



Bristol Community College

Institutional Review Board

Guidelines for Compliance with Federal Regulations on Human Subjects Research¹

Office of Institutional Research, Planning, and Assessment

The Bristol Community College Institutional Review Board strives to ensure that the College meets the objectives of protecting people's privacy, health, and safety, and people's ability to participate voluntarily in human subject research.

June 9, 2009

¹ Adapted from materials created by the IRBs of Fitchburg State College, Mount Wachusett Community College, and Greenfield Community College.

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Guidelines for Compliance with Federal Regulations on Human Subjects Research

Background

This document identifies guidelines and procedures for anyone associated with Bristol Community College who is conducting research involving human subjects. Research involving human subjects is governed by federal regulations. Bristol Community College assures that it will comply with the Office of Human Research Protection regulations (OHRP) for the Protection of Human Research Subjects.

Bristol Community College has established an Institutional Review Board (IRB) to ensure that the College is meeting the objectives of protecting people's privacy, health and safety, and people's ability to participate voluntarily in human subject research and meeting the federal regulations.

For all **federally**-funded research Bristol Community College follows an Institutional Review Board (IRB) process.

Institutional Review Board (IRB)

The goal of the IRB is to protect the rights and welfare of those individuals who agree to participate in research. The review and approval of proposals and activities by the IRB are meant to assist the researchers by having a review that will objectively analyze the potential risk involved to research participants, as well as ways to minimize that risk. As part of the process, the College IRB will evaluate the aforementioned ethical practices in determining risk.

Membership of the IRB consists of **at least** five members. The members will have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members and their diversity, including race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. One of the five members **must be** an individual with no connections to the College.

The BCC IRB members will include the Vice President of Institutional Research, Planning, and Assessment as Chairperson. IRB members are approved by the federal Office of Human Research Protections (OHRP) for three years.

See www.bristolcc.edu/administration/ir for a current list of BCC IRB members.

The BCC IRB will meet at least once per year and as needed to review plans for research by members of the institution and those associated with the College who are conducting human subject research. Review of research applications by the IRB can occur electronically. All personnel will receive notice of the existing Human Subjects Research Guidelines annually.

For research that requires IRB review, the IRB will oversee a series of procedures to govern the research process or activity procedures. If it is not clear whether the research involves human subjects, whether the activity is grant-funded, or whether the activity requires IRB review, the researcher must seek assistance from the College's IRB in making the determination. Please contact the College's Office of Institutional Research, Planning, and Assessment to access the BCC IRB.

The responsibility is with the researcher(s) to refer projects to the IRB whenever human subjects are used in research, even if they do not think that the subjects are at a high risk level. Federal legislation places the burden of liability for negligence and harm directly on the researcher and the College.

Faculty and/or staff associated with students who are conducting research are responsible for disseminating the guidelines to those students.

At the awarding of any newly-funded grant project, the designated grant personnel will submit the project for review by the IRB to assure compliance with this policy. The BCC Office of Institutional Research, Planning, and Assessment will assist with this process.

IRB approval must be obtained **prior** to conducting the research; this includes the IRB approval that the research meets exemption status.

Types of Review

There are three types of review conducted by the IRB: *Exempt Status*, *Expedited Review*, and *Full Board Review*.

I. *Exempt Status* reviews are those that involve research using human subjects for which an exemption to the federal regulations for human subjects is designated by the IRB.

*Note: if there is any possibility that information, results, or findings of research involving human subjects will be shared with entities outside of the College, such as at a conference or to publish the results either in print or in an electronic format, the proposed research cannot meet **Exempt Status**.*

Exempt Status requires review by one member of the Board, preferably its Chairperson, or by one or more of the experienced IRB members so designated by the Chairperson to conduct the review.

Once a decision is made to approve or disapprove a project's ***Exempt Status***, the researcher will be notified on a very timely basis. Proposals and activities that do not meet ***Exempt Status*** may be re-submitted upon making the necessary changes to either meet ***Exempt Status***, to move to an Expedited Review, or they may be withdrawn. Following review of Exempt Status notification, the IRB may request additional information.

The six federally-approved categories of exemption under 45 CFR 46.101(b) are as follows:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If the IRB observes that a research activity originally classified as *Exempt* later does not meet the *Exempt Status* regulations, the IRB can request a review of the activity.

II. Expedited Reviews are those that involve research involving human subjects who are not students in the class and do not involve:

- Students of a special population such as children, pregnant women, prisoners, or mentally challenged persons.
- Sensitive topics such as sex education.
- Deception.
- More than minimal risk to subjects.

If there is any possibility that the information will be shared with entities outside of the College such as at a conference or to publish the results either in print or in an electronic format, the proposed research must follow an *Expedited Review*.

Research that involves human subjects as part of an *Expedited Review* must maintain an adequate standard of informed consent as well as confidential data. Any information that is gathered on the

subjects must be safeguarded so as to ensure that the data cannot be linked either directly or indirectly to the subject.

The list of categories of research that may be reviewed by the IRB through an expedited review involves but is not limited to the following:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE:

Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects; or (b) where the remaining research activities are limited to data analysis; or (c) where no subjects have been enrolled and no additional risks have been identified.

Expedited Review requires review by one member of the Board, preferably its Chairperson, and by one or more of the IRB members so designated by the Chairperson to conduct the review. Reviewing IRB members will be selected based upon the type of human subject involved.

Once a decision is made to approve or disapprove a project the researcher will be notified on a very timely basis. Proposals that are not approved may be re-submitted upon making the necessary changes or be submitted for a different status or be withdrawn.

III. Full Board Reviews examine research that involves special populations, sensitive behavioral research, research involving deception, or research that has the potential to harm the subjects. A **Full Board Review** requires a meeting involving a quorum of the IRB members.

Federal regulations **require** that an Institutional Review Board give special consideration to protecting the welfare of special populations, such as children, prisoners, pregnant women, or mentally challenged persons. Research involving special populations, sensitive behavioral research, research involving deception, or research that has the potential to harm subjects **automatically** require a **Full Board Review**. Such a review will require the approval of a majority of members of the IRB.

It is understood that in some cases, the condition or status of the human subject may not be known prior to the research or the human subject may not self-identify to the research at the time of the research. For example, the researcher may not know the pregnancy status of a woman and the woman may not self-identify such status.

The IRB may *waive the requirement for the researcher to obtain a signed consent form* for participants under the age of 18 [under Title 45 CFR Part 46.117 (c)] providing the only record linking the subject to the research is the consent form and there will be little potential harm as the result of a breach of confidentiality, or that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. The waiver will be determined by the IRB.

Once a decision is made to approve or disapprove a project the researcher will be notified on a very timely basis. Proposals that are not approved may be re-submitted upon making the necessary changes.

Research Guidelines

Research is defined as a systematic investigation, including research development, testing and evaluation that are designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities (45 CFR 46.102 (d)).

Human subject is defined as 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 (45 CFR 46.102 (f)).

Most educational projects do not require an IRB review under federal law. Generally, classroom activities do not require an IRB review if the activity meets all the following criteria:

- part of pedagogy
- participants are only students and the instructor(s) enrolled in the class
- results are shared only with students and the instructor(s) enrolled in the class
- risk to students is nil or minimal
- special populations are not participants (children under 18 years, pregnant women, prisoners or cognitively impaired subjects)

If there is any possibility that the information obtained through a human subjects research project will be shared with entities outside of the college such as at conference or to publish the results either in print or in an electronic format, the proposed research may require additional procedures to meet federal regulations. When research is shared outside the college federal regulations consider it a contribution to general knowledge and the research falls under the Protection for Human Subjects guidelines. In most instances the additional procedure is a signed written consent from each participant.

All grants received by the College must be reviewed at the time of award to ensure compliance with the regulations described in these guidelines. This will be done by the Bristol Community College Grants Office in conjunction with the principal investigator and overseeing administrator of the grant. **All federal grant applications** must be reviewed by the IRB at the time of application to ensure compliance.

Researchers are responsible for notifying the IRB of human subjects research. All human subjects research conducted by BCC affiliated investigators must **be submitted to the BCC IRB** for review. All researchers must complete a BCC application for human subjects research and submit to the college Institutional Review Board via the BCC Office of Institutional Research, Planning, and Assessment (www.bristolcc.edu/administration/ir)

Ethical Principles

Bristol Community College is committed to the ethical guidelines set forth in the federal regulations regarding any human subjects research. The College assures that all activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles as stated in the Belmont Report (www.bristolcc.edu/administration/ir).

Voluntary Participation: Human subject participation in the research project must be voluntary; it must occur as the result of free choice; it cannot be based on compulsion or obligation. The disclosure of relevant information must be presented to the individual in a manner that is clear, concise and readily understandable. The subject cannot be made to feel they are being coerced.

Inducement to participate: There are times when students may be selected to participate in research. Oftentimes the faculty member may use an inducement to students to participate such as offering extra credit. Caution should be exercised to insure that the inducement is not so large to cloud the student's judgment about what is in his or her best interest. In addition, if extra credit is made available to student participants there must be a procedure in place whereby students not participating may also earn extra credit. Furthermore, students should not be recruited in the classroom as that may compromise the student's confidentiality.

Informed Consent: Any research that takes place under the College's auspices must have respect for persons as autonomous agents. Therefore, all subjects must be informed about what participation in the project entails. This requires that the individual subjects must read and sign an informed consent form prior to participating in the study. It is important that the researchers ensure that the potential participants understand what is required of them as research subjects. Federal law requires that only individuals that are 18 years or older are capable of giving informed consent.

Subjects that are under 18 years of age may participate in the research project only with the signature of the parent or legal guardian in addition to their own signature. This requirement also applies to the filling out of anonymous questionnaires since, again, only persons over the age of 18 are capable of giving informed consent. Similarly, if children are selected as participants, the research must be explained to them by their parent or their guardian in language that they can understand.

Identification and minimizing of risks: Just about all research involves some risk. It may be physical, social, economic, or psychological in nature. In approving the project, the IRB will make a determination on the risks involved. It will also assess if the risks have been minimized as much as possible without compromising the validity of the research. The IRB will also analyze the benefits of the research, whether the risk is reasonable in relation to its benefits, whether the selection of the subjects is equitable, if informed consent will be sought, and if there are adequate provisions in place to protect the confidentiality of the subjects.

Research involving deception: There may be times when it is necessary to withhold some pertinent information from the subjects when disclosure of this information would likely impair the validity of the study. In such cases, subjects should be told that they are being invited to participate in research in which some features will not be disclosed until their participation has ended or the research has concluded, whichever is more feasible. However, researchers are not to deceive subjects if the research involves physical harm, discomfort or unpleasant emotional experiences all of which, if disclosed, would affect their decision to participate.

Confidentiality and anonymity: It is important that all human subjects involved in research maintain their confidentiality. This is especially important if the research involves asking the participants questions regarding their personal life or other information that the individual does not want to be made public. A policy of total anonymity is preferred whenever possible. If the researcher needs access to the individual's name or other identifiable information, the researcher must tell the individual who will have access to the data, the purpose of the data and how the information thus gathered will remain confidential.

IRB Process

The IRB will keep adequate documentation of IRB activities including the following:

- A. Copies of all research applications reviewed, approved sample consent forms, and reports of any injuries to subjects.
- B. Minutes of all IRB meetings to include the names of people attending the meetings, actions taken by the IRB, the vote taken on those actions including who voted for the action, who voted against and who abstained from voting, the reasons for any requested change in the project or project disapproval, a written summary of the discussion of controverted issues and their resolutions, and any dissenting reports or opinions. If a member of the IRB has a conflicted interest in the project, the minutes must show that the member did not participate in its review except to provide information requested by the IRB.
- C. Records of any continuing reviews of project activity.
- D. Copies of all correspondence between the IRB and the researchers.
- E. A list of all IRB members as required by 45 CFR 46.103 (b) (3).
- F. Written procedures for the IRB as required by 45 CFR 46.103 (b) (4).
- G. Statements of significant new findings provided to subjects as required by 45 CFR 46.116 (b) (5).

The IRB will provide for the maintenance of records relating to a specific research activity for at least three years after termination of the last IRB. In turn, IRB records will be available for inspection and copying by authorized representatives of the federal Office of Human Research Protection (OHRP) at reasonable times and in a reasonable manner or the requested records will be copied and forwarded to OHRP when requested by an authorized Department of Health and Human Services representative which is the parent agency for OHRP.

IRB Records

As required by 45 CFR 46.103 (b) (3) the IRB records will include a list of the IRB members by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution; for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency Head (*sponsoring the project*).

The IRB must also have written procedures for (i) conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the College; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than investigators that no material changes have occurred since the previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject 45 CFR 46.103 (b) (4).

Student Research

The Guidelines for Compliance with Federal Regulations for Human Subjects Research apply to student research. Faculties who are overseeing a student(s) who is conducting research involving human subjects are responsible for informing the student(s) about the guidelines and for disseminating the guidelines to the student(s). Submission of an application to the IRB and approval of the IRB prior to starting the research is required. Research projects that are totally self contained within the course and among students enrolled in the course only, that do not put the participants at risk, and that will not be shared with entities outside the class do need to submit an IRB application.

Cooperative Research with another Institution

There may be times when the College engages in cooperative research with another institution. In such circumstances, one institution may agree to delegate responsibility for initial and continuing review of all or portions of the research activity to the other institution's IRB. For any portion of the research that the College's researchers do not delegate to another IRB, the researchers remain responsible to complying with BCC's policies and procedures. **Any research** conducted on any of this College's campuses must be reviewed by the College's IRB.

The agreement with another institution must be in writing with copies provided to all parties involved in the agreement and to those responsible for ensuring compliance with the IRB policies and procedures. If BCC receives IRB approval from another institution it must provide a copy of the approval letter to its IRB. Irrespective of the agreement, **each** institution is responsible for safeguarding the right, welfare and confidentiality of the human subjects.

Appeals

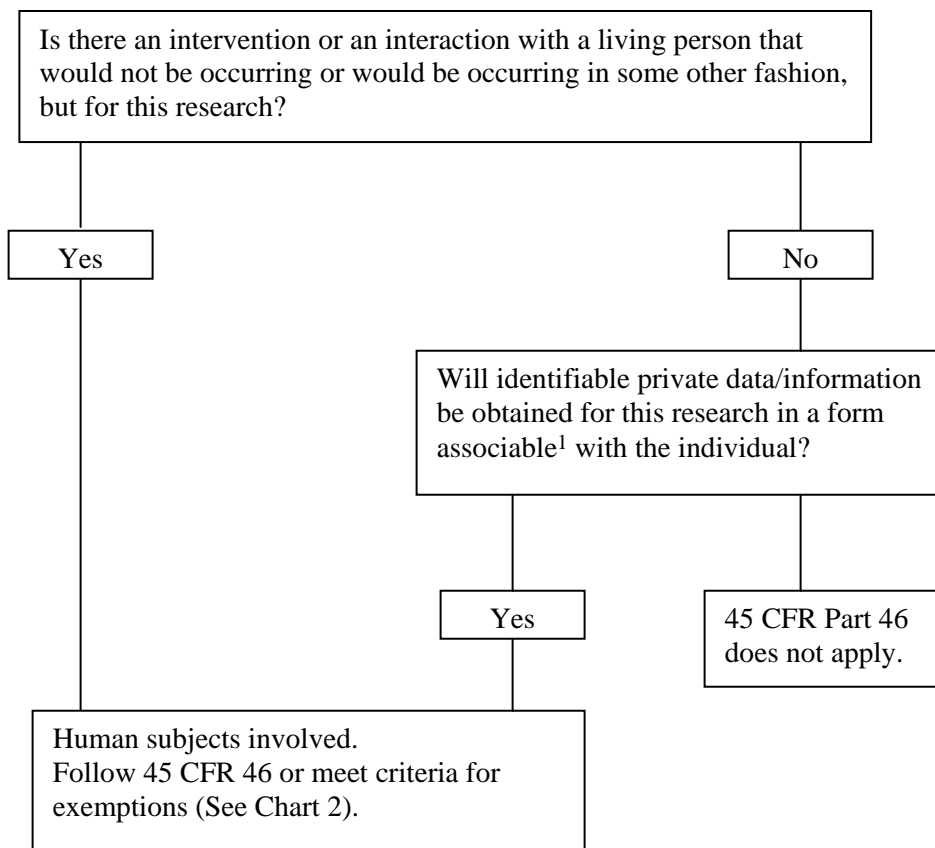
If the application is denied, the researcher has a right to appeal to the IRB. The researcher should submit a letter to the IRB Chairperson requesting another review and provide an appropriate rationale. An attempt will be made to resolve the problem(s) identified with the proposal. The IRB is the final authority over whether the proposal is approved.

Human Subject Regulations Decision Charts

The Office for Protection from Research Risks (OPRR) provides the following graphic aids to clarify portions of the Department of Health and Human Services (DHHS) human subject regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46). These portions of the regulations are the subjects of frequent inquiries to OPRR.

Chart 1: Definition of Human Subject at Section 46.102(f)

Is the definition of “human subject” at Section 46.102(f) met in this research activity?

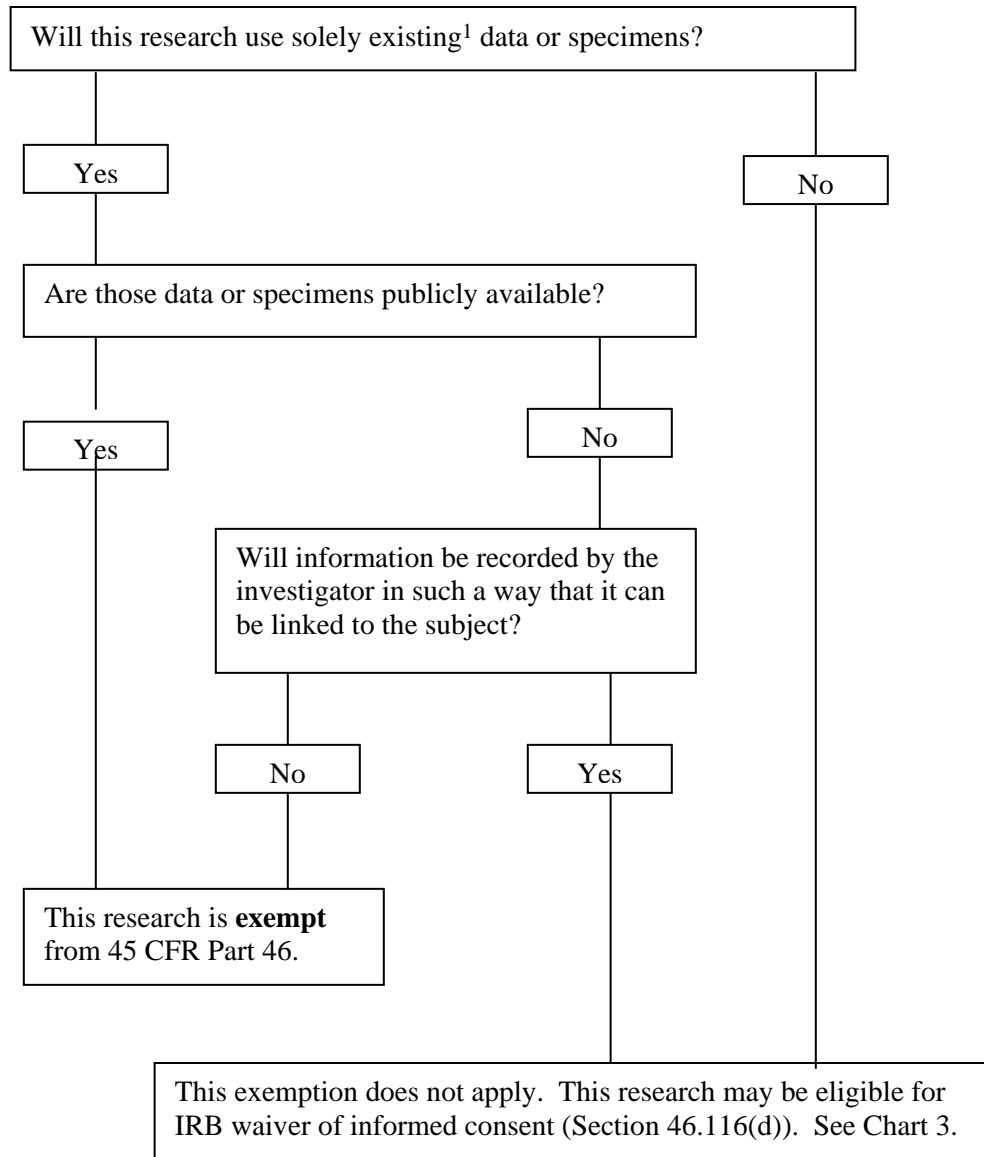


¹That is, the identity of the subject is or may readily be ascertained or associated with information.

Chart 2: Exemption at Section 46.101(b)(4) regarding research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Is the research exempt in accordance with Section 46.101(b)(4)?

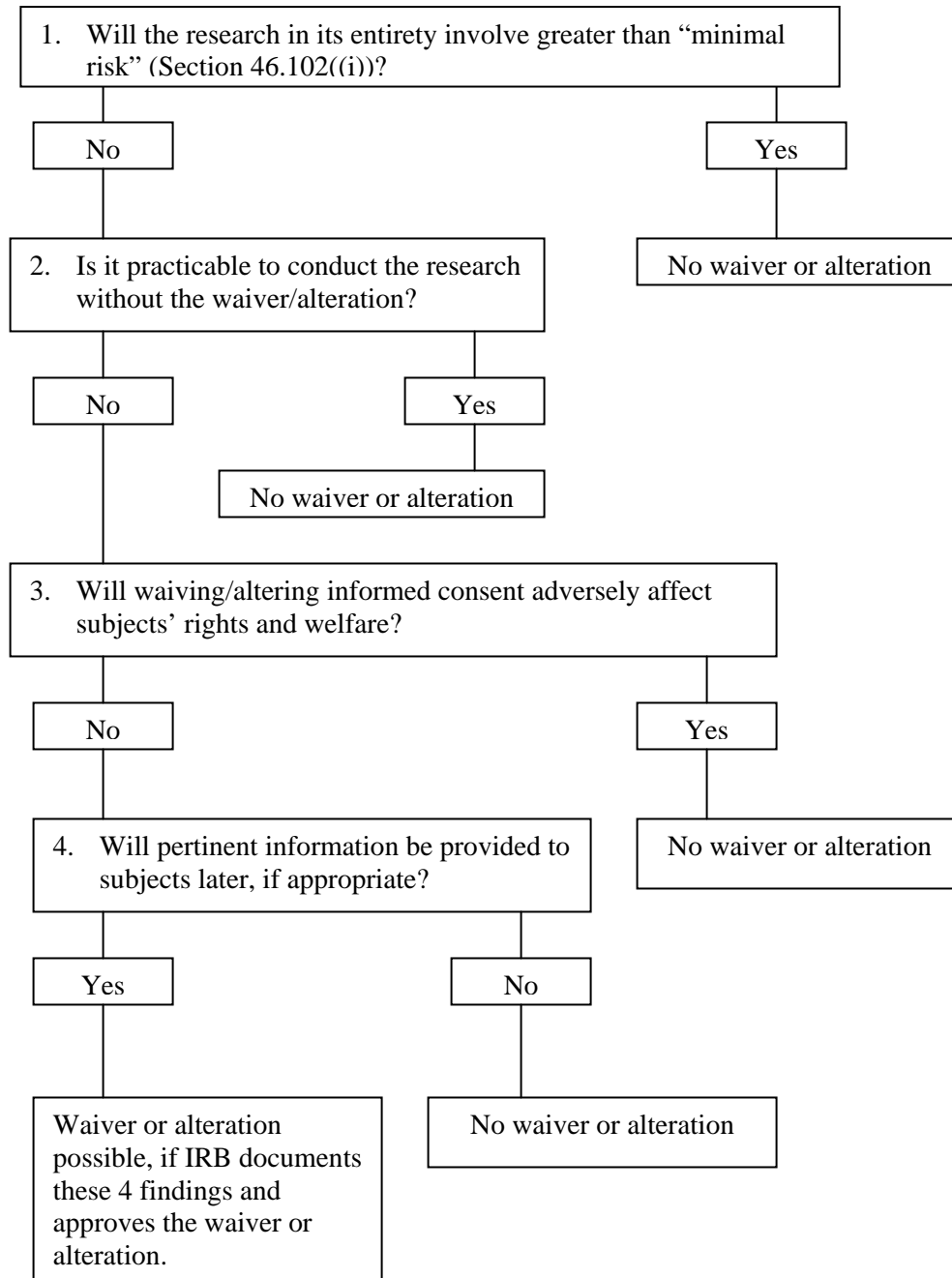
The regulations at 45 CFR Part 46 do not apply if the criteria for exemption under Section 46.101(b)(4) are met.



¹“Existing” means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and nonresearch activities.

Chart 3: Waiver or Alteration of Informed Consent under Section 46.116(d).

Can the Institutional Review Board employ Section 46.116(d) to waive informed consent or alter informed consent elements?



Instructions for Application for IRB Review of Human Subject Research

Before submitting an application to the Institutional Review Board, ensure that you review the College's [Guidelines for Compliance with Federal Regulations on Human Subjects Research](#). If you are not required to submit an application for IRB Review for Human Subject Research, please follow the ethical principles as identified in the Guidelines.

The Application for IRB Review of Human Subjects Research is available from the Office of Institutional Research, Planning, and Assessment (www.bristolcc.edu/administration/ir).

Directions on how to prepare an application are contained in the following pages.

A. Application Submission

Submit **three** hard copies and an electronic copy of the application to the IRB chairperson at least **one month prior** to the start of the project.

For all federally funded grant research, submit for a review at time of application.

Submit application and all supporting documentation to:

IRB Chairperson

Office of Institutional Research, Planning, and Assessment

Bristol Community College

777 Elsbree Street

Fall River, MA 02720

Email: Rhonda.Gabovitch@Bristolcc.edu

An expedited review will be conducted by the IRB chairperson. If necessary, the IRB chairperson will solicit input from the appropriate member(s) of the IRB or the full IRB.

The IRB will make one of the following decisions:

- The application is approved as submitted
- Approval is withheld pending application revisions
- Application requires review by more members of the IRB
- Application is denied approval

B. Application Instructions

Although the IRB is composed of individuals with an academic background, they come from different disciplines. Therefore, the application should be written so that it is easily understood. If the application includes technical terminology, the terminology should be explained.

To facilitate the review of the application, respond to each statement and do not refer the reviewers to information in a previous or later response.

Attach all relevant materials (e.g. copies of all questionnaires or survey instruments, informed consent document templates, letters of approval from cooperating institutions).

Sign the Researcher Assurance Statement/Supervisor Approval portion of the application. If

the researcher is a student, then the student, the faculty supervisor, and the faculty supervisor must sign.

C. Continuing Review and Submission of the Annual Update

Applications are approved for a maximum period of one year. For research projects that continue beyond one year, it is the responsibility of the researcher to submit a request for Annual Update to the IRB. The first update must be received by the IRB within twelve months following the application approval date. If the IRB determines that a project requires review more often than annually, the researcher will be notified. Projects can be updated annually for a maximum of five years. Continuation of projects beyond five years requires resubmission of the application.

D. Reporting Changes in Research Protocol

Any change in an activity that affects the human subjects must be approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the subjects. Researchers should submit a hard copy and an electronic copy requesting a change in the activity and identifying the change in activity to the IRB. If the change in the activity requires a change in the consent form, attach a new consent form to the request for change; please send one hard copy and an electronic version or attachment.

E. Reporting End of Project

When the project is completed, the researcher must send an End of Project report to the IRB. Include the end date of the project.

F. Submission of a Report of Injury

If a subject sustains an injury during the study, the researcher must take immediate action to assist the subject according to the safety policy of Bristol Community College and notify the IRB within 24 hours of the injury.

G. Reporting Non - Compliance with IRB Policies and Procedures

Any incident of noncompliance with IRB policies and procedures should be reported immediately to the IRB.

H. Record Keeping

The principal investigator, project director, or researcher must retain the approved application and signed consent form for a minimum of three years following the completion of the project, or longer if required by the IRB. For student research, the faculty supervisor must retain these documents. The IRB may request copies of these forms. Government funding agencies often require that all documents associated with research be retained for three years following the completion of the project or grant.

I. Forms

Copies of these materials and forms may be made as needed.