AGENDA

9:30 a.m.  Call to Order
Michael E. Charness, M.D. (Meeting Chair); U.S. Department of Veterans Affairs

9:35 a.m.  Charge to the Panel: What are the goals of the study?
Nora D. Volkow, M.D.; Director, National Institute on Drug Abuse
George F. Koob, Ph.D.; Director, National Institute on Alcohol Abuse and Alcoholism
Joshua A. Gordon, M.D., Ph.D.; Director, National Institute of Mental Health
Matthew W. Gillman, M.D.; Director, Environmental Influences on Child Health Outcomes (ECHO), Office of the Director, National Institutes of Health

10:00 a.m.  Introduction of Expert Panel

10:15 a.m.  Recap of Research Methodologies Expert Panel Meeting
Michael E. Charness, M.D.

10:45 a.m.  Break

11:00 a.m.  Session 1: Bioethical, Legal, Social Service Considerations
Lead: Melinda Baldwin, Ph.D.; Administration on Children and Families
   – Maggie Little, B.Phil., Ph.D.; Georgetown University
   – Dorothy Roberts, J.D.; University of Pennsylvania Law School – by phone
   – Amber Khan, J.D.; National Advocates for Pregnant Women – by phone
   – Anne D. Lyerly, M.D.; University of North Carolina School of Medicine – by phone

Topics for Discussion:
   – Foundational issues:
     • Studies without the prospect of direct benefit must be no more than minimal risk.
       o Risks include social, legal, and psychological
     • Is it ethical to conduct an observational study in populations who lack access to appropriate prenatal care and/or addiction treatment?
       o Are there direct benefits that the study can provide?
       o Can linkage to services be provided?
       o How to address variability in resources/services across sites
- Informed consent and mandated reporting
  - Who can consent for the child? How will this vary throughout the course of the study?
  - Certificates of Confidentiality—what is their scope of coverage?
  - How to work with child protective services (CPS)
  - IRB Requirements (e.g., state/local IRBs when children enter CPS)
- Role of the biological parents in the study
  - Respect for biological mother as a study participant
  - Measures of parental stress, outcomes
  - Parental involvement if child is removed from parental custody

12:30 p.m.  Break to Distribute Lunches

12:45 p.m.  Session 2: Study Design

Lead: Catherine Spong, M.D.; University of Texas, Southwestern Medical Center
- Christina Chambers, Ph.D., M.P.H.; University of California, San Diego – by phone
- Xiaobin Wang, Sc.D.; Johns Hopkins University
- Steve Heeringa, Ph.D.; University of Michigan
- Stephen J. Buka, Sc.D.; Brown University
- Margaret R. Burchinal, Ph.D.; UNC Frank Porter Graham Child Development Institute

Topics for Discussion:
- Study design
  - Prospective, longitudinal; Are there other models?
  - Staggering assessments
  - Intervals between follow-up
  - Planned missingness
- Sampling considerations
  - Size
  - Representative vs catchment areas
  - Diversity (geographic, socioeconomic, race/ethnicity, exposure, maternal age)
  - Stage of pregnancy (or birth) at enrollment
  - Exposure characteristics (timing, types, level)
- Site requirements
  - Pre/post-natal research experience
  - Neuro/psych/development/imaging expertise
  - Engagement, recruitment, retention of high-risk populations
  - Ability to manage high-throughput early in the study
  - Matching of research expertise and service infrastructure in same geographic location

2:15 p.m.  Break

2:30 p.m.  Session 3: Recruitment and Retention of High-risk Populations

Lead: Moriah Thomason, Ph.D.; New York University School of Medicine
- Hendrée Jones, Ph.D.; University of North Carolina at Chapel Hill
- Catherine Monk, Ph.D.; Columbia University
- Amy J. Elliott, Ph.D.; University of South Dakota
- Jane Waldfogel,
- Uma S. Ahluwalia, M.S.W.; Montgomery County Department of Health and Human Services
Topics for Discussion:

- Methods for recruitment - Multimethod approach to reach different populations
  - Home visit programs
  - Opioid treatment programs
  - Provider-based
- Participant engagement
  - Design recruitment & study to bring tangible benefits to participants
  - Situational and cultural sensitivity: flexibility to fit individual participant needs
  - Partnerships (with service providers, community organizations, advocacy agencies, service grant awardees)
- Retention
  - Long-term retention of participants and study staff
  - Use of technology (e.g., provide mobile phones)
  - Assessment burden and interval between assessments
  - Access to administrative data (e.g. Medicaid records, education, justice)

4:00 p.m.  Break/Prepare Summary

4:30 p.m.  What are we missing?
Michael E. Charness, M.D.

5:00 p.m.  Wrap-up
Michael E. Charness, M.D.

5:30 p.m.  Adjourn