April 18, 2016

Submitted electronically at http://www.icmje.org/

International Committee of Medical Journal Editors
c/o Annals of Internal Medicine
American College of Physicians
190 North Independence Mall West
Philadelphia, PA 19106-1572

RE: Response to ICMJE’s Proposed Requirements for Sharing Clinical Trial Data

Dear International Committee of Medical Journal Editors:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to respond to the International Committee of Medical Journal Editors (ICMJE)’s January 2016 editorial proposal for sharing clinical trial data.

Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science. PRIM&R’s Public Policy Committee discussed ICMJE’s proposal, and below is our response to the four provisions on which you requested feedback.

1) “As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the de-identified individual patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material)...”

PRIM&R fully supports initiatives to promote data sharing. The public availability of patient-level data can optimize the use and novel reanalysis of existing data sets, foster collaboration, enhance accountability and reduce research redundancy. By enhancing the scientific contribution of clinical trials and society’s investment in them,
data sharing supports the ethical justification for clinical research participation itself.

We ask individuals to assume risks and burdens associated with being research subjects for the benefit of science and public health. Data sharing multiplies the value of clinical trials and thereby honors subjects’ contributions to research. But the value of data sharing is not without risk.

Industry and academia have expressed concerns about subject privacy, costs and burdens, and unwanted impact on academic incentives and intellectual property rights, to name a few. PRIM&R asks whether the ICMJE alone is best positioned to consider and implement this substantial change to research policy and practice. We recommend thoughtful policy development related to privacy concerns, sensitivity to intellectual property matters, and a revision to the definition of “clinical trial” which is overly broad and encompasses research for which the balance of benefit and burden associated with the requirement is not reasonable.

2) Proposed 6 month timeframe following publication for sharing de-identified individual patient data.

For some studies, the 6 month timeframe will not be problematic, but for others—depending on the nature of the research—a longer timeframe, such as one or even two years, may be more appropriate (for example, for complex studies that involve multiple sub-analyses). Requiring the primary investigators to share data within 6 months could motivate them to delay publication of research because they believe they need time to conduct additional analyses with their data and are concerned that releasing their data before such analyses are complete will be detrimental to their ability to publish their research. This outcome would be bad for scientific progress and patient safety.

To address this possibility, PRIM&R suggests that ICMJE allow investigators to propose at the time of registration a reasonable alternative (but definitive) timeline within which they will share their patient-level data. ICMJE should also explore innovative ways to facilitate data sharing by researchers planning multiple articles from one data set. Finally, PRIM&R recommends that ICMJE consider developing an independent process to determine whether the data have been adequately de-identified and the security of information is properly maintained. The process should include expertise in human subjects research and privacy protection.

3) “The ICMJE will also require that authors include a plan for data sharing as a component of clinical trial registration.”

We support requiring authors to include a plan for data sharing as a component of clinical trial registration. Increased transparency fosters public trust in the research enterprise. However, we recommend that ICMJE provide further details on what constitutes an acceptable data sharing plan. ICMJE should clarify, for instance, whether the requirement for
data sharing entails that data sharing plans will be reviewed as part of manuscript review, or whether the mere existence of a plan at the time of submission will be considered adequate to meet the requirement.

Furthermore, the proposal does not make adequate provision for changes to data sharing plans. Researchers generating data may make changes to their protocols after registering their trial and providing a plan for data sharing. They may also decide there is a better mechanism for disclosing data after the original plan has been submitted. Disputes may arise between the original data generators and those who later request data access about whether the new data sharing plan is adequate. It is unclear how such disputes would be adjudicated. PRIM&R recommends that ICMJE consider developing an independent committee to resolve disputes in this area, and that the committee include a human subjects research representative.

4) “...those who generate and then share clinical trial data sets deserve substantial credit for their efforts. Those using data collected by others should seek collaboration with those who collected the data. However, because collaboration will not always be possible, practical or desired, an alternative means of providing appropriate credit needs to be developed and recognized in the academic community. We welcome ideas about how to provide such credit.”

PRIM&R strongly agrees that those who generate and then share clinical trial data sets deserve credit for their efforts and work product. Without such credit, data sharing could be detrimental to researchers’ careers and, by extension, to the advancement of science. We agree that when collaboration between secondary data users and data generators is mutually beneficial, it may be an appropriate method for crediting data generators for their work. But when it is not a viable option, we recommend that journal editors ensure that the source of data is always clear in publications. This will ensure that data-generators are given appropriate credit in any secondary analyses of the data and that their institutions have a basis on which to give them appropriate academic or professional recognition, for instance, during merit-review or tenure-decision processes.

Other Comments

PRIM&R also notes that guidance will need to be developed for IRB review of data sharing plans with respect to the adequacy of measures taken for protecting subject privacy and confidentiality. IRBs will be key partners in ensuring that informed consent processes include appropriate and understandable information about data sharing and conditions under which information will be shared. ICMJE should encourage researchers to inform their IRBs at the start of research about their plan for data sharing, so that the IRBs can advise the researchers about what human subjects need to know about data sharing.

We encourage ICMJE’s members to engage the scientific community in a dialogue about how best to pay for new data sharing requirements.
PRIM&R supports responsible collaboration and careful use of shared data. Policy should encourage authors of secondary analyses to incorporate important details such as inclusion/exclusion criteria, study location, and how end points were measured, where relevant. In addition, any systematic reviews or meta-analyses must address differences in study design. Finally, ICMJE should call for and participate in the development of ethical standards for the conduct of secondary analyses on shared data.

We hope that you will find our input on this matter useful as you finalize this proposal. If you have any questions or require any further information, please feel free to contact PRIM&R through its executive director, Dr. Elisa A. Hurley at (617) 423-4112 or ehurley@primr.org, or the chair of its Public Policy Committee, Dr. David H. Strauss at strauss@nyspi.columbia.edu.

Sincerely,

Elisa A. Hurley, PhD
Executive Director

cc: Board of Directors