

Title: PROCEDURES FOR THE REVIEW OF INITIAL APPLICATIONS TO CONDUCT HUMAN SUBJECTS RESEARCH

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I. Authority

The Procedures for the Review of Initial Applications to Conduct Human Subjects Research ("Procedures") are implemented pursuant to the New Jersey Department of Health & Senior Services' ("Department") [Policy on the Protection of Human Research Subjects](#) (v.1), [Federal regulations for the Protection of Human Subjects at Title 45, Part 46](#), and [Ethical Principles and Guidelines for the Protection of Human Subjects of Research set forth by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research](#) ("The Belmont Report"), incorporated herein as amended and supplemented.

II. Applicability

Initial applications to conduct human subjects research under the auspices of the Department's Federalwide Assurance with the U.S. Department of Health and Human Services will be reviewed by the Department's Institutional Review Board ("Board") in accordance with these Procedures.

III. Procedural Scope

The scope of the additional applicable criteria required for approval ("criteria for approval") set forth in Sections XVI and XVII of these Procedures are limited to the categories of human subjects typically recruited under the Department's Federalwide Assurance. Categories not accounted for in the additional criteria for approval, but that are permissible to be recruited under the Department's Federalwide Assurance, include research involving children that is greater than minimal risk with the prospect of benefit to the children, research involving children that is greater than minimal risk without the prospect of benefit to the children, and research involving wards, neonates of uncertain viability and nonviable neonates. Applications that include requests to recruit these unaccounted for categories of human subjects will be approved upon the Board's determination that the additional criteria for approval set forth in the Federal regulations for the Protection of Human Subjects at Title 45, Part 46, Subparts B and D, have been satisfied.

IV. Authorization to Accept Applications

Initial applications to conduct human subjects research shall only be accepted for review by the Board when submitted in accordance with the Department's [Procedures for the Submission of Initial Applications to Conduct Human Subjects Research](#) (v.1), incorporated herein as amended and supplemented.

V. Chairperson Pre-Review Actions

- A. Ascertain whether any Board member has a conflict of interests in accordance with the Department's [Policy & Procedures on Conflict of Interests in the Review & Oversight of Human Subjects Research](#) (v.1), and take action accordingly.

- B. Determine whether the Board possesses sufficient knowledge of the local research context and the expertise necessary to review the proposed research. If the Board does not possess a sufficient knowledge of the local research context or the expertise necessary to review the application, the Board's review will be assisted by consultant(s) in accordance with [Federal regulations](#) and guidance documents.
- C. Determine whether the application is eligible for [expedited review](#) in accordance with the Federal regulations for the Protection of Human Subjects at Title 45, Part 46.110.
 - 1. Applications eligible for expedited review will be reviewed in accordance with Section IX below.
 - a. The Chairperson may refer applications eligible for review by an expedited process for review at a convened meeting of the Board in accordance with Section VIII below, if doing so may add to the protection of human research subjects or provide an opportunity to further the Board's knowledge.
 - 2. Applications not eligible for expedited review will be reviewed at a convened meeting in accordance with Section VIII below.
- D. Appoint primary reviewers if an application is to be reviewed at a convened meeting of the Board, otherwise appoint expedited reviewer(s).
 - 1. Primary Reviewers: Two Board members will serve as primary reviewers; one will be a Board member whose primary concern is scientific, and the other will be a Board member whose primary concern is non-scientific; at the Chairperson's discretion additional primary reviewers may be assigned. When available, the primary reviewer whose primary concern is scientific will be appointed based on having the most appropriate disciplinary background for the proposed research.
 - 2. Expedited Reviewers: A Board member whose primary concern is scientific will serve as an expedited reviewer; at the Chairperson's discretion, additional expedited reviewers may be assigned. When available, a Board member whose primary concern is non-scientific will also serve as an expedited reviewer.
 - 3. When proposed research includes the recruitment of prisoners, one of the primary or expedited reviewers will be a prisoner representative who possesses the appropriate background and experience, unless the proposed research has been reviewed by another Board that has satisfied this requirement.
- E. Notify the Board members by email that an application has been accepted for review and that application materials are available in accordance with Section VI below.
- F. Notify the principal investigator in writing that his/her application has been accepted for review and assigned to reviewers. A copy of the notification will be sent to the principal investigator's direct supervisor, Research Liaison (if applicable) and the Department's Human Research Ethics Program (HREP). The notice shall include:
 - 1. A statement that the principal investigator is to direct all matters regarding their application to the Chairperson, and are prohibited from contacting any other Board member regarding their application, and
 - 2. Whether the application will be reviewed at a convened meeting of the Board or by an expedited process. If the application will be reviewed at convened meeting, the notice will include:
 - a. The date, time and location of the convened meeting of the Board at which the application will be reviewed,

- b. An invitation to the principal investigator to attend the convened meeting of the Board, in person or via conference call,
- c. A statement that the principal investigator's attendance is voluntary,
- d. A statement that the Board encourages principal investigators to have their co-investigators and research personnel attend the convened meeting of the Board, and
- e. A statement that the principal investigator may not designate someone to represent them at the convened meeting of the Board.

VI. Application Materials

- A. The application materials will be provided electronically to Board members who are Department employees via the Board's Network Folder; Board members who are not Department employees will be mailed a hard copy of the application materials.
- B. For applications that will be reviewed at a convened meeting of the Board, Board members will be provided with the application materials at least fifteen (15) business days prior to the convened meeting of the Board at which the proposed research will be reviewed.
- C. Board members will be provided with, at a minimum:
 - 1. The application form,
 - 2. The protocol,
 - 3. The informed consent, assent or parental permission documents,
 - 4. The recruitment materials (letters, phone scripts, advertisements, etc.),
 - 5. The instruments (surveys, questionnaires, etc),
 - 6. The grant application (or contract), if applicable,
 - 7. The curriculum vitas/resumes for all investigators and research personnel,
 - 8. The research ethics training certificates for all investigators and research personnel, and
 - 9. The documentation from prior Department Board reviews, if applicable.

VII. Primary & Expedited Reviewer Responsibilities

- A. Review all application materials in order to determine whether the proposed research satisfies the criteria for approval in Section X below.
 - 1. If the application will be reviewed at a convened meeting of the Board, Board members who are not primary reviewers will review, at a minimum, the application, informed consent, assent or parental permission documents, recruitment materials; and, if previously reviewed by the Department's former

Boards, documentation related to these prior reviews (to include at a minimum, the Debriefing Letters, Approval Letters, and the Principal Investigator's response(s)).

- B. As needed, obtain additional information, clarification or documentation necessary to complete the review.
 - 1. Reviewers will provide the Chairperson with their request for additional information, clarification or documentation via memorandum; requests may be submitted to the Chairperson by any Board member.
 - 2. All contact with the principal investigator will be through the Chairperson, who will document all related communications in writing.
 - 3. For applications being reviewed at a convened meeting of the Board, any information, clarification or documentation necessary for the primary reviewers to determine whether the proposed research meets the criteria for approval will be obtained prior to the convened meeting of the Board at which the application will be reviewed.
 - a. If the additional information, clarification or documentation requested is not provided at least five (5) business days prior to the convened meeting of the Board at which the application is scheduled to be reviewed, the application will be deferred until the next available convened meeting of the Board.
 - 4. The principal investigator's supervisor, the Research Liaison (if applicable) and HREP will be copied on all correspondence, with principal investigators required to copy the same individuals on all responses.
 - a. In the event the principal investigator does not copy his/her supervisor, Research Liaison (if applicable) or HREP on a response, the Chairperson will provide them with a copy.
- C. If a consultant has been appointed, as authorized by Section V(B) above, obtain his/her analysis, guidance and recommendations.
- D. Document determinations, recommendation(s) and the project-specific information justifying the determinations and recommendation(s) on a Board Reviewer Form. The possible recommendations consists of:
 - 1. Approve the application, and when applicable:
 - a. Approve the request to waive or alter the requirements for informed consent or documentation of informed consent.
 - b. Approve the request to waive or alter the requirements for assent or documentation of assent.
 - c. Approve the request to waive or alter the requirements for parental permission or documentation of parental permission.
 - d. Approve the request to include children as research subjects.
 - e. Approve the request to include pregnant women and fetuses as research subjects.
 - f. Approve the request to include prisoners as research subjects.

2. Defer the application.
 - a. Applications reviewed in accordance with Section IX below may be deferred to provide principal investigators with an opportunity to make modifications necessary for approval.
 3. Disapprove the application.
 - a. Expedited reviewers who are unable to approve an application will refer it to the Chairperson for review at a convened meeting of the Board in accordance with Section VIII.
- E. Submit completed Board Reviewer Form to the Chairperson.
1. Expedited Reviews: The expedited reviewer(s) will submit their Board Reviewer Form to the Chairperson within fifteen (15) business days of being provided with the application materials. If an expedited reviewer is unable to complete their review within fifteen (15) business days the Chairperson may re-assign the application to another Board member, who will complete their review in accordance with Section IX below.
 2. Reviews at Convened Meetings of the Board: The primary reviewers will submit their Board Reviewer Form to the Chairperson at least two (2) business days prior to the convened meeting of the Board at which the application is to be reviewed.

VIII. Review at a Convened Meeting

- A. Prior to beginning the review of an application at a convened meeting of the Board, the Chairperson will:
1. Ensure Board members with a conflict of interests have left the meeting room and that their recusal is noted in the meeting minutes,
 2. Determine whether there is quorum, defined as the presence of a simple majority of the membership, with at least one Board member present whose primary concern is nonscientific. If there is not a quorum, or if quorum is lost during the convened meeting (e.g., loss of a simple majority through recusal of Board members with conflicting interests or early departures), the Board will take no action on the application, and will defer the review until the next available convened meeting of the Board, and
 3. Provide Board members with a copy of the primary reviewers' completed Board Reviewer Form, with the identity of the primary reviewers redacted.
- B. If present, the principal investigator will provide a brief overview of his/her project and answer any questions; the Board may stop the primary reviewers' presentation, deliberations or voting to request information or clarification from the principal investigator.
1. The principal investigator will not be present in the meeting room during the primary reviewers' presentation, deliberations or voting.
 2. The principal investigator will be informed of the Board's decision by written correspondence in accordance with Section XI below.
- C. Deliberations & Determinations

1. The Chairperson will read to the Board members each criterion in succession from Section X below.
 - a. Deliberations on the criteria for approval will be conducted in the order listed in Section X below.
 - b. Deliberations will not be conducted on a criterion until deliberations have been completed on the preceding criterion.
2. The primary reviewer whose primary concern is scientific will provide a scientific and ethical critique of whether the proposed research satisfies the criterion being deliberated upon.
 - a. If the scientific primary reviewer does not believe the proposed research satisfies the criterion, they will propose the modifications necessary, if any, that would cause the proposed research to satisfy the criterion being deliberated upon.
3. The primary reviewer whose primary concern is non-scientific will provide an ethical critique of whether the proposed research satisfies the criterion being deliberated upon.
 - a. If the non-scientific primary reviewer does not believe the proposed research satisfies the criterion, they will propose the modifications necessary, if any, that would cause the proposed research to satisfy the criterion being deliberated upon.
4. The Chairperson will open discussion to all Board members on whether a) the proposed research satisfies the criterion being deliberated upon, b) modifications are necessary for the proposed research to satisfy the criterion being deliberated upon and c) additional information, clarification or documentation is needed in order to determine whether the criterion being deliberated upon has been satisfied.
 - a. If the consensus of the Board members is that the proposed research requires modifications in order to satisfy the criterion being deliberated upon, the Chairperson will facilitate deliberations on the specifics of the modifications that are necessary.
 - b. If the consensus of the Board members is that additional information, clarification or documentation is needed in order to determine whether the criterion being deliberated upon has been satisfied, the Chairperson will facilitate deliberations on exactly what additional information, clarification or documentation is needed.
5. Prior to completion of deliberations on the criterion being deliberated upon, the Chairperson will ask the Board members whether anyone has questions, concerns or issues regarding the criterion being deliberated upon, and will facilitate resulting deliberations.
6. Upon completion of deliberations on a criterion, Board members will individually record their determination of whether the criterion has been satisfied on a Board Reviewer Form.
 - a. The possible determinations of whether a criterion has been satisfied consists of:
 - i. Yes, the criterion has been satisfied,
 - ii. No, the criterion has not been satisfied,
 - iii. Unable to determine whether the criterion has been satisfied, and
 - iv. Not applicable.

7. After all Board members have recorded their determination on the criterion being deliberated upon, the Chairperson will read the next criterion in the order listed in Section X below, repeating the deliberation process specified in this Subsection for each criterion.
8. After recording their determinations for all of the criteria for approval, Board members will submit their completed Board Reviewer Form to the HREP staff present at the meeting for immediate tallying and announcement of the results.
 - a. HREP staff will record the results on a Convened Meeting Determination Form.
 - b. An application is only approved when a simple majority of the Board members present have documented their determination on a Board Reviewer Form that all criteria for approval have been satisfied.
9. Immediately following HREP's announcement that the application:
 - a. Has been approved, the Chairperson will facilitate deliberations and determinations on the conditions of approval in Section X(B) below, including how the conditions of approval will be operationalized.
 - i. The determinations regarding the conditions of approval will be based on consensus of the Board members present. In the event consensus cannot be reached, a condition of approval will be approved subsequent to an affirmative vote by a simple majority of the Board members present.
 - ii. Subsequent to the convened meeting of the Board, the Chairperson will issue the principal investigator a Board Approval Letter in accordance with Section XI.
 - a. The Chairperson will also provide the principal investigator with all approved informed consent, assent, parental permission and recruitment documents that have been stamped with an expiration date.
 - b. Has not been approved, the Chairperson will facilitate deliberations and determinations on whether the application was not approved because: 1) additional information, documentation or clarification is needed in order to determine whether the application satisfies the criteria for approval, 2) modifications are needed for the application to satisfy the criteria for approval, or 3) the criteria for approval has not been satisfied, and there are no modifications that can be made that would satisfy the criteria for approval.
 - i. If additional information, documentation or clarification is needed in order to determine whether the application satisfies the criteria for approval, the application will be deferred.
 - b. A decision to request additional information, documentation or clarification will be based on a consensus of the Board members present. In the event consensus cannot be reached, additional information, documentation or clarification will be required subsequent to an affirmative vote by a simple majority of the Board members present.
 - c. The principal investigator's response will be provided to the Board members in accordance with Section VI above, and will be reviewed at a subsequent convened meeting of the Board in accordance with this Section.
 - ii. If modification(s) are needed in order for the application to satisfy the criteria for approval, the application will be deferred.

- a. A decision to require modifications will be based on a consensus of the Board members present, as will the decision on the content and scope of the modifications. In the event consensus cannot be reached, a modification will be required subsequent to an affirmative vote by a simple majority of the Board members present.
 - b. If the modifications necessary for approval are specific, and the principal investigator need only agree to the specific modifications, then upon receiving the principal investigator's response the Chairperson may determine whether the modifications were made as specified; and if they were made as specified, approve the project on the Board's behalf. A decision to authorize the Chairperson to review the specified modification and approve the application on the Board's behalf will be based on a consensus of the Board members present.
 - c. If the modifications necessary for approval are not specific, the principal investigator's response will be provided to the Board members in accordance with Section VI, and will be reviewed at a subsequent convened meeting of the Board in accordance with this Section.
 - d. For applications reviewed at a convened meeting that are eligible for review by an expedited process, the Chairperson may determine whether the modification made by the principal investigator satisfies the criteria for approval, and approve the application on the Board's behalf. A decision to authorize the Chairperson to review the modification(s) and approve the application on the Board's behalf will be based on a consensus of the Board members present. If the Chairperson is not authorized to review the principal investigator's response on the Board's behalf, it will be provided to the Board members in accordance with Section VI, and reviewed at a convened meeting of the Board in accordance with this Section.
- iii. If the application does not satisfy the required criteria, and no modification would satisfy the required criteria, the application will be disapproved.
- a. A decision that there are no modifications that can be made that would permit the application to satisfy the criteria for approval will be based on a consensus of the Board members present. In the event consensus cannot be reached, the application will be disapproved subsequent to an affirmative vote by a simple majority of the Board members present.
 - b. The principal investigator will be sent a Disapproval Letter in accordance with Section XI(C) below. The principal investigator's response, if any, will be provided to the Board members in accordance with Section VI, and will be reviewed in accordance with this Section.
10. The Chairperson will document the Board's decision on a Board Application Disposition Form; the Chairperson will document all subsequent Board decisions' on a Board Application Disposition Form.

IX. Review by an Expedited Process

- A. Expedited reviewers will conduct their review in accordance with Section VII above.
- B. Applications will be approved only upon a recommendation for approval by all expedited reviewers assigned in accordance with Section V(D) above.
- C. Upon receiving the completed Board Reviewer Form(s), the Chairperson will take one of the following actions based on the expedited reviewers' determinations and recommendation(s):

1. Approve the application, and when applicable:
 - a. Approve the request to waive or alter the requirements for informed consent or documentation of informed consent.
 - b. Approve the request to waive or alter the requirements for assent or documentation of assent.
 - c. Approve the request to waive or alter the requirements for parental permission or documentation of parental permission.
 - d. Approve the request to include children as research subjects.
 - e. Approve the request to include pregnant women and fetuses as research subjects.
 - f. Approve the request to include prisoners as research subjects.
 2. Defer the application to provide the principal investigator with an opportunity to make modifications necessary for approval.
 - a. If the project is deferred to provide the principal investigator with an opportunity to make specific modifications necessary for approval, and the principal investigator need only agree to the modifications, the Chairperson may review the response and determine whether the modifications were made as specified; and if they were made as specified, approve the application on the expedited reviewers' behalf. The Chairperson may review the specific modifications and approve the application on the expedited reviewers' behalf only upon the mutual agreement of the Chairperson and expedited reviewer(s).
 - b. If the modifications necessary for approval are not specific, the principal investigator's response will be provided to the expedited reviewer(s) for action in accordance with this Section.
 3. Refer the application for review at a convened meeting of the Board in accordance with Section VIII, if the expedited reviewer(s) is unable to approve the application.
 4. Refer the application back to the expedited reviewer(s) with guidance because the reviewer(s) incorrectly applied applicable Federal regulations or the ethical principles set forth in the Belmont Report, their determinations are not supported by the information contained in the application, they did not consider information that may affect their determination(s) or recommendation(s), they lacked an understanding of, or important insight into, the proposed research, or their recommendation(s) are not supported by their determinations (not all inclusive).
 - a. Upon receipt of the expedited reviewers' revised Board Reviewer Form, the Chairperson will take action in accordance with Subsection C of this Section.
 - b. If an expedited reviewer(s) does not agree with the Chairperson's guidance, and the Chairperson and the expedited reviewer(s) are unable to come to a consensus, the application will be referred for review at a convened meeting of the Board in accordance with Section VIII.
- D. The Chairperson will document the expedited reviewers' recommendation(s) and the Chairperson's actions on a Board Application Disposition Form, subsequent recommendations and actions will also be documented by the Chairperson on a Board Application Disposition Form.

X. Criteria for Approving Human Subjects Research

A. The Board will approve applications upon determining the proposed research satisfies the following criteria:

1. The proposed research adheres to the ethical principles in the Belmont Report,
2. The justification, goals, design, procedures, methods and instruments of the proposed research are scientifically sound (i.e., the risks to the research subjects are minimized, the research subjects are not unnecessarily exposed to risk, and procedures already being performed for diagnostic or treatment purposes are used, when applicable),
3. The risks to research subjects are reasonable in relation to the anticipated benefits that is reasonably expected to result to the research subjects, if applicable,
4. The risks to research subjects are reasonable in relation to the importance of the knowledge that is reasonably expected to result,
5. The selection of the research subjects is equitable given the purpose(s) of the research, the setting(s) in which the research will be conducted, the population that will benefit from the research and the rationale for including a vulnerable population (e.g., children, prisoners, pregnant women, mentally disabled persons or those who are disadvantaged economically, educationally or otherwise),
6. The informed consent or assent of prospective research subjects or permission of their legally authorized representative will be sought in accordance with Sections XII and XIII, or waived in accordance with Section XIV,
7. The informed consent or assent of prospective research subjects or permission of their legally authorized representative will be documented in accordance with Section XII, or documentation will be waived in accordance with Section XV,
8. The research data will be monitored to ensure the research subjects' safety, if applicable,
9. The proposed research appropriately provides for the protection of research subjects' privacy,
10. The proposed research appropriately ensures investigators and research personnel will fulfill their obligation of confidentiality,
11. The proposed research includes additional safeguards for protecting the rights and welfare of research subjects who may be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons or those who are disadvantaged economically, educationally or otherwise), if applicable,
12. The proposed research includes detailed procedures for how the principal investigator will monitor all investigators and research personnel to ensure that a) only Board-approved research activities are conducted, b) research activities are conducted in accordance with the approved protocol, c) research activities are only conducted by individuals who have been approved by the Board to conduct the specific activity, d) investigators and research personnel comply with the scope and stipulations specified in the Board Approval letter and e) modifications are only implemented after obtaining the Board's prior written approval (unless the modification is necessary to eliminate an apparent immediate hazard to the research subjects),

13. The description of the proposed research as described in the application is consistent with the description in the corresponding funding document (e.g., grant application, memorandum of agreement, contract), if applicable,
 14. The recruitment of children as research subjects satisfies the additional criteria in Section XVI, if applicable,
 15. The recruitment of pregnant women and fetuses as research subjects satisfies the additional criteria in Section XVII, if applicable, and
 16. The recruitment of prisoners as research subjects satisfies the additional criteria for approval in Section XVIII, if applicable.
- B. The Board will make the following additional determinations for applications that have satisfied the applicable criteria in Subsection A of this Section:
1. The length of the approval interval,
 - a. The approval interval will not exceed 365 days, and will be based on an assessment of, but not limited to, the risk(s) to the research subjects or others (i.e., type, level, probability, magnitude and duration), the project's complexity, the risk/benefit ratio, and the (apparent) compliance history of the principal investigator, investigators or research personnel.
 2. The necessity to obtain verification from independent sources to ensure modifications are not implemented without the Board's prior written approval, and
 - a. This determination will be based on an assessment to include the risk(s) to the research subjects or others (i.e., type, level, probability, magnitude and duration), the project's complexity, the risk/benefit ratio and the (apparent) compliance history of the principal investigator, investigators or research personnel.
 3. The necessity to monitor for non-compliance to ensure the proposed research is conducted as approved.
 - a. This determination will be based on an assessment to include the risk(s) to the research subjects or others (i.e., type, level, probability, magnitude and duration), the project's complexity, the risk/benefit ratio and the (apparent) compliance history of the principal investigator, investigators or research personnel.

XI. Notification of Board Action(s)

A. Approval Letters

1. The Approval Letter will be sent to the principal investigator, Board members, HREP, principal investigator's immediate supervisor and Research Liaison (if applicable).
2. The Approval Letter will stipulate, at a minimum, the requirement to:
 - a. Report to HREP all complaints, adverse events and unanticipated problems involving risks to research subjects,

- b. Obtain the Board's written approval prior to implementing modifications, except when necessary to eliminate apparent immediate hazards to the research subjects,
 - c. Report to the Board modifications made without prior Board approval,
 - d. Use only informed consent, assent, parental permission and recruitment documents that have been approved by the Board, and stamped by the Board with an expiration date, and
 - e. Comply with the Board's oversight authority regarding the monitoring of approved projects.
3. The Approval Letter for applications involving the inclusion of prisoners will not be issued until the Board receives written approval for the inclusion of prisoners from the U.S. Office for Human Research Protections, in accordance with applicable [Federal guidance](#).

B. Debriefing Letters

1. The Chairperson will issue a Debriefing Letter upon an application's deferral.
2. The Debriefing Letter will be sent to the principal investigator, Board membership, HREP, principal investigator's immediate supervisor and Research Liaison, if applicable.
3. The Debriefing Letter for an application reviewed by an expedited process will stipulate the modifications necessary to obtain Board approval.
4. The Debriefing Letter for an application reviewed at a convened meeting of the Board will stipulate the additional information, documentation or clarification that is necessary for determining whether the application satisfies the required criteria, or the modifications necessary to obtain Board approval.
 - a. The principal investigator will be advised in the Debriefing Letter that if the additional information, clarification or documentation requested is not provided at least five (5) business days prior to the convened meeting of the Board at which the application is scheduled to be reviewed, the application will be deferred until the next available convened meeting of the Board.

C. Disapproval Letter

1. The Chairperson will issue a Disapproval Letter upon an application's disapproval at a convened meeting of the Board.
2. The Disapproval Letter will be sent to the principal investigator, Board membership, HREP, principal investigator's immediate supervisor, Research Liaison (if applicable), the principal investigator's Board and final signatory for the principal investigator's Agreement for Ethical Conduct of Human Subjects Research.
3. The Disapproval Letter will stipulate the reasons the application was disapproved and offer the principal investigator an opportunity to respond within ten (10) business days.

D. Convened Meeting Referral Letter

1. The Chairperson will issue a Convened Meeting Referral Letter when expedited reviewer(s) are unable to approve an application.

2. The Convened Meeting Referral Letter will be sent to the principal investigator, Board membership, HREP, principal investigator's immediate supervisor and Research Liaison (if applicable).
3. The Convened Meeting Referral Letter will stipulate the reason(s) why the expedited reviewer(s) were unable to approve the application and the date of the convened meeting of the Board at which the application will be reviewed.

E. Prisoner Certification Letter

1. Upon the Board's determination that an application requesting the inclusion of prisoners satisfies the criteria for approval in Sections X and XVIII below, the Chairperson will send a letter of certification and the required documentation to the U.S. Office for Human Research Protections, in accordance with applicable [Federal guidance](#).

XII. Criteria for Approving an Informed Consent, Assent & Parental Permission Process

The Board will approve consent, assent and parental permission processes upon determining:

- A. The prospective research subjects or their legally authorized representatives will be provided with a sufficient opportunity to consider whether to participate,
- B. The prospective research subjects or their legally authorized representatives will be approached for recruitment in a manner that minimizes the possibility of coercion or undue influence,
- C. The prospective research subjects or their legally authorized representatives will have adequate opportunity to read the informed consent, assent or parental permission document before being asked whether they want to volunteer as a research subject, or to sign the document,
- D. The prospective research subjects or their legally authorized representatives will sign the informed consent, assent or parental permission document, and
- E. The prospective research subjects or their legally authorized representatives will be given a copy of the signed informed consent, assent or parental permission document.

XIII. Criteria for Approving an Informed Consent, Assent & Parental Permission Documents

The Board will approve consent, assent and parental permission documents upon determining the documents:

- A. Are written in the prospective research subjects' primary language or that of their legally authorized representative,
- B. Are written in an understandable manner (e.g., appropriate reading level, formatted to foster readability, do not contain unexplained esoteric terms) given the anticipated population(s) to be recruited,
- C. Do not contain exculpatory language, through which prospective research subjects or their legally authorized representatives are made to 1) waive, or appear to waive, any of their legal rights, or 2) release, or appear to release, the investigators, research personnel, funding agency, sponsor, institution or any agents thereof from liability for negligence, and
- D. Contain:

1. A statement that the study involves research,
2. An explanation of the purpose(s) of the research,
3. The expected duration of the research subjects' participation,
4. A description of the procedures to be followed,
5. Identification of any experimental procedures, if applicable,
6. An explicit description of any reasonably foreseeable risks or discomforts to the subject,
7. An explicit description of any benefits to the subject that may reasonably be expected from the research. If benefits to the research subject are not reasonably expected, that must be explicitly stated,
8. An explicit description of any benefits to others (e.g., society) that may reasonably be expected from the research,
9. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, if applicable,
10. A statement describing how, and to what extent, the confidentiality of information about the research subjects will be maintained,
11. A statement describing the procedures for protecting the research subjects' privacy,
12. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs; and if so, what they consist of and where further information may be obtained,
13. A statement that the principal investigator or designee is available to a) answer questions about the research at any time and b) respond to concerns that a research subject may have been harmed, and includes the name and phone number for the principal investigator or designee.
14. A statement that anyone with complaint or questions about research subjects' rights should contact the HREP, and includes the contact information for the HREP.
15. A statement that participation is voluntary,
16. A statement that a research subject's voluntary decision not to participate will not result in any penalty or loss of benefits to which they are entitled,
17. A statement that the research subject may discontinue participation at any time without penalty or loss of benefits to which they are entitled,
18. Additional information required by Department policy or procedures, or Federal or New Jersey laws, regulations or guidance documents, or that in the Board's judgment may add to the protection of the research subjects' rights or welfare,
19. A statement that the particular treatment or procedure may involve risks to research subjects (or their embryos or fetuses, if they are or may become pregnant) that are currently unforeseeable, when appropriate,

20. Anticipated circumstances under which research subjects' participation may be terminated by the investigator without regard to their consent, when appropriate,
21. Any additional costs to the research subjects that may result from their participation in the proposed research, when appropriate,
22. The consequences of a research subject's decision to withdraw from the proposed research, and the procedures for orderly termination of participation by the research subject, when appropriate,
23. A statement that significant new findings developed during the course of the proposed research that may relate to research subjects' willingness to continue participation will be provided to the research subject, when appropriate, and
24. The approximate number of research subjects involved in the proposed research, when appropriate.
25. For research involving prisoners, a statement that provisions have been made for follow-up examinations or healthcare after the end of their participation, when applicable.

XIV. Criteria for Approving a Waiver or Alteration of the Informed Consent, Assent and Parental Permission Requirements in Sections XII and XIII

The Board will approve a waiver or alteration of the informed consent, assent and parental permission requirements in Sections XII and XIII upon determining:

- A. The research involves no more than minimal risk to the research subjects,
- B. The waiver or alteration will not adversely affect the research subjects' rights or welfare,
- C. The research cannot practicably be carried out without the waiver or alteration, and
- D. When appropriate, the research subjects will be provided with pertinent information after participation.

XV. Criteria for Approving a Waiver of the Requirement to Obtain a Signed Informed Consent, Assent and Parental Permission Document

The Board will waive the requirement to obtain a signed informed consent, assent or parental permission document upon determining:

- A. The proposed research presents no more than minimal risk of harm to research subjects, and does not involve procedures that normally require documentation of informed consent, assent or parental permission outside of the research context, or
- B. The only record linking research subjects to the proposed research is the informed consent, assent or parental permission document, and the principal risk is the potential harm resulting from a breach of confidentiality. In these circumstances, the research subjects will be asked whether they want documentation linking them to the proposed research, and their wishes will govern.

XVI. Additional Criteria for Approving Human Subjects Research Involving Children

The Board will approve the inclusion of children as research subjects upon determining:

- A. The level of risk presented by the research is no more than minimal,
- B. Adequate provisions have been made for soliciting the assent of the children,
 - 1. The determination of whether the children proposed to be recruited have the decision-making capacity to assent is based on, at a minimum, their age, maturity and psychological state. This determination may be made for the children as a group, or on an individual basis.
 - a. Assent may be waived if the Board determines that some or all of the children proposed to be recruited lack the decision-making capacity to assent.
- C. Adequate provisions have been made for documenting the assent of the children, and
- D. Adequate provisions have been made for obtaining permission from at least one parent (or guardian).
 - 1. If obtaining permission from a parent or guardian is not a reasonable requirement to protect the research subjects (e.g., research is on neglected or abused children), this requirement may be waived if another mechanism for protecting the children is substituted, and the substituted mechanism does not conflict with Federal or New Jersey laws or regulations.
 - a. The determination of whether an alternative mechanism is appropriate will be based on, at a minimum, the nature and purpose of the research, the risk(s) and anticipated benefit(s) to the research subjects, and their age, maturity, status and condition.

XVII. Additional Criteria for Approving Human Subjects Research Involving Pregnant Women and Fetuses

The Board will approve the inclusion of pregnant women and fetuses as research subjects upon determining:

- A. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses,
- B. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus,
 - 1. If there is no prospect of benefit, the risk to the fetus must not be greater than minimal, and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
- C. Any risk is the least possible for achieving the objectives of the research,
- D. The informed consent of the pregnant women will be obtained when:
 - 1. The risk to the fetus is minimal,
 - 2. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, and
 - 3. The research holds out the prospect of:

- a. Direct benefit to the pregnant woman,
 - b. Direct benefit to the pregnant woman and the fetus, or
 - c. No benefit for the woman or fetus,
- E. The informed consent of the pregnant woman and the father will be obtained if the research holds out the prospect of direct benefit solely to the fetus,
- 1. The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, temporary incapacity or the pregnancy resulted from rape or incest.
- F. Each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate,
- G. For children who are pregnant, their assent and parental permission is obtained,
- H. No inducements, monetary or otherwise, are being offered to terminate a pregnancy,
- I. Individuals engaged in the research have no part in any decisions regarding the timing, method or procedures used to terminate a pregnancy, and
- J. Individuals engaged in the research have no part in determining the viability of the neonate.

XVIII. Additional Criteria for Approving Human Subjects Research Involving Prisoners

The Board will approve the inclusion of prisoners as research subjects upon determining:

- A. The proposed research solely consists of one or more of the following:
- 1. The possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects,
 - 2. The prisons as an institutional structure or prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects,
 - 3. The conditions particularly affecting prisoners as a class (e.g., vaccine trials and research on hepatitis, alcoholism, drug addiction and sexual assaults),
 - 4. The practices, both innovative and accepted, that have the intent and reasonable probability of improving the research subjects' health or well-being,
 - 5. An epidemiologic study that's sole purpose is to describe the prevalence or incidence of a disease by identifying all cases, or study potential risk factor associations for a disease, and:
 - a. The research presents no more than minimal risk,
 - b. The research presents no more than inconvenience to the research subjects, and
 - c. Prisoners are not a particular focus of the research.

- B. Any possible advantages accruing to the prisoner through his/her participation (e.g., general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) are not of such a magnitude as to impair his/her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison.
- C. The risks involved in the research are commensurate with risks that would be accepted by nonprisoners.
- D. The procedures for the selection of research subjects are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
 - 1. Control subjects must be selected randomly from the group of available prisoners who meet the inclusion criteria for the proposed research.
- E. The Board has been provided with adequate assurance that parole boards will not take a prisoner's participation in the research into account when making parole decisions.
- F. All prospective research subjects are clearly informed that their participation in the research will have no effect on his/her parole.
- G. When applicable, adequate provisions have been made for follow-up examination or care of the research subjects after the end of their participation, taking into account the varying lengths of individual prisoners' sentences.