

CORRECTIONAL MANAGED HEALTH CARE POLICY MANUAL	Effective Date: 1/8/2016	NUMBER: I-72.1
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BIOMEDICAL RESEARCH		

PURPOSE To describe the process for biomedical research involving inmates in the custody of the Texas Department of Criminal Justice (TDCJ).

POLICY:

- I. The practice of biomedical research involving TDCJ inmates is permitted only if consistent with the Code of Federal Regulation (45 CFR 46).
- II. Applications for biomedical research involving TDCJ inmates must be submitted to TDCJ Executive Services and include:
 - A. proof of review and approval by an Academic Center Institutional Review Board (IRB) with assurance by the IRB that the research is within guidelines as required by the 45 CFR 46, and
 - B. written approval by the respective university executive medical director.
- III. Biomedical research involving inmates is permitted by TDCJ Executive Services only after obtaining written approval by the Division Director for Health Services, the TDCJ Office of General Counsel, and the directors of all other TDCJ divisions potentially affected by the proposed project biomedical.
- IV. TDCJ Executive Services approval will occur only if it is clearly established that the research is reasonably likely to improve the health and well-being of the subject(s).
- V. Once a research project is approved, the researchers must execute a Research Agreement with TDCJ Executive Services and, thereafter, abide by its terms.

Reference: Code of Federal Regulation (45 CFR 46)
 ACA Standard 4-4402 (Ref. 3-4373) Research (Mandatory)
 TDCJ Administrative Directive – 02.28 Research