Yale Radiology and Biomedical Imaging Title: Clinical Trials Office Budget and Revenue Allocation	SOP 000.002 Version Number: 1	Effective Date: September 2018 RAD Mission: / Clinical / Education
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1.0 Purpose

This standard operating procedure (SOP) sets out the requirements for the budget process and defines revenue allocations for clinical research studies conducted in the Yale Department of Radiology (YDR) by clinical faculty. Its purpose is to provide guidance for the preparation and/or creation of clinical research budgets within YDR. The Principal Investigator is responsible for ensuring the YDR Clinical Trials Office is informed of all funded clinical research trials which will be conducted in YDR. Clinical trials are encouraged as a potential source of scholarly output which may prove helpful for promotion. Clinical trials should not be undertaken for a faculty members personal financial gain. **All clinical trial requests must be reviewed and approved by research administration and the YDR Business office before moving forward with any additional resource allocation or effort allocation devoted to the actual trial (see clinical Trials Office SOP).**

2.0 Scope

This SOP provides investigators and staff with guidelines for appropriate clinical research budget preparation and creation. It also defines the role of the research team in the clinical research budget and execution process.

3.0 Materials

None

4.0 Procedures:

4.1 Establishing Appropriate Fees

4.1.1 The clinical research team will meet with the principle investigator (PI) to obtain the following information prior to the start of the budget creation. Once this information is obtained from the PI, it will be the responsibility of the clinical research team to prepare and establish all other aspects of the clinical research budget.

4.1.1.1 Distinguish which procedures/imaging studies involved in the clinical research are standard of care vs. research related.

4.1.1.1.1 It is the responsibility of the research team to retain this source documentation throughout the study.

4.1.1.2 Determine how much time will be involved to complete each research related diagnostic or clinical process and/or procedure required.

4.1.1.3 Define the appropriate fee to charge as the investigator fee, based on current billing data.

4.1.1.4 Identify any sub-investigators to be listed on the clinical research study.

4.2 Disbursement of Fees

4.2.1 Clinical Research Work

4.2.1.1 All funded clinical research dollars allocated to PI effort will be assessed at a 10% department administrative fee.

4.2.1.2 The department administrative fee will be used to offset the department costs associated with conducting clinical research studies, managing all transactions associated with the trial, and reporting associated with the trial.

4.2.1.3 The first use of the funds should be to cover the time and effort of the PI for clinical trials work that is funded by a grant or other funding source.

4.2.2 End of Study

4.2.2.1 At the end of the study, once all revenue is received and all expenses have been paid (PI, YNHH, YDR Administrative and coordinator, etc.) and the study is closed, any remaining funds will be split 50/50 between the PI (with the funds going into a staff or section account) and the department. **Regardless of remaining balances or dollars allocated to PI efforts there will be no "Y" payments made directly to the PI or physician.**

5.0 Definitions/Abbreviations

SOP: Standard Operating Procedure

Standard of Care: Any diagnostic or clinical process and/or procedure which an investigator should perform given the particular patient illness or clinical circumstances.

Research Related: Any diagnostic or clinical process and/or procedure which is being performed solely for the purposes of the clinical research.

Source Documentation: Any document used to validate the designation of standard of care vs. research related procedures and/or clinical processes.

6.0 References

Reviewed by

7.0 Revision History

Version	Date	Reason For Revision