Title: **Vulnerable Populations: Participants Who Become Prisoners**	*Applicable to: **Beaumont Health**	Effective Date: **03/19/2018** Last Periodic Review Date: **03/19/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, Research Institute**

***For This Document, Beaumont Health Includes**:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE:

The purpose of this policy is to describe Institutional Review Board (IRB) and principal investigator (PI) responsibilities when an enrolled participant incidentally becomes a prisoner during the course of a research study at Beaumont Health (Beaumont).

II. SCOPE:

This policy applies to investigators, key research personnel, IRB members and IRB staff.

III. BACKGROUND:

The Beaumont Health IRB serves as the Institutional Review Board (IRB) for all human participant research conducted at Beaumont. Prisoners are considered a vulnerable population because of their limited choice environment and are entitled to additional protections. Federal regulations restrict the types of research to be conducted with this population and impose additional requirements for IRB review. The IRB does not possess the appropriate composition to review prisoner research in accordance with federal regulations. For this reason, the IRB does not review prisoner research and Beaumont does not enroll prisoners into research studies.

IV. DEFINITIONS:

A. **Prisoner -** Any individual involuntarily tethered, 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.

V. POLICY:

A. **When Participants Become Prisoners during Research Participation - If a research participant becomes a prisoner during the course of their research participation, the PI must immediately notify the IRB in writing.** It is imperative that **all** research interactions and interventions with and/or obtaining identifiable private information about the now incarcerated participant be immediately suspended and the participant- prisoner must stop participating in the research.

In exceptional circumstances an investigator may assert continued participation in the study is necessary to assure the participant-prisoner's safety. Federal regulations provide a provision for such individuals but the IRB would have difficulty meeting federal requirements. Cases where removal would result in harm will be carefully scrutinized and dealt with by the IRB and Research Administration on a case by case basis.

B. **Research Involving or Supported by the Department of Defense (DoD)**
If a participant becomes a prisoner, and the PI asserts to the IRB it is in the best interest of the prisoner-subject to continue to participate in the DoD supported research while a prisoner, the IRB Chair may determine the prisoner-subject may continue to participate until the convened IRB can review the request to approve a change in the research protocol and until the Institutional Official (and DoD Component office, when applicable) review the IRB's approval to change the research protocol. Otherwise, the IRB Chair shall require all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review the request to approve a change in the research protocol. The convened IRB, upon receipt of notification a previously enrolled human participant has become a prisoner, shall promptly re-review the research protocol to ensure the rights and wellbeing of the human participant, now a prisoner, are not in jeopardy.

During its' review, the IRB will:

1. Confirm the participant meets the definition of a prisoner.

2. Decide whether it is in the best interest of the participant to remain in the study or to terminate enrollment.
3. Decide whether it is feasible for the participant to remain in the study.
4. Determine whether Subpart C applies;
    a. If Subpart C applies - find an external IRB that can review the study or refer to the federal regulations and identify a prisoner representative so the Beaumont Health IRB can review the study.
    b. If Subpart C does not apply - find an IRB that can review the study or develop procedures for providing equivalent protections.

The IRB should consult with a subject matter expert having the expertise of a prisoner representative and Beaumont legal when necessary. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, and the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.

If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C:

1. When the IRB does not have written procedures for research involving prisoners:
    a. Confirm the participant meets the definition of a prisoner.
    b. Decide whether it is in the best interest of the participant to remain in the study or to terminate enrollment.
    c. Decide whether it is feasible for the participant to remain in the study.
    d. Determine whether Subpart C applies.
2. If Subpart C applies:
    a. Find an external IRB that can review the study or refer to the federal regulations and identify a prisoner representative so the Beaumont Health IRB can review the study.
3. If Subpart C does not apply:
    a. Find an external IRB that can review the study or develop written procedures for providing equivalent protections.

In the very limited circumstances described above, in which the IRB would be reviewing a DoD-supported project as it relates to prisoner participation, the following will be adhered to:

1. Research involving prisoners cannot be reviewed by the expedited procedure.
2. At least one prisoner representative must be present for quorum.

3. In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
   a. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
   b. The research presents no more than minimal risk.
   c. The research presents no more than an inconvenience to the participant.

Research involving a detainee as a human participant is prohibited. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

VI. REFERENCES:

OHRP Guidance on the Involvement of Prisoners in Research (May 2003)
45 CFR 46 Subpart C; Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

VII. ASSOCIATED POLICIES:

IRB policy *IRB Initial Review of Research Protocols*
IRB policy *Research Supported by the Department of Defense*
Research policy *Research Administration Oversight*

CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.