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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***Research Involving Prisoners***	Policy #:	**0330-1020**
		Replaced #:	ORMC 6000-403; MDACCO 1000-0001
Page 1 of 3		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
Revision Dates:	1/1/01, 5/17/05, 11/9/07, 8/11/14, 4/4/17, 4/21/20		

I. PURPOSE:

To impose additional safeguards to protect certain vulnerable classes of human research subjects.

II. DEFINITIONS:

A. Prisoner: Any individual involuntarily confined or detained in a penal institution (for example, jail, prison, juvenile offender facility, and alcohol and drug treatment facility). 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. This definition applies to minors as well as to adults.

B. "Minimal Risk" as it pertains to research involving prisoners: 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 (i.e., healthy individuals who are not prisoners).

III. POLICY:

In addition to the responsibilities described in the *Ethical Principles* IRB Policy, the Orlando Health IRB shall require additional safeguards in research involving prisoners as subjects or enrolled subjects who become prisoners after the time in which they were enrolled.

IV. PROCEDURE:

A. Research involving prisoners cannot be exempt as listed under 45 CFR 46.101(b).

B. IRB composition requirements for review of research involving prisoners as subjects (including initial review, continuing review, and review of amendments):
   1. A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
   2. At least one member of the Board must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research proposal is reviewed by more than one IRB (e.g., a multi-site study), only one IRB need satisfy this requirement.

C. In accordance with 45 CFR 46.305 (a), the IRB will require the following additional duties when prisoners are used as research subjects:
   1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2).
   2. 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 a 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 prison is impaired.
   3. The risks involved in the research are commensurate with risk that would be accepted by non-prisoner subjects.
   4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides to the

IRB written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the criteria for that particular research project.

5. The information is presented in language that is understandable to the subject population.
6. 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.
7. Where the IRB finds there is 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.

D. When a research subject becomes a prisoner during the course of research:
   1. The Principal Investigator or their research staff must immediately inform the IRB Office of the situation.
   2. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject **must cease immediately**, except in special circumstances.
   3. The prisoner subject must stop participating in the research with one exception: if the Principal Investigator asserts it is in the best interests to have the prisoner-subject remain in the study while incarcerated, then
      i. The Principal Investigator must communicate this occurrence in writing to the IRB.
      ii. The IRB must re-review the proposal in accordance with the requirements of subpart C. Note that some of the findings required by 45 CFR 46.305(a) may not be applicable. For example, the finding required under 45 CFR 46.305(a)(4) regarding the selection of subjects within the prison may not be applicable, if the subject was recruited outside of an incarcerated context. The IRB should document findings of non-applicability.
      iii. For HHS-supported research, the institution(s) engaged in the research involving the prisoner subject must send the following to OHRP at subpartc@hhs.gov and wait for a letter of authorization in reply prior to initiating any research involving prisoners:
         1. A Prisoner Research Certification letter which indicate that the IRB reviewed the research under Subpart C and made the applicable findings under 45 CFR 46.305(a) and includes the name and address of the institution, specific identification of the research protocol, the relevant grant number, institution's Federalwide Assurance (FWA) number, IRB registration number for reviewing IRB, date(s) of IRB meeting(s) (including date of initial IRB review and date of Subpart C review, if different).
         2. A copy of the IRB-approved protocol, all documents contained in the initial IRB submission, and any relevant HHS grant application/proposal.

V. REFERENCES:

A. Code of Federal Regulations: 45 CFR 46.101(b), 45 CFR 46.303(c), 45 CFR 46.305(a), and 45 CFR 46 Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.
B. Prisoner Involvement in Research (2003), Office for Human Research Protections, found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-ohrp-guidance-2003/.

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C. Prisoner Research Certification, Office of Human Research Protections, found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-certification/.
D. IRB Policy #0330-1017: *Ethical Principles.*

VI. ATTACHMENTS:

A. None