university of washington

OFFICE OF RESEARCH

**Human embryo and human embryonic stem cell line (hESC) research**

**Funding and Facilities Guidelines**

According to current U.S. law, research that involves the fertilization of human oocytes or the destruction of human embryos for research purposes, including the derivation of human embryonic stem cell lines, may not be funded with Federal government funds, other than research using hESC lines in the [NIH Human Embryonic Stem Cell Registry](https://grants.nih.gov/stem_cells/registry/current.htm).

.At the University of Washington, investigators conducting this type of research may do so with non-Federal funds, in facilities and with equipment paid for with non-Federal funds and after seeking and receiving approval to proceed. If you are considering conducting human embryo and/or hESC research, other than research using HESC lines in the NIH registry,, please complete the [ESCRO application](https://www.washington.edu/research/wp-content/uploads/ESCRO-Application-Form-for-new-renewals-and-closures.docx) and [Financial Supplement](https://www.washington.edu/research/wp-content/uploads/Financial_Supplement.docx), an attachment to this page.

Contact [escro@uw.edu](mailto:escro@uw.edu) with questions.

1. **Cost-Allocation Guidelines:**
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   2. Financial Definitions
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2. **Introduction**

The UW is providing these guidelines, which are consistent with federal hESC research restrictions, in order to set forth the steps that researchers and administrators must take to ensure that hESC research is compliant with federal law. These guidelines describe steps to take in managing resources used for hESC research, including (1) facilities, (2) equipment, (3) personnel, (4) materials, supplies, and other commodities, (5) non-capitalized equipment, (6) purchased services (7) derivatives from hESC research, and (8) data and intellectual property associated with hESC research.

These guidelines are intended to address only those issues presented by current federal hESC research policy. They supplement, but do not replace, other UW financial and accounting policies, rules and procedures.

1. **Financial Definitions**

The following shall apply to these cost-allocation guidelines:

[**Uniform Guidance (2 CFR 200)**](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II)

Principles for Determining Costs Applicable to Grants, Contracts and Other Agreements with Educational Institutions, promulgated by the federal Office of Management and Budget. A document promulgated by the Office of Management and Budget entitled “Office of Management and Budget Guidance for Grants and Agreements.”

**Facilities and Administrative (F&A) costs**

Indirect costs incurred for common or joint objectives that cannot be identified readily and specifically with particular sponsored projects and instructional activity or any other institutional activity ([Uniform Guidance (2 CFR 200)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II).

**Materials, supplies, and other commodities**

Consumable goods and reusable items, including laboratory supplies and equipment, with an acquisition cost of less than $5000 and an expected useful life of one year or less.

**Non-capitalized equipment**

Reusable items, including laboratory supplies and equipment, with an acquisition cost of less than $5000 an expected useful life of more than one year.

**Purchased services**

Professional contract services, such as the services of consultants, laborers, or maintenance and repair technicians.

1. **General Cost Allocation Principles**

The cost principles set out in [Uniform Guidance (2 CFR 200)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II) do not prohibit institutions that receive federal support from engaging in “unallowable” activities. Instead, they restrict the use of federal funds to pay for these activities. For example, costs of bad debts, donations and contributions, and entertainment, among others, are unallowable. Even though certain costs are unallowable, the UW and its researchers may still be reimbursed for other allowable expenses incurred in connection with federally supported projects.

Uniform Guidance indicates that federally-supported institutions can avoid the impermissible shifting of costs of unallowable activities to the federal government if it does not either (1) impose the direct costs of such activities on the federal government, or (2) request reimbursement from the federal government for F&A costs associated with unallowable activities. Examples of indirect costs are building depreciation and use allowances, maintenance expenses, library expenses, and student and department administration expenses.

* + 1. **Direct Costs**

To determine if a particular direct cost can be charged to the federal government, the cost must be allowable, reasonable, and allocable to work conducted under federally sponsored agreements, and it must not include any unallowable costs.

Although the direct costs of unallowable activities may not be charged to the federal government, the government will pay its share of resources that are used for both federal and non-federal purposes. [Uniform Guidance (2 CFR 200)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II) states that “a cost is allocable to a particular cost objective (i.e., a specific function, sponsored agreement, department, or the like) if the goods and services involved are chargeable or assignable to such cost objective in accordance with relative benefits received or other equitable relationship.” For example, if personnel time or general-purpose laboratory materials are being used for both federally sponsored research and ineligible hESC research, the federal government will pay the cost of that proportion of the resource being used for federally sponsored research.

The process of determining the direct costs of resources used for human embryonic and hESC research does not differ in practice from the allocation process generally used to separate activities that may not be charged to the federal government because they are not associated with a federal agreement. To illustrate, assume that a faculty member divides time and effort as follows: 60% to a federally sponsored grant, 15% to teaching and administrative duties, and 25% to ineligible hESC research. In this example, only 60% of the faculty member’s time and effort could be allocated to the federal grant. For cost allocation purposes, it is irrelevant whether the other 40% devoted to performing unallowable hESC research (25%) or other activities that do not benefit the federally sponsored research (15%). In this illustration, none of the 40% time and effort may be charged to the federal government.

* + 1. **Indirect Costs**

In general, UW F&A costs are calculated and allocated to the federal government by multiplying the direct costs of a federal project by the government-approved UW F&A rate. This approach assumes that there is an established relationship between the direct costs of research projects and the F&A costs as reflected in the F&A rate and that it is therefore possible to identify the F&A costs associated with a particular project by applying the predetermined rate to the total amount of direct costs associated with the project. The NIH guidance on hESC research indicates that the indirect costs of hESC research may be included in the regular F&A cost allocation base, and associated indirect costs may be allocated pursuant to ordinary cost allocation principles. The NIH Frequently Asked Questions on these subject states that compliance with these methodologies “will prevent the shifting of unallowable stem cell research costs to federally sponsored programs.”

1. **Application of Federal Cost Principles to Specific Resources**

In addition to obtaining required approvals to conduct human embryo and hESC research, a PI must obtain confirmation from the PI’s school or college that the proposal conforms to the guidelines set out below. These cost-allocation guidelines apply to facilities, equipment, personnel, materials, supplies, non-capitalized equipment, and purchased services, devoted in whole or part to human embryonic and hESC research, regardless of funding source. The schools and colleges are responsible for implementing the guidelines for these specific resources including recharge and cost centers involved in human embryo and hESC research activities.

* + - 1. **Facilities**

UW facilities may be used to conduct human embryonic and hESC research only if they are approved for that use in advance. NIH guidance specifically provides that an investigator receiving NIH support may create new hESC derived cell lines and engage in other hESC research providing (i) all direct costs of such activities are allocated to a non-federal funding source, and (ii) the UW has in place a reasonable method of separating costs so that the appropriate F&A costs allocable to the hESC research are allocated to non-federal accounts so as to prevent federal funds from improperly supporting hESC research. Prior to commencing hESC research, the PI must (i) have written confirmation from the school or college that the facility has been approved for use in the conduct of hESC research, and (ii) adhere to any limitations contained in the written approval regarding the usage of facilities and related recordkeeping. The following guidelines apply to the approval of facilities in which hESC research is conducted.

* + - * 1. **Responsibility for Seeking Approval.** The PI retains primary responsibility for seeking approval for facilities to be used in the conduct of hESC research.
        2. **Tracking Usage of Facilities.** UW’s existing policies and procedures for tracking and confirming the usage of facilities for federally funded research, and the direct and indirect costs associated with that usage, will apply so that only allowable costs are charged to federal grants, and so that the costs of using facilities for other activities, including hESC research, are not supported by federal funds.
        3. **Limitations on the Usage of Facilities.** UW facilities may be used for hESC research, subject to approval on appropriate conditions. Such conditions may include, for example, limitation on time, allocation of space, or percentage of use and will in any event take into account other commitments for the facilities, if any, to federally sponsored projects and to other UW activities, including non-federally sponsored research.
        4. **Use of Multiple Facilities.** As part of the approval process, the PI must disclose all locations, both on-campus and off-campus, where any hESC research,will be conducted.
        5. **Approval of Changes in Usage of Facilities.** Any change in space usage where hESC research is conducted, whether addition or deletion of existing space, or changes in time or percentage of hESC research or usage, is also subject to these guidelines. Changes must be reviewed and approved by the school or college in accordance with usual and customary procedures.
      1. **Equipment**

UW equipment may be used to conduct hESC research with advance approval of the school or college. According to current NIH guidance, the acquisition of equipment used in the conduct of hESC research may not be federally supported. Federal regulations ([Uniform Guidance (2 CFR 200)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II)) contain additional rules that restrict the use of federally-owned equipment or other equipment acquired with federal funds. Prior to commencing hESC research, the PI must (i) have written confirmation from the school or college that the equipment has been approved for use in the conduct of hESC research and (ii) agree to any limitations in the written approval regarding the use of equipment and related recordkeeping. Limitations may involve, for example, restrictions on time or percentage limits on equipment capacity. The following guidelines apply to the approval of equipment to be used in hESC research:

* + - * 1. **Responsibility for Seeking Approval.** The PI retains primary responsibility for seeking approval for equipment, whether existing or proposed for acquisition, to be used in the conduct of hESC research.
        2. **Tracking Usage of Equipment.** UW’s existing policies and procedures for tracking and confirming the acquisition and usage of equipment for federally funded research, and the direct and indirect costs associated with acquiring and using equipment, will apply so that only allowable costs are charged to federal grants, and so that the costs of acquiring or using equipment for other activities, including hESC research, are not supported by federal funds.
        3. **Use of Equipment.** The school or collegewill issue approval as follows:

**Equipment owned by UW.** Equipment owned by UW may be used to conduct hESC research if the following conditions are satisfied:

Acquisition of the equipment was not supported by federal funds, and

Use of the equipment is not subject to any other restrictions, including restrictions imposed by non-federal sponsors.

**Equipment owned by the Federal Government.** Equipment owned by the federal government may be used in conducting hESC research only in the following circumstances:

Use of the equipment is expressly permitted pursuant to the terms of the federal award under which the equipment was obtained, the terms of an equipment rental agreement, or the approval of the appropriate federal agency; or

UW purchases the equipment from the federal government and has documentation of such transaction, including title transfer.

**Equipment owned by UW but Purchased with Federal Support.** Equipment owned by UW but acquired, in whole or in part, with federal funds may be used in conducting hESC research only in the following circumstances:

All competitive segments of the federal grant or contract supporting the equipment purchase have been completed and UW retains title to the equipment without restriction, observing any preferences for federal usage; or

Use of the equipment for hESC research is permitted pursuant to the terms of the federal grant or the approval of the appropriate federal agency; or

UW purchases the equipment in full, without federal restriction, and has documentation of such a transaction.

**Approval in changes in Usage of Equipment.** Any anticipated changes in usage of equipment are also subject to these guidelines. Changes must be reviewed and approved by the schools, and sponsor approval obtained, if required by the sponsor per the terms of the award.

* + - 1. **Personnel**

All UW personnel participating in hESC research must have prior approval from the UW regardless of whether the research is eligible for federal funding and whether any of the personnel receive federal funding for any purpose. Prior to commencing hESC research, the PI must (i) ascertain that any required approvals have been obtained from the ESCRO Committee, (ii) have an approved eGC-1 on file, if funded by an external entity, and (iii) obtain the agreement of all UW personnel participating in the hESC research to follow all UW rules and procedures regarding hESC research, including GIM 36 and these hESC cost-allocation guidelines. In addition to the foregoing, the following rules apply to the approval of personnel to participate in hESC research, regardless of funding source:

* + - * 1. **Responsibility for Seeking Approval.** The PI shall have primary responsibility for ensuring that approvals are sought and obtained for all personnel participating in hESC research.
        2. **Tracking Effort.** UW’s existing policies and procedures for tracking and confirming work effort, both direct charged and cost shared, on federally funded research will apply so that appropriate effort is devoted to commitments under federal grants, and so that other activities including hESC research, are not supported by federal funds (See [GIM 35 – Effort Reporting Policy for Sponsored Agreements](https://www.washington.edu/research/policies/gim-35-effort-reporting-policy-for-sponsored-agreements/)
        3. **Support and Cost Sharing.** Non-federal funds may be used to support all hESC research. Efforts expended on hESC research cannot be used to meet cost share commitments to federal projects.
        4. **Individuals Holding Multiple Appointments.** Many UW personnel have appointments or relationships elsewhere, including with affiliated hospitals and other institutions. The process for approving UW personnel to engage in hESC research will consider in the usual and customary fashion other appointments, relationships, and commitments of such personnel.
        5. **Work Benefiting Multiple Research Aims.** From time to time certain research activities may require further analysis to determine whether they may be supported in whole, part, or not at all by federal funds. Research activities on approved hESC lines may be supported by federal funds to the extent permitted by the particular grant. On occasion, certain types of activities may be directed to research aims with respect to approved hESC lines and hESC lines not listed on the NIH hESC registry, for example, the development of a reagent of assay that can be used on both types of hESC lines. In such instances, time and effort performing such activities should be allocated in proportion to the benefit each receives.
      1. **Materials, Supplies, Non-Capitalized Equipment, and Purchased Services**

Materials, supplies, non-capitalized equipment, and purchased services owned or acquired by UW may be used in conducting hESC research. Prior to commencing hESC research, the PI must (i) determine, for cost-allocation purposes, which materials, supplies, non-capitalized equipment, and purchased services were purchase specifically to carry outhESC research, (ii) agree to recordkeeping requirements for tracking the usage of general-purpose materials, supplies, non-capitalized equipment, and purchased services, to ensure that the federal government is not charged for hESC research. For acquired materials, supplies, non-capitalized equipment, and purchased services this should be done through appropriate financial accounting methods. The following guidelines apply to the usage of materials, supplies, and purchased services:

* + - * 1. Consumable Materials and Purchased Services.
        2. Specific Purchases. If purchased services, such as the services of consultants, laborers, or maintenance/repair technicians, or purchase materials are used to carry out hESC research, neither the direct costs of those items nor the indirect costs associated with their acquisition may be charged to the federal government.
        3. Use of Materials from General Supply. Materials withdrawn from general supply should be charged at their actual costs “under any recognized method of pricing inventory withdrawals, consistently applied.” ([Uniform Guidance (2 CFR 200)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II). Transportation charges may be included. The PI must track usage and apply a written plan for allocating costs among different projects. In such cases, the indirect cost must be transferred as well. For example, if the PI of aproject desires to consume one-half of the cost of existing materials initially purchased with federal funds for $100, then the $50 of the Materials plus the associated indirect costs must be transferred to non-federal sources prior to using or consuming the materials.
        4. Non-Capitalized Equipment. The cost of non-capitalized equipment must be allocated among the projects for which they are used, under a reasonable allocation plan consistent with UW policies.
      1. **Data, Information and Intellectual Property Obtained from hESC Research**

Researchers may use data, information and intellectual property obtained from any hESC research in subsequent hESC research, regardless of whether the subsequent projects are federally or non-federally funded. However, the federal government may not be charged for generating data for subsequent use in hESC research. These cost-allocation guidelines govern the determination as to whether resources engaged in the generation, analysis, or manipulation of data from hESC research may be charged to the federal government. Any use of data is subject to the usual consideration of third-party intellectual property rights, as well as any specific grant or contract constraints on data usage imposed by the suppliers or sponsors of the data, including other research institutions and federal funding agencies.

**5. Further Questions and Information**

These cost-allocation guidelines are subject to revision in light of any changes in law, rules or regulations. Any questions about these guidelines and their application to specific research projects should be referred through the school or college. I In order that UW personnel do not receiving conflicting or incomplete information, formal inquiries on behalf of UW to federal agencies about the application of federal cost principles to hESC research shall be made through the Office of Sponsored Progams (OSP).