**F-1 Application for Health Effects Institute**

**Research Agreement**

*All Agreements Use the Cost Reimbursement Format*

*Number (Leave Blank)*

**1. TITLE OF APPLICATION** **(***20 words maximum***)**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. RESPONSE TO RFA OR RFPA NUMBER AND TITLE**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**3. TYPE OF ORGANIZATION** *(Check all that apply*)

\_\_ Private Non-Profit \_\_ Private Profit \_\_ Minority Owned

\_\_ Educational \_\_ Small Business

\_\_ Public ( \_\_ Federal, \_\_ State, \_\_ Local) \_\_ Woman Owned

**4. PRINCIPAL INVESTIGATOR**

**4A. NAME (LAST, FIRST, MIDDLE)** *With Signature and Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature and Date*

**4B.MAILING ADDRESS** *(Organization, Street, City, State, Zip Code)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**4F. POSITION TITLE**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**6. HUMAN SUBJECTS OR DERIVED MATERIALS INVOLVED?**

YES \_\_\_\_\_ NO\_\_\_\_\_

**4C. TELEPHONE NUMBER** *(Area Code, Extension)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**4D. FAX NUMBER** *(Area Code)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**4E. EMAIL**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**5. TOTAL COST REQUESTED FIRST 12-MONTH PERIOD**

*(Enter from Page F-4a)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**7. TOTAL COST REQUESTED ENTIRE PROJECT PERIOD**

 *(Enter from Page F-5a1) / Number of Years*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/ Years

8. **APPLICANT INSTITUTION, CONGRESSIONAL DISTRICT, AND DUNS NUMBER**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. **NAME, TITLE, ADDRESS, EMAIL & TELEPHONE NUMBER OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE AGREEMENT**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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*Signature and Date*

**10. NAME, TITLE, ADDRESS, EMAIL & TELEPHONE NUMBER OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE AGREEMENT (***if different than above***)**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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*Signature and Date*

**F-2 TABLE OF CONTENTS OF APPLICATION**

*Number pages consecutively at the bottom throughout the application (automatic page numbering is activated but please double check).Type the name of the Principal Investigator at the top of each page and each continuation page (see page header).*

 **FACE PAGE** (Signed) ----------------------------------------------------------------------------------------------------------------------------- F-1

**TABLE OF CONTENTS** ---------------------------------------------------------------------------------------------------------------------------- F-2

**ABSTRACT** ----------------------------------------------------------------------------------------------------------------------------------------- F-3

**BUDGET**

Detailed Budget for First 12-Month Budget Period ----------------------------------------------------------------------------- F-4a

Detailed Budget for First 12-Month Budget Period (Subcontract) ------------------------------------------------------------ F-4b

Estimated Budget for Total Project with Justification -------------------------------------------------------------------------- F-5a

Estimated Budget for Total Project with Justification (Subcontract) --------------------------------------------------------- F-5b

**PROJECT PLAN** ------------------------------------------------------------------------------------------------------------------------------------F-6

A. Specific Objectives

B. Significance *(Sections A + B + C should not exceed 4 pages total)*

C. Related Previous Studies

D. Experimental Plan and Methods

E. Statistical Design and Analysis Plans *(Sections D + E should not exceed 15 pages total)*

F. Milestones and Timeline

G. Literature Cited

**OTHER SUPPORT** ------------------------------------------------------------------------------------------------------------------------------- F-7

Other Support/Principal Investigator

Other Support/Co-Investigators

**RESOURCES AND ENVIRONMENT** --------------------------------------------------------------------------------------------------------------- F-8

**BIOGRAPHIES** ------------------------------------------------------------------------------------------------------------------------------------- F-9

Bibliographical Sketch/Principal Investigator *(Maximum 2 pages)*

Other Biographical Sketches *(Maximum 2 pages per person)*

**ADDITIONAL SUBMISSIONS**

Human participants, laboratory animals, quality assurance, sponsor participation, consultant(s), statistician(s)--------F-10

**Human Subjects, Derived Materials, or Data** -------------------------------------------------------------------------------------- F-11

**Personal Data** *(Optional – please submit separately)--*--------------------------------------------------------------------------------- F-12

**F-3 ABSTRACT OF PROJECT PLAN**

**PRINCIPAL INVESTIGATOR:** *(Name, Title, and Institution)*

..

**PROJECT TITLE:***(20 words maximum)*

..

**ABSTRACT OF PROJECT PLAN**: *Concisely describe the application’s specific aims, methodology, and long-term objectives, making reference to the scientific disciplines involved and the relationship of the project to the objectives of HEI and the Request for Applications. The abstract should be self-contained so that it can serve as a succinct and accurate description of the application when separated from it. DO NOT EXCEED ONE PAGE.*

..

**F-4a BUDGET FOR FIRST 12 MONTH PERIOD**

|  |  |
| --- | --- |
| From  | Through  |
| Personnel  | Time Effort  | Dollar Amount Requested *(omit cents)*  |
| NAME  | Title or Position  | Role in Project  | %  | Hours /Week  | Salary  | Fringe Benefit  | Totals  |
|  |  | Principal Investigator  |  |  |  |  |  |
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| **Subtotals**  |  |  |  |
| Consultant Costs  |  |
| Supplies (itemized)  |  |
| Other Expenses (itemized)  |  |
| Travel (domestic only)  |  |
| Subtotal Direct Costs  |  |
| Indirect Costs - Limited to 30% of direct costs excluding equipment and subcontracts. See budget instructions.  |  |
| Equipment (itemized)  |  |
| Subcontractors *(Enter total from 4b)*  |  |
| Total First 12-Month Budget Costs *(Enter on Form 1 Item 5 and on Form 5a)* |  |

**F-4b BUDGET FOR FIRST 12 MONTH PER**I**OD (Subcontract) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*(Enter subcontractor name)*

|  |  |
| --- | --- |
| From  | Through  |
| Personnel  | Time Effort  | Dollar Amount Requested *(omit cents)*  |
| NAME  | Title or Position  | Role in Project  | %  | Hours /Week  | Salary  | Fringe Benefit  | Totals  |
|  |  | Principal Investigator  |  |  |  |  |  |
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| **Subtotals**  |  |  |  |
| Consultant Costs  |  |
| Supplies (itemized)  |  |
| Other Expenses (itemized)  |  |
| Travel (domestic only)  |  |
| Subtotal Direct Costs  |  |
| Indirect Costs - Limited to 30% of direct costs excluding equipment and subcontracts. See budget instructions.  |  |
| Equipment (itemized)  |  |
| Total Subcontract Costs *(Enter on Form 4a under Subcontracts)* |  |

**F-5a BUDGET FOR TOTAL PROJECT**

|  |  |  |
| --- | --- | --- |
| **BUDGET CATEGORY** | **1ST BUDGET PERIOD (***From page F-4a***)** | **ADDITIONAL YEARS SUPPORT REQUESTED** |
| **2ND** | **3RD** | **TOTAL** |
| **PERSONNEL** (Salary and Fringe Benefits) (Applicant Organization Only)  |  |  |  |  |
| **CONSULTANT COSTS**  |  |  |  |  |
| **SUPPLIES**  |  |  |  |  |
| **OTHER EXPENSES**  |  |  |  |  |
| **TRAVEL**  |  |  |  |  |
| **SUBTOTAL DIRECT COSTS**  |  |  |  |  |
| **INDIRECT COSTS** (*Note 30% Cap*)  |  |  |  |  |
| **EQUIPMENT**  |  |  |  |  |
| **SUBCONTRACTS (***From Form 5B***)**  |  |  |  |  |
| **TOTAL COSTS**  |  |  |  |  |
| **TOTAL FOR ENTIRE PROPOSED PROJECT** *(Enter on Form 1, Item 7)*  |  |

**Budget Justification: Total Budget**

*Briefly describe the specific functions of the personnel and consultants. For each year, justify any cost for which the need may not be obvious, such as equipment, foreign travel, alterations and renovations, and contractual or third party costs. For future years, justify any significant increases in any category. If a recurring annual increase in personnel costs is anticipated, give percentage.* *Note that an Institutional Cost Rate Agreement should be submitted once the project has been approved for funding.*

..

**F-5b BUDGET FOR TOTAL PROJECT (Subcontract) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*(Enter subcontractor name)*

|  |  |  |
| --- | --- | --- |
| **BUDGET CATEGORY** | **1ST BUDGET PERIOD (***From page F-4a***)** | **ADDITIONAL YEARS SUPPORT REQUESTED** |
| **2ND** | **3RD** | **TOTAL** |
| **PERSONNEL** (Salary and Fringe Benefits) (Applicant Organization Only)  |  |  |  |  |
| **CONSULTANT COSTS**  |  |  |  |  |
| **SUPPLIES**  |  |  |  |  |
| **OTHER EXPENSES**  |  |  |  |  |
| **TRAVEL**  |  |  |  |  |
| **SUBTOTAL DIRECT COSTS**  |  |  |  |  |
| **INDIRECT COSTS** (*Note 30% Cap*)  |  |  |  |  |
| **EQUIPMENT**  |  |  |  |  |
| **SUBCONTRACTS (***From Form 5B***)**  |  |  |  |  |
| **TOTAL COSTS**  |  |  |  |  |
| **TOTAL FOR ENTIRE PROPOSED PROJECT** *(Enter on Form 5a under Subcontracts)* |  |

**Budget Justification: Subcontract Budget**

*Briefly describe the specific functions of the personnel and consultants. For each year, justify any cost for which the need may not be obvious, such as equipment, foreign travel, alterations and renovations, and contractual or third party costs. For future years, justify any significant increases in any category. If a recurring annual increase in personnel costs is anticipated, give percentage.*

..

**F-6 PROJECT PLAN**

*The Project Plan should contain the sections listed below. Sections A, B, and C together should not exceed 4 pages. Sections D and E combined should not exceed 15 pages. Please refer to the instructions for details.*

**A. Specific Objectives**

..

**B. Anticipated Results and Significance**

..

**C. Related Previous Studies**

..

**D. Experimental Plan and Methods**

..

**E. Statistical Design and Analysis Plans**

..

**F. Milestones and Timeline**

..

**Milestone Chart**

|  |  |  |
| --- | --- | --- |
| Year | Year 1 | (etc) |
| Quarter | 1 | 2 | 3 | 4 | (etc) |
| Specific Aim 1: (add text) |  |  |  |  |  |
| Task 1: (add text) |  |  |  |  |  |
| Task 2: (add text) |  |  |  |  |  |
| (etc) |  |  |  |  |  |

**G. Literature Cited**

..

**F-7 OTHER SUPPORT**

*Describe current and pending grants or contracts from which each of the investigators proposed for this project are now drawing or anticipate drawing support. Identify project by title, agency, or organization supporting such work, the total level of financial support given for the project, the percentage of time (or calendar months) spent on each project, and the (projected) start and end dates. Briefly describe the contents of each. If any of these overlap, duplicate, or are being replaced or supplemented by the present application, justify and delineate the nature and extent of the scientific and budgetary overlaps or boundaries.*

1. **Active Support**

..

1. **Pending Support**

..

**F-8 RESOURCES AND ENVIRONMENT**

**FACILITIES***: Describe all the facilities to be used and, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Using continuation pages if necessary include a description of the nature of any collaboration with other organizations and provide further information in the RESEARCH PLAN.*

**Laboratory** ..

**Animal** ..

**Clinical** ..

**Computer**..

**Other** ..

**MAJOR EQUIPMENT**: *List the most important equipment items available for this project, noting the location, and pertinent capabilities of each*.

..

**SPONSOR PARTICIPATION**  \_\_\_ YES \_\_\_ NO

*If yes, on a separate page identify and explain role of any individuals employed by the EPA or industry sponsors of HEI who are involved with any aspect of the project. Also, list any resources provided by sponsors (such as facilities or animals).*

**F-9 BIOGRAPHICAL SKETCH**

*Give the following information for professional personnel and consultants beginning with the Principal Investigator. Please do not exceed 2 pages per individual. Copy this page for each additional person.*

|  |  |  |
| --- | --- | --- |
| **NAME**.. | **TITLE**.. | **BIRTH DATE**.. |

**Education** (*Begin with baccalaureate training and include postdoctoral training*)

|  |  |  |  |
| --- | --- | --- | --- |
| **INSTITUTION AND LOCATION** | **DEGREE** | **YEAR CONFERRED** | **FIELD OF STUDY** |
|  |  |  |  |
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**RESEARCH AND/OR PROFESSIONAL EXPERIENCE:** *Concluding with present position, list in chronological order previous employment, experience, and honors. List, in chronological order, the titles and complete references to recent representative publications, especially those most pertinent to this application.*

..

**F-10 ADDITIONAL SUBMISSIONS**

*Please refer to the instructions for details. Headers that do not apply to your application can be deleted.*

**Human Participants** *(see also form F-11)*

..

**Laboratory Animals**

..

**Quality Assurance Plan**

..

**Sponsor Participation** *(if checked “Yes” on form F-6)*

..

**Consultant(s)**

..

**Statistician(s)**

..

**Conflict of Interest**

..

OMB No. 0990-0263 Approved for use through June 30, 2024

**F-11 Protection of Human Subjects**

**Assurance Identification/IRB Certification/Declaration of Exemption**

**(Common Rule)**

*Policy*: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule unless the activities are exempt from or approved in accordance with the Common Rule. The “pre-2018 Common Rule (or pre-2018 Requirements)” was originally promulgated in 1991 and amended on June 23, 2005 (70 FR 36325). The “2018 Common Rule (or 2018 Requirements)” was originally published on January 19, 2017 (82 FR 7149) and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497). The categories of exempt research are provided in Section 101(b) of the pre-2018 Common Rule and Section 104(d) of the 2018 Common

Rule.

The pre-2018 Common Rule requires institutions to certify that each application or proposal for research has been reviewed and approved by an Institutional Review Board (IRB) (Section 103(f)). The 2018 Common Rule requires institutions to certify that each proposed research study has been reviewed and approved by an IRB (Section 103(d)). Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal, or proposed research study, unless otherwise advised by the Department or Agency.

|  |  |  |
| --- | --- | --- |
| 1. Request Type\_\_ ORIGINAL\_\_ CONTINUATION\_\_ EXEMPTION | 2. Type of Mechanism\_\_ GRANT \_\_ CONTRACT \_\_ FELLOWSHIP\_\_ COOPERATIVE AGREEMENT\_\_ OTHER: \_\_\_\_\_\_\_ | 3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. |
| 4. Title of Application of Activity | 5. Name of Principal Investigator, Program Director, Fellow, or Other |

6. Assurance Status of this Project *(Respond to one of the following)*

 [ ] This Assurance, on file with Department of Health and Human Services, covers this activity:

 Assurance Identification No \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the expiration date \_\_\_\_\_\_\_\_\_\_\_ IRB Registration No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ] This Assurance, on file with *(agency/dept)*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, covers this activity.

 Assurance No. \_\_\_\_\_\_\_\_\_\_\_, the expiration date\_\_\_\_\_\_\_\_\_\_ IRB Registration/Identification No.\_\_\_\_\_\_\_\_\_\_\_\_ *(if applicable)*

 [ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

 [ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under the pre-2018 Common Rule, Section 101(b), paragraph \_\_\_\_\_

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under the 2018 Common Rule, Section 104(d), paragraph .

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This Activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations. By:

 [ ] Full IRB Review on (date of IRB meeting) \_\_\_\_\_\_\_\_\_\_ or [ ] Expedited Review on (date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ] If less than one year approval, provide expiration date \_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

|  |  |
| --- | --- |
| 9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided. | 10. Name and Address of Institution |
| 11. Phone No. (*with area code*) |  |
| 12. Email: |  |
| 13. Name of Official |  | 14. Title |
| 15. Signature  |  | 16. Date |

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**F-12 PERSONAL DATA ON PRINCIPAL INVESTIGATOR
(OPTIONAL – PLEASE SUBMIT SEPARATELY)**

Health Effects Institute has a continuing commitment to monitoring the operation of its review and award process to detect, and deal appropriately with, real or imagined inequities with respect to age, ethnicity, race, or gender of the proposed principal investigator. To provide HEI with the information it needs for this important task, please complete this form and send it together with the application. This form will be updated as new federal guidance becomes available.

**Upon receipt of this application by HEI, this form will be kept separate from the application. This form will not be duplicated, and it will not be a part of the review process. Data will be confidential. All analyses conducted on the data will report aggregate statistical findings only and will not identify individuals.**

HEI strongly appreciates completion of this form to support its efforts to track diversity of applications and funded investigators and to expand investment into diversity, equity, and inclusion as part of its [2020 action plan](https://www.healtheffects.org/announcements/taking-steps-toward-action-inclusiveness). If you decline to provide this information, it will in no way affect consideration of your application.

Your cooperation will be appreciated.

DATE OF BIRTH *(month/day/year)*:\_\_\_\_\_\_\_\_ SEX: \_\_ Female \_\_ Male

RACE AND/OR ETHNIC ORIGIN *(check one)*

\_\_ American Indian or Alaskan Native

\_\_ Asian or Pacific Islander

\_\_ Black, not of Hispanic origin

\_\_ Hispanic

\_\_ White, not of Hispanic origin

NOTE: The category that most closely reflects the individual’s recognition in the community should be used for purposes of reporting mixed racial and/or ethnic origins. Definitions are as follows:

American Indian or Alaskan Native: A person having origins in any of the original peoples of North America and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands and Samoa.

Black, not of Hispanic origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

White, not of Hispanic origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.