Checklist – Accessing the Medicaid/Medicare Database

- Must sign the CCEB **Data Use and Approval Agreement.** (Link to online form)

- Must get protocol review and approval from the **Penn IRB**:

  Application procedures:
  http://www.upenn.edu/regulatoryaffairs/index.php?option=com_content&task=view&id=17&Itemid=8
  IRB Guidance:
  http://www.upenn.edu/regulatoryaffairs/index.php?option=com_content&task=view&id=21&Itemid=8

  All applications must be submitted electronically through The Human Subjects Electronic Research Application (HS-ERA), a PennKey is required:
  https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do.

- **General questions**:
  General questions regarding the data, processes, or file cost should be directed to *Cristin P. Freeman*, MPH (cpf@mail.med.upenn.edu) or *Charles E. Leonard*, PharmD (celeonar@mail.med.upenn.edu).

  CCEB faculty and staff, experienced in the use of these data, are available to assist CTSA researchers in the application, approval, and data acquisition processes.

- **Application process:**
  Interested ACARD researchers should mail or email the following information to *Cristin P. Freeman,* MPH (826 Blockley Hall, 423 Guardian Drive, Philadelphia, PA 19104-6021) cpf@mail.med.upenn.edu.

  1) Cover letter indicating their study name, funding source, intent, CMS files of interest, and contact person.
  2) A 1-3 page protocol summary outlining their research in the format required by the University of Pennsylvania's Institutional Review Board (IRB).
  3) Confirmation of IRB approval, most specifically the letter from the University of Pennsylvania's Office of Regulatory Affairs.
  4) Acknowledgement of CMS processing fee ($2,000/re-use agreement)

- **Penn approval phase**:
  - Application will be reviewed by CCEB faculty and staff.
  - Accepted applications will be assigned to a member of the CCEB research team. This member shall act as a resource to the researcher.

- **CMS approval process via ResDAC:**
  Must get protocol review and approval from the **Centers for Medicare & Medicaid Services (CMS)** within the Department of Health and Human Services. Specifically, a **request packe**t will need to be completed for review and approval by the Research Data Assistance Center of the University of Minnesota (**ResDAC**) and the Centers of Medicare & Medicaid Services (**CMS**). The request packet typically consists of:

  1) A written request letter
  2) Executive summary (+ data management plan, and key personnel)

3) Study plan or protocol (+federally funded executive summary)
4) Data Use Agreement (http://www.cms.hhs.gov/cmsforms/downloads/cms-r-0235.pdf)
5) IRB approval + waiver of informed consent and HIPAA
6) Evidence of funding – to cover the $2,000 re-use fee
7) Data specification worksheet
8) Privacy board summary review sheet
9) Formal cost estimate (http://www.resdac.umn.edu/docs/Cost_estimate_researcher.doc)
10) Letter of support from federal project officer, among others.

**Please note this step can take 2-4 months to complete

Main website CMS:
http://www.cms.hhs.gov

Main website ResDAC:
http://www.resdac.umn.edu

Files available for order
http://www.cms.hhs.gov/FilesForOrderGenInfo

Identifiable data files overview
http://www.cms.hhs.gov/IdentifiableDataFiles

- After obtaining approval from ResDAC and CMS, the CCEB team member will coordinate the researcher's acquisition of (access to) data.

Revised August, 2010