

Touro University Nevada **I**nstitutional **R**eview **B**oard **IRB**)

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**Addendum 3: Research with Prisoners**

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| **Principal Investigator:** |  |
| **Study Title:** |  |

This is form is applicable to research that is aimed at a prisoner population by design. A study aimed at a broader population in which prisoners are incidentally included, and the prisoners are not a sub-group of interest, is not considered ‘research with prisoners’ (45 CFR 46.104). Additional considerations apply to review of research for prisoners (45 CFR 46.305). For research involving prisoners, “minimal risk” is the probability and magnitude of physical or psychological harm (as opposed to harm or discomfort) relative to risks normally encountered in the daily lives, or routine medical, dental, or psychological examination of healthy persons.

TUN Institutional Review Board adopted a broader definition of "prisoner" to alert TUN researchers that individuals in the community under custodial supervision would be reviewed as vulnerable subjects by the TUN IRB.  “Prisoner" is defined by TUN Institutional Review Board as "any individual involuntarily confined or detained in a penal institution or under community supervision of a jail or prison system or a court. 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."

**Explain each of the following conditions, all of which are critical to conducting a study on prisoners.**

1. Are there any advantages accruing to participants in the research that are of such magnitude that the prisoner’s ability to weigh the risks against the advantages could be impaired? **Explain:**
2. Are risks commensurate with risk that would be accepted by non-prisoner volunteers? **Explain:**
3. Are procedures of selection of subjects fair and immune from intervention by prison authorities or prisoners? **Explain:**
4. Is information presented in a language understandable to the subjects? **Explain:**
5. What provisions have been made if there is a need for follow-up examination or care, taking into account the varying length of individual prisoner’s sentences and the need to inform participants? **Explain:**

**The research under review represents which of the categories (A, B, C, D) of research*?*** *Please check and explain below:*

1. [ ]  Study of the possible causes, effects, and processes of incarceration-or of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects. **Explain:**
2. [ ]  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 subjects.**Explain:**
3. [ ]  Research on conditions particularly affecting prisoners as a class (for example, research on hepatitis which is more prevalent in prisons than elsewhere-or research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). *Requires Secretary of DHHS or delegate to publish approval in Federal Register.* **Explain:**

1. [ ]  Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of prisoner populations.*Requires Secretary of DHHS or delegate to publish approval in Federal Register.*

**Explain:**