

Kirkwood Community College

Regulations and Policies Human Subjects Research

Research Guidelines

Research involving human subjects is governed by federal regulations and Kirkwood Community College policy. The college assures that it will comply with the Office of Human Research Protection regulations for the Protection of Human Research Subjects (45 CFR 46 as amended).

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)).

As noted in 45 CFR 46.101 (b) unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are **exempt** from this policy:

- (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 subjects at the 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 (b) (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.

Institutional Research Board

Research is defined in federal regulations as a systematic investigation that includes research development, testing and evaluation designed to develop or contribute to general knowledge. It consists of work that is conducted on or off campus, including questionnaires, interviews, surveys, tests, observations, and experiments, even if the work is preliminary to a more extensive study. Research also includes any systematic collection of data from human subjects that occurs in conjunction with classroom projects.

As required by federal regulation (45 CFR 46) Kirkwood has an Institutional Research Board (IRB) consisting of **at least** five members with varying backgrounds to promote complete an adequate review of research activities commonly conducted by the institution. One of the five members has no connections to the college community. The college's Institutional Review Board is composed of the Director of Institutional Research, one administrator, two faculty members, and one qualified person from outside of Kirkwood. Additional faculty or staff members may serve in an advisory capacity where appropriate.

The goal of Kirkwood's Institutional Review Board (IRB) is to protect the rights and welfare of those individuals who agree to participate in research. The review and approval of proposals by the IRB is meant to assist the subjects and the researchers by having a peer review that will objectively analyze the potential risk involved as well as ways to minimize that risk.

Research investigators shall make an initial determination whether the research will involve human subjects as defined in 45 CFR 46.102 (f)

If it is not clear whether research involves human subjects as defined in 45 CFR 46, research investigators will seek assistance from the IRB in making this determination. It is the responsibility of researchers to refer their 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. Although the college is exempt under federal law for most classroom activities, should the faculty member share the information with entities outside of the college such as a conference or intends to publish the results, the proposed research must be reviewed by the IRB.

Kirkwood's Institutional Review Board meets as needed to review research by members of the institution. At the initiation of any new grant project, the designated grant personnel will submit the project for review by the IRB to assure compliance with this policy.

Ethical Principles

For research that is not exempt from the legal requirements involved in using human subjects, the college has instituted a series of procedures to govern the process. If it is not clear whether the research involves human subjects as defined in 45 CFR 46.102 (f), the researcher will seek assistance from the college's IRB in making the determination. The college is committed to the ethical guidelines set forth in The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research – *The Belmont Report*—as authorized by the National Research Act (Pub. L. 93-348). As part of the process Kirkwood's IRB will evaluate the following ethical practices in determining risk:

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, it must be based upon disclosure of relevant information 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: As noted in *The Belmont Report* any research that takes place under the college's auspices must have respects 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 the 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, the selection of the subjects is equitable, if informed 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 did not want to be made public. A policy of total anonymity is preferred whenever possible. If the researcher needs access to the individual's names 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 maintains 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).

Types of Review

There are two types of review conducted by the IRB. The first one only requires review by one member of the Board, preferably its chairperson. In all instances the appropriate **review must be conducted** if there is any possibility that the information will be shared with entities outside of the college such as at a conference or published in a journal that is either in print or in an electronic format. The IRB review process must **also** be followed if the agency funding the sponsored project requests a copy of the college's human subject research policies and procedures.

An expedited review will be conducted by the IRB chairperson or by one or more of the experienced IRB members so designated by the chairperson to conduct the review.

Type I reviews are those that involve research using human subjects who are not students in the class and do not:

- Involve students of a special population such as children, pregnant women, prisoners, mentally challenged persons, economically or educationally challenged persons
- Involve sensitive topics such as sex education
- Do not involve deception
- Do not involve more than minimal risk to subjects.

Research that involves human subjects as part of a Type I 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 insure that the data cannot be linked either directly or indirectly to the subject. If the results of the project are to be presented outside the college, e.g. in a conference, the project must undergo a Type I review. Projects that involve special populations or research that is harmful to the subjects shall require a Type II review.

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

Type II reviews research that involves special populations, sensitive behavioral research, research involving deception, or research that has the potential to harm the subjects. A Type II review requires a meeting involving a quorum of the IRB members.

Federal regulations **require** that Kirkwood's Institutional Review Board give special consideration to protecting the welfare of special populations, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons. Research involving special populations, sensitive behavioral research, research involving deception, or research that has the potential to

harm subjects **automatically** require a Type II review. Such a review will require the approval a majority of members of the IRB.

Student Research

The college's policies and procedures also apply to student research. Instructors are responsible for screening student research projects and determining if they require IRB approval. If the project is assigned for the purpose of producing generalized results that may be presented outside of the class, be published, or has the potential to put the participant's at risk, the researcher must comply with these policies. Submission of an application to the IRB prior to starting the research is required. **It is important to note** that not all classroom research assignments require IRB approval. Only those assignments that will be presented outside of the college need such approval.

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 portion 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 Kirkwood'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 Kirkwood 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

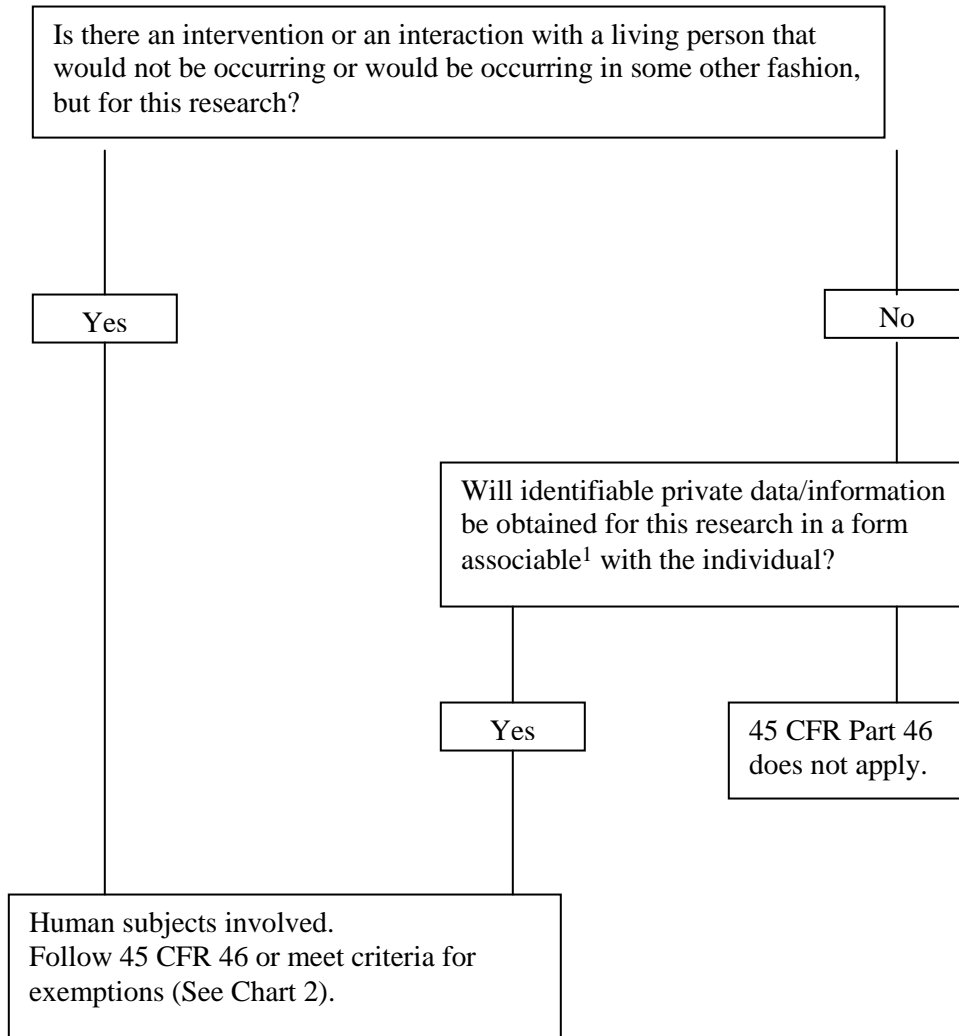
If the application is denied, the researcher has a right to appeal to the IRB. The researcher should submit a letter to the IRB chairperson requesting another review and provide an appropriate rationale. An attempt will be made to resolve the problem(s) identified with the proposal. The IRB is the final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

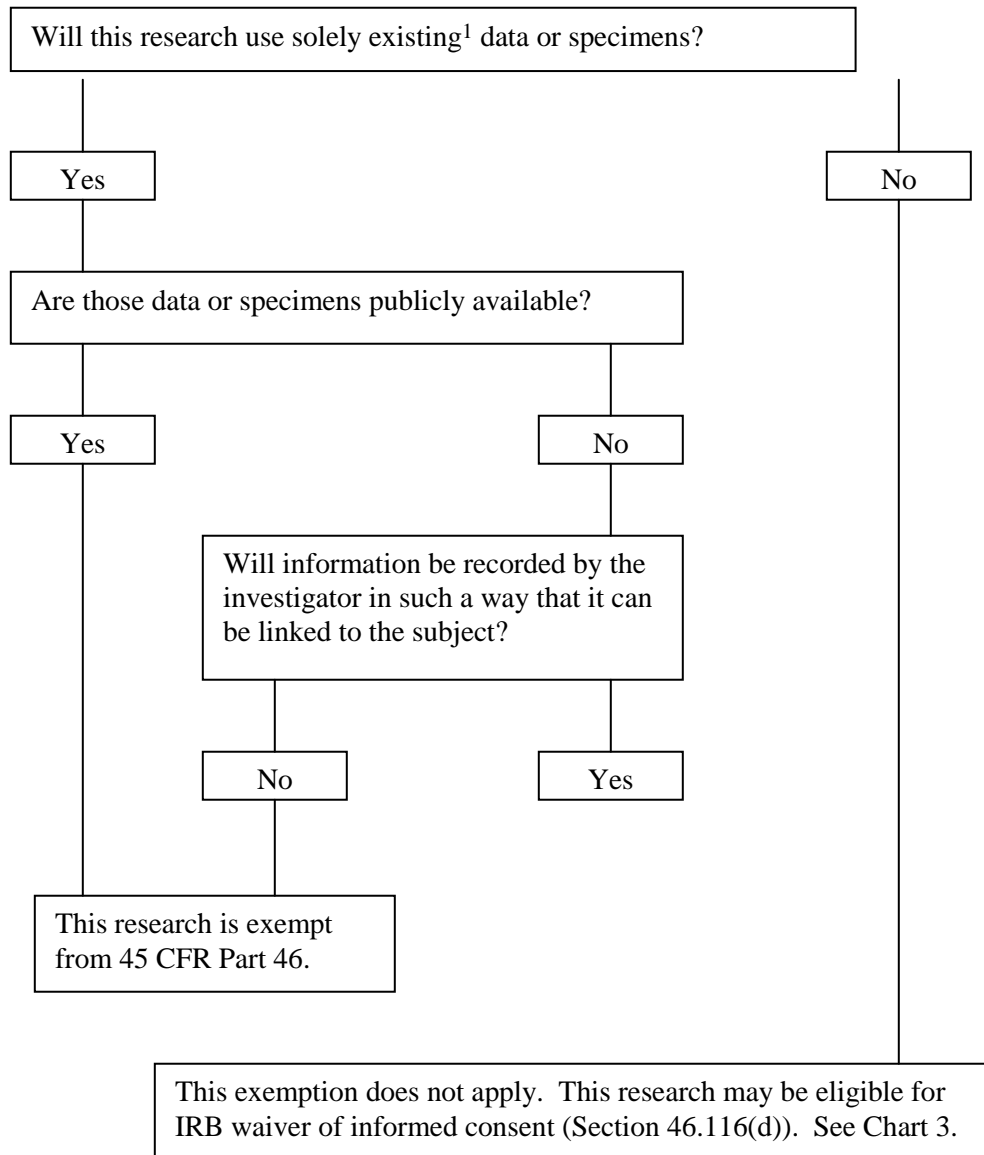


¹That is, the identify of the subject is or may readily be ascertained or associated with information.

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 non-research 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?

