

**Understanding Data Sharing Statements for Individual Participant Data (IPD)**

As a condition of publication of clinical trial results, ICMJE journals require that a Data/(IPD<sup>1</sup>) Sharing Statement be included in the ClinicalTrials.gov registration.

Before enrolling participants, carefully consider if you may potentially submit to an ICMJE journal. If so, this requirement applies to clinical trials that begin enrolling on or after January 1, 2019.<sup>2,3</sup>

- The statement must be in the original ClinicalTrials.gov registration.
- The answer to “will data be available?” must be No or Yes - (per the [ICMJE data sharing recommendations](#). – 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.<sup>2,3</sup>

**IPD Sharing Statement Examples**

The statement consists of answers to seven questions; see the ICMJE [press release](#) for complete details, including the following table<sup>2</sup> with examples of statements that fulfill their requirements:

**Table.** Examples of Data Sharing Statements That Fulfill These ICMJE Requirements\*

ICMJE Questions	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at ( <i>Link to be included</i> ).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website ( <i>Link to be included</i> ).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University’s data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at ( <i>Link to be provided</i> ).	Not applicable

\* These examples are meant to illustrate a range of, but not all, data sharing options.

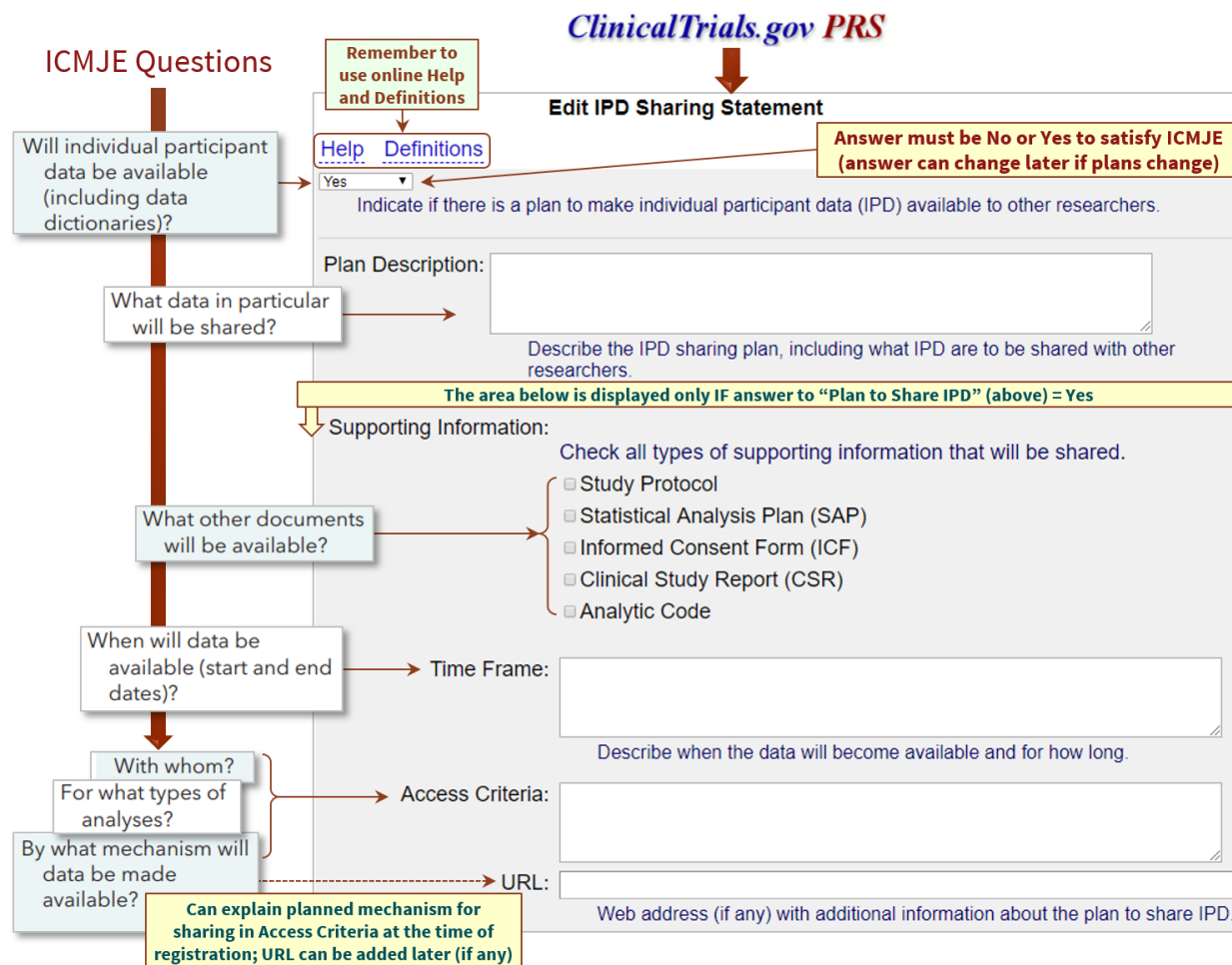
<sup>1</sup> IPD = Individual Participant Data; “data sharing statement” and “IPD sharing statement” are synonymous  
<sup>2</sup> Taichman et al., [Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors \(ICMJE\)](#). Ann Intern Med. 2017 Jul 4;167(1):63-65  
<sup>3</sup> <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>, section 2

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**Mapping the Data Sharing Statement in ClinicalTrials.gov<sup>4</sup>**

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:



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<sup>4</sup> Mapping is based on ClinicalTrials.gov Protocol Data Element Definitions (<https://register.clinicaltrials.gov/prs/html/definitions.html>)