Ethical and Human Subjects Considerations for Data Sharing in IS

Scott Fisher
Director – NYU IRB

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CONSENT

From whom?
- Subjects
- Research sites?

About what?
- Identifiability
- Sharing with whom
- Risks of sharing
- Optional or required
- Commercial use
- Withdrawal (limitations)

What if?
- Data misused
- Consent too limited
- Consent not obtained
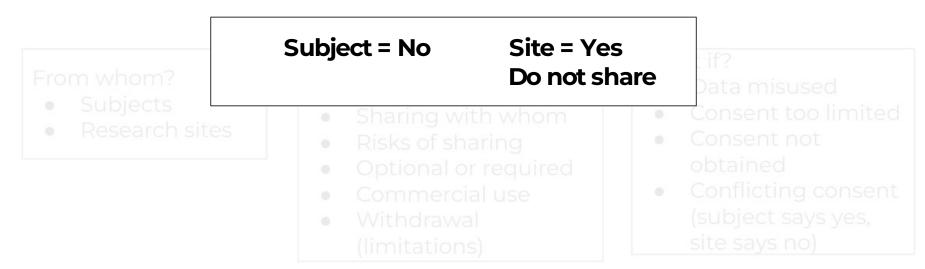
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CONSENT

Subject = No   **Site = Yes**
Do not share

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...if?
- Data misused
- Consent too limited
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- Conflicting consent (subject says yes, site says no)

CONSENT

Subject = No	**Site = Yes** **Do not share**

From whom?
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- Research sites

- Sharing with whom
- Risks of sharing

(limitations)

What if?
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Subject = Yes	**Site = No** **????**

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CONSENT

Identifiability
1. **Certificate of Confidentiality**
2. **Common Rule**
3. **EU GDPR**
4. **HIPAA**
5. **FERPA**
6. **Research subjects?**
7. **Research sites?**

From whom?
- Subjects
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Optional or Required

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Funding Proposal/DMS Plan

- Investigators
- Research Administrators
- Funder

Data Sharing Process

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Funding Proposal/DMS Plan

- Investigators
- Research Administrators
- Funder

- *IRB?*
- *Repository/data receiver?*
- *Contracts office?*
- *Research site?*

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Data Sharing Process

Funding Proposal/DMS Plan	**IRB Review**

• Investigators • Research Administrators • Funder	• Investigators • Research Administrators • IRB

- *IRB?*
- *Repository/data receiver?*
- *Contracts office?*
- *Research site?*
- *IT/Data services*

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Data Sharing Process

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Data Sharing Process

Funding Proposal/DMS Plan	IRB Review	Data Collection
• Investigators • Research Administrators • Funder	• Investigators • Research Administrators • IRB	• Investigators • Research Subjects
• *IRB?* • *Repository/data receiver?* • *Contracts office?* • *Research site?* • *IT/Data services*	• *Repository/data receiver?* • *Funder?* • *Research site?* • *IT/Data services*	

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Data Sharing Process

Funding Proposal/DMS Plan	IRB Review	Data Collection	Data Sharing
● Investigators ● Research Administrators ● Funder	● Investigators ● Research Administrators ● IRB	● Investigators ● Research Subjects	*Data Owner* ● Investigators ● Contracts ● IT/Data Service *Data Repository* ● Curator ● Contracts ● IT/Data service
● *IRB?* ● *Repository/data receiver?* ● *Contracts office?* ● *Research site?* ● *IT/Data services*	● *Repository/data receiver?* ● *Funder?* ● *Research site?* ● *IT/Data services*	● *IRB?* ● *Research site?*	*Data User/Receiver* ● Investigators ● Contracts ● IT/Data services

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Data Sharing Process

Funding Proposal/DMS Plan	IRB Review	Data Collection	Data Sharing
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Data Sharing (continued)

Data User/Receiver
- Investigators
- Contracts
- IT/Data Services

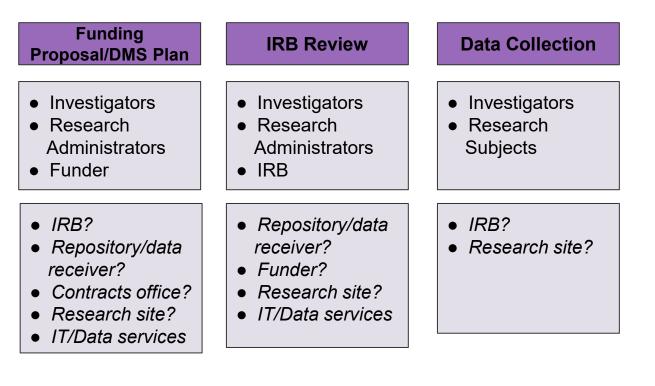| Funding Proposal/DMS Plan	IRB Review	Data Collection	Data Sharing
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Data Sharing Process

Certificate of Confidentiality vs. DMS Policy

Individual Risk vs. Social/Group Risk

Quality/Standardized Data vs. Just/Inclusive Data

Researchers vs. Subjects/ Communities

Compliance vs. Ethics

Some tensions...?

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