DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Project Accounting	Policy #: CRP-1021
	PAGE: 1
DEPARTMENT: DHR Health Institute for Research & Development	OF: 2
	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21

Purpose:
The purpose of this policy is to describe the internal process within the DHR Health Institute for Research & Development to ensure payment of research activities performed are timely, appropriate and no charges are missing or duplicated.

Applies To:
This policy applies to the following potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic Institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

Definition:

A. **Clinical Trial Agreement:** A Clinical Trial Agreement (CTA) is a legally binding agreement that manages the relationship between the sponsor/Clinical Research Organization (that may be providing the study drug or device, the financial support and /or proprietary information) and the institution that may be providing data and/or results, publication, input into further intellectual property.

Policy:
The principal investigator or delegated staff should review the research accounts routinely to ensure that Clinical Research Organizations or grants are received in a timely manner and no payments are missing or duplicated.

Each sponsor/Clinical Research Organization will have different guidelines for invoicing. The invoicing requirements for a clinical trial will be found within the CTA. The act of invoicing may be as easy as submitting the case report forms (CRFs), entering data into electronic case report forms (eCRFs) or data base, or by submitting a paper invoice to the sponsor. Any invoice submitted to a sponsor for payment should, at a minimum, include the department name, PI name, sponsor name and contact, date of the invoice, sponsor protocol number, study title, itemized activities submitted for payment, total amount due, payment information and contact information if the sponsor has questions regarding the invoice.

Procedure:

Project Accounting:

- Study Log will aid the Principal Investigator and delegated staff in maintaining project financial accountability.
- Upon approval of the budget and contract, the template will be pre-populated with the approved amounts in order to track subject visit status and project balance.

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A. Project Invoicing & Billing
   - According to the final sponsor approved contract, the invoicing requirements will be laid out.
   - Using the Study Log, the delegated staff member will invoice as per contract requirements.
   - Designated staff in DHR Health Institute for Research & Development will review, edit, and approve the draft before submitting the offer to the sponsor.

B. Interim Contract re-negotiation
   - Some billing issues may arise during the conduct of the project that was overlooked or un-accounted for during study start up negotiations.
   - The Research Coordinator, Principal Investigator, or delegated staff will notify the designated staff in DHR Health Institute for Research & Development of the need for a re-negotiation or amendment to the contract.
   - Designated staff in DHR Health Institute for Research & Development will either approve or deny the need for an amendment or re-negotiation.
   - If approved, the designated staff in DHR Health Institute for Research & Development will send the amendment to the contract or the budget to the sponsor.
   - Sponsor will approve or deny the amendment.