

Requirements and Application Procedures for Obtaining Restricted Medicare Data from PSID

Background. Recognizing that administrative records from the Medicare program are a valuable source of supplemental information on health and policy issues, PSID has made linkages to nearly 20 years of Medicare claims. PSID was one of the first national panel surveys to link Medicare-eligible respondents to claims data starting in 1990 (Lillard et al. 1993). In that year, Medicare-eligible respondents were asked to give written consent to link to one year of claims. Through 1995 consent was renewed annually (for those who originally said yes) and another 1-year linkage was made (Lillard & Rogowski 1995). Research based on these data has provided important insights into predictors of health insurance status, service utilization and cost (Lillard & Farmer 1997; Lillard & Rogowski 1995; Lillard et al. 1997).

Beginning in 2005, with support from NIA, PSID resumed asking eligible respondents (who were either age 65 or older or receiving Medicare through the Disability Insurance or DI program) to provide their Medicare number and consent to link to (all) their Medicare records (rather than a single year). Information on consent has been preloaded from one year to the next so that respondents who refuse or provide an unusable number are re-asked permission. For example, initially (in 2005), 59% of eligible respondents gave permission to link Medicare data to their survey responses; however over the next two waves, an additional 14% of 2005-eligible respondents agreed after being re-asked so that by 2009 the percentage of the 2005 cohort consenting was 73%. In total, we have obtained permission from 948 PSID respondents out of a total 1,465 who were eligible in any of the waves 2005-2009 (65%). We have found those individuals without chronic conditions, who are thus less likely to have claims, are more likely to refuse permission. Starting in 2011, we will begin to tailor our consent so that individuals who report no chronic conditions are told that even if they do not have any health problems, it is important for statistical purposes to get this information from Medicare.

Linkages have been performed by MedRIC. 86% of the 2,180 eligible PSID respondents (those who consented plus decedents after 1990 who had never refused permission) who were sent to MedRIC were linked to up to 18 years of claims (1991-2008). Claims data begin with a respondent's first service after Medicare entitlement, which is at age 65 or when qualification for DI is met. Claims files include short-stay inpatient, skilled nursing facilities, hospital outpatient, physician/supplier, home health, and hospice services. Health plan enrollment files provide exact dates of respondent enrollment in Medicare health maintenance organizations. Although utilization information has not been reported for HMO enrollees in the past, characteristics of respondent health plans are reported. Summary files are compiled annually and by quarter. To access these data files, researchers are required to complete a data use agreement with CMS and the University of Michigan.

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There are two linked approval processes that must be completed In order to obtain the Medicare records linked to PSID respondents, **First:** Users must obtain approval from PSID for the use of the restricted Medicare data (see below). **Second:** Users must obtain a Data Use Agreement (DUA) from the Centers for Medicare & Medicaid Services (CMS), working through

the **Research Data Assistance Center** (ResDAC; <http://www.resdac.umn.edu/>). Formally, the request for a DUA from CMS must come from the program officer of the funding agency that supports your research. Requests for PSID-linked CMS data are processed and provided by the MedRIC division of **Acumen LLC** (<http://www.acumen-llc.com/>). Inquiries regarding data file specifics should be sent to **Acumen/MedRIC** (MedRIC@acumenllc.com).

Section I provides a description of the requirements for obtaining PSID approval to use the restricted Medicare data. The procedures for obtaining approval from both PSID and CMS are described in Section 2.

References

Lillard, L.A., Berry, S.H., Brown, J., Buchanan, J.L., & Rogowski, J. (1993). **Elderly Health Supplement to the PSID: Survey Instruments and Item Source Listings. (RAND Working Paper DRU-494-NIA).**

Lillard, L.A. & Rogowski, J. (1995). Does Supplemental Private Insurance Increase Medicare Costs? (Rand Labor & Population Working Paper DRU-1124). Retrieved from: <http://www.rand.org/pubs/drafts/DRU1124/>

Lillard, L. A. & Farmer, M.M. (1997). Linking Medicare and National Survey Data. *Annals of Internal Medicine*, 127, 691-695.

Lillard, L.A., Rogowski, J., & Kington, R. (1997). Long-Term Determinants of Patterns of Health Insurance Coverage in the Medicare Population. *The Gerontologist*. 37(3), 314-323.

1. REQUIREMENTS FOR OBTAINING PSID APPROVAL TO USE RESTRICTED MEDICARE DATA

Below is a description of requirements that investigators must meet in order to obtain PSID restricted Medicare data.

A. Requirements for Receiving Institution

The receiving institution with which the primary researcher is affiliated must have obtained an *Assurance of Compliance* from the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS). Note: Under the DHHS human subjects protection regulations (45 C.F.R. 46.103), every institution engaged in human subjects' research that is funded or conducted by DHHS must obtain an Assurance Of Compliance approved by OHRP. This Assurance Of Compliance, when granted, is called a *Federal-Wide Assurance*.*

Although nearly all research colleges and universities in the United States meet this requirement, we are aware that there are institutions that have not received such certification, and that some legitimate researchers may be excluded from access under this condition. **Researchers who fall into this category may wish to use the Michigan Center on the Demography of Aging Data Enclave in order to gain access to PSID restricted Medicare data.**

B. Requirements for Investigator

The investigator must meet requirements specified under either Category 1 OR Category 2.

Category 1.

- a) An individual who has a permanent, full-time, doctoral-level appointment **and**
- b) Principal Investigator of a grant funded by a US federal agency; or

Category 2.

- a) An individual who has a permanent, full-time, doctoral-level appointment **and**
- b) Not a Principal Investigator on a grant funded by a US federal agency, **and**
- c) Affiliated with a federally funded research center **and**
- d) Center Director **and** Principal Investigator of a federally funded Research Center agrees to serve as Co-Investigator.

The justification for these requirements is that the primary sanction available to PSID for violations of the Agreement by researchers is notification of the violations to the appropriate United States government funding agency, with a possible recommendation of termination of current, and denial of future, research funding to the investigators.

If funding from a United States government agency is still pending at the time of application for access to PSID restricted Medicare data, all aspects of the application process except contract signing and proof of a federal research award can be completed pending a decision on your proposal. If needed, PSID may be willing to make a written statement to your sponsor that, on the basis of the materials you have provided us to date, you will be approved by PSID for the restricted Medicare data after completion of the contractual conditions.

C. Requirements for Co-Investigators and Research Staff

1. Co-Investigators are individuals who have a permanent, full-time, doctoral-level appointment involved in the research with the Medicare data at the same institution as the Investigator. All Co-Investigators must sign the contract.
2. Investigators who have collaborators/Co-Investigators at other institutions should contact PSID for guidance.
3. All other research staff who are paid employees of the Receiving Institution, excluding the Investigator and Co- Investigator, who will have access to Sensitive Data must sign the contract.

D. Research Proposal

Applicants for PSID restricted Medicare data must provide to PSID staff a short (1-3 page) research proposal, that includes a synopsis (or a full statement, if necessary) of your research goals, and specifies:

- Each specific variable from restricted Medicare dataset you intend to use in your research; and
- Each dataset, if any, to which the restricted Medicare data will be merged. Note that no merges to geocode data at any level are permitted.

E. Restricted Data Protection Plan

Examine the document “Data Protection Plan Requirements and Guidelines for Obtaining PSID Restricted Data” 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. Once you have assured yourself that you can meet the requirements set forth in both documents, draft your restricted Medicare data protection plan and e/mail a copy to PSID as specified in 2.F. below. PSID staff will examine the draft plan, and may require some amendments. Your plan may require revision before it can be approved by PSID.

Note that the restricted data protection plan must define and treat variables/fields derived from the original restricted dataset as restricted data.

F. Human Subjects Review

The chairperson of your institution's Institutional Review Board/Human Subjects Review Committee must certify that the Committee has reviewed and approved your restricted Medicare data protection plan (and the portions of your Research Plan that deal with respondent anonymity and data security, if any), as approved by ISR, in accordance with the standards and procedures used for *live human subjects*. Depending on your institution's IRB requirements, either expedited or full review is permissible. However, 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.

The enclosed *Certification of Human Subjects Review* form should be used for the certification. Because the IRB/HSRC review at your institution must include the Research Plan and restricted Medicare data protection plan that *have been* approved by PSID, you should not submit your proposal for IRB/HSRC review until you have received the PSID approvals.

G. Agreement for Use of Restricted Medicare Data from the PSID

The Restricted Data Investigator applying for PSID restricted Medicare data, *all* other persons who will have access to the restricted data, if any, and a representative of the Receiving Institution, must sign the Agreement for Use of Restricted Data from the PSID. The following requirements are part of the Agreement:

1. Restricted Data can be used *only* for research and statistical purposes, and the Research Plan must specify *all* of the research projects that will make use of the restricted data. It is *not* permitted, for example, for a faculty member to obtain the data for her own research project and then "lend" it to a graduate student to do related dissertation research, even if the graduate student is a Research Staff signatory, unless this use is specifically stated in the Research Plan.
2. The PSID restricted Medicare data cannot be merged with PSID restricted geocode data, at any level. The specific variables involved in merges with any other data must be specified.
3. In order to maintain the highest standards of respondent protection, the data are provided in two parts. Acumen will send a CD containing the Medicare data files to user (encrypted) and PSID will provide an ID cross-reference file (encrypted) that links respondents to the record set created by Acumen. You will be subject to two requirements regarding the disposal of the data at the close of the project. First, you will be required to destroy the files sent to you by Acumen and provide CMS with certification to that effect. Second, within 30 days of the end date of the contract, you must either destroy and provide a certificate of destruction, or return to PSID, the file provided by the PSID that allows the linking of the data provided by Acumen with PSID respondents. Researchers who need additional time should make a formal written request for an extension at least 30 days prior to the expiration date, and PSID will give prompt consideration to such requests. However, neither the initial time period, nor any extension of it, may exceed the time period of the grant or contract under which the data are being analyzed. One implication of the time limits is that you should assure yourself that you have adequate time available to do the data management and analysis you have planned. In brief, you may *not* retain *any* copies of or data derived from the Restricted Data, after the conclusion of the contract period.
4. A user fee structure is being developed by Acumen to offset their costs to generate and distribute the claims data. In addition, a non-refundable fee of \$750 is required by PSID to cover administrative costs related to the processing of application materials and to support random in-person audits of investigators' work environments to ensure compliance of data security requirements.
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.
7. Investigator must sign agreement to be audited.

2. APPLICATION PROCEDURES

A. Obtain:

1. The Federal-Wide Assurance number and expiration date for your institution. (This is issued by the United States Department of Health and Human Services Office for Human Research Protections; it informs PSID that your institution's IRB is registered with OHRP);
2. a copy of your current federal research grant or contract award letter(s);
3. 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
4. a copy of your resume or *curriculum vitae* or NIH biosketch.

B. Write:

1. your Research Plan;
2. your Restricted Medicare Data Protection Plan

C. Email or mail the items in A. and B. to PSID

D. Apply for a Data Use Agreement (DUA) from the Centers for Medicare & Medicaid Services (CMS)

1. While application is under review by PSID, complete the data request packet (New Use Request) for CMS. A complete description of the required documentation can be found at the ResDAC *Requesting CMS's Identifiable Data Files (RIFs) - New Use Requests* page: (http://www.resdac.umn.edu/Medicare/requesting_data_NewUse.asp)
2. Receive PRELIMINARY approval from PSID.
3. Finalize CMS data request packet, incorporating data plan approved by PSID, and send all draft paperwork, including PSID approval, to ResDAC. Retain documents with original signatures until requested by ResDAC.
4. ResDAC verifies, completes, and returns the DUA to the researcher to obtain funding agency signoff
5. Funding agency signs off on the request and forwards to CMS.
6. CMS approves data request and notifies user, Acumen, and PSID.

E. Obtain and email or mail to PSID (following PSID approval of your Research Plan and Restricted Medicare Data Protection Plan):

1. The fully executed DUA with CMS;
2. the Certification of Human Subjects Review (based on your submission of your Research Plan and Restricted Medicare Data Protection Plan); and
3. TWO originals of the Agreement for Use of Restricted Medicare Data from the PSID (both will be countersigned by PSID and one returned to you).

F. Data Distribution

As described above, in order to maintain the highest standards of respondent protection, the data are provided in two parts. Acumen will send a CD containing the Medicare data files to user (encrypted) and PSID will provide an ID cross-reference file (encrypted) that links respondents to the record set created by Acumen.

Questions and application mailings should be directed to:

PSID Help psidhelp@isr.umich.edu

3. Sanctions for Violation of the Agreement

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

1. denial of all future access to PSID 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 PSID under law.

When PSID staff determine that there may have been a violation of the Agreement, PSID will communicate the allegations in writing to the Restricted Data Investigator and offer the investigators an opportunity to respond in writing. PSID may also, at the time the allegations are communicated, notify CMS and Acumen to 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 PSID Data Confidentiality Committee determines that the allegations of violations were incorrect, PSID will return any copies of the Restricted Data to the Restricted Data Investigator under the conditions of the original Agreement.

If the PSID Data Confidentiality Committee determines that the allegations of violations of the Agreement were 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 PSID Data Confidentiality Committee will communicate its notification of violations and recommendations to the PSID Program Officer at the National Institute on Aging, who will in turn convey it to appropriate officials at the NIH Office of Scientific Integrity, the National Science Foundation, the Social Security Administration, the Health Care Financing Administration, and other federal agencies.