

Data Sharing and Privacy and Consent Implications for the Collaboratory:

Background



HEAL Initiative Additional Requirements (Terms in NOA)

- **Declaration of Exceptional Circumstances (DECs)**
 - This award is funded through the NIH HEAL Initiative (<https://www.nih.gov/researchtraining/medical-research-initiatives/heal-initiative>).
 - The requirements here include but not limited to **reporting requirements and data sharing** ... due to the need to respond to the national opioid public health crisis
 - NIH intends to maximize the availability of publications and the sharing of underlying data for NIH HEAL Initiative supported research projects
 - Award recipients are expected to cooperate and comply with all NIH data sharing including ... central data sharing platform requirements developed for this public health emergency during the project period



HEAL Initiative Additional Requirements (Terms in NOA)

- **Participation in Annual Investigator Meetings**
 - The NIH HEAL Initiative will require a high level of coordination and sharing between investigators.
 - It is expected that NIH HEAL Initiative awardees will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings
- Next annual Virtual HEAL Investigators Meeting to be on **May 17-19, 2021**
 - Principal Investigators- attend with at least one per award attending



HEAL Initiative Additional Requirements (Terms in NOA)

- **HEAL Central Data Sharing Platform Requirements**
 - The award recipient and its collaborators must comply with all NIH HEAL Initiative Data Sharing policies established during the project period.
 - Compliance with the NIH HEAL Initiative central data platform requirements and timelines developed through the HEAL consortium.
 - Expected that all data collected by award recipients and their collaborators, as part of the NIH HEAL Initiative, will be shared with the NIH HEAL Initiative central data platform.
 - All data collected as part of the NIH HEAL Initiative are so collected under a Certificate of Confidentiality and entitled to the protections thereof.
 - Institutions who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative...



HEAL Initiative Public Access

- Given the urgency of this crisis, as highlighted by the declared public health emergency, rapid availability of Publications and the primary data behind them promotes dissemination of new knowledge, enhances reproducibility and accelerates the ability of researchers to build upon NIH HEAL Initiative research to make new discoveries.
 - NIH HEAL Initiative Research Projects are required to submit a Public Access and Data Sharing Plan that
 - 1) Describes their proposed process for making resulting Publications and, to the extent possible, the Underlying Primary Data immediately and broadly available to the public or
 - 2) If applicable, provides a justification to NIH if such sharing is not possible. Underlying Primary Data should be made as widely and freely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data.
- <https://heal.nih.gov/about/public-access-data>



HEAL Initiative Public Access

- The Public Access and Data Sharing Plan should, at a minimum, address the following general elements:
 - Release of Publications
 - How publications will be made **immediately** available to the public
 - The methods through which the public, including other researchers, will locate and access the publication
 - Any anticipated limitations to the immediate and broad release of publications with an associated justification
 - Sharing of Underlying Primary Data
 - The type of data that is expected to be generated by the research
 - The data that will be shared
 - Who will have access to the data
 - The timing and the medium for immediate sharing of the data
 - The methods through which the public, including other researchers, will locate and access the data
 - Any anticipated limitations to the immediate and broad sharing of data with an associated justification



HEAL Initiative Data Sharing

- Must think about this now!
- Informed consent documents must describe the data sharing aspect of the HEAL Initiative
 - Per the public access policy:
 - “Before submitting Underlying Primary Data, Awardees through their institutional review boards (IRBs), privacy boards, or equivalent bodies will assess the informed consent materials to determine whether the Underlying Primary Data may be shared as contemplated in this Policy.”
- <https://heal.nih.gov/about/public-access-data>

