

Proposed Criteria for Donor Reimbursement

In addition to the eligibility and priority guidelines discussed above, the following criteria for donor reimbursement are proposed:

1. Any individual who in good faith incurs qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs (see special provision). This criteria is specifically discussed in the authorizing statute.

2. Donor and recipient of the organ are either U.S. citizens or lawfully admitted residents of the U.S.

3. Donor and recipient have primary residence in the U.S. or its territories.

4. Travel is originating from the donor's primary residence.

5. Donor meets the criteria for informed consent for the planned procedure according to applicable State and Federal laws.

6. Donor and recipient are not participating in a paired exchange program or a living donor/deceased donor exchange for the particular donation procedure for which reimbursement is being sought unless the legality of such practices is clarified by the Federal Government.

7. Donor and recipient attest to full compliance with section 301 of the National Organ Transplant Act (NOTA), as amended (42 U.S.C. 274e) which stipulates in part that “ * * * [i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”

8. The transplant center where the donation procedure occurs attests to its status of good standing with the Organ Procurement and Transplantation Network (*i.e.*, it is not a Member Not in Good Standing) and assurance that the program follows best practices for the health and safety of living donors such as the recommendations provided in the Consensus Statement of the Ethics Committee of the Vancouver Forum on living organ donation (Source: *Pruett TL, Tibell A, Alabdulkareem A, Bhandari M, Cronin DC, Dew MA, Dib-Kuri A, Gutmann T, Matas A, McMurdo L, Rahmel A, Rizvi SA, Wright L, Delmonico FL. The ethics statement of the Vancouver Forum on the live lung, liver, pancreas, and intestine donor. Transplantation 81(10):1386–1387; (2006).*

The public is invited to submit comments on these criteria.

Proposed Qualifying Expenses

For the purpose of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, qualifying expenses presently include only travel, lodging, and meals and incidental expenses incurred by the donor and/or accompanying person(s) as part of:

(1) Donor evaluation clinic visit or hospitalization;

(2) Hospitalization for the living donor surgical procedure; and/or

(3) Medical or surgical follow-up clinic visit or hospitalization within 90 days after the living donation procedure.

The Program will pay for up to five trips per donation or intended donation. Three of these trips may be for the potential living donor and up to two trips may be for any accompanying person(s). The total Federal reimbursement for qualified expenses during the donation process for the donor and accompanying individuals shall not exceed \$6,000.

The public is invited to submit comments on these criteria.

Special Provisions

The authorizing statute provides that the Secretary may consider as an eligible donating individual a person who in good faith incurs qualifying expenses toward the intended donation of an organ but with respect to whom, for reasons the Secretary determines to be appropriate, no donation of the organ occurs. Many factors may prevent the intended and willing donor from proceeding with the donation. Such circumstances include present health status of the intended donor or recipient that would prevent the transplant or donation from proceeding, perceived long-term risks to the intended donor, circumstances such as acts of God (e.g., major storms or hurricanes), or other unforeseen events outside of the intended donor's control. In such cases, the intended donor and accompanying persons may receive reimbursement for the qualified expenses incurred. In the case that a potential donor no longer wishes to donate, he or she may receive reimbursement for qualified expenses incurred. However, payments received for expenses that were not incurred by the intended donor and accompanying persons must be refunded. Otherwise, such payment will be treated as income to the intended donor, and in accordance with Internal Revenue Service (IRS) regulations, the Regents of the University of Michigan shall notify the IRS (Form 1099) that a payment has been made to the intended donor in the

amount equivalent to the unexpended payment.

Dated: March 30, 2007.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment; Pursuant to the Federal Advisory Committee Act, as Amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), Announces the Establishment of the Council of Councils (Council)

The Council shall provide advice and recommendations to the Director, NIH, or other appropriate delegated officials on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives including making recommendations with respect to the conduct and support of research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning.

Duration of this committee is two years from the date the Charter is filed.

Dated: March 29, 2007.

Elias A. Zerhouni,

Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and