1. **Purpose:**
   This standard operating procedure (SOP) defines the process for conducting reviews of research billing associated with human subject research conducted in the Perelman School of Medicine (PSOM).

2. **Scope:**
   This SOP applies to all human subject research conducted in PSOM in which hospital services, billable by Penn Medicine, are utilized.

3. **Instructions**
   The Office of Clinical Research (OCR) Finance Unit is responsible for conducting research billing compliance reviews. The goal of a research billing compliance review is to mitigate risk associated with erroneous billing. Examples of research billing errors are:
   - A charge that should have been posted to a research grant is charged to a patient/patient’s insurance
   - A charge that should have been sent to a patient/patient’s insurance is erroneously posted to a research grant
   - A charge that belongs to one research grant is erroneously billed to a different grant account

4. **Procedures**
   At the beginning of each quarter, OCR identifies patient charges from the prior quarter that will undergo a billing compliance review. Both routine and for-cause reviews are included in the plan. OCR notifies the Principal Investigator, study coordinator, and business administrator (or appropriate department financial representative) prior to commencing the review. OCR will review the charge activity for selected patients, as described below, to determine whether charges were routed appropriately, based upon a completed Medicare coverage analysis. Upon completion of the review, OCR provides a final report noting any findings, providing guidance and assistance as needed to help implement corrective action. Recipients of the final
report are the Principal Investigator, study coordinator, business administrator (or appropriate department financial representative), and Department Chair.

The methodology for selecting studies for research billing compliance reviews and for conducting the reviews is delineated below:

I. For-Cause Research Billing Compliance Reviews

A pool identifying for-cause reviews is generated from a list OCR maintains of studies that have had reported billing errors in the past quarter. This list is gathered from the following sources:

i. Billing errors reported to OCR Finance for correction
ii. Billing errors submitted to Patient Accounting directly for correction

These errors may be reported by a study team, business administrator or a study participant.

OCR reviews the charge activity from the previous quarter for three patients or 10% of total enrollment up to 100 patients, whichever is higher, on each research study from the list referenced above. If errors are found OCR will issue a report with findings and recommendations. OCR will assist the study team in providing necessary information to UPHS patient accounting if billing adjustments are required.

II. Routine Research Billing Compliance Reviews

A pool for random selection is generated using the following criteria:

a. The charge does not qualify for a "for-cause" review as defined above
b. The patient must not have been subject to a randomized review within the past year. OCR will track the patients selected for each audit period and ensure that each patient was not audited in the prior year. If the selected patient was audited in the prior year, OCR Finance will select an alternate patient to audit.

From this pool of qualifying charges, ten patients are chosen using a randomizing function in Microsoft Excel. If two patients are selected from the same study, OCR Finance will select an alternate patient in a different study in lieu of one of the previous selections.

OCR reviews the charge activity from the previous quarter for the cohort of patients selected. If errors are found, OCR issues a report with findings and recommendations. OCR assists the study team in providing necessary information to UPHS patient accounting if billing adjustments are required.
In situations where deficiencies or non-compliance are observed:

If deficiencies are observed during a research billing compliance review, a Corrective and Preventive Action (CAPA) plan is developed by the study team and signed by the Principal Investigator within 5 business days of receiving OCR’s completed report. The CAPA addresses any deficiencies observed during the review and addresses how any risk of recurrence of deficiencies will be mitigated in the future.

If more than 20% of reviewed charges in a study are erroneous, that study is deemed to be in serious non-compliance. Studies in serious non-compliance are reviewed for an additional quarter, with the study team providing all study visit dates occurring in the following quarter. OCR will review 3 additional patients’ charges. In addition, studies in serious non-compliance will be escalated by sending the report to the Principal Investigator, Department Chair, Department COO, department financial representatives, the COO of Clinical and Translational Science and Corporate Alliances and the Vice Dean for Clinical Research.

If the CAPA is not developed and signed within 5 days, or if it is not implemented within the quarter following receipt of the OCR report, OCR escalates the situation to the Department Chair, Department COO, the COO of Clinical and Translational Science and Corporate Alliances, and the Vice Dean for Clinical Research for appropriate action.

5. Roles and Responsibilities:

The Office of Clinical Research Finance:
- Creates a quarterly plan identifying patient charges to be reviewed, including for-cause and routine reviews
- Notifies and coordinates the review with appropriate study team and department finance staff
- Provides final report, including findings and recommendations
- Provides guidance and assistance in implementing recommendations and any CAPA
- Assists with communicating and providing information to Patient Accounting, if patient bills need to be corrected

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Perelman School of Medicine
Office of Clinical Research
6. References

CITI Training: Clinical Trial Billing Compliance: https://www.citiprogram.org/index.cfm?pageID=14


CMS Approved IDE studies: https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html