categories, consideration shall be given to including an individual on the IRB who is knowledgeable about and experienced in working with these subjects.

No member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Such a person may not vote with the IRB.

Role of Office of Sponsored Programs (OSP)

OSP shall identify proposals that entail possible research with human subjects. A full copy of the proposal shall be forwarded to the IRB chair within ten days of the date on which institutional approval is obtained to submit the proposal to the (initial) potential funding agency. Should the University subsequently approve of pre-award changes to a previously approved proposal, the changes also shall be forwarded to the IRB chair within ten days of approval.

OSP shall obtain and forward to the chairperson the current federal policies and guidelines applicable to the proposal under review. These shall be forwarded with the copy of the full proposal (see above).

At the time of proposal approval by the University, OSP shall inform the project director(s) that the proposal must be reviewed and either exempted or approved by the IRB as soon as possible and prior to the commencement of research or the use of external funds (unless excepted in accordance with 45 CFR 690.118 as discussed below). OSP shall direct the project director to the IRB chairperson for additional information about policies and procedures.

OSP shall communicate with the project officer of the potential funding agency (or agencies) about the status of board review. Should the University be required to enter into an assurance in order for the board to review a proposal being considered for funding by the government, OSP will contact the appropriate officials and obtain the assurance so far as is possible.

In accordance to 45 CFR 690.118, OSP shall ensure that board approval or exemption from review has been obtained for each project which utilizes human subjects, prior to releasing any funds granted to Bentley University. In addition, OSP shall require written notification of continued approval according to the timetable established by the board (and communicated to the project director following review) before additional funds are expended beyond the required date(s) communicated in the timetable.

The only exception to this involves applications and proposals which do not involve human subjects or that lack definite plans for involvement of human subjects as

described in 45 CFR 690.118. In these applications, definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by the board before an award may be made, however, except for research exempted or waived by the board under 45 CFR 690.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the board.

Projects to be Reviewed

The scope of the IRB shall include funded and non-funded research by Bentley University faculty, staff and students, including:

1. projects funded by a federal or non-federal agency, through an award to Bentley University or to a separate institution or organization, if research with human subjects shall take place on property owned by Bentley University,
2. projects funded through a grant or contract to Bentley University, on behalf of a member of the faculty or staff, which shall involve research with human subjects at any location. OSP (possibly after consultation with the board chairperson) shall determine if the project entails research and if human subjects shall be involved,
3. projects funded through Bentley-sponsored Requests for Proposals (RFPs) that involve research with human subjects; and
4. non-funded projects by Bentley faculty, staff and students that is considered as research (see definition above) that involved human subjects.

Projects that are excluded from any involvement by the IRB are:

1. projects for which other institutions have received funding which do not take place on the Bentley campus; and
2. projects which shall not involve research (see definition above) or human subjects.

Review of Projects

Meetings shall be called at the discretion of the chairperson or acting chairperson.

Meetings shall not be open to individuals other than board members and invited guests and considerations and opinions about specific projects that are offered by individual members shall not be communicated to members outside the board.

More than 50 percent of the membership must be present for there to be a quorum. The primary concerns of at least one member must be in non-scientific areas. The board shall not have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the board.

A majority of voting members attending a meeting can act on an application.

The board may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the board. These individuals may not vote.

Initial decision on a completed application shall take place within ten business days. The board may specify changes required in order for a project to be reviewed and shall promptly review proposals that are revised accordingly. At his or her discretion, the chairperson may approve of revisions without additional full board review. In this case, the chairperson is not required to consult with one or more board members.

The board must confirm that research is in conformance with the Common Rule (or amended federal agency regulations) and as applicable, requirements of non-governmental agencies considering funding, before any aspect of research with human subjects occurs.

The chairperson of the IRB or an experienced committee member appointed by the chairperson may make a determination (according to the Common Rule) that a project is exempt from institutional review board oversight. In this case, the individuals responsible for conducting the project must forward a written description to the chairperson (or the experienced committee member) at least annually of any changes to the protocol that may be planned. Research cannot continue after twelve months without written approval of the chairperson or the experienced committee member.

The IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 690.117.

The chairperson and one other member of the board may determine that the project involves minimal risk or minor change in approved research as defined in the Common Rule and shall be conducted under the expedited procedure described in 45 CFR 690.110. This consists of a review of the complete proposal by only the chairperson and one or more experienced reviewers designated by the chairperson who together, exercise all the authorities of the board except for disapproval of the research. Other board members shall be advised of the expedited review of any project.

Criteria for approval are listed in 45 CFR 690.111.

The IRB has the authority to approve, require modifications in, or disapprove the covered human subject research.

The board may at its discretion require an outsider to document the process of informed consent.

The chairperson shall send an applicant written notice of the IRB’s actions, and in the case of tentative approval or disapproval, reason will be given.

In any instance in which a project has been exempted or approved by the IRB of another institution, which has a multiple project assurance with the federal government,

at the chairperson’s discretion the other board’s exemption or approval may be accepted as the same as, and in lieu of, a review by Bentley University’s IRB.

Formal notification to the project director shall include a timetable established by the board for continuing review of the project. The timetable shall be established in accordance to the degree of risk involved, and shall not be of shorter length than one year. The project director shall be required to adhere to the timetable.

Researchers responsible for all projects reviewed and approved must in all cases make a written report, to the chairperson of the board, of changes in the protocol prior to implementation.

Records maintained by the board shall conform to requirements stated in 45 CFR 115.