Exhibit A: Is data sharing permitted?

1. Data Sharing Request
2. Are the data from Human Subjects Research?
   - Yes: Does Informed Consent Document or relevant IRB waiver permit disclosure? (IRB review required)
   - No: Were data collected as part of Sponsored Research?
     - Yes: Has Sponsor prohibited data sharing?
       - Yes: Sharing not permitted, Contact DSP
       - No: Sharing not permitted, Contact HSO/IRB
     - No: Were data received under contract from another Party?
       - Yes: Does contract prohibit sharing?
         - Yes: Sharing not permitted, Contact DSP
         - No: Sharing Permitted, Contact DSP
       - No: Does policy, law, or regulation prohibit sharing?
         - Yes: Sharing Permitted, Contact DSP
         - No: Sharing Permitted, Contact the appropriate office

3. No: Sharing not permitted, Contact DSP
Exhibit B: If Data sharing is permitted, when is a Data Use Agreement necessary.

1. Please see 2.a. of the accompanying guidance for more information.

2. UI Health Care consists of the Carver College of Medicine, UI Physicians, UI Hospitals and Clinics, and affiliated entities. Data leaving UI Health Care may require UIHC Data Governance review. Contact icts-bmi-consulting@healthcare.uiowa.edu with questions.

3. A BAA should not be applied to data generated from a research project. It is designed for protection of healthcare data transmitted to a provider’s business partner for execution of business responsibilities.

4. Examples of access rules could be the rules governing a public database where PI obtained data, or limitations present in the funding agreement that supported the collection of the data. Contact DSP to learn more.

5. OHRP does not consider research involving only coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met: (1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example: (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);