The YODA Project Data Request Review Process

**START**
YODA Project receives Clinical Trial Data Request*

- Request for CSR Summary only
- Request sent to Data Holder to prepare
- Request fulfilled

**YODA Project Performs Review**
- Complete registration information and COI forms
- Proposal has scientific merit, including intention to use the data to inform science and public health

- Scientific Merit is Unclear
  - Review materials posted

- Request has Clear Scientific Merit
  - Review materials posted

**Data Holder Performs Due Diligence Assessment**
- Assess the state of data requested (e.g., are data in an electronic format?)
- Partner considerations
- Informed consent considerations
- Estimate the resources needed to redact CSR(s) or de-identify IPD

- YODA Project reviews Data Holder’s Due Diligence Assessment
  - Review materials posted

- Data are unable to be shared externally
  - YODA Project Does Not Approve
  - Request Not Approved - Decision Posted - END

- Data are able to be shared externally

**To External Review**

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*Inquiries regarding data availability can be submitted to the YODA Project prior to the submission of a full Data Request*
The YODA Project
Data Request Review Process

External Review
- YODA Project solicits two independent peer reviews to assess scientific merit, including public health importance
- Steering Committee Member(s) review review

Data Holder redacts CSR(s) and/or de-identifies IPD

Request Fulfilled
- Decision Posted
- END

End

External Review
- YODA Project and at least one Steering Committee member discuss reviews

Scientific Merit is Unclear

YODA Project Consolidates and Reviews:
- YODA Project Review finding
- Data Holder’s Due Diligence Assessment
- External Review finding (if applicable)

Review materials posted

Request has Clear Scientific Merit

Data are able to be shared externally and request has scientific merit

YODA Project Approves

Data are able to be shared externally but request does not have clear scientific merit

YODA Project Does Not Approve

Request Not Approved
- Decision Posted
- END

Request has Clear Scientific Merit

Data are able to be shared externally and request has scientific merit

YODA Project Approves

Data are able to be shared externally but request does not have clear scientific merit

YODA Project Does Not Approve

Request Not Approved
- Decision Posted
- END