



**HUMAN EMBRYO AND HUMAN EMBRYONIC STEM CELL
RESEARCH (hESC)
STATEMENT ON COST ALLOCATION**

GUIDANCE STATEMENT

Harvard University is committed to research aimed at the advancement of human health and scientific progress. In order to facilitate human embryo and human embryonic stem cell research, Harvard University has developed the following Statement on Cost Allocation.

The Federal government allows for the use of federal funds to support certain research activities involving human embryonic stem cells (hESC). It does, however, specifically prohibit the use of federal funds for certain research that involves human embryos or hESC lines that are not included as eligible lines on the NIH Human Embryonic Stem Cell Registry. This statement provides guidance to Harvard researchers and research administrators regarding compliance with these restrictions.

This guidance statement supplements, but does not replace, the University’s other research and personnel policies.

GUIDANCE RATIONALE

- **Dickey-Wicker:** In 1995, the Dickey-Wicker¹ Amendment was first included in a federal appropriations act, stating that federal funds may not be used for the following purposes:
 - The creation of a human embryo or embryos for research purposes; or
 - Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in *utero*.

Since 1995, the Dickey-Wicker Amendment has been included in each subsequent federal appropriations act. In order to comply with Dickey-Wicker, researchers and institutions that receive federal funding must ensure that no federal funds are used, directly or indirectly, to support research that would violate the Dickey-Wicker Amendment (hereafter “ineligible research”). According to NIH instructions, institutions will comply with the funding restrictions if they treat the costs of ineligible research as “unallowable” costs

¹ Originally included in the HR 2880, in 2014, the amendment appears as Section 508, Omnibus Appropriations Act, 2014, Pub. L. 111-8, 3/11/09. <http://www.gpo.gov/fdsys/pkg/CPRT-113HPRT91668/pdf/CPRT-113HPRT91668.pdf>



under federal research funding policy, and follow applicable federal cost principles of the Uniform Administrative Requirements, Cost Principles, And Audit Requirements For Federal Awards - Uniform Guidance (2CFR200).

- **Additional restrictions on federal funding:** In addition to the Dickey-Wicker Amendment, the NIH Guidelines on Human Stem Cell Research state that the following research activities are also ineligible for federal funding:
 - Research using hESC lines not included in the new NIH registry;
 - Research in which hESCs (even if derived from embryos donated in accordance with NIH Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts;
 - Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with NIH Guidelines) or human induced pluripotent stem cells may contribute to the germ line; and
 - Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes.

Each of the above-listed activities also are hereafter referred to as “ineligible research.”

APPLICABILITY

All Harvard PIs, faculty members, visiting scientists, postdoctoral fellows, students, OSP or SPA officers, and research administrators conducting or facilitating research with embryos or involving the derivation and use of human embryonic stem cells at Harvard University must comply with this policy.

SCOPE

- **Statement on derivation research and embryo research:** The Dickey-Wicker Amendment prohibits the use of federal funding for the derivation of stem cells from human embryos or for research that involves the creation of human embryos for research or results in the destruction of a human embryo.
- **Statement on required approvals:** Harvard requires that all embryo research and all hESC research be reviewed and approved by Harvard’s Embryonic Stem Cell Research Oversight Committee² (ESCRO) and all other University authorities and committees vested with the responsibility of overseeing research at the University. Harvard’s ESCRO requires a statement that the research, as described in the research protocol provided to the ESCRO, will occur in a lab where cost-allocation practices are in place to ensure that Harvard complies with funding restrictions on human embryo and human embryonic stem cell research.
- **Statement that the segregation of facilities is not necessary:** The federal government does not require that ineligible research be conducted in segregated facilities.

² Details of Harvard University ESCRO are described at: <https://hwpi.harvard.edu/escro>



- **Statement that 2 CFR 200 govern all sponsored programs:** Harvard’s sponsored expenditures policies require that the allocation of costs on federal awards³ follow Uniform Administrative Requirements, Cost Principles, And Audit Requirements For Federal Awards (2 CFR 200)⁴
- These principles will, by definition, ensure that no costs allocable to ineligible activities are supported by federal funds and will allow Harvard to meet the requirements of the funding restrictions by (1) not allocating the **direct costs** of ineligible research to the federal government and (2) not requesting reimbursement from the federal government for the **indirect costs** associated with ineligible research.⁵
 - **Direct Costs:** To determine whether the costs of resources, such as personnel or materials, can be borne by the federal government, Harvard must determine that the costs are reasonable, allowable, and allocable to work on federally sponsored agreements. The process of determining the direct costs of resources used for ineligible human embryo or hESC research does not differ in practice from the allocation process for research activities not funded by the federal agreement.
 - **Personnel:** Harvard’s existing policies for tracking and confirming work effort on federally funded research will apply to ensure that allocable and allowable effort is devoted to commitments under federal grants and that other activities, including ineligible research, are not supported by federal funds.
 - **Other costs:** Materials, services or commodities owned or acquired by Harvard may be used in eligible and ineligible research. Harvard’s existing policies for allocating costs to sponsored awards will apply to ensure that only allocable and allowable costs are charged to federal awards. Materials withdrawn from general supply should be charged to projects using laboratory practices for cost distribution, consistently applied.
 - **Equipment:** Equipment whose acquisition was not supported by federal funds may be used in conducting ineligible research. Equipment whose acquisition was supported with federal funds may not be used in conducting ineligible research: (a) until the supporting federal grant has been completed and Harvard has title to the equipment without restriction; or (b) unless Harvard purchases the equipment or a portion of it from the federal government and acquires title.

³ For non-federal awards, sponsor-specific policies and/or restrictions will apply in addition to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

⁴ 2CFR200: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl

⁵ Note: Effective December 26, 2014, 2CFR200 supersedes the requirements of a number of OMB Circulars including A-21 and A-110 which were the basis of “cost allocation”.



- **Indirect Costs:** Indirect costs, or facilities and administrative (F&A) costs, are recovered from the federal government by applying a government-approved F&A rate to the direct costs of individual federal projects. Only the federal share of Harvard’s indirect costs is charged to the government using this method. For indirect costs rate calculations, Harvard follows Uniform Guidance (2CFR200) (previously Circular A-21; Section C12e). Unallowable direct costs, including ineligible research expenses, are segregated into a cost base for which no indirect rate is federally negotiated. An allocation of indirect costs will be allocated in this non-negotiated pool through the regular allocation method. The Office for Sponsored Programs (OSP), Cost Analysis Group should be notified of ineligible research so that the direct cost and relevant space related indirect costs are segregated.
- **Statement about data:** It is Harvard policy that publicly available data or written information obtained from ineligible research can be used in federally funded research, provided that (1) none of the costs of generating the data obtained from ineligible research are charged to the federal government, and (2) none of the costs of manipulating data are charged to the federal government if the data are being used primarily for the benefit of an ineligible research project. Data usage is subject to the usual consideration of third-party intellectual property rights.
- **Statement about derivatives:** Harvard will follow the NIH guidance⁶ quoted below in terms of identifying which products of hESC research are “derivatives” whose research use may not be supported with federal funds if they were derived from ineligible hESC lines.
 - **Can a scientist use federal funds to conduct research using derivatives of human embryonic stem cell lines that are not listed on the NIH Human Embryonic Stem Cell Registry?** No federal funds may be used, either by an awardee or a sub-recipient, to support research using derivatives of human embryonic stem cell lines (hESCs) that are not listed on the NIH Human Embryonic Stem Cell Registry, with the exception described below. Derivatives include, but are not limited to, subclones of hESC lines, modified hESC lines (such as a line expressing green fluorescent protein), differentiated cells developed from hESC lines (such as muscle progenitor cells), and cellular materials (such as DNA, RNA, and proteins). Thus, no federal funds may be used for the generation of new data from unapproved hESC lines or derivatives. However, publicly accessible data from unapproved lines or derivatives may be used and analyzed with federal funds.”

CONTACTS

Office of the Vice Provost for Research: <http://vpr.harvard.edu/>

⁶ NIH-Stem Cell Policy Questions and Answers- NIH Guidelines: http://stemcells.nih.gov/research/pages/newcell_qa.aspx#der

