



# Protocol/Instrument Development for the NCS Vanguard Study

Ruth Brenner, MD, MPH  
National Children's Study Program Office  
*Eunice Kennedy Shriver* National Institute of Child Health and Human  
Development  
NIH, DHHS

Presentation to the Federal Advisory Committee  
January 24, 2012

# NCS Vanguard Study Goals



- The Vanguard Study is designed to evaluate the
  - Feasibility (technical performance)
  - Acceptability (the impact on participants, study personnel, and infrastructure)
  - Cost (personnel, time, level of effort and money)
- of
  - Study recruitment
  - **Study visits and study visit assessments**
  - Logistics and operations





# Study Visits and Assessments

# Base Data Collections



- Preconception (High Probability)
- First pregnancy (in person)
- Second pregnancy (in person)
- Birth (in person)
- 3 month (phone)
- 6 month (in person)
- 9 month (phone)
- 12 month (in person)
- 18 month (phone)
- 24 month (phone)
- Health Care Logs (Pregnancy and Infancy)



# Expanded Data Collections



- Base data collections
- Two maternal blood and urine collections at first two visits (preconception and 1<sup>st</sup> pregnancy or 1<sup>st</sup> and 2<sup>nd</sup> pregnancy visits)
- Cord blood
- Dust and water collection 1<sup>st</sup> pregnancy visit – initially technician collect, more recently participant collect
- Father interview



# Currently Under Development



- Core interview
- 30 month interview
- Non-interview respondent questionnaire
- Biospecimens at 6 and 12 months
- Physical assessments at 6 and 12 months
- Modifications to a subset of existing instruments
  - Father interview
  - 24 month interview



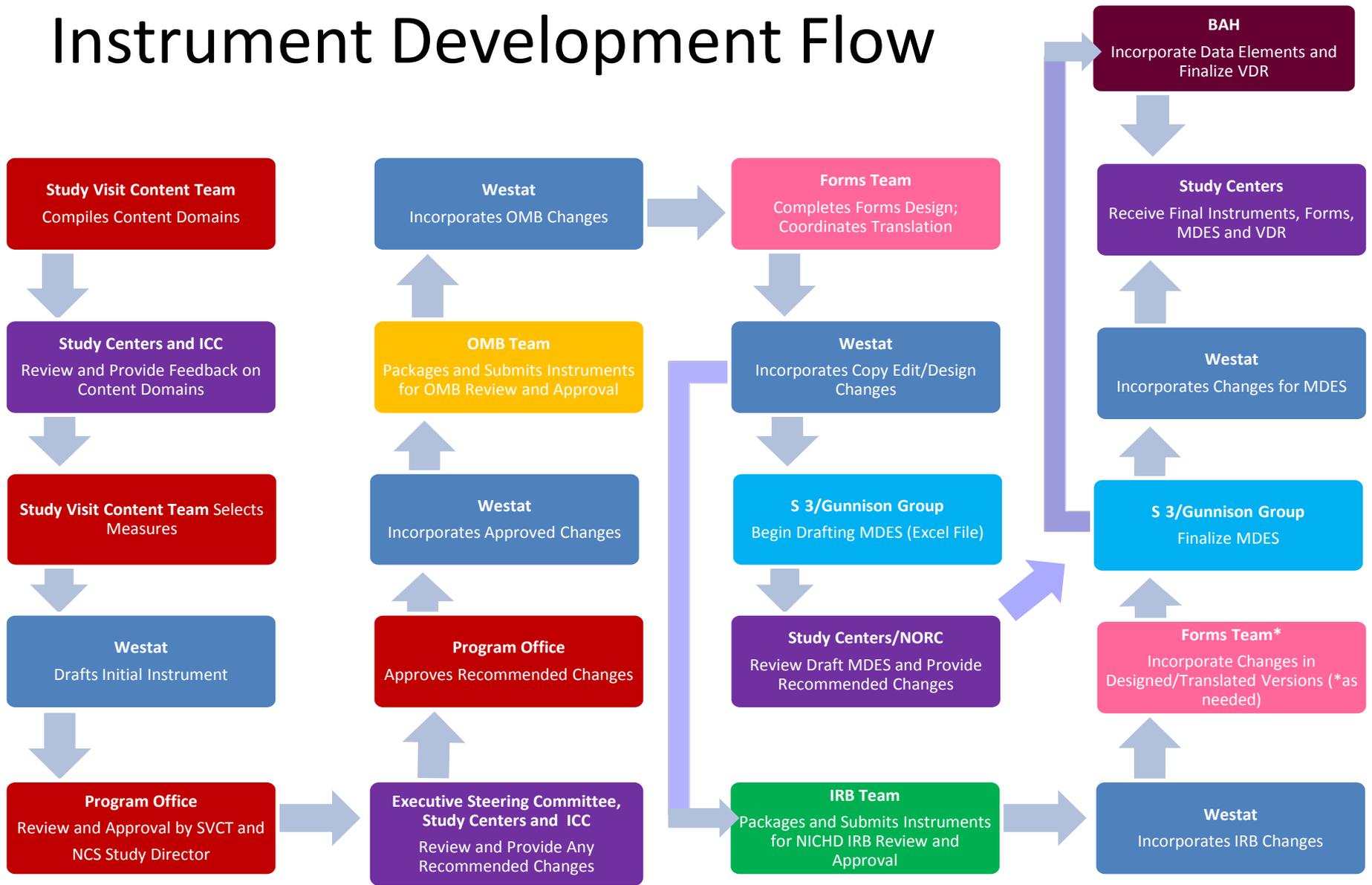
# Overview of Process for Development of Data Collections



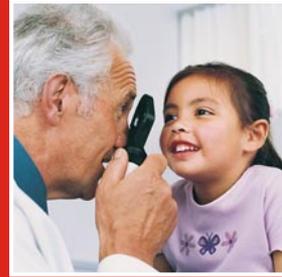
- Development of domains and subdomains by the Study Visit Content Team (SVCT)
  - Review by Study Director, Study Centers, ICC
  - Revisions to domains/subdomains
- Development of data collection instruments by SVCT
  - Review by Study Director, Study Centers, ICC
  - Revisions to data collection instruments
- Regulatory reviews
- Review by the public (included as part of the review by Office of Management and Budget)
- Post approval processing (e.g. design of forms, programming of instruments)



# Instrument Development Flow



# Study Visit Content Team



- Study Visit Content Team
  - Ruth Brenner (general oversight)
  - Mike Dellarco (environmental)
  - Carol Kasten (physical, genetics, medical history)
  - Jack Moye (biospecimens)
  - Christina Park (psychosocial and demographics)
  - Gitanjali Taneja (neurodevelopment, psychosocial, early childcare and education)
  - Julia Slutsman (IRB)
  - Colleen Lee (OMB)



# Guidelines for Proposal of Items for Inclusion in the Questionnaire



- Validated instrument or questions (with known scientific properties)
- Widely used in standard surveys
- Least burdensome
- Analytic utility in relation to other concurrent and longitudinal data collections in the NCS
- Harmonization with other studies, as appropriate



# Sample Guidance: Questionnaire/Measure Proposals



- Name of instrument and source/author
- Copyrighted? If so, cost of the instrument
- Justification for the instrument
- # of question items
- Anticipated administration time
- Reference or other surveys using the instrument



# Current Status of Core and 30 Month Questionnaire Development



- Domains and Sub-domains defined by Program Office
- Reviewed by Study Director and Study Centers
- Changes incorporated
- Questionnaires drafted and posted to Study Portal
  - Review by Study Centers
  - Review by ICC
  - Posted in both a Wiki format and as stand-alone documents
- Comment period of 45 days
- Incorporation of changes
- Public posting around the time of the 30 day federal register notice, as part of OMB review





**Thank You**