

Cooperative Multicenter
Reproductive Medicine Network
RFA HD06-008

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Reproductive Medicine Network (RMN)

- Established in 1990 to conduct large, multi-centered clinical trials
- Areas of interest: reproductive medicine, infertility, reproductive endocrinology
- Began with 6 clinical sites, expanded to 8 in first re-competition
- Currently, 8 clinical sites with 1 DCC



RMN Recent Protocols

- Efficacy of superovulation and IUI: Guzick *et al.*, 1999; Guzick *et al.*, 2001
- Utility of endometrial biopsy in infertility
Dx: November 2004 Fertility and Sterility
- Pregnancy in Polycystic Ovary Syndrome, just completed

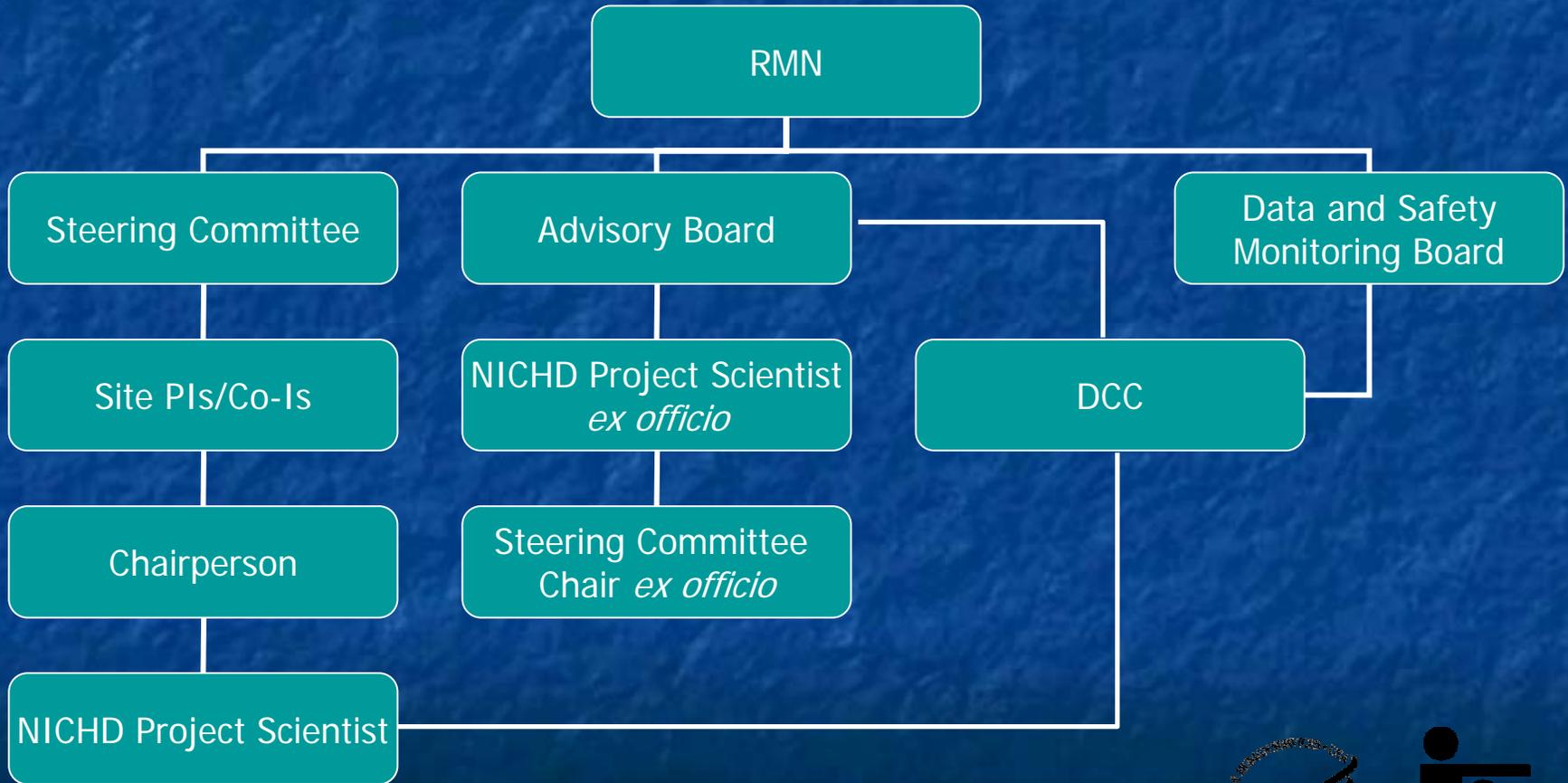


RMN Consultation Committee

- Called by NICHD to review the RMN
- Assessed impact, benefit to field of multi-site clinical network, strategies to advance clinical research in reproductive medicine, role of NICHD
- Final report to IC Director
- New RFA published March 2006



RMN Organization



Network Players

- Principal Investigators/co-Investigators
- NICHD Project Scientist: substantial programmatic involvement
- NICHD Project Officer: normal stewardship
- Grants Management Officer: \$\$
- Branch Chief



Important stuff

- U10 Cooperative Clinical Research
- \$6.6 million for FY 2007
- 8-10 clinical sites, 1 DCC
- Letter of intent: August 25, 2006
- Application due date: September 25, 2006
- Review: February/March 2007
- Council: June 2007
- Earliest start: July 2007



Application

Who's eligible?

- Institutions: no foreign; current members of the RMN; prospective members
- Individuals: those with skills, knowledge, resources; clinician for clinical sites; expert in biostatistics, clinical study design, data analysis, etc... for DCC PI



Application—DCC Scope

- Study Design, Conduct, Analyses, Pubs
- Data Management
- Site Monitoring
- Regulatory
- Committee management



Application—DCC requirements

- Successful past performance
- Staff expertise and capability
- Data management and communications capacity and ability
- Reporting/publication
- Logistical support experience
- Monitoring and management capability



Application—DCC budget

- Network managed with a capitated budget
- Core costs: personnel, admin costs, etc...
- Protocol initiation costs
- Protocol support costs



DCC Budget—con't

- Core costs
 - PI—50% effort
 - Administrative costs—staff salary
 - Site and data management costs
 - Statistical support costs
 - IT costs (web site development, etc...)
 - Committee management expenses
 - Travel



DCC Budget—con't

- Protocol initiation costs—assume 1-2 active trials, one is RCT
 - Protocol manual
 - Developing data forms and questionnaires
 - Recruitment materials
 - Database structures



DCC Budget—con't

- Protocol support—assume 1-2 active trials, one is RCT
 - Pharmacy
 - Drug costs
 - Data entry and analysis
 - Quality control
 - Manuscript preparation



DCC—Budget, con't

- 1st year: \$500,000 in directs, assume development of at least one protocol
- Out-years: \$2 million in patient care category for approved protocols—final amount TBD
- \$2 million managed by DCC and distributed to clinical sites when protocol(s) approved and subjects enrolled



Clinical Sites--scope

- Identify priority areas of research
- Develop and implement protocols
- Recruit/enroll subjects
- Collect/transmit data to DCC
- Data analysis
- Manuscripts/presentations



Clinical Sites--requirements

- Principal Investigator: physician with clinical expertise in reproductive medicine in women and/or men (20% effort)
- Co-Investigators
 - Ph.D. biostatistician/epidemiologist (10% effort)
 - Clinical expert in opposite gender (10% effort)



Clinical Sites—requirements, con't

- Institutional environment
- Additional staff: nurse coordinator, lab facilities, imaging services
- Department/institutional commitments
- Access to adequate patient population
- New applicants—experience in RCTs
- Competing—RMN participation



Concept Protocol

- Required of both new and competing continuation applications
- One study—10 pages maximum
 - Background and significance
 - Objectives
 - Study design
 - Data analysis
 - Power analysis



Dickey-Wicker proscriptions

- Funds may not be used to support human embryo research
 - No invasive procedures
 - No research on eggs that have been exposed to sperm
 - No harm or destruction of embryos



What is allowable under Dickey-Wicker

- Research on eggs that have not been exposed to sperm
- Noninvasive studies on discarded culture medium
- Noninvasive microscopy
- Noninvasive assessments
- Retrospective analyses not *a priori* excluded



Clinical Sites--Budget

- Base budget--\$200,000 directs
 - PI: 20% effort
 - Co-Is: 10% effort each
 - Research Coordinator: 100% effort
 - Program Assistant: 25% effort
 - Travel: 4 trips/year
 - Supplies and advertising for protocol recruitment



Clinical Site--Budget

- 3% escalation for out-years
- On-going annual budget based on individual protocols
- Funds disbursed from DCC on a per subject basis



Review process

- Applications will be reviewed by the NICHD through the Division of Scientific Review
- Reviewers recruited through DSR
- Review criteria for DCC and Clinical Sites listed in RFA



Cooperative Responsibilities

- Principal Investigator
 - Member of Steering Committee
 - ID areas of research, develop protocols and implement
 - Transmit data to DCC
 - Analyze and publish findings

All cooperatively with NICHD staff, Advisory Board and DSMC; each site has one vote in Steering Cmte



Cooperative Responsibilities

- Data Coordinating Center
 - Statistical leadership
 - Centralize and standardize data
 - Logistical services to RMN clinical sites
 - Prepare DSMC reports
 - Committee management
 - Regulatory compliance

DCC PI will have one vote on the Steering Committee



Collaborative Responsibilities

■ NICHD

- Technical assistance, advice and coordination
- Protocol review and comment
- Management and technical performance advice
- Acquisition of resources
- Liaison/facilitator between pharma and other government agencies

NICHD Project Scientist will have one vote on the Steering Cmte



For more information

- RMN RFA:

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-06-008.html>

- RFA FAQs:

<http://www.nichd.nih.gov/about/cpr/rs/workshops.htm>



For more information

- Review questions: Dr. Robert Stretch, stretchr@mail.nih.gov
- Programmatic questions: Dr. Tracy Rankin, rankint@mail.nih.gov
- Financial/budget: Ms. Cecilia Bruce, bruceec@mail.nih.gov

