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GENERAL STATEMENT

Broward College has established an Institutional Review Board ("IRB") to assure that any research conducted at the College involving the collection or analysis of data collected from or about human subjects conforms to the ethical principles of the Belmont Report, as required by the Department of Health and Human Services ("HHS"). The IRB is responsible for the review of all research involving human subjects conducted under the auspices of Broward College by its faculty, students, staff, or administrators, as well as by outside investigators wishing to use Broward College students, faculty, staff, and/or administrators as research subjects, whether the research is funded or not.

IRB COMPOSITION/MEMBERSHIP

The IRB Committee at Broward College is composed of faculty, administrators, and staff, and an external community member (non-college affiliate). HHS regulations for IRB membership stipulate that an IRB must have at least five members with varying backgrounds to promote complete and adequate review of the research activities and include at least one member who is not otherwise affiliated with the institution. The IRB must have at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB at Broward College consists of nine members with varying research backgrounds and expertise, who serve on the IRB for a minimum of three years. Prior to serving on the IRB, all members must complete external training provided by a qualified organization preparing them for their role as an IRB member at Broward College.

THE IRB PROCESS

The IRB process, including all information related to required documents and the submission of said documents can be found at www.broward.edu/irb. The contact information for the IRB Chairperson and committee members, scheduled meeting dates and deadlines, links to all required forms, and a description of the IRB review and notification processes can be found at www.broward.edu/irb.

STEPS IN THE PROCESS

Researchers who wish to submit a proposal to the IRB for review must submit a certificate of completion from a human subject's research protection course. The National Institutes of Health (NIH) offers a free online training course at http://phrp.nihtraining.com/users/login.php. When applicable, researchers must also submit an IRB approval letter from the IRB at their graduate institution. The Broward College IRB will only review research protocols that have been approved by the researcher's advisor/committee and their graduate institution's IRB.

Researchers wishing to conduct human subject research at Broward College must complete and submit an IRB Protocol Form. When completing the Protocol Form, researchers must select one of the three types of IRB review that they believe their study falls under. However, the IRB reserves the right to change the type of review based on federal regulation. The IRB will make the final determination.

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The three types of IRB review are: Exempt, Expedited, and Full Board Review, as stipulated by the Office for Human Research Protections (OHRP), Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects (45 CFR 46). The description of the three types of review can be found below.

EXEMPT

- 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 (45 CFR 46.101(b)(1)).
- 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 that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation (45 CFR 46.101(b)(2)).
- 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 (45 CFR 46.10(b)(3)).
- 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 (45 CFR 46.101(b)(4)).
- 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 (45 CFR 46.101(b)(5)).
- 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 (45 CFR 46.101(b)(6)).

EXPEDITED

- Clinical studies of drugs and medical devices only when condition (I) or (II) is met:
  - I. 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.)
  - II. 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.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

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- 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
- From other adults and children, considering the age, weight, and health of the subjects, the collection procedures, 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.
- Prospective collection of biological specimens for research purposes by noninvasive means.
- 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.)
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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.

FULL BOARD REVIEW

Studies involving more than minimal risk and/or a vulnerable population ["children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons" (HHS, para 1)].

Note: even if a researcher deems their study to be exempt from review, they must still submit a Protocol Form and supporting materials to the IRB. The Chairperson and/or the Committee will make the final determination. After selecting the type of review, researchers must complete Sections I-VI of the Protocol Form.

Once completed, researchers must sign and date the certification at the end of the Protocol Form. All researchers working on the study (primary investigators and co-investigators) must submit a certificate of completion to show they have completed a human subject's protection training course. Researchers are required to submit a copy of an informed consent form for each study submitted for IRB review in addition to a copy of their IRB approval letter from their graduate institution, if applicable. The Informed Consent Template provides instructions and guidelines for creating a consent form and can be found at www.broward.edu/irb.

A submission checklist is also available at www.broward.edu/irb to assist researchers with submitting complete proposals. The items on the checklist are as follows:

- Completed IRB Protocol Form with Signature(s) (required)
- Human Subjects Protection Course Certificate(s) (required)
- IRB Approval Letter from Graduate Institution (required)
- Informed Consent Form(s) (required)
- Stimulus Materials (surveys, questionnaires, etc.)

- Recruitment Materials (flyers, emails, etc.)
- Other documents (debriefing forms, letters of support, etc.)

Completed IRB Protocol Forms should be submitted electronically with required and supporting documents as attachments to irb@broward.edu, in one communication. Please note the IRB reserves the right to request a hard copy of the IRB Protocol Form and supporting documents, if deemed appropriate.

THE IRB REVIEW PROCESS

The IRB convenes once a month during the academic year for a total of nine meetings. IRB submissions must be received at least two weeks prior to the scheduled meeting dates. For more information regarding the IRB meeting schedule and deadline dates, please see the IRB Schedule at www.broward.edu/irb. Researchers should allow three weeks to receive a response about the status of their proposal from the IRB.

IRB members review research protocols, informed consent forms, IRB approval letters and materials from researchers' graduate institutions, stimulus materials/instruments, recruitment materials, etc. An Expedited review procedure consists of a review by the IRB Chairperson or by one or more experienced reviewers designated by the Chairperson from among the members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

There are four possible IRB actions: 1) approve research, 2) require modifications in order to secure approval, 3) disapprove research, and 4) suspend or terminate previously approved research. The IRB will provide researchers with a formal letter regarding the status of their proposal. If a study has been approved, researchers will receive an approval number from the IRB along with consent forms and recruitment documents that have been stamped by the IRB with the study's approval date. An expiration date will be provided for all approved protocols. IRB approval is typically granted at intervals within one year, contingent upon the level of risk associated with the research. Researchers will also receive a formal letter from the IRB to request modifications needed to secure approval. Researchers must make all changes specified by the IRB in order for their study to be approved. If the IRB decides to disapprove research (must be voted on during a convened meeting), it must include in its written notification a statement of the reasons for its decision and give the researcher an opportunity to respond in person or in writing (45 CFR 46.109(d)). The researcher has the right to appear before the IRB at a convened meeting to appeal the decision. Requests to appeal research disapproval before the convened IRB must be received in writing two weeks prior to a scheduled meeting date.

REPORTING ADVERSE EVENTS

Federal regulation requires that any adverse events associated with participation in a research study be reported to the IRB. The Department of Health and Human Services (HHS) defines an adverse event as follows:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

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If an adverse event occurs while conducting a research project, the researcher must submit an IRB Adverse Event Form to the IRB as soon as feasible. The form can be found at www.broward.edu/irb. For more information regarding reviewing and reporting unanticipated problems and adverse events see http://www.hhs.gov/ohrp/policy/advevntguid.html.

AMENDMENTS AND CHANGES TO APPROVED RESEARCH

Federal regulation requires the IRB to review any proposed changes to research protocols. Researchers wishing to make changes to their approved IRB protocols must first receive permission from the IRB. Researchers should complete and submit an Amendment Form to the IRB prior to implementing any changes to their approved protocols. The IRB Amendment Form can be found at www.broward.edu/irb.

CONTINUING REVIEW OF APPROVED RESEARCH

Federal regulation requires the IRB to conduct continuing review of approved research protocols set at a time interval appropriate to the level of risk associated with the research, but no less than annually. One month prior to the IRB approval expiration date, the researcher must submit a Continuing Review Form to the IRB. The IRB will notify the researcher in writing, 60 days prior to the approval expiration date, to inform the researcher that their study is subject to continuing review. If the researcher wishes to continue conducting the approved research, even if only coding or analyzing data, the researcher must complete a Continuing Review Form. The form must be submitted one month prior to the approval expiration date and can be found at www.broward.edu/irb. No research may be conducted passed the expiration date unless the study has been reviewed and renewed by the IRB.

RESEARCH CLOSURE

The completion or termination of a research protocol is a change in research activity that must be reported to the IRB. The closure of an approved research protocol means that no further research, data collection, follow-up, and coding of data or data analysis will be conducted. Even if a study is no longer enrolling subjects, it remains active until data analysis, write-up of research results, and manuscript preparation that requires the use of personally indefinable information is complete. Upon final completion of a research project, a Research Closure Form must be completed and submitted to the IRB. The IRB Research Closure Form can be found at www.broward.edu/irb.

Records relating to approved research must be retained for at least 3 years after the completion of the research project. All research materials, consent forms, questionnaires, data, etc. must be retained for at least 3 years and may be subject to review by the IRB, if deemed necessary.

VIOLATION OF POLICY/PROCEDURE

Any violation of the policy and or procedure will be reviewed by the IRB Committee and the College Provost and Senior Vice President for Academics and Student Success (or designee). The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that is associated with unexpected serious harm to subjects (45 CFR 46.113). A suspension or termination of IRB approval of research may occur at any time during the period for which IRB approval had already been granted. At any time during the approval period, if further participation is deemed to not be in the best interest of the College, the College Provost and Senior Vice President for Academics and Student Success (or designee) may suspend or terminate the research and the researcher will be notified immediately. In all cases, the College will take the necessary action(s) to maintain the integrity of all research projects

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being conducted at and through Broward College to ensure that the rights and welfare of all research subjects, as well as the College, are sufficiently protected.

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