TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 65.10, **Residual Funds Derived from Drug Studies, Clinical Trials, Fixed-Price Contracts, and Investigator-Initiated Research.**

PURPOSE: The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to establish a uniform procedure for processing residual amounts from externally funded drug studies, clinical trials, fixed-price contracts, and investigator-initiated research.

REVIEW: This HSC OP will be reviewed on July 1 of each even-numbered year (ENY) by the Director of Accounting Services and the Associate VP for Sponsored Programs, with recommendations for revision forwarded to the Senior Vice President for Research and Innovation (SVPRI) and the Executive Vice President for Finance and Operations.

POLICY/PROCEDURE:

1. **Definitions.**

Residual Amounts. Residual amounts are amounts remaining in a restricted FOP at the conclusion of a drug study, clinical trial, or other research project. A restricted FOP is established to account for the fiscal activity of research sponsored by a source external to HSC. All amounts received from the sponsor must be deposited into this FOP and all expenditures allowed by the sponsor in support of the research project must be paid from this FOP. Residual amounts may not be retained if HSC is contractually obligated to return any unspent amounts to the sponsor.

Fixed-Price Contract. Fixed-Price Contracts are contracts which are awarded for a specific dollar amount, do not require invoices for reimbursable expenses, and do not require the return of unspent amounts. Contracts may be for and payment may be determined by the completion of a "deliverable" item, based on a set payment per activity, based on a set payment per patient, or based on payments made at established intervals (such as monthly, quarterly, or annually) during the contract period.

Investigator-Initiated Research. Investigator-Initiated Research is research with protocol or research design that has been developed by the investigator and presented to a sponsor for funding. A project can be for basic research or clinical research. Industry-sponsored clinical trials with protocols and/or research designs that are developed by the sponsor are not included in this definition and are not classified as Investigator-Initiated. Investigator-Initiated Research projects for the purposes of this policy are those not solicited under any formal, peer-reviewed grants program.

2. **Procedures.**

a. **General**

Upon completion of a drug study, clinical trial, or fixed-price contract, the following steps must be performed:

- A determination must be made that all amounts received from the external sponsor in support of the research project have been deposited into the restricted FOP.

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