

MONMOUTH UNIVERSITY

Policies and Procedures

Policy Name: Human Participant Research

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Approved By: President and Cabinet **Issued By:** Thomas Pearson, Vice
President for Academic
Affairs/Provost

I. POLICY FOR USE OF HUMAN PARTICIPANTS IN RESEARCH:

- A. Except as set forth herein, this policy applies to any research activity conducted at or sponsored by Monmouth University that involves human participants. It is relevant whenever an investigator conducts research in which he or she (1) obtains data through intervention or interaction with an individual or (2) obtains private information by which an individual could be identified. The policy is therefore applicable to research involving living human beings whose physical, emotional, or behavioral conditions, responses, tissues, or fluids are investigated for research purposes (that is, for any reason other than the sole purpose of benefiting the participant as an individual). It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups, as well as the study of existing public or privately held records where the identity of individuals is known.
- B. The policy is applicable whether the research is undertaken on a large or small scale and whether it is externally funded or not. Pilot projects, faculty research, student dissertations and thesis, projects, independent study projects, and course projects must follow this policy if they involve research with human participants and are not otherwise excepted under this policy.
- C. This policy does not apply to routine course, workshop, or curriculum development using accepted educational practices sponsored by the University or to aid or services provided by professionals to their clients. This policy also does not apply to student, or other, research projects that are not published, or publicly disseminated, and thus do not contribute to generalizable knowledge as that term is used in applicable federal regulations governing human participant research. For the purposes of this paragraph, publication or public dissemination shall not include the oral presentation of student research projects in classrooms as part of a course, at undergraduate research colloquiums or other University events where the primary purpose of the presentation is not to disseminate information to individuals or groups outside the University community. The presentation of student research or other research projects at external conferences or at University events where the presentation of the information to individuals outside the University is a primary purpose of the event or the placement

of the research on file at the University library shall be considered to be publication and/or public dissemination of the research for the purposes of this paragraph.

- D. This policy delineates the responsibilities of the University and the Institutional Review Board (IRB) for the protection of human participants and the Research Investigator and sets forth when research projects must receive full review (Section VIII A.3), expedited review (Section VIII A.2) or are exempt from review (Section VIII A.1).
- E. This policy asserts that research that meets the requirements of this policy shall be approved and not rejected for reasons that fall outside the purview of this policy. The IRB shall not consider general policy or political reasons as a basis for making its decisions.

II. **COMPLIANCE WITH APPLICABLE LAWS:**

In accordance with Monmouth University policy governing the use of human participants in research, all human participants research under the aegis of Monmouth University will be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (45 CFR 46). In addition, Monmouth University will also adhere to all applicable federal, state and local laws and regulations.

III. **THE INSTITUTIONAL REVIEW BOARD:**

- A. The Institutional Review Board (“IRB”) is designed to assist researchers and institutional administrators with their duty to protect the rights and welfare of human research participants.
- B. The IRB is responsible for:
 - 1. Providing initial and continuing review (See Section X) of nonexempt research,
 - 2. Ascertain acceptability of proposed research in terms of University policies and procedures,
 - 3. Documenting that reviews are conducted according to University policy,
 - 4. Providing assistance and information to investigators engaged in research involving human participants,
 - 5. Developing policy, procedures, information, and instructions regarding human participants research,
 - 6. Adjudicating differences and reviewing problems arising in research involving human participants,
 - 7. Ensuring compliance with externally mandated policies and regulations,

8. Reporting to the appropriate institutional officials and, for research governed by HHS regulations, to the Secretary of HHS, any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

C. The IRB shall consist of the following members:

1. six tenured full-time faculty members knowledgeable and experienced in conducting human participant research and the protection of human participants, with no more than two faculty members from any school. Faculty members are chosen by the Faculty Council. Faculty serving on the IRB shall be paid a stipend for their services as determined by the Provost.
2. the Vice Provost for Graduate Studies (ex officio-voting member).
3. a member of the University's administration chosen by the Provost.
4. a member of the surrounding community, chosen by the Provost, who is not affiliated with the University.
5. the Administrator of the IRB will serve as a voting member.

D. Both the Provost and Faculty Council shall be guided by the requirements of federal regulations, specifically 45 C.F.R. §46.107, in making the selections for individuals to serve as members of the IRB.

E. Individuals serving on the IRB shall serve for a term of three (3) years and shall not serve more than two (2) consecutive terms with the exception of the Vice Provost of Graduate Studies who shall serve as an ex-officio member of the IRB. If someone is appointed to an unexpired term of the IRB (to replace a member who cannot serve), then the replacement will continue the term until it expires and may serve (if selected by the Provost) two more terms. If this occurs, the IRB will refer to the most recent pool of candidates to find a replacement.

Each yearly period of a term shall commence at the beginning of the academic year (first day of classes in the fall semester) and shall conclude the day before the first day of classes of the next succeeding academic year.

Ongoing appointments of faculty members to the IRB shall be made in such a manner so that no more than two (2) faculty members' terms shall expire at the end of each academic year).

- F. At its last meeting of the academic year, the IRB shall choose a chairperson by a majority vote of its members. The chair shall serve for a one (1) year renewable term, but shall in no event serve for more than three (3) consecutive years.
- G. The Provost shall appoint sufficient staff to assist the IRB in the fulfillment of its duties and responsibilities. The IRB staff shall be responsible for ensuring that the IRB is properly supported for its meetings and other activities and shall report to the Provost through the Chair of the IRB.
- H. The IRB shall meet at least once each month to conduct its business. The IRB Chair may cancel any monthly meeting of the IRB if it has no business for its consideration for any particular monthly meeting. Any determinations made by the IRB at its meetings shall be communicated to affected parties within two business days of the meeting.
- I. Quorum. A simple majority shall be necessary to constitute a quorum for the transaction of business. Any action may be taken without a meeting if consent in writing is signed by all members. One non-scientist must be a part of the quorum.
- J. Telephone Conference. Members may participate in a meeting by means of a telephone conference or similar communications equipment by means of which all persons participating in the meeting can hear each other at the same time.

IV. **REVIEW OF RESEARCH**

- A. All research involving the collection of information involving human participants for the purpose of advancing knowledge that is not exempted under

Sections I or VIII A.1 of this policy must be reviewed and approved prior to commencing such studies.

- B. The requirements of this section apply to any research project conducted at the University or elsewhere, by anyone affiliated with Monmouth University (i.e. all faculty, staff, undergraduate, and graduate students).
- C. Any researcher, faculty or student that plans to conduct research projects involving human participants that is not exempted under Sections I or VIII A.1 of this policy must complete an Institutional Review Board Application Form online.

V. **INFORMED CONSENT OF RESEARCH PARTICIPANTS:**

- A. The decision of human participants to participate in research governed by this policy must meet the standards of *informed consent* set forth below:
 - 1. Voluntary—it must occur as the result of free choice, without compulsion or obligation;

2. Based on full disclosure of the information needed to make an informed decision about whether or not to participate;
 3. Based on the participant's comprehension of the information provided.
- B. If children are involved as participants and are capable of assent, their assent to participate must be solicited in addition to the permission of the parent(s) or legal guardian(s). For any children under the age of 18 years old involved as subjects, the permission of the parent(s) or legal guardian(s) to participate must be obtained.
 - C. The selection of research participants must be fair. Participants should not be selected for potentially beneficial research on the basis of favoritism, nor should risky research be targeted to vulnerable participants.
 - D. The procedures for recruiting participants must protect their privacy and be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation.
 - E. Any payment made to participants should not be so large as to constitute excessive inducement for participation.
 - F. When access to participants is gained through cooperating institutions or individuals, prior commitments made to the participants about the confidentiality or other terms of the primary relationship should not be abridged.
 - G. Risks to participants must be minimized and should be justified by the anticipated benefits to the participant or society.
 - H. Adequate provision must be made to protect the privacy of participants and to maintain the confidentiality of identifiable information.
 - I. Approval for conducting research with human participants must be obtained prior to any involvement of participants. All such research must either be reviewed or designated as exempt from review by the University's IRB (See Section VIII). All approved projects must be periodically reevaluated (See Section X).
 - J. Both the content, form and documentation of the informed consent of the research participants shall meet all requirements of 45 C.F.R. Sections 46.116 and 46.117.
 - K. In making its decisions with regard to this area, the IRB shall consult with the appropriate ethical guidelines of relevant professional organizations.

VI. **PROJECT INVESTIGATOR RESPONSIBILITIES:**

- A. The individual responsible for the conduct of the activity, i.e., the responsible project investigator, has primary responsibility for the protection of the rights

and welfare of human participants. Specifically, the investigator is responsible for:

1. Carefully designing research methods,
2. Adhering to ethical codes and applicable policies and procedures of the University, the sponsoring agency, relevant professional organizations and cooperating institutions, if any,
3. Training and supervising personnel carrying out the research, both with respect to appropriate research methods and the rights of human participants,
4. Obtaining prior (i.e. before any involvement of human participants) approval for non-exempt human participants research,
5. Obtaining prior approval for changes in a nonexempt research activity,
6. Applying to the IRB Administrator and IRB Chair for a determination of whether research can be exempt from full review,
7. Reporting promptly to the IRB all problems involving risks to participants or others,
8. Retaining required records.

VII. ACADEMIC DEPARTMENT CHAIR/DESIGNEE RESPONSIBILITIES:

The chair of each academic department, or his/her designee, is responsible for:

1. Ensuring that faculty, staff, and students are kept informed of the University and departmental policies and procedures and of their responsibilities for protecting the rights and welfare of human participants involved in research,
2. Reporting promptly in writing to the IRB any problems involving risks to participants or others.

VIII. CATEGORIES OF IRB REVIEWS

A. The following categories of review shall be applied to research proposals involving human participants:

1. Exempt Review
 - a. Research activities where there are no apparent risks for the involved human participants as outlined in the Exempt Review Criteria set forth in 45 C.F.R. Section 46.101(b) may be reviewed by the members of a departmental review body.

- b. The determination of whether a research activity meets the exemption criteria set forth in subparagraph 1 (c) below shall be made by the IRB Chair/Designee.
- c. Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from full review by the IRB and may be reviewed by a departmental review body:
 - (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 participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 A.1 (c) (2) above, if:
 - (i) The human participants 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 participants cannot be identified, directly or through identifiers linked to the participants.
 - (5) Research and demonstration projects which are conducted by or participant 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 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.

2. Expedited Review

- a. Research activities that present no more than minimal risk to human participants as outlined in subparagraph A.1 (c) above may be reviewed by the IRB Chair or one or more experienced IRB reviewers designated by the Chair/Designee.
- b. Other categories of research which may be reviewed on an expedited basis are set forth in Attachment A to this policy.
- c. The activities listed should not merely be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.
- d. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- e. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.

3. Full Committee Review

- a. All proposals that do not meet the criteria for expedited or exempt review shall be considered as a full review that requires a quorum of IRB members to attend. Such proposals must be reviewed and approved by the IRB prior to any involvement of human participants in the research.
- b. Upon completion of any of the above reviews, a letter shall be issued by the reviewing official or body authorizing initiation of the project or containing

stipulations that must be met before approval may be granted. Once approval is granted, the use of human participants may begin.

- c. If a researcher makes a significant change from a previously approved research project, an amendment must be submitted to the IRB for review. Researchers should inform the IRB in writing to obtain the committee's approval for continuance of the research project.

IX. STUDENT SUBMISSION OF PROTOCOLS

Students submitting a research proposal must have a faculty member who certifies that the student is knowledgeable about the regulations and policies governing research with human participants and has sufficient training, experience and knowledge to conduct the particular study. The supervising faculty member must have completed the required NIH training and attach their certification to the student IRB application. Supervising professors must certify that they have reviewed the protocol and assure the IRB that it is scientifically and ethically sound by submitting a completed Supervising Professor's Consent form.

X. CONTINUATION REVIEWS

The IRB and departmental review bodies shall conduct continuing reviews of nonexempt research at intervals appropriate to the degree of risk, but at least once per year.

XI. RECORD RETENTION

Federal regulations require that all records relating to the IRB and to human participant research activities be retained for at least three years after completion of the research. Records, including signed consent forms and collected data, must be accessible for inspection at any time and for copying by authorized representatives of the University or the agencies sponsoring the research.

XII. DEPARTMENTAL POLICIES

- A. Each academic department in which faculty and/or students are engaged in human participant research projects that are not governed by this policy (for example, Section I. Paragraph C. above) shall develop a policy governing such research involving human participants.
- B. Each departmental policy developed pursuant to this section shall require compliance with the general ethical principles governing human participant research but shall not require compliance with all aspects of the federal regulatory requirements governing human participant research.
- C. Each departmental policy developed pursuant to this section shall also include an educational component for student researchers regarding the issues surrounding human participant research that will be required for students acting as researchers in human participant research projects within the department.

- D. Each departmental policy developed pursuant to this section shall be approved by the University IRB.
- E. Any faculty or student research project involving human participant research that is initially reviewed under this section because there are no plans to publish or publicly disseminate the research must be reviewed by the University IRB under this policy, if a determination is later made to publish or publicly disseminate the research, prior to its publication or public dissemination. For the purposes of this section publication shall be defined as the presentation of information either electronically or by hard copy in any medium for the purpose of disseminating the information therein to third parties.

XIII. INSTITUTIONAL OVERSIGHTS:

- A. The University IRB has the authority to suspend or terminate approval of any research conducted at or sponsored by the University that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and to the appropriate institutional officials. For any HHS supported work so terminated or suspended, HHS regulations require that the Secretary of HHS be notified as well.
- B. Research that has been approved by the IRB may be subject to further appropriate review and approval by officials of the University. University officials may not approve the research if it has been disapproved by the IRB.

XIV. REPORTING OF ADVERSE EVENTS:

The responsible project investigator must promptly notify the IRB in writing of any problems involving human participants that arise during the course of the research project. Upon receipt of such notification, the IRB shall conduct a continuing review of the research project pursuant to Section X of this policy. Problems include unanticipated side effects or adverse reactions from participation in the project and, of course, any injuries. For research projects at more than minimal risk, the consent form should include information on available medical treatment if injury should occur and whether any compensation is available for treatment of injuries.

XV. RESEARCH INVOLVING SPECIAL GROUPS:

Any research conducted or supported by the Department of Health and Human Services involving any of the following categories:

1. fetuses, pregnant women, or human in vitro fertilization (45 C.F.R. Section 46.201 et seq.)

2. prisoners (45 C.F.R. Section 46.301 et seq.)
3. children (45 C.F.R. Section 46.401 et seq.)

must follow all requirements of the above referenced federal regulations pertaining to those categories.

XVI. INSTITUTIONAL EDUCATIONAL PROGRAM

- A. The University IRB shall develop educational programs for members of the University community engaged in human participant research issues in order to ensure that members of the University community are properly educated and aware of issues and requirements in this area.
- B. Such educational programs shall be designed for various constituencies of the campus community including the University IRB and its staff, principal investigators, faculty involved in student research exempt under Section XII of this policy and others.
- C. The University IRB shall report annually to the Provost with regard to recommendations for the educational programs for the upcoming academic year including their frequency and the method of their delivery. Upon adoption of this policy by the University, the University IRB shall provide the Provost with a recommendation of an immediate educational program within thirty (30) days of the commencement of their activities.

**CATEGORIES OF RESEARCH THAT MAY BE REVIEWED
BY THE
INSTITUTIONAL REVIEW BOARD (IRB)
THROUGH AN EXPEDITED REVIEW PROCEDURE**

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.
 - (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 participants, 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 participants, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these participants, 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 participant or an invasion of the participant's 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).
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.
8. Continuing review of research previously approved by the convened IRB as follows:
 - (a) Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
 - (b) Where no participants have been enrolled and no additional risks have been identified; or
 - (c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.