OFFICE OF RESEARCH & GRADUATE STUDIES
CENTRAL MICHIGAN UNIVERSITY

POLICY

•	Retrieval Number:	11,018
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•	Originator:	Melinda Brakenberry
•	Applicable Area:	Pre and Post Award
•	Original Date:	10/06/2023
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OFFICE OF SPONSORED PROGRAMS

SUBJECT: Clinical Study Facility and Administrative Costs (Indirect Costs)

Indirect costs (also know as IDC, overhead, Facilities & Administrative costs, or F&A) are real costs of University operations that are not readily or uniquely assigned to a funded project. The importance of recovering IDC as part of the full cost of a sponsored project cannot be overstated.

It is CMU's determination that the following are the applicable indirect cost rates for clinical studies.

Key Definitions:

Clinical Study:

A clinical study involves research using human volunteers (also often called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies.

Clinical Trial:

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet.

Observational Study:

In an observational study, investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants may receive interventions (which can include medical products such as drugs or devices) or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial).

Investigator Initiated Study (IIS):
IISs are "homegrown" ideas from CMU researchers and investigators who are active in the lab and clinical settings. For the purposes of this policy, IIS references externally funded projects in which the CMU investigator, or team of investigators and researchers, of the study conducts the study. The CMU Investigator is responsible for creating, coordinating, and carrying out the IIS. (federally funded clinical research grants are a common example)

Sponsor Initiated Study (SIS):
SISs originate with a sponsor (individual, institution, company, or organization) external to the CMU. The sponsor accepts the responsibility to initiate, manage, and finance the clinical trial. (industry sponsored clinical trials are a common example)

Industry Sponsor:
Primarily pharmaceutical companies, and occasionally other non-federal entities, which fund clinical

studies under their protocols which they design and own. Often, the sponsors work with Contract Research Organizations (CROs) that act as a representative for the sponsors.

Applicable IDC Rates:
Regardless of the funding mechanism, the following rates apply to clinical studies:

Investigator Initiated Study (IIS):
IIS is considered **Organized Research** (OR) and will be budgeted as follows:

- In accord with the federally negotiated IDC rate for OR: 46.5% MTDC (Modified Total Direct Costs).

Sponsor Initiated Study (SIS):
SIS is considered **Other Sponsored Activities (OSA)** and will be budgeted as follows:

- If industry sponsored, 34% TDC (Total Direct Costs)
- If federally sponsored, in accord with CMU's federally negotiated rate, 34% MTDC

At times, the determination of IIS or SIS may not be evident. In those cases, the checklist in Attachment A, *Checklist – Clinical Study Indirect Cost Rate Determination*, must be completed and an OSP certified copy documented within the agreement's audit file to support the indirect cost rate utilized in a proposal budget.

Waivers:
An indirect cost rate waiver is required when, for any reason other than a sponsor having an official, written, and publicly available policy, which is consistently applied, or when a public solicitation contains a limited indirect cost rate, a Principal Investigator (PI) would like to request less than full indirect costs in the budget.

All indirect cost rate waiver requests must be made in writing to the Executive Director for Research and Innovation (EDRI) and the Vice President for Research and Innovation (VPRI) at least 10 business days prior to the proposal submission date. The VPRI's, or delegate's, determination will be provided in writing within 5 business days of the request. Approval from the VPRI, or delegate, must be received prior to the submission of a proposal budget inclusive of a reduced IDC rate that requires VPRI review to a sponsor.

Checklist – Clinical Study Indirect Cost (IDC) Rate Determination
For Internal Use Only

CMU Principal Investigator (PI): _____
Funding Source/Sponsor: _____
Project Title: _____

For human clinical studies documented to meet **ALL** of the following conditions, the **Other Sponsored Activities** rate of 34% MTDC will apply:

☐ Yes ☐ No 1. Prime funding from a **Federal** entity, including flow-through funds from an external sponsor to CMU.

☐ Yes ☐ No 2. Protocol or research orders are prescribed and controlled by the sponsor or the prime agency.
If yes, select all that apply:

- ☐ The local CMU principal investigator (PI) does not have scientific freedoms generally understood to be a part of fundamental and/or basic research projects.
- ☐ The protocol(s) follow a clinical calendar, prescribing visits, data and order tissue/sample collections.
- ☐ The study includes observational or data-collection-only studies without analytical reports provided to the Funding Source/Sponsor.

☐ Yes ☐ No 3. The compensation for the study is driven by milestones or deliverables, such as:

- Enrollment or accrual (per case reimbursement language or capitation language)
  - Also, sometimes referred to as "completely enrolled subjects"
  - Generally, as a protocol site, CMU is permitted only a finite number of enrollment slots
- Payment Fact Sheets from US Department of Health & Human Services/National Institutes of Health divisions, such as the National Cancer Institute–National Clinical Trials Network-Cooperative Groups (e.g. **COG** *(Children's Oncology Group))*.
- Upon completion of "case report forms" commonly called CRF's or eCRF's

Additional Information :

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If the CMU PI has control over the scope of work and experimental design or if the CMU PI must submit analytical reports on the study data and results, the federally negotiated Organized Research rate applies.

IDC Rate Determination – to be completed by the Office of Sponsored Programs

Clinical Study IDC Rate Determination: _____

Determination Certified by: _____ _____
Name Date