**The research involves no more than minimal risk to the participants.**

This data repository will collect and store datasets which have been collected either for other purposes (eg administrative or claims data) or for other research projects (eg HRS, Danish Biobank). We have gone to great lengths to protect patient confidentiality as outlined in our DMP in section 16.

**The waiver will not adversely affect the rights and welfare of the participants.**

There are study procedures are in place to protect confidentially as described in our data management plan in section 16. Administrative or medical records may be used without patient their authorization if the use is approved by the IRB. Because study procedures are in place to protect confidentially (outlined in the DMP) information learned during the study will not affect the treatment of the participants and thus will not adversely affect their welfare.

**The research could not practicably be carried out without the requested waiver.**

**For research using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format**

3a. If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting hundreds of millions of patients and other individuals, many of whom are long dead. Additionally, in most cases Stanford PHS will not have access to identifiers, so this would be impossible. In the case where it was possible, identification and contact of patients would represent a greater violation of privacy and risks than using their de-identified data.

3b. In the case where data are delivered to the Data Core with identifiers, we remove them prior to making them available for research unless the investigator provides a compelling reason why a particular identifier is necessary and receives IRB approval for the use of the identifiable data.

**Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.**

It is not expected that the information learned from this these research studies will directly impact participants' treatment. Thus, it is not anticipated that there will be pertinent information for study participants. The study may lead to new knowledge that may affect the treatment of future patients. Additionally, in almost all cases, PHS will not have access to patient contact information, so contacting individuals would be impossible, unethical or both.

That said, in the event of an important and actionable discovery, PHS will inform the data owner of the finding so that they may decide how to act upon the information. As PHS did not collect the data and, in most cases, does not have access to direct identifiers, direct contact would be inappropriate or take place under a completely separate protocol and agreement.

**Waiver of HIPAA Authorization**

**Describe the Protected Health Information (PHI) needed to conduct the research. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR , use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.**

As this is a data repository identifiable, or potentially identifiable, fields will vary widely by dataset. In many cases data will arrive at Stanford de-identified

We expect databases may contain PHI and PII as described in Section 11b. In the event PHS will carry out de-identification, we have attached a detailed description of procedures to protect and de-identify data to prepare it for research in Section 5.2 of the DMP attached in Section 16. Identifiers are often necessary in order to conduct linkage and data enrichment. We will use tools such as Choice Maker or Datavant so that it will not be necessary to vend explicit identifiers to researchers in most cases. These tools append a scrambled code to records that allow linkage without inclusion of sensitive fields.

In the event an investigator needs to use identifiers (eg, dates of service, zip code or census tract etc) they must complete a separate IRB and justify the need for these fields.

**Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

In many cases, data will arrive at Stanford de-identified. In the event we do receive PHI or PII, we have attached a detailed description of our security and de-identification strategy in the DMP attached in Section 16.

**Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**

Plans to destroy the data vary by dataset and agreement with the data owners or generators. As datasets often represents a considerable investment, and destruction of identifiers makes further linkage impossible, for the most part, we will elect to strongly protect and limit access to identifiers rather than destroy them outright. These procedures are detailed in the DMP attached in Section 16.