



## Prisoners in Research

### 1. SCOPE

#### 1.1. System Wide

### 2. DEFINITIONS & EXPLANATIONS OF TERMS

#### 2.1. Prisoner

- Defined by Dept. of Health & Human Services (DHHS) regulations at 45 CFR part 46.303 (c ) as "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."
- Parolees who are detained in residential treatment (i.e. residing in a treatment center) as a condition of parole (which is an alternative to incarceration in a penal institution) are prisoners, for purposes of research taking place within that facility.
- Persons living in the community and sentenced to court supervised monitoring or treatment, regardless of whether they are described as parolees or probationers, are not prisoners. Persons 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. OHRP may be contacted when questions arise about research involving these populations.

### 3. PROCEDURE BODY

This procedure sets forth the position of MCRF IRB regarding the review of research involving prisoners. DHHS regulations at 45 CFR 46, Subpart C, provide additional protections to prisoners involved as subjects in research. Food and Drug Administration (FDA) regulations 21 CFR 56.111 (3) acknowledges the potential special problems of research involving vulnerable populations, including prisoners. Subpart C, codifies specific special duties an IRB has when reviewing prisoners research at 45 CFR 46.305. Additional IRB composition requirements are documented at 45 CFR 46.304.

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- It is the policy of MCRF IRB to not review research involving prisoners. There is no history of prisoners research at the institution and therefore, MCRF IRB is not constituted to conduct required reviews. Research protocols that target prisoner populations as subjects will not be accepted for review.

- 3.2. Should a subject enrolled in a research study become a prisoner once his or her participation has commenced, the principal investigator of the study must contact the IRB Chairperson or Administrator immediately to determine the steps to take for orderly disenrollment of the prisoner subject.

#### 4. ADDITIONAL RESOURCES

- 4.1. References:  
• None

#### 5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #950.3 ( no changes made)
2.0	
3.0	

#### 6. DOCUMENT PROPERTIES

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