POLICY:

I. Potential research subjects who are prisoners are at increased risk for coercion and undue influence as a result of their incarceration. To ensure their participation in research is uncoerced and voluntary, additional protections are afforded this population. Only UIC IRBs that meet composition requirements in the “Procedure” Section, Item III, of this document are permitted to review protocols involving prisoners as subjects. The applicable UIC IRBs approve research involving prisoners only if the research complies with the safeguards described in this policy. This policy applies whether the research involves individuals who are prisoners at the time of enrollment in the research, who become prisoners after they are enrolled in the research, or their status as prisoners is incidental to the research.

II. Definitions. The following definitions are taken from 45 CFR 46.303.

A. PRISONER: any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Common examples fitting the regulatory definition of prisoner include:

1. Individuals in any kind of penal institution, such as a prison, jail, or juvenile offender facility whose ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

2. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

3. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been
voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

4. Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

5. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

B. MINIMAL RISK: the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. Note: This definition of minimal risk differs from that in 45 CFR 46 Subpart A by replacing “harm or discomfort” with “physical or psychological harm” and using “healthy person” as the reference point for the medical, dental or psychological examinations.

III. For research involving prisoners as participants, the UIC IRB follows federal regulations at 45 CFR 46 Subpart C in addition to those imposed under other UIC HSPP policies and procedures, ethical considerations and other applicable federal, state and local laws for review and approval regardless of funding source.

IV. The exemptions from IRB review at 45 CFR 46.101(b) do not apply to research involving prisoners.

V. Expedited procedures for review of prisoner research are allowed:
   A. when research does not involve interaction with prisoners (e.g., record review, existing data) and a determination is made that the research involves no greater than minimal risk for the prison population being studied, or
   B. to secure approval for minor or administrative modifications.
   C. Protocols originally approved by the convened IRB and remain active only for data analysis may be eligible for expedited review (expedited category 8c).

VI. VA Research (limited to research reviewed by CHAIRb): Research involving prisoners cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer (CRADO).

VII. Department of Defense (DoD). The DoD applies subpart C with some modifications. Please refer to UIC HSPP policy Research Involving Department of Defense Components for more detail.

VIII. Medical, cosmetic, or pharmaceutical experiments involving prisoners are prohibited for research to be conducted within the Illinois Department of Corrections. (Title 20
Research Involving Prisoners, Version 1.2

Corrections, Criminal Justice, and Law Enforcement Chapter 1: Department of Corrections: part 106, Research and Evaluation) Therefore, even though these types of research with prisoners may be approvable under federal regulations, they are not permitted under Illinois state law.

PROCEDURE:

I. Special Protections for Research Involving Prisoners. When the IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make (and document in the meeting minutes in a protocol specific manner) the following seven findings (45 CFR 46.305(a)) for approval:

A. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2) and listed in item II. below;

B. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prisoner is impaired;

C. The risks involved in the research are commensurate with the risks that would be accepted by non-prisoner volunteers;

D. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the investigator provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

E. The information is presented in language which is understandable to the participant population;

F. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

G. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

II. Categories of Research Involving Prisoners. When reviewing a protocol involving prisoners as subjects, the IRB must determine and document whether the study falls within one of the categories allowed for prisoner participation: (45 CFR 46.306(a)(2); June 20, 2003, DHHS Secretarial Waiver)

A. Study of 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 participants;
B. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;

C. Research on conditions particularly affecting prisoners as a class (e.g. research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of the Secretary's intent to approve such research; or

D. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in the division of criminology that deals with the philosophy and practice of society in its efforts to deter criminal activities, medicine, and ethics and published notice, in the Federal Register, of the Secretary's intent to approve such research.

E. In 2003, a fifth category of permissible research was added by DHHS Secretarial Waiver for Certain Epidemiologic Research. The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. Also, UIC must certify to the OHRP that the IRB found the research to fulfill criteria B - G in Item I of the “Procedure” Section (45 CFR 46.305(a)(2)-(7)) and find and document that the research presents no more than minimal risk, no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research.

III. Composition of the IRB when Prisoners are Involved in Research.

A. When the IRB reviews a protocol involving prisoners as participants, the composition of the IRB must satisfy the following requirements of HHS regulations at 45 CRF 46.304 (a) and (b):

1. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB; and

2. At least one voting member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one IRB need satisfy this requirement.

3. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
B. In the absence of choosing someone who is or has been a prisoner, the IRB should choose as a prisoner representative a person with a close working knowledge, understanding and appreciation of prison conditions from the prospective of a prisoner. Suitable individuals could include prison chaplains, prison psychologists, prison social workers, other prison service providers, or persons who have conducted advocacy for the rights of prisoners. The IRB must meet the special composition requirements for all types of review of protocols, including initial review, continuing review, review of protocol modifications, review of reports of adverse events or unanticipated problems involving risk to participants or others, or in the event an individual becomes a prisoner while participating in a research protocol.

C. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative receives all review materials pertaining to the research (same as primary reviewer).

D. The prisoner representative must be present at the convened meeting when research involving prisoners is reviewed. The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.

E. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

F. When expedited procedures are followed, the prisoner representative serves as a reviewer.

G. The prisoner representative presents their review either orally or in writing at the convened meeting or in writing if the review is expedited for research involving prisoners.

H. The IRB must notify OHRP of any change in the IRB roster due to the addition of a prisoner representative. Specifically, the IRB should:
   1. Notify OHRP of the name and qualifications of the prisoner representative, if the approved IRB roster does not currently reflect this information; and
   2. Maintain the CV of the prisoner representative serving on the IRB.

IV. Expedited Review
   A. Expedited procedures for review of prisoner research are only allowed:
      1. when research does not involve interaction with prisoners (e.g., record review, existing data) and a determination is made that the research involves no greater than minimal risk for the prison population being studied, or
      2. to secure approval for minor or administrative modifications.
      3. Review of greater than minor modifications and continuing review, except when expedited review category 8.c. is met, must use the same procedures as initial review.

   B. The prisoner representative reviews the research as a reviewer or consultant as designated by the IRB chair.
V. Measures to be Taken When a Current Research Subject Becomes a Prisoner.

A. If a subject becomes a prisoner, or the discovery of subjects with incidental prisoner status have been included in the research, after enrolling in a research study which was not approved for prisoner participation, the investigator is responsible for notifying the IRB as soon as possible and reporting the event in writing to the IRB using the **Prompt Reporting to the IRB** form within 5 working days.

B. If the study was not previously reviewed and approved by the IRB in accordance with the requirements of Subpart C, all research interactions and interventions with, and the obtaining of identifiable private information **must cease** until the requirements of Subpart C are satisfied. This is necessary because it is unlikely that review of the research and the informed consent document contemplated the constraints imposed by the possible future incarceration of the participant. **NOTE:** The IRB Chair may determine that the participant may continue to participate in the research until the requirements of Subpart C are satisfied when the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated. The investigator should submit this request using the UIC OPRS **Protocol Exception** form.

C. If the investigator would like to have the participant continue in the research, an amendment requesting prisoner review and Appendix C should be submitted to the OPRS. The convened IRB constituted as described above reviews the application for prisoner review and protocol, taking into consideration the additional ethical and regulatory concerns for prisoners involved in research. If the IRB to which the research was originally assigned does not have appropriate membership, the review will be transferred to an appropriately composed IRB.

D. The review and approval is limited to the individual participant.

E. Because Illinois law prohibits medical, pharmaceutical or cosmetic experiments involving prisoners, participants in this type of research who becomes prisoners will need to be withdrawn from the study in a manner which protects the safety and welfare of the subject. The plan for this process should be provided to the IRB for their review and approval when reporting the incarceration.

VI. Research Conducted or Supported by DHHS.

A. For research involving prisoners that is conducted or supported by HHS, UIC must certify to the DHHS Secretary (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46 Subpart C and made the seven additional findings required under 45 CFR 46.305 (Item I of the "Procedure" Section on p. 3). The UIC IO or designee sends to OHRP a letter certifying the above and including the name and address of the institution and identity of the research protocol and any relevant HHS grant application or protocol. UIC also submits:

1. Copy of the research proposal, including IRB-approved protocol, any relevant HHS-grant application, any IRB application forms, and any
other information requested or required by the IRB to be considered during initial IRB review;
2. Relevant grant number;
3. OHRP FWA number;
4. IRB registration number for designated IRB; AND
5. Date(s) of IRB meeting(s) in which protocol was considered, including brief chronology that encompasses the date of initial IRB review and date of Subpart C review, if different.
6. All prisoner research certification letters should be emailed to subpartc@hhs.gov.

B. The Secretary (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2) and give approval prior to the initiation of research activities.

VII. Research that is not HHS funded or conducted.
A. If an investigator engages in non-HHS supported research involving prisoners, certification to DHHS (OHRP) is not required.
B. If the IRB deems the research involving prisoners to fall within categories C or the appropriate portion of D, the UIC IRB will provide copies of the protocol and the IRB minutes to the HPA for a determination regarding whether an ad hoc panel of experts should be convened to review the research in a process parallel to that of OHRP expert panel review. In this case, UIC IRB approval will not be released until either the HPA determines an ad hoc panel is not necessary or the ad hoc panel issues a recommendation that the research is acceptable.

VIII. Additional Approvals.
A. Federal Bureau of Prisons Research:
   1. The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons under 28 CFR 512. The provisions under 28 CFR 512 specify additional requirements for prospective investigators (both Bureau employees and non-employees) to obtain approval to conduct research within the Bureau of Prisons and responsibilities of Bureau of Prisons staff in processing proposals and monitoring research projects.
   2. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
   3. The research design must be compatible with both the operation of prison facilities and protection of human subjects. The Research must observe the rules of the institution or office in which the research is conducted.
   4. Investigators who are non-employees of the Bureau must sign a statement in which the Investigator agrees to adhere to the requirements of 28 CFR 512.
   5. All research proposals will be reviewed by the Bureau Research Review Board (BRRB).
6. Research conducted within the Bureau of Prisons must have an adequate research design and contribute to the advancement of knowledge about corrections. In addition, the Investigator must have academic preparation or experience in the area of study of the proposed research.

7. Medical, cosmetic, or pharmaceutical experiments involving prisoners are prohibited for research to be conducted within the Bureau of Prisons.

8. The selection of participants within any one organization must be equitable.

9. Incentives may not be offered to help persuade inmate participants to participate; however, soft drinks and snacks to be consumed at the test setting may be offered.

10. Reasonable accommodations such as nominal monetary compensation for time and effort may be offered to non-confined participants who are both:
    a) No longer in Bureau of Prisons custody, and
    b) Participating in authorized research being conducted by Bureau employee or contractors.

11. The Bureau of Prisons requires that specific language be included in the consent document. For additional information, please refer to the UIC HSPP document Guidance for Investigators: Informed Consent.

12. A non-employee of the Bureau may receive records in a non-individually identifiable format when advance and adequate written assurance that the records will be used solely as a statistical research or reporting record is provided to the agency.

13. Except as noted in the consent statement to the participant, the research must not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

14. Except for computerized data records maintained at an official U.S. Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

15. If the research is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving the ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

16. Investigators conducting research within the Bureau of Prisons must submit a research protocol that includes the following:
a) Summary statement, consisting of:
   (1) Names and current affiliations of the Investigators,
   (2) Title of the study,
   (3) Purpose of the study,
   (4) Location of the study,
   (5) Methods to be employed,
   (6) Anticipated results,
   (7) Duration of the study,
   (8) Number of participants (staff or inmates) required and amount of time required from each,
   (9) Indication of risk or discomfort involved as a result of participation,

b) A comprehensive statement, consisting of:
   (1) Review of related literature,
   (2) Detailed description of the research method,
   (3) Significance of anticipated results and their contribution to the advancement of knowledge,
   (4) Specific resources required from the Bureau of Prisons,
   (5) Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
   (6) Description of steps taken to minimize any risks.

c) Description of physical or administrative procedures to be followed to:
   (1) Ensure the security of any individually identifiable data that are being collected for the study,
   (2) Destroy research records or remove individual identifiers from those records when the research has been completed.

d) Description of any anticipated effects of the research study on organizational programs and operations.

e) Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

17. The Investigator must assume responsibilities for actions of any person engaged to participate in the research as an associate, assistant, or subcontractor to the Investigator.

18. At least once a year, the Investigator shall provide the Chief, Office of Research and Evaluation, with a report of the progress of the research.

19. At least 12 working days before any report of findings is to be released, the Investigator shall distribute one copy of the report to each of the following: chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The Investigator shall include an abstract in the report of findings.
20. In any publication of results, the Investigator shall acknowledge the Bureau’s participation in the research project.

21. The Investigator shall expressly disclaim approval or endorsement of the published materials as an expression of the policies or views of the Bureau.

22. Prior to submitting for publication the results of a research project conducted under this subpart, the Investigator shall provide two copies of material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

B. National Institute of Justice (NIJ) Research:
1. The National Institute of Justice (NIJ) requires that research funded by the NIJ follow specific guidance.
2. All NIJ funded projects are required to have a privacy certificate approved by the NIJ human subjects protection officer and on file with the Office of Research Services (ORS). NIJ privacy certificates are to be submitted to ORS with the grant proposal.
3. All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.
4. The Bureau of Prisons requires that specific language be included in the consent document. For additional information, please refer to the UIC HSPP document Guidance for Investigators: Informed Consent.
5. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

C. Illinois Department of Corrections (IDOC) Research:
1. Any research involving former or present committed persons (including access to inmate records), staff, programs, or facilities, must comply with Illinois laws, including Title 20 Corrections, Criminal Justice, and Law Enforcement Chapter 1: Department of Corrections: part 106, Research and Evaluation, federal laws and guidelines.
2. The investigator must submit the a research protocol that contains the following:
   a) Abstract of the project, consisting of:
      (1) Names and current affiliations of the Investigators,
      (2) Title of the study,
      (3) Purpose of the study,
      (4) Location of the study,
      (5) Methods to be employed,
      (6) Anticipated results,
      (7) Duration of the study,
      (8) Number of participants (staff, inmates, or inmate records) required and amount of time required from each,
      (9) Indication of risk or discomfort involved as a result of participation,
      (10) Dissemination plan,
(11) Testing or measurement instrument (i.e., questionnaires),
(12) Department resources to be utilized;

b) Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires or other testing instruments, and interview schedules;

c) Grants awarded, sources of funding, or descriptions detailing intentions to respond to official requests for proposals;

d) A signed Research Agreement which shall contain a statement that any rights of privacy, informed consent, confidentiality, and protection from harm are met in accordance with accepted professional and scientific ethics and that the requirements of any applicable Illinois and federal law or regulation have and will continue to be met;

e) IDOC specific consent document for employees; and

f) Any other information deemed necessary in order to conduct the review.

g) Documentation of IRB approval must be submitted to the IDOC Director with the documents listed above.

3. The IDOC Director will review the proposal.

a) Requirements of approval include, but are not limited to: the proposed study is ethical, feasible, methodologically sound, and meets the relevant needs and goals of the Department.

b) Proposals may be denied for reasons which may include, among other factors, the nature and risk of the research, concern for security, and the level of demand on staff time and Department finances.

c) Medical, cosmetic, or pharmaceutical experiments involving prisoners are prohibited for research to be conducted within IDOC.

4. Requirements for conducting research studies with IDOC:

a) The researcher shall provide periodic reports on the progress of the research project as required. Any changes in the scope or methodology of the project shall be reported.

b) Permission to conduct the current study and any further research may be discontinued for, among other matters, violation of Department rules or security requirements or for violation of applicable Illinois or federal law or regulations. The factors to be considered in determining whether to discontinue a project shall include, but not be limited to, whether the violation was intentional; the seriousness of the violation; whether the project is placing greater demands on Department resources than originally stated; or whether the project has been expanded beyond the stated purpose and scope of the project.

c) Prior to publication of the results of a research project, the researcher shall provide copies of the material accepted for publication to the Department for informational purposes.
d) Following publication, additional copies may be provided for the Department without cost, if so specified in the signed Research Agreement.

D. VA Research (limited to research reviewed by CHAIRb): After IRB approval, a waiver must be obtained from the CRADO.

IX. Additional Considerations.
A. When a prisoner is under 18 (e.g., an adolescent in a juvenile detention facility is a prisoner), the HSPP and UIC IRB policy and procedures regarding children in research also apply. For additional information, please refer to the UIC HSPP policy Research Involving Children (including Wards of the State).

X. Investigator Responsibilities.
A. Investigators are responsible for obtaining and providing documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.

B. Investigators must provide any additional documents or materials required for certification to the Secretary (through OHRP) for federally funded research involving prisoners.

C. Investigators may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval and any other applicable approvals (IDOC, BRRB, etc.). If the biomedical or behavioral research is conducted or supported by HHS, it also requires review and written approval by the Secretary (through OHRP) before any research activities may begin, including screening and enrollment.

D. If the investigator anticipates that some subjects may become prisoners during the study, submission for prospective IRB review for research involving prisoners should occur.

REFERENCES:

28 CFR 512
45 CFR 46.101(b), 45 CFR Part 46, Subpart C 46.301-46.306
VHA Handbook 1200.05, 11/12/2014.
The Illinois Department of Corrections: Title 20 Corrections, Criminal Justice, and Law Enforcement Chapter 1: Department of Corrections: part 106, Research and Evaluation
Prisoner Research FAQs, OHRP, DHHS
Prisoner Research, OHRP Guidance, May 23, 2003

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