



Sam Houston State University

A Member of The Texas State University System

INSTITUTIONAL REVIEW BOARD

IRB Guidance: Data Release Agreements

This guidance addresses requirements when receiving research data or other information covered by a contract, MOU, data sharing and/or data transfer and use agreement.

Many research projects include a contract or other legal agreement as part of the proposed application. These agreements, while presented with different acronyms and titles (e.g., Data Use Agreements [DUA], Data Transfer and Use Agreements [DTUA], Memorandums of Understanding [MOU], Business Associate Agreement [BAA]) all fall under the umbrella of Data Release Agreements (DRA). For the purposes of this guidance document, “Data Release Agreement” is used. However, please note that the same or similar provisions are applicable to all agreements mentioned above.

A DRA is a contractual document used for the transfer of non-public or restricted use data. Examples of DRAs include, but are not limited to, records from governmental agencies or corporations, student records information, existing human research subjects data, laboratory notebooks created by faculty, and limited data sets.

Importance of Data Release Agreements

Data Release Agreements address critical issues such as limitations on use of the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. These agreements also assure that the recipients are using the data in accordance with applicable law, as they contractually obligate the recipient to use the data only for the purpose described in the Data Release Agreement. Data Release Agreements prevent inappropriate use of protected or confidential information that could cause harm to research subjects, the investigator, or the university.

Data Release Agreements Required

For human subjects data, a Data Release Agreement is typically required when:

- Disclosure of data is for research purposes.
- Individual authorization for disclosure to this recipient is not/has not been obtained (i.e., through use of a subject-signed informed consent authorization).
- When no other form of contract concerning the data transfer exists between the provider and the recipient (i.e., sub-award agreement or a contracted services agreement).

Examples

Data that might be exchanged under a Data Release Agreement include:

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- Records from governmental agencies or corporations.
- Student record information.
- Existing, identifiable human subjects data.
- A limited or restricted use data set.

Family Educational Rights and Privacy Act (FERPA) and Data Release Agreements

The Family Educational Rights and Privacy Act (FERPA) requires a written agreement to disclose Personally Identifiable Information (PII) from educational records without consent. These written requirements must meet the Code of Federal Regulations (CFR) 99.31(1)(6)(iii)(C) or 99.35(a)(3).

Data Release Agreements Not Required

For human subjects research data, a Data Release Agreement is NOT typically required when:

- Data are publicly available in public domain.
- Data are exchanged that are not subject to legal or other restrictions on its use.
- A research subject signs a consent authorization form that authorizes data sharing with the recipient.
- Another agreement, such as a sub-award agreement or a contracted services agreement is in place.
 - Data transfer as part of such a collaborative research project is often addressed in the study protocol or in the funding agreement terms and conditions (i.e., grant, contract, sub-award, contracted services agreement, etc.). In these cases, a separate Data Release Agreement is generally not necessary.

IRB Requirements for Data Release Agreements

If a Data Release Agreement is a part of the project submitted to the IRB, the IRB may request for it to be included in the protocol application. However, regardless of whether the IRB requests it or not, any language in these agreements in regard to data protection, storage, access, and/or destruction should be mirrored in the protocol application, likely in the Privacy & Confidentiality section.

The Office of Research and Sponsored Programs (ORSP) serves as a campus signatory for Data Release Agreements. Data Release Agreements must be routed through ORSP or through another signatory for final sign-off and approval. Signatories are charged with reviewing the agreements and signing on behalf of the institution, ensuring compliance with appropriate policies and regulations.

For human subjects research purposes, only official campus signatories are authorized to enter into contractual agreements, including Data Release Agreements, on behalf of the university. Researchers are **NOT** authorized to sign Data Release Agreements on behalf of the institution.

- It is important for researchers to read the terms of a Data Release Agreement before forwarding it to a signatory for review and approval. It is the researcher's responsibility to understand and follow the terms of the agreement and to only use data for purposes specified in the agreement. Campus signatories assume that a researcher who transmits a Data Release Agreement has read and agrees to conform to those terms on the agreement itself.

*All questions regarding Data Release Agreements routed through ORSP should contact that office at irb@shsu.edu.