

ICMJE Guidelines

Policy: Recommendations for the Conduct, Report, Editing, Data Sharing and Publication of Scholarly Work in Medical Journals

<http://www.icmje.org/icmje-recommendations.pdf>

Scope: ICMJE recommends that all medical journal editors require registration of clinical trials in ClinicalTrials.gov prior to the start of participant enrollment. The ICMJE expects authors to meet all requirements that have been outlined by their funding and/or regulatory agency. ClinicalTrials.gov records listed in the system for publication purposes only are required to indicate if the investigators will make individual participant data (IPD) available for use by other researchers. Only trials that meet the definition of a clinical trial are covered by the ICMJE policy.

The International Committee of Medical Journal Editors (ICMJE) has released a new requirement for publication. ICMJE will **require** ClinicalTrials.gov records to indicate if investigators will make individual participant data (IPD) available for use by other researchers. **The requirement is not that investigators must share data, but only acknowledge if IPD will be available.**

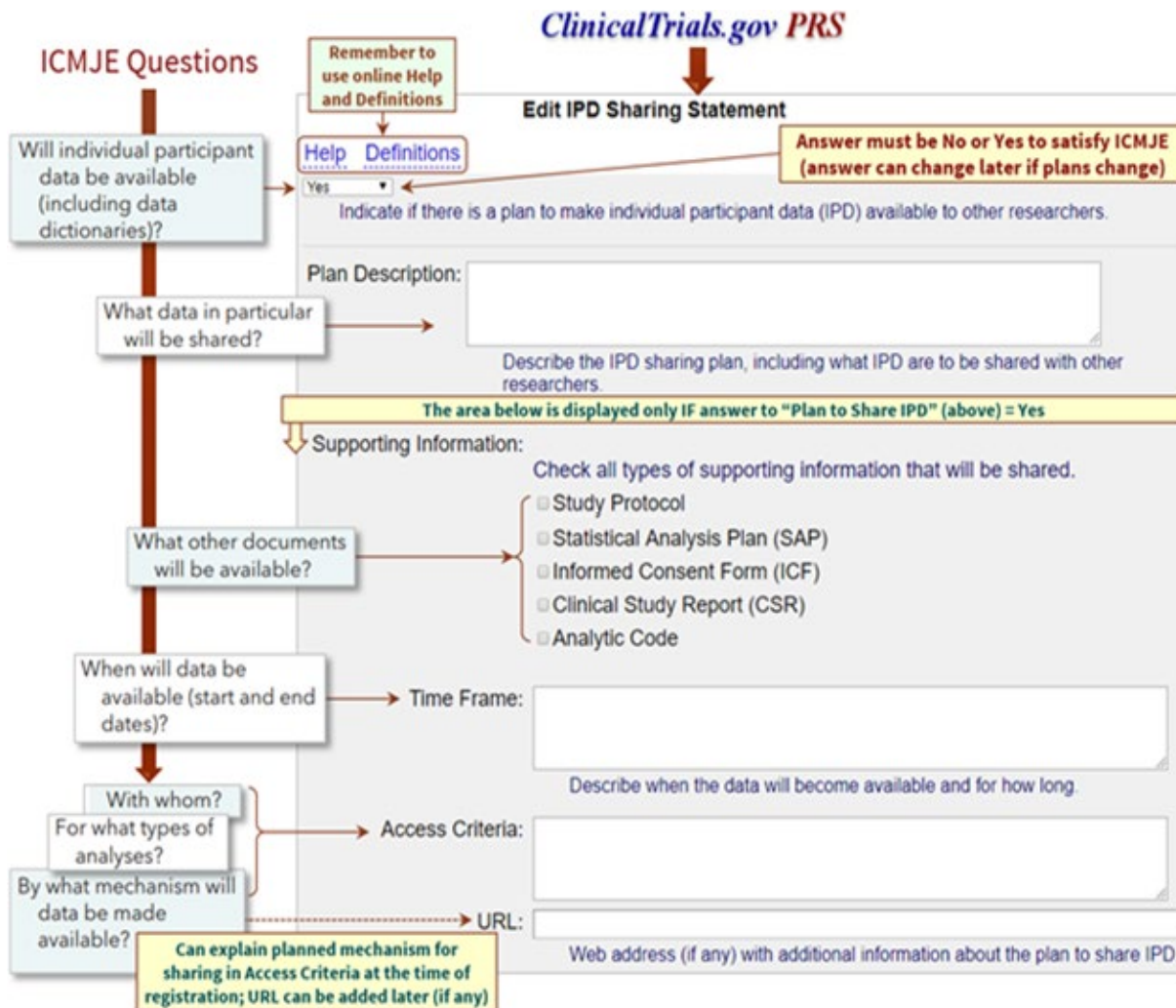
ICMJE believes there is an obligation to share data generated by interventional clinical trials. To facilitate this obligation, a data sharing statement will be required for all interventional clinical trials.

Effective January 1, 2019

Clinical trials that begin enrolling participants on or after, January 1, 2019, must include a data sharing statement (plan) in the trial registration (ClinicalTrials.gov)

- Whether individual de-identified participant data (including data dictionaries) will be shared
- What data in particular will be shared
- Whether additional, related documents will be available (e.g., protocol, SAP, ICF)
- When the data is available, and for how long
- By what access criteria data will be shared (with whom, what types of analyses, and by what mechanism).

ClinicalTrials.gov will facilitate this requirement by including a new data sharing statement module in the record. See diagram on the following page.



If the data sharing statement indicates that IPD is available to other researchers, please verify that the ICF language coincides with this sharing information. Template language is available in the ICF.

Failure to comply with the requirement may cause publication denial. The original Clinicaltrials.gov registration must acknowledge if IPD will be shared but may be altered (yes or no) at any time with an explanation.

The requirement is NOT to share data, rather a statement if the investigator is willing to share their data or not.

Additional information

http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf

<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>