**Guidance: Research Using “Publicly Available” Data**

14Nov2021

Under the Revised DHHS Common Rule, research that includes access to and/or use of identifiable “publicly available” datasets or biospecimens may be exempt from IRB review. The purpose of this guidance is to help define what constitutes publicly available data or biospecimens to establish if a project may qualify for exempt determination under category 4(i).

**What is the definition of “publicly available” data?**

“Publicly available” refers to data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions, or privileges.   Examples include data/biospecimens available for public purchase, searchable online, or available at a library.

**What are examples of types of identifiable data/biospecimens that are not considered publicly available?**

* Data in the electronic medical record;
* Social media data labeled as “private” or not readily available without permission of the site Owner/Administrator under the Terms of Service of the site;
* Data protected by Copyright; and
* Data or biospecimens that have access restrictions [e.g. are only available to clinicians or qualified researchers or may only be accessed on a secure server].

**Questions about access/use of data/biospecimens may be referred to the IRB for clarification.**