

Clinical Trial Fixed and Upfront Fees

The following fixed and upfront fees are charged on all clinical trials, as applicable. These fees should be non-refundable as they will be charged whether or not any subjects are recruited. If a sponsor will not compensate for these fees, please provide justification.

1. IRB fees (initial, amendments, and renewals)
2. DMC fees
3. OnCore/CRSC fees
4. Indirect Cost Rate of 32%

IRB FEES (INITIAL, RENEWALS AND AMENDMENTS, AS APPLICABLE)

IRB FEE SCHEDULE FOR INDUSTRY/FOR-PROFIT SPONSORED/RESEARCH

<https://research.wayne.edu/irb/irb-fees>

Wayne State University charges for IRB review of research studies supported by industry and for-profit entities.

Investigators submitting industry/for profit-sponsored research protocols are required to include the cost of initial protocol review, continuing review, and sponsored initiated full-board amendments requiring IRB review in the study budget.



Division of Research

Institutional Review Board

Home (/) > Institutional Review Board (/irb) > IRB fees

IRB fees

IRB fee schedule for industry/for-profit sponsored/research

Industry and for-profit IRB fees		
Rates for M1, MP2, and B3 IRBs		
Type of review	Fees Prior to June 1, 2018	Effective June 1, 2018
Initial submission, Full Board review	\$2,000	\$3,000
Initial submission, Expedited review	\$2,000	\$2,000
Continuing review	\$750	\$1,250
Full Board Amendment review	\$500	\$750
Expedited Amendment review (includes key personnel amendments)	NC	\$100
Final report/close-out	NC	\$250

Rates for PHI IRB		
Initial submission review	\$3,500	\$3,500
Continuing review	\$1,750	\$1,750
Full Board Amendment review	\$750	\$1,000
Expedited Amendment review (includes key personnel amendments)	\$200	\$200
Adverse Events/Unexpected Problem/Safety Oversight	\$500	\$500
Close out fee	\$500	\$500
There is no charge for a revised protocol submitted in response to a review		
Rates for WIRB Industry Sponsored Clinical Trials		
WIRB Initial Submissions-Only	\$750	\$750
Rates for External IRB Review-Commercial IRB		
Initial Submissions-Only		\$750

IRB Administration Office

87 East Canfield Street, 2nd Floor

Detroit, MI 48201

(313) 577-1628

IRBQuestions@wayne.edu

irbstatus@wayne.edu

DMC FEES

DMC RESEARCH REVIEW FEES

The Detroit Medical Center (DMC) is the primary hospital affiliate of Wayne State University. Wayne State University has an agreement with DMC which provides that DMC shall adhere to the provisions of agreements related to sponsored research conducted by Wayne State University on DMC premises, and will assist Wayne State University in carrying out its obligations pursuant to such agreements.

<https://www.dmc.org/health-professionals/clinical-translation-research-office>

Our mission is to support clinical researchers across the Detroit Medical Center hospitals by providing comprehensive legal, regulatory and billing consultation on in-patient and out-patient studies. The office was established to:

- Develop and implement a pre-IRB application and approval process
- Institute policies and procedures related to research billing compliance
- Provide pre-study billing coverage analyses
- Consult with and educate principal investigators, research coordinators, residents and students on appropriate budgeting and billing practices
- Provide assurance that all research at the DMC is ethical, safe and compliant with regulatory standards
- Support the growth of clinical and translational research at the DMC

The following hospitals are part of the Detroit Medical Center:

Children's Hospital of Michigan
3901 Beaubien Boulevard
Detroit, MI 48201

DMC Detroit Receiving Hospital
4201 St. Antoine Boulevard
Detroit, MI 48201

DMC Heart Hospital
311 Mack Avenue
Detroit, MI 48201

DMC Huron Valley-Sinai Hospital
1 William Carls Dr
Commerce Charter Twp, MI 48382

DMC Harper University Hospital
3990 John R Street
Detroit, MI 48201

DMC Hutzel Women's Hospital
3990 John R Street
Detroit, MI 48201

DMC Rehabilitation Institute of Michigan
261 Mack Boulevard
Detroit, MI 48201

DMC Sinai-Grace Hospital
6071 W. Outer Drive
Detroit, MI 48235



DMC RESEARCH REVIEW FEES

- Retrospective Chart Review (FRC review is not required; internal DMC CRO review only) = \$100 per study
- Prospective, Observational, Incidental to Research Review (FRC review is not required. Examples include questionnaires, surveys and interviews. Does not involve billing of third party payors) = \$200 per study
- Low Complexity (FRC review and cost and time analysis required. Defined as minimal risk by federal regulations. Examples include collection of discarded or waste samples, or other procedures defined as minimal risk by federal regulation, blood drawing by venipuncture) = \$300 per study
- Moderate Complexity (FRC review and cost and time analysis required. Clinical research study involving one DMC Hospital Department) = \$1,850 per study
- High Complexity (FRC review and cost and time analysis required. Clinical research study involving two or more DMC Hospital Departments) = \$2,900 per study

Questions – Contact Mary Jo Terrell MTerrell2@dmc.org

WSU FEES - CRC REVIEW

<https://clinicalresearch.med.wayne.edu/wsuo-oncore-pricing>

The WSU Clinical Research Service Center (CRSC) is a university core that provides the high quality resources and infrastructure needed to support and conduct industry and investigator clinical trials. The CRSC includes a state of the art Clinical Research Center (CRC) that is HIPAA compliant and functions under Standard Operating Procedures that meet Good Clinical Practice (GCP) and Food and Drug Administration (FDA) requirements. The CRC is staffed by a qualified research team that are BLS and/or ACLS certified. The team provides comprehensive protocol implementation from initial study feasibility analysis to study closeout.

OnCore® is a Clinical Trial Management System (CTMS) that has the ability to manage all components of a clinical trial in one central location. The software has the capacity to manage multi-site trials both nationally and internationally. The Oncore CTMS is managed through the WSU CRC; it is utilized university wide to support all aspects of clinical trial as the software has been adopted by faculty and staff in many Departments.



School of Medicine (<https://www.med.wayne.edu>)

Clinical Research Services Center - Home of WSU OnCore ([/](#))

WSU Fees - CRC Review

NIH/Foundation

NIH/Foundation INITIAL Review-OnCore	\$1532
NIH/Foundation Annual Review-OnCore	\$529

Pharmaceutical Trials

Pharma CRSC INITIAL Review-OnCore	\$2355
Pharma CRSC Annual Review-OnCore	\$791

*All fees inclusive of applicable IDC fees

Clinical Research Service Center

6135 Woodward Avenue

Detroit, MI 48202

313-577-1400

[Map](#)

INDIRECT COST RATE OF 32%

F&A COSTS POLICY FOR CORPORATE SPONSORED CLINICAL TRIALS

<https://research.wayne.edu/spa/proposals/fringe-benefits>


These rates are applied to a Modified Total Direct Cost (MTDC) base. All direct costs are included in this base except the following: Alterations, improvements, renovations, tuition, stipends, patient care charges, equipment, and the portion of each individual subgrant or subcontract in excess of the initial \$25,000. These costs should be requested on all proposals unless the policy of the sponsoring agency specifically prohibits them or offers other predetermined rates.



OFFICE OF THE PRESIDENT
4200 Faculty/Administration Building
313.577.2230/313.577.3200 fax

MEMORANDUM

TO: Cabinet, Deans, Directors and Department Heads

FROM: M. Roy Wilson, President 

SUBJECT: University Policy 03-05: Facilities and Administrative Costs Distribution Policy

DATE: February 5, 2016

Attached you will find an update to the Facilities and Administrative Costs Distribution Policy, U.P. 2003-05 (third release). The policy has been updated as a result of a review recently performed on the current F&A Rate for Corporate Sponsored Clinical Trials. The current rate at WSU for those trials is 26%.

The F&A rate for Corporate Sponsored Clinical Trials is not a negotiated rate, and is distinct from the University's negotiated federal F&A rate, which is currently 53%.

Based upon comparative analysis of F&A rates for Corporate Sponsored Clinical Trials at other institutions, and our own internal costs for trial management and regulatory oversight, we are increasing our F&A rate for Corporate Sponsored Clinical Trials from 26% to 32%. This change is effective immediately. All negotiated F&A rates remain unchanged.

If you have questions about the policy, please contact Gail Ryan at 313-577-3726.

/jhm

University Policy 2003-05
(Third Release)

Policy-Making by the President

FACILITIES AND ADMINISTRATIVE COSTS DISTRIBUTION POLICY

1.0 Purpose

- 1.1 The purpose of this university policy is to define the policy and process for the distribution of facilities and administrative (F&A) recovery resulting from externally sponsored grants and contracts.

2.0 Guidelines

- 2.1 The following guidelines will be applied to the submission of proposals in order to achieve appropriate F&A cost recovery. The guidelines also apply to grants and contracts that are awarded without the submission of a formal proposal.
- A. Proposals submitted to the Federal Government will include full F&A costs, except where an agency rate is specified or the nature of the program precludes F&A cost recovery.
 - B. Proposals to any state or local governmental agencies will contain full F&A cost requests except where an agency rate is specified. If the agency sets specific rates for F&A costs, the maximum allowed rate will be used. Any F&A cost rate that differs from those established above must receive written approval from the Sponsored Program Administration (SPA) office prior to submission to the granting agency.
 - C. Proposals submitted to private non-profit associations and foundations will contain F&A cost requests consistent with established association/foundation policies. SPA will review policy statements by non-profit organizations regarding the level of F&A cost support and determine the rate to be applied. University acceptance of these awards will not constitute a waiver of F&A costs.

- D. Proposals submitted to profit-making corporations will contain requests for the appropriate on or off-campus F&A cost rate as determined by SPA.
- E. The vice president for research or his/her designee is the authorized representative to assign appropriate F&A cost charges to sponsored research, education and public service grants and contracts. He/she will also distribute the revenues to be returned to individuals and units pursuant to university policy governing such returns.
- F. Requests to waive F&A costs in whole or in part require the support of the faculty member, departmental chairperson and dean, and is based upon written documentation of corporate policy. If approved by the vice president for research or his/her designated representative, the agreed upon F & A amount will be divided in the same proportions as if full F&A costs were collected.

3.0 F&A Cost Return Policies

- 3.1 F&A cost recovery offsets real and actual costs incurred by the university as part of externally-sponsored research. The F&A cost rates are negotiated on a regular schedule with the Federal Government and are based on real costs associated with conducting research with the following components included: building use/depreciation; equipment use/depreciation; interest; operation and maintenance; and library and administration components.

3.2 Cost Recovery

Percentage portions of the F&A costs recovered through sponsored projects within a school, college, institute or center will be returned to the principal investigator, department, dean/director, provost and vice presidents where appropriate, following collection from the sponsor of the allowable costs. The distribution will be set periodically by the vice-president for research based upon the review of recommendations received from a committee appointed by the president of the university or his/her designee.

3.3 Uses of F&A Cost Shares

Funds recovered pursuant to this policy will be given discrete account identities. Principal investigators, departmental chairpersons and dean/directors may use these funds for equipment, supplies, research-

University Policy 2003-05 (Third Release)
Facilities and Administrative Costs Distribution Policy

related travel and allied services to increase research capabilities and meet research costs.

Limited salary uses may be made of these funds in accordance with the following principles:

- A. Recovered funds may not be used to supplement salaries for faculty or staff during the period of the individual's contract obligation to the university. This will not prevent the use of such funds for summer salary determined in accordance with policies prescribed by the university. Use of these funds for summer salaries requires written approval of the dean.
- B. Since funds recovered under this university policy are not recurring, they will not be used for any personnel purpose that creates a continuing obligation for the university. Accordingly, these funds will not be used to hire any full-time or part-time personnel who, upon expiration of recovered funds, would still have an employment right at the university. This will not prevent these funds from being used, however, for salary for research assistants/associates/scientists or post-docs on subsidy condition, nor will it prevent the use of these funds for hiring support staff for limited durations or on subsidy condition, consistent with university policies.

3.4 Individual Accounts

A minimum of \$100 will be required to establish individual accounts for project directors and principal investigators or co-principal investigators. When there is more than one principal investigator, the F&A costs distribution amount due will be divided equally between or among co-principal investigators unless a different arrangement is established prior to receipt of the grant and is filed in writing, with all pertinent signatures, with SPA.

SPA will periodically compute returns based on accounting records of actual revenue earned and report to the investigator(s).

When a principal investigator leaves the university, the balance of his/her share of F&A cost funds will revert to the department.

3.5 Departmental Accounts

Departments will receive a return of all F&A cost recovery generated by their faculties in their role as principal investigators and co-principal investigators who are separately budgeted in inter-departmental grants.

When faculty are engaged jointly in funded projects across departmental lines, F&A cost funds will be shared equally between or among the departments of the co-principal investigators unless a different arrangement is established prior to receipt of the grant and is filed in writing, with all pertinent signatures, in SPA.

Computation and periodic reporting of departmental shares will be the responsibility of SPA. The funds may be distributed within the department by the chair or his/her designee for research-related activities.

3.6 College/School Accounts

College/schools will receive a prescribed return of F&A cost revenues generated by their faculty in their role as principal investigators and co-principal investigators who are separately budgeted in inter-collegiate grants.

When college/school faculty are engaged jointly in funded projects across collegiate lines, F&A cost funds will be shared equally between or among the colleges/schools of the co-principal investigators unless a different arrangement is established prior to receipt of the grant and is filed in writing, with all pertinent signatures, with SPA.

Computation and periodic reporting of college/school shares will be the responsibility of SPA. The funds may be distributed within the college/school at the discretion of the dean or his/her designee for research-related activities.

In colleges/schools that are not departmentalized or otherwise subdivided, both the normal departmental and college/school shares will go to the college/school.

3.7 Center/Institute Accounts

Because centers/institutes vary in their organizational relations with colleges/schools, and because the commitment of faculty members to the activities of centers/institutes varies, special principles will apply to the recovery of F&A cost funds by centers/institutes.

- A. Only those centers and institutes that have approval for operation consistent with the provisions of the Statute on Center and Institutes adopted by the Board of Governors on March 29, 1985, are eligible for F&A cost recovery. In cases of research entities informally entitled "centers" or "institutes," only the principal investigator(s) will receive distribution shares. Shares that would

normally go to the department and the dean will be added to the share of the Research Stimulation Fund.

- B. Accounts will be established for centers/institutes for any F&A cost funds due the center/institute from sponsored research activities conducted by center/institute staff or faculty or by college/school faculty who engage as principal or co-principal investigators in the sponsored programs of centers/institutes.
- C. Individual accounts will be established for principal or co-principal investigators who are assigned full-time to the center/institute. F&A cost recovery will be treated for the purposes of these accounts as are faculty in paragraph 3.5.
- D. In those instances which a center/institute is part of a college/school:
 - 1. A grant awarded to an investigator engaged wholly by the center/institute will result in the school/college receiving the normal college share and the center/institute receiving the normal department share;
 - 2. A grant awarded to a center/institute for one or more co-principal investigator(s) who is (are) assigned primarily to academic departments within the college/school will result in the college/school receiving the normal college share and the department(s) and the center/institute sharing the normal departmental share equally unless another arrangement has been made prior to receipt of the grant and filed in writing, with all pertinent signatures, with SPA; and
 - 3. A grant awarded to a center/institute for one or more co-principal investigator(s) who is (are) assigned primarily to academic departments in different colleges/schools will result in:
 - a. The college/schools receiving equal portions of the normal college/school share; and
 - b. The center/institute and department(s) receiving equal portions of the normal departmental share.

These standards for distribution will vary only in instances in which other arrangements have been made in advance of receipt of the grant and filed in writing, with all pertinent signatures, in SPA.

University Policy 2003-05 (*Third Release*)
Facilities and Administrative Costs Distribution Policy

- E. In those instances in which a center/institute is not part of a college/school:
1. A grant to a center/institute, or to a faculty or staff member representing a center/institute, will result in the center/institute receiving the normal departmental share and the appropriate vice president to whom the director reports receiving the normal college/school share;
 2. A grant awarded to the center/institute listing one or more principal investigators or co-principal investigators assigned primarily to colleges/schools and departments outside of the center/institute will result in:
 - a. the center/institute and the department receiving equal portions of the normal center/institute share; and
 - b. the vice president to whom the director reports and the college/school receiving equal portions of the normal college/school share.

These standards for distribution will vary only in instances in which other arrangements have been made in advance of receipt of the grant and filed in writing, with all pertinent signatures, with SPA.

- F. In all instances, computation and periodic reporting of F&A cost funds from accounting reports of revenues received will be the responsibility of SPA. The custodians of the funds may, at their discretion or by action of their designees, distribute the funds within the units of their respective jurisdictions for research-related activities.

3.8 Academic Support Units

In academic support units, the only distribution of F&A cost recovery will be to the Research Stimulation Fund, according to the distribution formula and to the unit director (equivalent to the normal departmental share). F&A cost pursuant to Section 3.3 will be awarded to the principal investigator(s) only in cases of competitive grants or contracts similar to those earned by faculty members. All other F&A cost funds will be allocated to the general fund. F&A cost funds received on grants of student financial aid will be allocated entirely to the general fund, without any allocation to the various units of the university. F&A cost funds

received on grants in support of laboratory animal facilities will be allocated entirely to the University Research Facilities Fund, without any allocation to the various units of the university.

3.9 F&A Cost For Corporate Sponsored Clinical Trials

A F&A rate of 32% is applied to non-federally funded clinical trials.

3.10 Carry Forward Balances Beyond Fiscal Year Closing

Balances in all F&A cost return accounts (principal investigator, department, college/school, center/institute, University Research Stimulation Fund, University Research Facilities Fund, Vice President for Research Operations, and the General Fund) will be carried over entirely from one fiscal year to the next except in face of events deemed by the president sufficiently serious to suspend this regulation.

4.0 Annual Report and Evaluation

4.1 On December 1 of each year, the vice president for research will report to the president on the F&A cost distribution in the previous fiscal year. The report will include, at a minimum, F&A cost received by the university, its distribution to individuals and units and its probably impact upon the research program of the university.


5.0 Duration

5.1 This university policy is revocable by the president at any time and without notice.

6.0 Effective Date

6.1 This executive order is effective upon issuance.

6.2 This University Policy supersedes University Policy 2003-05, Second Release.



M. Roy Wilson
President

Feb. 4, 2016

Date