APPLICATION MATERIALS AND BASIC REQUIREMENTS
for Obtaining the Human Capital Dataset

1. INTRODUCTION

The Human capital dataset (2002-04) is restricted, and is available only under specific contractual conditions because of the risks of identifying respondents in the survey. The remainder of this document describes those conditions.

The restrictions exist because the Human Capital Study staff members take the promise of respondent anonymity very seriously. The Guatemalan respondents have provided large amounts of information about their lives. This large amount of information and the fact they were born in only four villages greatly increases the likelihood that an individual (or family, household) can be identified. Violations of respondent anonymity would not only violate a commitment to the respondents, but also would inflict an enormous loss on the entire research community because they undermine the willingness of individuals to participate in surveys. Because the potential damage is so great, the procedures outlined below are strict.

The following materials have been developed by the Human capital Study staff, using as a model the procedures developed by the Health and Retirement Survey (HRS), in an effort to permit dissemination of the Human Capital dataset to the maximum number of responsible researchers while satisfying its own concerns about respondent anonymity. Each application for access to the Human Capital Dataset will be reviewed by the Human Capital staff for conformance with the spirit and letter of the requirements outlined in these materials, and no Restricted Data will be distributed without staff approval.

The procedures and requirements below are somewhat complex, so we realize that applicants for Restricted Data may have questions during the process. Procedural questions should be addressed to Human.Capital@sph.emory.edu.

2. OUTLINE OF REQUIREMENTS

Researchers may be eligible to receive the Human Capital Dataset only if and when they meet all of the following requirements:

A. Affiliation with an Institution with an NIH-certified Human Subjects Review Process for All Researchers. The National Institutes of Health has certified over 300 institutions as having met procedural criteria for Institutional Review Boards/Human Subjects Review Committees. Only persons with formal affiliations with such institutions may receive the Human Capital Dataset. Although nearly all the research universities in the United States have received NIH certification, we are aware that many universities in the United States and elsewhere have not received such certification, and that many legitimate researchers will be excluded from access under this condition. However, until we can devise an alternative means of assuring the quality of human subjects review that is implied by the NIH certification, this requirement will stay in place.

B. Human Subjects Certification of All Researchers Who Will Use the Data. The Institutional Review Boards/Human Subjects Review Committees noted in A will require such certification
and can provide information regarding procedures for obtaining this certification.

C. Restricted Data Protection Plan. Examine Developing a Data Protection Plan (below) and investigate the mechanisms that are available to you to meet its requirements at the site(s) at which the Restricted Data will be managed, analyzed, and stored. This may require some discussion with computing personnel at your institution, and perhaps even obtaining permission to acquire special hardware or software. If you intend to maintain Internet connectivity, you should read The Restricted Data Environment: Issues Relating to Network-Connected Clients. Once you have assured yourself that you can meet the requirements set forth in both documents, draft your Restricted Data Protection Plan and mail a copy to the Human Capital staff as specified in Section III.D. below. The Human Capital Study staff will examine the draft plan, and may require some amendments. Do not be surprised if your Plan requires revision before it can be approved. Take careful note that the Restricted Data Protection Plan must define and treat variables/fields derived from the original Restricted Dataset as Restricted Data. (Aggregate statistical summaries of data and analyses, such as tables and regression formulae, are not "derived variables" in the sense used in the Agreement, and are not subject to the requirements of the Restricted Data Protection Plan and the Agreement.)

D. Human Subjects Review. The chairperson of your institution's Institutional Review Board/Human Subjects Review Committee must certify that the Board/Committee has reviewed and approved this document and your Restricted Data Protection Plan, in accordance with the standards and procedures used for live human subjects. No abbreviated review, or lower standards, such as are sometimes used for "secondary data analysis", may be used in this aspect of the human subjects review. Human Capital Study respondents are live human subjects, and the Human Capital Study staff may be going back to them for more data in the future. The IRB/HSRC review at your institution must include the Restricted Data Protection Plan that have been approved by the Human Capital Study staff, you should not submit your proposal for IRB/HSRC review until you have received the Human Capital Study staff approvals.

E. Agreement for Use of Restricted Data from the Human Capital Study Staff. The Restricted Data Investigator applying for the Human Capital Study dataset must make sure that ALL persons who will have access to the Restricted Data, and a representative of the Receiving Institution, must sign a Notarized Agreement for Use of Restricted Data from the Human Capital study. You may wish to submit the blank form of the Agreement in advance to your institutional signatory, to determine whether they are willing to sign it.

You should especially note the following in the Agreement:

1. Restricted Data can be used only for research and statistical purposes for those explicitly covered by the agreement. It is not permitted, for example, for a faculty member to obtain the data for his/her own research project and then "lend" it to a graduate student to do related dissertation research, unless this use is specifically stated in the Agreement.

2. You must either destroy, or return to the Human Capital Study staff, all versions of the Restricted Data and data derived from it, regardless of the form in which it exists (tapes, hard disk, diskettes, and other physical media) within 24 months, or such other period as is specified in the approved Agreement, or upon a demand from Human Capital staff. Researchers who need additional time should make a formal written request for an extension at least 30 days prior to the expiration date, and the Human Capital Study staff will give as prompt consideration to such requests as possible. In brief, you may not retain any copies of or data derived from the
Restricted Data, after the conclusion of the contract period. Human Capital Study staff will store the physical media containing such data for you, at your request for up to two years, so that it can be available to you if you obtain a second Agreement for further analysis.

3. The Restricted Data Investigator must be affiliated with the receiving institution with a position or title equivalent to a permanent tenured or tenure-track faculty member.

4. All Co-Investigators and Research Staff must have a formal affiliation with the receiving institution, and must specify that affiliation and job title in the signature blocks of the Agreement and Supplemental Agreement of Research Staff. If new persons become affiliated with the research project, and are to have access to the Restricted Data, an additional Supplemental Agreement of Research Staff must be signed by the new persons and the Restricted Data Investigator, and approved by Human Capital Study staff before the new person is given access to the Restricted Data.

5. Your institution must agree to treat violations of this agreement, and allegations of such violations, as violations and allegations of violations of its policies on scientific integrity and misconduct, as to substance, procedures, and penalties.

6. The representative of your institution who signs the Agreement must have the authority to bind the institution contractually.

3. RECOMMENDED PROCEDURES FOR APPLICANTS

A. Obtain:
   a. a copy of the National Institutes of Health Certification of your institution’s Institutional Review Board/Human Subjects Review procedures;
   b. a copy of your institution’s policies and procedures on scientific integrity and misconduct, including the name and address of the person or office responsible for enforcing them; and
   c. a copy of your resume or curriculum vitae.
   d. copies of Human Subject Certification for ALL research investigators who, it is proposed, will use the Restricted Data.

B. Write:
   a. your Restricted Data Protection Plan.

C. Mail the items in A. and B. to: The Human Capital Study, Hubert Department of Global Health, Rollins School of Public Health of Emory University, 1599 Clifton Road, N.E., Room 6.433, Atlanta, GA 30322, USA.

D. Obtain and mail to: The Human Capital Study, Hubert Department of Global Health, Rollins School of Public Health of Emory University, 1599 Clifton Road, N.E., Room 6.433, Atlanta, GA 30322, USA (following Human Capital Study staff’s approval of your Restricted Data Protection Plan):
   a. the Certification of Human Subjects Review (based on your submission of your
Restricted Data Protection Plan); and

b. TWO originals of the Agreement for Use of Restricted Data from the Human Capital Study (both will be countersigned by Human Capital Study staff and one returned to you).

4. SANCTIONS FOR VIOLATION OF THE AGREEMENT

The Agreement for Use of Restricted Data from the Human Capital Study specifies four possible sanctions against researchers who violate the terms of the agreement:

1. Denial of all future access to Human Capital Study Restricted Data;
2. report of the violation to the Receiving Institution's office responsible for scientific integrity and misconduct, with a request that sanctions be imposed under the institution's scientific integrity and misconduct policy;
3. report of the violation to federal research funding agencies, with a recommendation that all current research funds be terminated, and all future funds be denied, to the Investigator(s) and to all other persons implicated in the violation; and
4. such other remedies as may be available to the Human Capital Study under law.

When the staff of the Human Capital Study determine that there may have been a violation of the Agreement, the Human Capital Study staff will communicate the allegations in writing to the Restricted Data Investigator and offer the investigators an opportunity to respond in writing. The Human Capital Study staff may also, at the time the allegations are communicated, demand return and/or destruction of all copies of Restricted Data in the possession of the Investigator(s), Research Staff, and any unauthorized persons, and certification of the return/destruction by the Restricted Data Investigator. If the Human Capital Study staff determines that the allegations of violations were incorrect, the Human Capital Study staff will return any copies of the Restricted Data to the Restricted Data Investigator under the conditions of the original Agreement.

If the Human Capital Study staff determines that the allegations of violations of the Agreement are in any part correct, it will determine the appropriate sanction. If the sanction includes notification of federal funding agencies with a recommendation to terminate current and deny future federal research funding, the Human Capital Study staff will communicate its notification of violations and recommendations appropriate officials at the NIH Office of Scientific Integrity.