# Yale University Open Data Access (YODA) Project
# Response to Major Public Comments

The YODA Project would like to thank all individuals and groups that submitted comments on the Draft Policies and Procedures to Guide External Investigator Access to Clinical Trial Data. All comments were closely reviewed and several major themes were identified. The YODA Project's responses to each of these major themes are provided below. The YODA Project seeks to continually improve its policies and procedures, and thus may modify them in the future based on experience.

## MAJOR THEMES ELICITED DURING PUBLIC COMMENT ON DRAFT POLICIES AND PROCEDURES

### *Clarity on scope of available trials*

Commenter(s) voiced concern that the current policy language suggests that Data Holders with whom the YODA Project is working to facilitate access to clinical trial data will not be required to proactively define which trials are available. As data sharing efforts are increasingly undertaken, it has become clear that there are legal and regulatory considerations that must be considered by Data Holders in order to determine if they have legal and ethical rights to make the data available to external investigators for scientific purposes. For this reason, while a clear "list of available trials" is not yet publicly available, the YODA Project will work with Data Holders to proactively identify trials that will be available, using the parameters set forth in Section 1: Data Availability from Data Holder of the YODA Project Procedures. As trials are identified for potential external use, a "list of available trials" will be posted on the YODA Project website.

In response to this comment, and to ensure that complete Data Requests are not submitted for trials that are not able to be made available due to legal and regulatory considerations, we have modified the YODA Project Policies and Procedures to allow researchers to submit brief inquiries about the availability of clinical trial data not included on the "list of available trials" posted on the YODA Project website.

### *Absence of a requirement for a lay summary of research proposals*

Commenter(s) voiced concern that the Data Request requirements do not include submission of a lay summary, suggesting that this requirement may be valuable to ensure transparency and confidence in how data are being re-used. Among the parameters set forth in Section 2: Data Access Request Requirements of the YODA Project Procedures is the submission of a research

proposal, which includes project specific aims, main and secondary outcomes of interest, and statistical analysis plan that describes the methods to be used to address each of the research questions proposed, as well as a timeline and publication plan.

In response to this comment, we have modified the YODA Project Policies and Procedures so that the research proposal will also require the inclusion of a scientific abstract and a narrative summary written in lay language.

***Research team qualifications***

Commenter(s) voiced concern that the Data Request requirements do not include a requirement for a statistician as part of the research team. The YODA Project has considered this comment and concluded that a biostatistician is not necessary to ensure integrity of the analyses. We expect that many early stage clinical investigators and pre- and post-doctoral trainees will request access to clinical trial data in order to pursue scientific research that may advance science or lead to improvements in individual and public health and healthcare delivery, and many other investigators who work independent of biostatisticians have the skills to appropriately conduct their proposed analyses.

***Steering Committee members***

Commenter(s) voiced concern about the identity of the YODA Project Steering Committee members. The YODA Project Steering Committee is an independent group of leaders in the fields of clinical research and biomedical ethics convened by the YODA Project to provide guidance. These members will continue to serve on the committee for the duration of the project, per their discretion. The names, credentials, and affiliations of the Steering Committee members are available on the YODA Project website: http://medicine.yale.edu/core/projects/yodap/steering_committees.aspx.

***External review criteria***

Commenter(s) voiced concern about the criteria for escalation of a data request to External Review. The External Review is intended to solicit feedback from the YODA Project Steering

Committee and other independent experts in the field if the YODA Project is unable to verify the scientific merit of the proposal or if it is unclear whether the data requested will be used to create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health. In such an instance, reviews will be solicited from investigators with sufficient clinical expertise in the broader scientific community who are unaffiliated with the Data Holder or the YODA Project to help the YODA Project better understand the proposed use of the data by the requestor. However, there are no other explicit criteria that will be used to guide requests for External Review. Importantly, any reviews from external investigators or the YODA Project Steering Committee and the YODA Project's decision to grant or deny data access will be publicly posted, so that the public can evaluate how often the YODA Project is soliciting External Reviews and the outcome of these solicitations.

***Impact of the Due Diligence Assessment***

Commenter(s) voiced concern about the following requirement: "Requests for data that are not already available in a secure Safe Harbor (data sharing) platform will undergo a Due Diligence Assessment by the Data Holder," suggesting that this assessment will impact the YODA Project's final decision on whether to grant access to data. The purpose of the Due Diligence Assessment is for the Data Holder to provide the YODA Project with an assessment of its ability to make the data available to be shared externally, in line with the parameters set forth in Section 1: Data Availability from Data Holder of the YODA Project Procedures. While this assessment will include the resources required, its main purpose is to review the Data Holder's legal and regulatory considerations in order to determine if they have legal and ethical rights to make the data available to external investigators for scientific purposes. In response to this concern, we have modified the YODA Project Policies and Procedures to explain that the resource estimation is only one factor of the Due Diligence Assessment and is intended to provide education and information for future data sharing efforts.

***Difficulty of determining research for non-commercial purpose***

Commenter(s) voiced concern about the following requirement: "The requested data will not be used in pursuit of litigation or for commercial interests," suggesting that the definition of commercial purpose or litigation may be vague. In response to this concern, we have modified the YODA Project Policies and Procedures such that data requestors will be required to attest

that the requested data will not be used in pursuit of litigation or for commercial interests both when submitting a Data Request and when signing the Data Use Agreement.

***Protecting patient privacy***

Commenter(s) voiced concern that the policy does not explicitly state whether potentially identifiable information contained within shared documents is redacted. Among the parameters set forth in Section 1: Data Distribution of the YODA Project Procedures is the provision that all relevant clinical trial data will be appropriately de-identified or redacted to protect patient privacy.