**As a condition of publication of clinical trial results, ICMJE journals require that a Data (IPD[[1]](#footnote-1)) Sharing Statement** be included in the ClinicalTrials.gov registration.

* Applies to clinical trials thatbegin enrolling participants on or after January 1, 2019.[[2]](#footnote-2),[[3]](#footnote-3)
* The statement must be **in the original ClinicalTrials.gov registration**.
* The **answer to “*will data be available?*” must be No or Yes.**
*(per official ICMJE correspondence – even though ClinicalTrials.gov provides an “Undecided” option)*
* The answer can change; explain in the *Plan Description* when updating the record.
* Should match the data sharing statement required to be submitted (as of July 1, 2018) with the results manuscript for publication in ICMJE journals.2,3

## IPD Sharing Statement Examples

The statement consists of answers to seven questions; see the ICMJE [press release](http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf) for complete details, including the following table2 with examples of statements that fulfill their requirements:

|  |
| --- |
|  |

## Mapping the Data Sharing Statement in ClinicalTrials.gov[[4]](#footnote-4)

ClinicalTrials.gov provided the **IPD Sharing Statement Module** to accommodate data sharing statements.

1. Log into the Protocol Registration and Results System (PRS)
2. Open the ClinicalTrials.gov study record
3. Open the Protocol Section, then Edit the IPD Sharing Statement Module
4. Answer the ICMJE questions using the corresponding PRS data elements:

|  |
| --- |
|  |

***Questions?*** **University of Iowa PRS Administrator**

**Brian Brotzman,** **ct-gov@uiowa.edu****, 319-384-4623**

1. IPD = Individual Participant Data; “data sharing statement” and “IPD sharing statement” are synonymous [↑](#footnote-ref-1)
2. Taichman et al., [Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors (ICMJE).](http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf) Ann Intern Med. 2017 Jul 4;167(1):63-65 [↑](#footnote-ref-2)
3. <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>, section 2 [↑](#footnote-ref-3)
4. Mapping is based on ClinicalTrials.gov Protocol Data Element Definitions (<https://register.clinicaltrials.gov/prs/html/definitions.html>) [↑](#footnote-ref-4)