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NOT-OD-20-013, “Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance”

Dear Dr. Jackson-Dipina:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments to the National Institutes of Health (NIH) in response to NOT-OD-20-013, *Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance*.

ASH represents more than 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell disease, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

After reviewing the draft policy and supplements, the Society is fully supportive of the NIH policy for data management and sharing. We believe that such a policy will provide an important foundation to improve the reproducibility and reliability of research findings and to promote collaborative interactions. We are especially supportive of NIH’s proposal to collect data management and sharing plans as part of “Just-in-Time” documentation for extramural awards. Allowing the applicant to submit the plan later in the process instead of in the initial proposal will greatly reduce administrative burden for applicants and reviewers. In addition, having NIH staff review the plans will allow for a more uniform and streamlined process. We look forward to working with NIH to implement the final version of the policy, for example through workshops at our annual meeting.

The Society would like to highlight some specific issues related about the proposed policy’s scope and implementation.

While we fully support data sharing of almost all types, the draft policy is not clear about exactly which types of data NIH expects to be shared. While NIH is relatively clear on what is *not* expected to be shared, there may be benefit to NIH on being specific about which data *are to be* shared. The draft policy suggests the “incorporation of principles that respect the autonomy and privacy of research participants and protection of confidential

data,” but the supplement suggests that data from human participants might be shared in an aggregated or summarized form and that each institute or center would have authority to determine which data ultimately must be shared. More precision in this area would be helpful to researchers; specificity will allow investigators to know exactly what is expected and will prevent the submission of data that is not wanted. As an example, there is information that should not or cannot be shared, such as PET scans from lymphoma clinical studies.

The Society is also concerned that data sharing plans will vary quite a bit from institution to institution and across NIH institutes and centers and thus will impact our members differently. As such, we recommend that NIH ensure that reasonably uniform standards are being applied across all entities. This will also help Institutional Review Boards craft consistent and acceptable consent forms.

Patient privacy, confidentiality, and institutional responsibility are not defined or discussed in the draft policy. Upon implementation of the data sharing policy, we are concerned that the ambiguity about privacy/confidentiality issues might be a barrier to the deposition of patient data. For example, the current genomic data sharing plans, that attempt to include patient consent for future data sharing, have proven difficult to implement because of these concerns. ASH recommends that NIH provide a model for how patient data is to be obtained with informed consent about deposition. While outside the scope of the draft data sharing policy, ASH would like to work with NIH in the long-term to address the legal issues regarding the public deposition of patient data.

ASH very much appreciates NIH’s recognition of the effort and costs associated with data deposition and sharing and the supplemental guidance defining possible allowable costs. However, the draft policy is not clear about where the resources will come from to collate, submit, and store all of these data. Furthermore, the guidance only addresses those costs incurred during the term of the award but does not address costs associated with long-term data retention, stewardship and accessibility. Additional information and guidance from NIH on these points are recommended.

Finally, an important addition to the guideline would address the difficulty of depositing or using data in central repositories such as dbGaP. We feel that a commitment on the part of NIH to make central repositories more user-friendly would be an important addition to the NIH data sharing policy and would enhance acceptance of the final data sharing and management policy by our members.

Thank you again for the opportunity to submit comments. Please contact Suzanne Leous, Chief Policy Officer (sleous@hematology.org or 202-292-0258) if ASH can provide additional expertise as the data sharing and management policy is finalized.

Sincerely,

A handwritten signature in black ink, appearing to be 'S. Lee', written in a cursive style.

Stephanie J. Lee, MD, MPH
President