

# ***Forum on Data Sharing***

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# Scope

## *Regulatory & Standards Requirements:*

- *Requirements for data sharing: NIH & Others*
- *Data quality/data standards*

## *Ethical Issues on concerns regarding:*

- *Privacy and security issues – concerns and potential barriers to progress/innovation*
- *Potential harmful uses (related to privacy)*

## *Other ethical concerns for IRB*

# Key Themes

- *Legal Landscape*
  - *Requirements regarding data sharing: NIH & Others*
  - *Gaps / Differences in regulations and practices in Human Subject Research*
  - *Data standards*
- *Concerns about tools commonly used to protect privacy*
  - *Broad Consent*
  - *De-identification*
  - *Privacy & Security in Health (Big) Data*
- *Data Sharing Policy & Management*  
*(Preventing/Limiting/Redressing about harms)*
  - *Collection & Access & Release*
  - *Governance: Control & Transparency*

# ***Key Themes***

- ***Requirements Regarding Data Sharing : NIH & Others***
- ***Ethics & Regulations Regarding: Human Subject Research vs. Data Research***
- ***Broad consent***
- ***Protection of identification: HIPAA, FERPA & others***
- ***Ethics of Data Science (Big Data)***
- ***Data Sharing Policy & Management***
- ***Standards for FDA Data Sharing: CDISC***