


Biospecimen Task Force Update

For the ADCs



Membership

- Eileen Bigio – Northwestern
 - Virginia Buckles – Wash U
 - Doug Galasko – UCSD
 - Brad Hyman – Mass Gen
 - Ruth Mulnard – UC Irvine (Chair)
 - Elaine Peskind – U Washington
 - Joe Rogers – Sun Health
 - Julie Schneider – Rush
 - Les Shaw - UPenn
 - Bud Kukull – NACC (ex officio)
 - Tony Phelps – NIA (ex officio)
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Task Force Goal

- Long-term goal – evolve guidelines that capture “best practices” for the ADCs
 - To provide interim guidance for the Alzheimer’s Disease Centers until HHS or the NIH issues agency-wide regulations
 - Our interim document can be modified at that time
 - Create guidelines that are generic enough to allow each Center to operationalize per Center-specific special needs
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Guidelines Developed To Date

- Plasma, Serum and Blood Constituents
 - Cerebrospinal Fluid
 - Brain and DNA/RNA
 - Informatics
 - Informed Consent, Confidentiality, and Privacy
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Review Process for ADC Input

- Draft documents developed by Task Force
 - All guidelines distributed via NACC listservs for 30-day comment period
 - Center Directors
 - Clinical Core Leaders
 - Neuropathology Core Leaders
 - Center Administrators
 - Guidelines re-distributed as 14-day reminder through same listservs
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Who Sent Comments?

- Input received from 15 Centers
 - $15/29 = 51.7\%$ of the Centers
 - Types of comments received
 - Blood Guideline
 - Fasting status – **may be preferred for some studies**
 - Funding for BUN, creatinine measurements – **should be considered if funding permits**
 - Preference for anticoagulant - **optional**
 - Back-up freezer necessity – **to be considered**
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Comments

- Brain, DNA/RNA Guideline
 - Autopsy technician & tissue bank technician
 - Agonal state – at the discretion of the Center
 - Spinal or *ventricular* fluid – cerebrospinal fluid
 - Usefulness of postmortem CSF – optional collection
 - CJD cases should be optional – CJD surveillance program participation is recommended
 - Hepatitis or HIV testing – disclaimer; excluded from donation unless specific research question exists; universal precautions
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Comments

□ CSF Guideline

- Use of 25 gauge needle and withdrawal technique questioned – **used in ADNI; may be considered**
 - Use of recumbent position for 1-hour recovery questioned – **a common clinical practice**
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Comments

□ Informatics

- Documentation should include HIPAA policies - **added**
- Biospecimens may exist in multiple environments - **noted**

□ Informed consent, confidentiality

- Capacity to consent should be assessed as per local IRB guidelines - **added**
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Other Guidelines Under Development

- ❑ Dissemination, Discarding - *draft*
 - ❑ Material Transfer - *draft*
 - ❑ Intellectual Property - *draft*
 - ❑ Cost Recovery - *draft*
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Next and Final Steps

- ❑ October conference call for Task Force to review edits to last 4 guidelines
 - ❑ Revised documents generated
 - ❑ Listserv distribution to ADCs in early November
 - ❑ 30-day comment period
 - ❑ Final conference call to review comments
 - ❑ Final documents generated and posted on NACC website
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We invite your feedback!

- Prompting through the Center listservs
 - PROVIDE FEEDBACK
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