Massachusetts Department Of Correction **POLICY**	Effective Date 11/29/2021 Annual Review Date 12/19/2022	Responsible Division Deputy Commissioner, Clinical Services and Reentry
Policy Name 103 DOC 662 CLINICAL TRIALS AND MEDICAL RESEARCH INVOLVING INMATE PARTICIPATION	M.G.L. Reference: 45 CFR 46; MGL Ch. 124, Sec.1(c),(k),(q); NCCHC Standard: P-72 DOC Policy Reference: 103 CMR 180 ACA/PREA Standards: 2-CO-1F-14; 2-CO-4E-01; 5-ACI-6C-09; 4-ACRS-4C-20	
Attachments Yes ☒ No ☐ / Inmate Library Yes ☒ No ☐	Applicability: Staff/Inmates	
Public Access Yes ☒ No ☐	Location: DOC Central Policy File Institution Policy File Health Services Division Policy File	

PURPOSE:
The purpose of this policy is to establish guide-lines and procedures for inmate participation in clinical trials and medical research.

RESPONSIBLE STAFF FOR IMPLEMENTATION AND MONITORING OF POLICY:
Deputy Commissioner, Clinical Services and Reentry
Assistant Deputy Commissioner, Clinical Services

CANCELLATION:
This policy cancels all previous Department policy statements, bulletins, directives, orders, notices, rules and regulations regarding clinical drug trials and medical research involving inmates which are inconsistent with this policy.

SEVERABILITY CLAUSE:
If any part of this policy is for any reason held to be in excess of the authority of the commissioner, such decision will not affect any other part of this policy.

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662.01 GENERAL GUIDELINES FOR CLINICAL TRIALS AND MEDICAL RESEARCH INVOLVING INMATE PARTICIPATION

1. All clinical trials conducted under this policy shall conform to the requirements of the code of federal regulations (45 CFR 46) establishing special provisions which protect prisoners involved as human subjects in research activities, and applicable Massachusetts law;

2. All clinical trials projects must be reviewed and approved by the Assistant Deputy Commissioner, Clinical Services prior to any inmate enrollment. Such trials must also be reviewed and approved by the Lemuel Shattuck Hospital Institutional Review Board (IRB).

3. Inmates may enroll in clinical trials only upon the recommendation and approval of the Department's contractual medical director or his designee.

4. Clinical trials shall afford the potential of clinical benefit to the individual inmate. Inmates shall not be permitted to participate in phase I clinical trials, directed at determining toxicity level of drugs. Inmates shall not be permitted to enroll in clinical trials not generally available to the community at large.

5. The contractual medical provider for the Department shall establish procedures relating to the enrollment of inmates in clinical drug trials.

6. Each proposal for medical research that may involve inmate volunteers or may involve review of inmate medical records by an outside organization shall be submitted in writing to the Assistant Deputy Commissioner, Clinical Services.

662.02 APPLICATION PROCESS TO CONDUCT CLINICAL DRUG TRIALS USING INMATE VOLUNTEERS

Each proposal for a clinical trial seeking inmate enrollment shall be submitted in writing to the Assistant Deputy Commissioner, Clinical Services. Such proposal shall contain, but not be limited to, the following information:

1. Title of trial;

2. Name, address, telephone number of principal investigator, and designated supervisory clinical research staff;

3. A summary of the potential diagnostic or therapeutic gains of the clinical trial;

4. An analysis of the efficacy and/or associated risks of the alternative therapy or diagnostic procedures;

5. A copy of the research protocol;

6. A statement as to the place, time period for the trial;

7. The procedures for selection of inmate volunteers;

8. Copies of the informed consent forms;

9. Procedures for obtaining consent from potential inmate volunteers, including procedures for insuring that information is presented in bilingual languages as necessary;

10. Security precautions to protect confidentiality and privacy of inmate volunteers;

11. A statement as to any costs to be borne by the Department of Correction (DOC), direct or indirect, associated with the clinical trial.

12. A completed and signed Massachusetts Department of Correction indemnification agreement (see Attachment #2).

662.03 APPROVAL PROCESS

1. Administrative Approval

The review and approval process begins with an administrative review by the Assistant Deputy Commissioner, Clinical Services. The application will be referred to the Lemuel Shattuck Hospital IRB only after it is determined that it is appropriate for Massachusetts DOC inmates to be included in the proposed trial.

a. The Assistant Deputy Commissioner, Clinical Services in consultation with such medical providers and/or consultants as deemed necessary will review all proposed clinical trials. A copy of each such proposal shall be sent to the medical director for review. A copy of such proposal shall also be forwarded to the central office research division of the DOC.

b. The Assistant Deputy Commissioner, Clinical Services will approve or disapprove of the proposed clinical trial based on the appropriateness of the proposal within the correctional environment. The administrative review period commences when

the Assistant Deputy Commissioner, Clinical Services has received a complete proposal. If the proposal is deemed appropriate by the Assistant Deputy Commissioner, Clinical Services, it will be sent to the LSH IRB for clinical review and consideration. The IRB will submit a recommendation to the Assistant Deputy Commissioner, Clinical Services and he/she/they will then notify the applicant of the IRB determination.

c. If the proposal provides for inmate enrollment in existing trials which have already received the appropriate IRB approval, the Assistant Deputy Commissioner, Clinical Services will render a decision within a reasonable time after receiving the information required by section 662.01, section 1, of this policy.

2. Institutional Review Board Review and Recommendation

a. The IRB, as defined by this policy, shall review a proposed clinical trial involving inmate volunteers and provide the Assistant Deputy Commissioner, Clinical Services with its determination in writing.

b. The IRB shall include, but not be limited to the following members:

i. Contracted independent medical consultant for the DOC;
ii. an employee of the health services division management staff;
iii. a prisoner advocate offering sufficient credibility including background and experience to represent the ethical and clinical interests of potential inmate volunteers.

Inmates shall not be permitted to act as members of such board.

c. In reviewing clinical trials, the IRB shall ensure that:

i. The risks involved with the clinical trials are commensurate with risks that would be accepted by non-inmate volunteers.
ii. The clinical trial affords the potential of clinical benefit to the inmate volunteer;
iii. No financial or other incentives, other than the potential for clinical benefit, will be gained or offered to inmate volunteers;
iv. Inmate participation shall not gain any special advantages (living conditions, medical care, quality of food, amenities, financial or parole incentives) through participation in

clinical trials that may impair their objectivity in deciding upon participation;

v. The selection procedures for participation are fair, impartial, and without influence from prison authorities or other inmates. Control subjects, if applicable, should be randomly selected from the prison population;

vi. Information about participation should be presented in a language understandable to the inmate population

vii. The parole board shall provide assurance that an inmate's participation in research will not be taken into account in making decisions regarding parole and each inmate must be clearly informed in advance that such participation in the research will have no effect on his/her/their parole;

viii. Adequate arrangements for follow up care or examination, if necessary, have been made even for those inmates who have served their sentences or have been paroled during the clinical trial.

662.04 ENROLLMENT OF INMATE VOLUNTEERS

1. Inmate participation in clinical trials will be authorized by the Assistant Deputy Commissioner, Clinical Services on a case by case basis, after recommendation by the program medical director.

2. The program medical director or his designee shall conduct a complete physical examination to determine the inmate's appropriateness for participation in the proposed clinical trial and shall provide his/her/their written determination to the Assistant Deputy Commissioner, Clinical Services promptly.

3. The program medical director or his designee shall perform a complete mental health evaluation to determine the individual's competency to understand and consent to the clinical trial. Such written documentation shall also be forwarded to the Assistant Deputy Commissioner, Clinical Services promptly.

4. The program medical director's determination shall be documented in the medical chart of the individual.

5. All potential inmate volunteers shall be provided with both verbal and written explanations of all aspects of the proposed research protocol, a discussion of the risks and benefits of participation, a description of available options for management and an assurance that refusals to participate in, or any withdrawal from, the clinical trials would not

prejudice his/her/their clinical care or prison status. Such information shall be presented in language which is understandable to the inmate volunteer.

6. All inmates will be given a copy of the informed consent (bilingual, if necessary) to review and sign.

7. An inmate's consent to participate in the clinical trial must be fully documented in the inmate's medical record and a copy of the executed informed consent form shall be included in the inmate's medical record.

8. Confidentiality of inmates' medical histories and records shall not be compromised during the clinical trial. Record keeping requirements are the responsibility of the clinical trial investigators in collaboration with the DOC's medical provider.

662.05 COSTS RELATED TO CLINICAL TRIALS

The cost of the proposed clinical trial shall be the responsibility of a clinical investigator and/or sponsor of the clinical trial. Neither the DOC, nor the Department's contractual medical provider, shall be responsible for costs, direct or indirect, related to the participation of inmate volunteers in clinical trials.

662.06 APPLICATION PROCESS TO CONDUCT MEDICAL RESEARCH USING INMATE VOLUNTEERS

Each application/proposal to conduct medical research using inmate volunteers shall contain, but not be limited to, the following information:

1. Title of the research proposal;

2. Names, addresses, telephone numbers of the principal investigator, and designated supervisory clinical research staff;

3. An endorsement by a recognized research organization such as university, college, private foundation, consulting firm, or public agency that has a mandate to perform research certifying that the research proposal is for valid scientific, educational, or other public purpose;

4. A summary of the goals of the study and justification for the research.

5. A copy of the research protocol/design including:

    a. Department of Correction resources and personnel that may be needed, e.g., correction officer coverage, space and equipment needs;

b. statement as to the place and time period for the project;

c. The procedures for the selecting inmate volunteers/subjects or records as appropriate to the proposal, along with the criteria that will be used for selection;

d. Procedures for obtaining consent from potential inmate volunteers, including procedures for insuring that information is presented in bilingual languages as necessary.

e. procedures for data collection and copies of research instruments to be used, including interview schedules, questionnaires, data collection forms, tests, etc.;

f. details of compensation, if any, to be paid to inmate subjects;

g. security precautions to protect confidentiality and privacy of inmate subjects;

h. a written summary in layman's language and if necessary in bilingual language explaining the study. A copy of the summary shall also be provided to each subject;

i. written agreement to abide by any and all requirements of the Commonwealth of Massachusetts, the Department of Correction 103 CMR 180, *Regulations Governing Research and Evaluation*, to the extent such regulations apply to the proposed medical research study.

662.07 APPROVAL PROCESS

1. Administrative Approval

The review and approval process of medical research projects starts with an administrative review by the Assistant Deputy Commissioner, Clinical Services. Applications not in compliance with 103 DOC 662.07 will be returned with a written request for additional information or clarification as needed. Only after it has been determined to be administratively appropriate for Department of Correction participation will the application be referred to the medical director of the current contractual medical provider.

2. Contractual Medical Provider Review and Recommendations

The medical director of the current contractual medical provider will review all proposed medical research projects. Additional consultation from DOC medical consultants, physicians employed by the contractual medical provider in Massachusetts or in other locations may be requested. The medical director will submit comments and recommendations in writing to the Assistant Deputy Commissioner, Clinical Services.

3. Superintendent(s) Comments and Recommendations

   Superintendents at institutions that may be impacted by the proposed medical research project will be asked to submit comments and recommendations in writing to the Assistant Deputy Commissioner, Clinical Services.

4. If, during the review process, additional information is needed, the Assistant Deputy Commissioner, Clinical Services will request in writing that the principal investigator of the proposed research project submit that information in writing to the Assistant Deputy Commissioner, Clinical Services.

5. Final Decision Regarding Approval

   Final decisions regarding participation by the Massachusetts Department of Correction in any proposed medical research projects will be made in writing by the Assistant Deputy Commissioner, Clinical Services as soon as possible after the review process is completed.

6. At the conclusion of the review process a copy of the medical research proposal and the written final decision will be sent to the director of DOC research division.

662.08 COSTS

The cost of any medical research project will be the responsibility of the principal investigator and/or the sponsor of the research project. Neither the Department of Correction, nor the contractual medical provider shall be responsible for costs, direct or indirect, related to medical research projects.

662.09 CONTINUED PARTICIPATION OF INMATES INVOLVED IN CLINICAL TRIALS OR MEDICAL RESEARCH PRIOR TO INCARCERATION

When notified by an inmate allegedly involved in, or by a sponsor of, a clinical trial or medical research project within a reasonable time after admission to the Department, the following guidelines shall be followed:

1. The Health Services Administrator (HSA) shall contact the principle investigator of the clinical trial or research project and request the following information:

    a. a copy of the original informed consent signed by the inmate/detainee at the time of enrollment in the trial or research project;

    b. a copy of the research protocol and IRB approval;

    c. a copy of the on site supervision schedule;

    d. appropriate contact personnel with the drug trial or research program.

2. Submit the above information to the program medical director and the Assistant Deputy Commissioner, Clinical Services for review.

3. The institution medical director, in concert with the program medical director, must:

    a. review a copy of the study;

    b. discuss the clinical trial/research project with the principal investigator;

    c. notify the Assistant Deputy Commissioner, Clinical Services regarding their opinion as to the continued participation of the involved inmate in the particular drug trial or research project;

    d. if the program medical director, Assistant Deputy Commissioner, Clinical Services, and institution medical director are in agreement that continued participation is appropriate, the institution medical director should write orders to allow continued participation in the clinical trial or medical research project by the inmate involved;

    e. update the inmate's medical record according to applicable standards.

4. Upon approval and written physician orders, the HSA or designee will arrange authorization for entry into the institution for the sponsored staff

according to DOC policy. The HSA or designee will insure appropriate medical staff are trained regarding medications, communication with research/clinical trial staff, and proper record management.

662.10 CLINICAL TRIAL AND MEDICAL RESEARCH RESULTS

Research results/reports should be submitted to the Assistant Deputy Commissioner, Clinical Services and Superintendent(s) of institutions involved for review prior to dissemination and or publication. Confidentiality of participants in the research project/clinical trial must be maintained according to applicable state and federal guidelines.

Attachment #1

Checklist for Review and Approval of Clinical Drug Trials

Application Process: Submitted in writing to Assistant Deputy Commissioner, Clinical Services

1. Title
2. Principle Investigator and Staff
3. Certify That Application Sent to LSH IRB
4. Summary of Benefits
5. Discuss Risks/Efficacy/ Alternatives
6. Copy of Protocol
7. Location and Time Period
8. Procedures for Selection of Volunteers
9. Copies of Informed Consent Forms
10. How to Obtain Consent - Bilingual
11. Confidentiality/Privacy of Volunteers
12. Costs Associated with Trial

Approval Process

Administrative Approval:

1. Assistant Deputy Commissioner, Clinical Services confers with Department Senior Medical Consultant
2. Assistant Deputy Commissioner, Clinical Services confers with Contractual Program Medical Director
3. Key Factor: Appropriateness of the trial in the correctional environment
4. If appropriate, proposal and comments sent to LSH IRB for Clinical Review
5. IRB submits recommendation to Assistant Deputy Commissioner, Clinical Services
6. Assistant Deputy Commissioner, Clinical Services notifies the applicant of IRB decision

IRB Approval:

1. Committee Members:
   a. Department Senior Medical Consultant
   b. Health Services Division Management Staff
   c. Prisoner Advocate
   d. LSH Members and Presenters

2. Committee Review Includes:
   a. Risks
   b. Benefits
   c. No incentives offered
   d. No special advantages offered
   e. Impartial selection process
   f. Language issues
   g. No effect on parole
   h. Follow up for inmates who are discharged/released
   i. Bilingual Consent Forms
   j. Medication containers
   k. Potential transportation issues
   l. Research personnel access to inmates

How does an inmate become enrolled in an approved Clinical Drug Trial?

1. Determined on a case by case basis, after recommendation of Medical Director;
2. Must have written recommendation to Assistant Deputy Commissioner, Clinical Services upon completion of physical examination;
3. Must have written recommendation to Assistant Deputy Commissioner, Clinical Services upon completion of mental health evaluation;
4. Determination of Contractual Program's Medical Director must be documented in the Medical Record;
5. Verbal and written explanations of the clinical drug trial to the inmate;
6. Signed informed consent obtained from the inmate;
7. Inmate's signed informed consent filed in his/her/their medical record;
8. Collaboration documented between contractual medical provider and research staff regarding record keeping and confidentiality matters.

Attachment #2

Indemnification Agreement
Clinical Trials
Massachusetts Department of Correction

The sponsor, _____, agrees to indemnify and hold the Commonwealth of Massachusetts, the Department of Correction, its agents, officers and employees, (name of contractual medical vendor), Inc., its agents, officers and employees, harmless from any and all claims, debts, demands, costs, expenses, including without limitation, medical expenses, attorneys' fees, liabilities, and losses, which may be asserted against the Commonwealth, the Department of Correction, or (name of contractual medical vendor), inc., resulting from or arising out of the clinical drug trial entitled: _____

The sponsor, _____, represents that the consent form to be signed by each volunteer participant, contains a full and complete disclosure of any and all known or anticipated side effects. If a volunteer participant in the custody of the Department of Correction experiences an adverse reaction resulting from or arising out of his/her/their participation in the (trial name): _____ which requires medical services and/or treatment, the sponsor, _____ agrees to pay (name of contractual medical vendor), Inc., within 30 days of receipt of invoice for any and all medical services or treatment rendered.

_____

Title

_____

Date