NCRAD Updates

Biomarker Assay Laboratory

- Mission – Provide reliable and consistent research biomarker results that can be compared through time and across studies to facilitate research on the etiology, early detection and therapeutic development for Alzheimer's disease and related dementias

- Implement core set of blood biomarker assays in a manner to facilitate the consistent and reliable return of research biomarker results
  - Initial Assays: P-tau, NfL, $A\beta_{1-40}$ and $A\beta_{1-42}$
  - Next to be validated: GFAP/NfL 2-Plex assay

Keeping the End in Mind – Research Biomarker Results

- Historical issues that slow implementation and learning from ADRD biomarkers
    - Availability of sample sets and aliquots to enable assay evaluation
    - Performance characteristics of biomarker assays
    - Comparison of research results across labs and platforms
    - Standardization of research results through reference standards
    - Standardization and testing of pre-analytical conditions
    - Quality control and performance testing
    - Selection and implementation of new biomarker assays

- Deliverable: Advance neurodegenerative disease research where standardization of processes and delivery of reliable and consistent research biomarker results can be achieved

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The Need for Standardization and Harmonization of Biomarker Data

- Assays and platforms for Aβ 42/40, P-tau, and NfL are expanding quickly

- Harmonization will improve quality and simplify interpretation of results

- Pooling data across centers will improve characterization of ADRD phenotypes

- Biomarker innovation may be accelerated with harmonized data

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Questions

- NCRAD Project Managers:
  - Kelley Faber: kelfaber@iu.edu
  - Kaci Lacy: lacy@iu.edu

- BAL Coordinator:
  - Clairisa Stayton: cbstayto@iu.edu

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