forms should not be excluded even though they may contain personnel and medical information of which a disclosure would be an unwarranted invasion of personal privacy. Instead, ACRL encourages NIH to include case reports,other medical records, or data containing PII in the definition of scientific data and clearly note that researchers should share them in accordance with federal policy and other best practices (e.g., HIPAA, restricted sharing, aggregation to a level that will reduce the possibility of disclosure).

ACRL also requests that NIH reconsider the exclusion of laboratory notebooks, as their exclusion is in tension with Section V, Part 1.2 of the Proposed Provisions, which states that the DMP must:

> *Describe any other information that is anticipated to be shared along with the scientific data, such as relevant associated data, and any other information necessary to interpret the data (e.g., study protocols and data collection instruments).*

should consider requiring that the Data Management Plan address how laboratory notebooks will be managed and how the information contained within them will be shared.

II. The requirements for Data Management and Sharing Plans.

An NIH requirement for a Data Management and Sharing Plans at all funding levels would be a new requiremen
Implementation Guidance
(https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm). The expansion to include all funding levels, wholly or partially funded by NIH, helps bring NIH in closer alignment with other federal agencies and creates a more comprehensive treatment of data in the funding landscape. A new NIH Data Management and Sharing Policy based on the proposed revisions has the potential to clarify the importance of the data management and sharing by creating mechanisms to ensure that researchers follow it.

Part V provides the potential for stronger compliance and enforcement mechanisms, although it may be worthwhile to consider how the data management and sharing plan compliance could be integrated into eRA Commons and MyNCBI, to create a similar workflow as exists for publication public access compliance via PubMed Central. Moreover, ACRL encourages NIH to provide the guidance for making data shareable via the NIH Data Catalog, or available via PMC and linked to any published articles. Providing guidance and low-burden interfaces to researchers will help adoption of NIH-supported public access methods, which should reinforce the parameters laid out in this proposal.

y manner for

NIH policy would establish requirements for responsible management and sharing. We suggest that any policy NIH creates should have a clear defini

interpretations by the community. Looking to other federal agencies for precedent, directorates across NSF have dictated the embargo periods in the data management plan guidance.

Within the Proposed Provisions (Section IV), NIH suggests that Data Management Plans (DMPs) remain an Additional Review Consideration. Although this is one method for considering DMPs, because Additional Review Considerations are not individually scored and do not influence the overall score, ACRL encourages NIH to consider designating the DMP as Additional Review Criteria and incorporating review of the DMP in the overall impact score. Failing that designation, ACRL encourages NIH to expand upon when and to what degree this integration would be appropriate.

A well-conceived and well-described DMP requires significant investment of time for grant applicants and conveying such may well require more than the proposed limit of two pages. Although this could be required at the time of submission, it would be more reasonable to require the detailed DMP as a condition and term of the award. A detailed DMP required at the time of award would outline specifics that would be incorporated into the terms and conditions, and NIH could

Relatedly, it is impossible to predict changes in technology standards over the life of a research grant. ACRL suggest that NIH explicitly allow the DMP to be revised as part of the annual report process. This would ensure that researchers are following the most up-to-date standards and increase the appropriate and successful preservation of data.

include a stronger statement requiring the inclusion of scripts and require a justification from the researchers as a decision to use non-open source sofs1 .5 the ggee(rs )-7(a)ri3rg 0.02446 2o46 9[thwET EMC /P <