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INFORMED CONSENT FOR DATA SHARING

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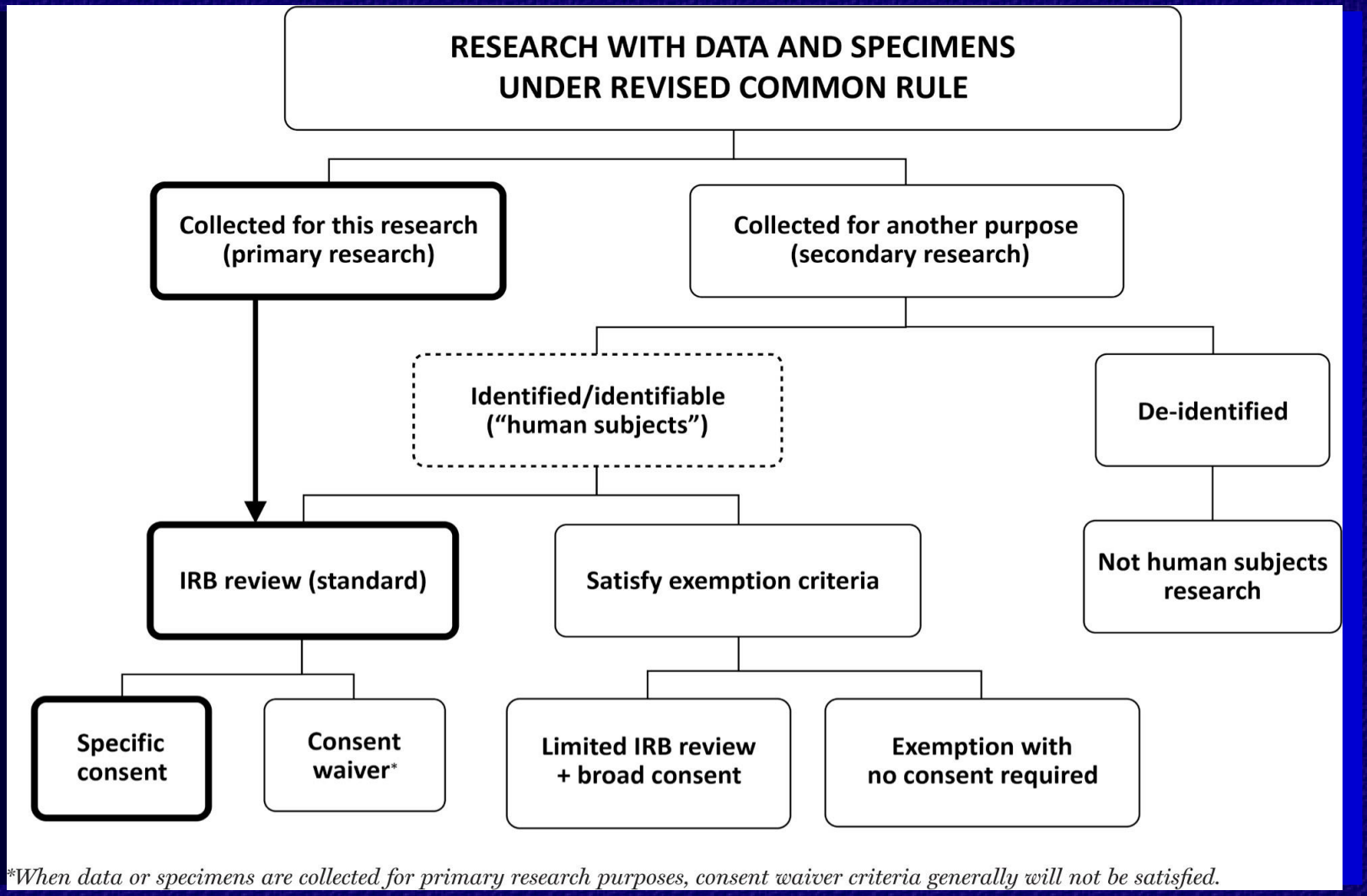
OUTLINE OF THIS TALK

- *Consent for Secondary Research*
- Deidentified Data
- Big Data
- Consent Bias
- Unregulated research
- *Recommendations*

CONSENT FOR SECONDARY RESEARCH



Source: H.F. Lynch, L.E. Wolf, and M. Barnes, Implementing regulatory broad consent under the revised Common Rule: Clarifying key points and the need for evidence. Journal of Law, Medicine& Ethics 47(1) (2019): 213-231, 221.

DEIDENTIFIED DATA

NIH: “Researchers should consider whether access to scientific data derived from humans, even if deidentified and lacking explicit limitations on subsequent use, should be controlled.”

Concerns about the use of deidentified data and specimens:

1. Reidentification
2. Group harms
3. Objectionable uses
4. Commercial exploitation
5. Undermining trust

BIG DATA RESEARCH

Definition: Big data is the collection, linkage, and analysis of disparate data sets that, taken together, may identify unusual trends.

- It is an important element of many large data research projects including NIH's All of Us research.

- Identifiable data sets may be linked with publicly accessible information, such as:
  - Vital statistics of family members
  - Military service records
  - Employment records
  - Financial and consumer information
  - Educational records
  - Travel information and geo-location data
  - Social media postings
  - Government records

Should these possible uses by third-party researchers be disclosed in the informed consent process?

CONSENT BIAS

Definition: A type of selection bias when those who consent to participate in research differ from those who decline to participate.

- Some researchers might assert that new consent requirements (e.g., data management and sharing) will increase consent bias.
- Unrepresentative sample ≠ biased sample.
- Common statistical techniques can adjust for selection bias.

UNREGULATED RESEARCH

- Research not subject to Common Rule or FDA research regulations.

Includes research by independent or self-funded researchers, citizen scientists, patient-directed researchers, DIY researchers, and self-experimenters.

- Growth has been fostered by:
  - Traditional research is seen as slow, expensive, unresponsive, and dominated by commercial interests.
  - Social media, crowdsourcing, and online communities facilitate collaboration.
  - DTC genetic testing, open-source data, and smartphone apps lead to vast troves of data.
- Should all researchers have access to NIH-mandated data sharing?

  If so, what, if anything, should be included in the consent?

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RECOMMENDATIONS

- Consent requirements should be flexible because of the variety of research subjects and methodologies, types and sensitivities of data, and characteristics of participants.
- Consent requirements should balance the need for disclosure to enable decision making with concerns about overwhelming or discouraging participants.
- Consent requirements should recognize the importance of researchers' asking for consent and pledging certain protections to potential participants.

References

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