TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

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

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP 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 HSCEP OP will be reviewed on July 1 of each even-numbered year (ENY) by the managing director of Accounting Services, the directors of Sponsored Programs (SP), the assistant managing director of the Office of Research (OR), and the vice president for research (VPR), with recommendations for revision submitted to the chief financial officer by July 15.

POLICY/PROCEDURE:

1. **Definitions.**

Residual Amounts. Residual amounts are amounts remaining in a restricted Fund Organization Program (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 TTUHSC El Paso. 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 TTUHSC El Paso 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, and do not require invoices for reimbursable expenses. Contracts may be made 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 that 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, as defined by this policy, are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups or cooperative groups. The researcher assumes the legal and regulatory responsibilities of the trial sponsor for the conduct and management of the study, as defined in applicable laws and regulations.

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.
- A determination must be made that all expenses in support of the project, including salaries, have been paid from the restricted FOP.
- A determination must be made that all indirect cost fees have been properly calculated and paid from the FOP.
- Residual amounts will be further assessed a full indirect cost fee, at the current institutional rate, to capture the remaining indirect cost budget.
- Any remaining encumbrances on the FOP must be released.

Once final assessment takes place, remaining amounts will then be transferred to a single general designated fund under the control of the department. If a FOP has not been established for the department, Contracts and Grants Accounting (CGA) will notify the department to establish a new fund. The designated FOP will hold the residual balances from all drug studies, clinical trials, and fixed-price contracts completed by investigators within the department. If individual departments wish to segregate the balances in the residual account by individual researcher, they may do so by using a multiple ORGNS spreadsheet or other accounting software.

b. Investigator-Initiated Research.

When an Investigator-Initiated Research project is complete and residual funds remain in the restricted FOP, the residual amount can be transferred into a general designated account with the principal investigator named as the fund manager. A single fund will be established for each principal investigator to hold the residual amounts from all Investigator-Initiated Research. Upon agreement by the department chair and the principal investigator, residual amounts from Investigator-Initiated Research may be deposited into a general designated account under the control of the department. All of the requirements listed in the general section above must be completed before the transfer will be processed.

c. Residual Funds from Other Institutions.

Funds transferred to TTUHSC El Paso from another educational or research institution that were residual amounts held by a principal investigator at that institution become the property of TTUHSC El Paso. The amounts will be treated in the same manner as residual amounts derived from Investigator-Initiated Research. Any exception to these procedures must be approved by both the Vice President for Research and the Assistant Vice President for Finance and Administration.

d. Amounts Used for Research.

All residual amounts transferred to the designated FOP of the department or a principal investigator must be used for expenditures in support of research. Special Augmentation cannot be paid to faculty or staff from the residual amounts.

e. Contractual Obligation to Return Funds.

If a contractual obligation exists to return unused amounts to the sponsor, CGA will request a check be issued to return the residual amounts to the sponsor after completion of the steps listed in 2.a. above.