Consent Processes for Longitudinal Research with 'Rich" Behavioral & Biospecimen Data from Multiple Family Members

Workshop on Proposed Revisions to the Common Rule in Relation to the Behavioral and Social Sciences

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Board on Behavioral, Cognitive, and Sensory Sciences

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CONSENT PROCESS & SPECIAL POPULATIONS

My research focus:

- > 30 years studying effects of social stress on the emergence and course of depression throughout childhood, adolescence and adulthood

Primary social stressor: Conflict in families & close relationships
- Adolescents (14 – 17 yrs) and parents
- Emerging adult (18-19 yrs) dating couples
- Newlywed couples
- New parents, fetus, infant (0 – 12 mths)

Consent Issues Relevant to Type of Data

- "Rich" data with unknown analysis possibilities
    - Biospecimen
    - Behavioral

- Interdependent data involving individuals in relationships

- Longitudinal follow-up

- Risk research: mental health data ranging from subclinical to clinical severity; social & physical development data

Consent Issues Relevant to Special Populations

- Underage subjects
    - Future use when adult
    - Longitudinal follow-up when adult
    - Adolescents with legal adult status

- Emergent clinical disorders

RICH DATA:

Biospecimen or behavioral data, which can be re-coded, re-assayed, or re-tested to yield new information not proposed in the original study.

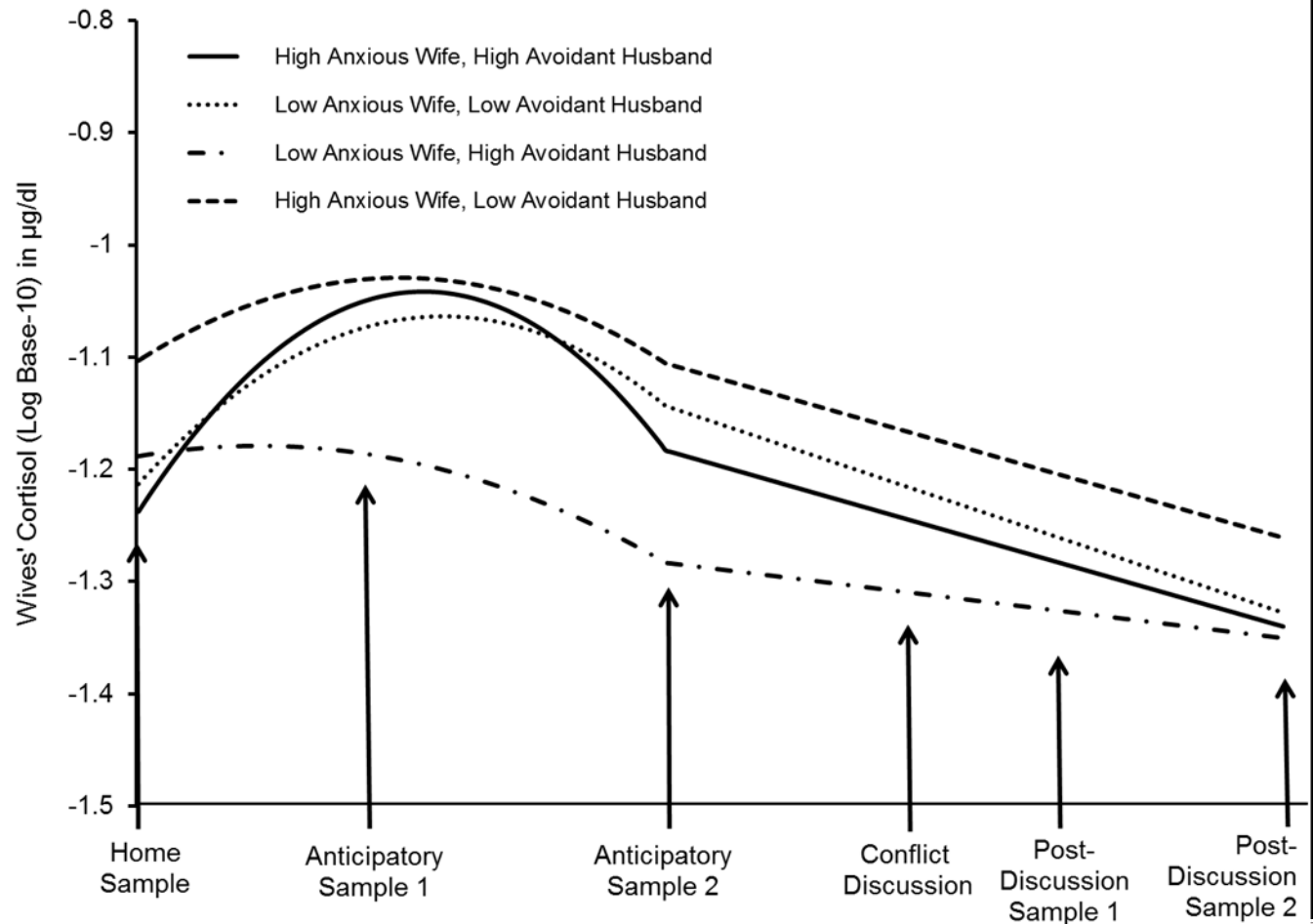Distinct from secondary analysis of large survey datasets, which reanalyze existing coded information.

RICH DATA: SALIVA BIOSPECIMENS

Saliva sampling throughout couple conflict

Interdependent data

Beck et al., 2013

RICH DATA: HAIR BIOSPECIMENS

RICH DATA: CURRENT SALIVA ANALYTES

- 17a-Hydroxyporgesterone
- Aldosterone
- Alpha-Amylase
- Androstenedione
- Beta-Endorphin
- C-Reactive Protein
- Chromogranin A
- Corticotropin-Releasing Hormone
- Cortisol
- Cotinine
- Dexamethasone
- DHEA
- DHEA-S

- DNA analysis
- Estradiol
- Estriol
- Estrone
- Interleukin-1 Beta
- Interleukin-6
- Melatonin
- Neopterin
- Nerve Growth Factor
- Progesterone
- Secretory Immunoglobulin A
- Serum IGF-1
- Testosterone
- TNF-a
- Total Protein
- Transferrin & Blood Cont.

http://www.salimetrics.com/analytes

RICH BIOSPECIMEN DATA:

- **What are the changes being considered for new uses of existing biospecimens?**
    - Current: de-identified biospecimens may be used without re-consent; identified biospecimens require re-consent or prior consent
    - Proposed: Prior consent required whether de-identified or not, but consent is for 'open-ended' use.

- **How might the changes affect my research?**
    - All longitudinal research is identifiable by its nature.
    - We receive prior consent for broad areas of testing, rather than completely 'open-ended' use.
    - Participants are very concerned about open-ended use
    - We, but not participants, can assume that all biospecimens will be identifiable in the future.

RICH BEHAVIORAL DATA:

- Proposed changes address issues with biospecimen data, but should consider identifiable rich behavioral data similarly.

- If behavioral data is not considered, IRB decisions will vary widely from site to site on consent procedures for future use.

RICH BEHAVIORAL DATA: CONFLICT VIDEOS

- Multiple behavioral coding schemes

- Original coding: submission

- Later coding to contrast with a different sample: secure base (attachment behaviors)

RICH BEHAVIORAL DATA: CONFLICT VIDEOS

Working with computer scientists to amplify minute color changes to clearly show and analyze cardiovascular stress reactions to family conflict

RICH BEHAVIORAL DATA

- Do proposed changes for biospecimens work for rich (videotaped) behavioral data?

  - Current: is there a consistent common rule for video data? (Identified biospecimens require re-consent or prior consent)

  - Proposed: Prior consent required whether de-identified or not, but consent is for 'open-ended' use.

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- "Rich" data with unknown possibilities
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- Longitudinal follow-up

- Risk research: mental health data ranging from subclinical to clinical severity; social & physical development data

INTERDEPENDENT LONGITUDINAL DATA

- Do proposed changes address longitudinal follow-up of rich, interdependent relationship data?
  - Current: re-consent is necessary for new data from original participant
  - Unclear: IRBs differ on whether investigators can re-contact participants for new study, using contact info from original study
    - We obtain consent in our original study for follow-up through multiple contact sources (specific friends, parents, online sources)
  - Special case of interdependent data

Consent Issues Relevant to Type of Data

- "Rich" data with unknown possibilities
    - Biospecimen
    - Behavioral

- Interdependent data involving individuals in relationships

- Longitudinal follow-up

- Risk research: mental health data ranging from subclinical to clinical severity; social & physical development data

MENTAL, SOCIAL & PHYSICAL DATA

- Normal life is somewhat uncomfortable.
- Are current 'warnings' appropriate or unnecessarily disturbing, limiting potentially beneficial research?

  - Mental health symptoms
  - Stressful life experiences
  - Adolescent social activities
  - Adolescent pubertal changes

- Minimal risk

Consent Issues Relevant to Special Populations

- Underage subjects
  - Future use when child is an adult
  - Longitudinal follow-up when the child is an adult: Harvard Three Generational Study
  - Adolescents with legal adult status: Prenatal depression in teenage mothers; appropriate access to research and parenting interventions

- Emergent clinical disorders