



# OAI Ancillary Studies, Biospecimen Access and Application Procedures

Gayle E. Lester, Ph.D.

Project Officer, The Osteoarthritis Initiative  
2007 World Congress on Osteoarthritis

December 6, 2007

Fort Lauderdale, FL USA



# Current NIH Opportunities

---

- Submission of “unsolicited” grants to NIH for use of OAI data or additions to OAI as ancillary studies
  - Data/image use with or without OAI investigator collaborations
  - Additions to existing protocol require coordination with OAI investigator
  - Reviewed at NIH study sections
  - Currently we have 4 active NIH-supported grants that interact with OAI

# Existing Ancillary Studies

---

- Medial-lateral “thrust” and risk of knee OA
  - Dynamic laxity during walk by observation
  - Primary outcomes: cartilage loss and meniscal damage
  
- Does static malalignment modify risk factors for knee OA?
  - Measurement of alignment from full limb films in Progression and Incidence cohorts
  - Primary outcomes: cartilage loss and incident OA

# Existing Ancillary Studies

---

- Bone changes and knee OA
  - DXA and high resolution MRI measures of periarticular bone, vitamin D
  - Primary outcome: cartilage loss
- Does physical activity reduce disability due to knee OA? – pending support
  - Physical activity measured by accelerometer
  - Primary outcome: disability

# Future NIH Opportunities

---

- Program Announcements
  - Use of image and/or clinical data by Investigators
    - Broad purposes related to OA outcomes
    - Development of algorithms for image analysis
    - General use for analysis of change over time
    - Identification of imaging biomarkers
  - Use of image and/or clinical data by US-based small businesses and/or academic center + US-based small business consortia
    - Development of algorithms for image analysis
    - Identification of imaging biomarkers

# Other OAI Activities Underway

---

- Efforts are underway to
  - To possibly extend follow up of OAI cohort for additional years (through 2015)
  - To make imaging data available in real time and easy for downloading
  - To link clinical data to imaging data for easy access to selected data sets

# Rationale for OAI Cohort Follow up

---

- To allow accrual of more incident cases among unaffected participants that can be linked/related to imaging and biochemical markers from prior visits and
- To follow affected individuals in progression cohort to total joint replacement or the clinical equivalent and identify predictive markers of these outcomes and
- To provide information on the relationships between osteoarthritis of the knee, other co-morbidities and outcomes.

# Ideas for Related Ancillary Studies

---

- Laboratory gait analysis of subsets of individuals
- dGEMRIC or ultrasound for assessment of synovitis in those with effusions
- T1rho or other assessments of early cartilage loss
- High resolution MR or multislice CT scans for trabecular bone in early OA
- Measure selected biochemical markers and other analytes



# Access to Biospecimens

---

- ❖ Biospecimen Review and Allocation Committee (BRAC) is being established
- ❖ Announcement will be made on NIAMS web site and emails sent to all registered OAI data users
- ❖ Proposals will be accepted three times per year for review by BRAC
- ❖ Priority given to longitudinal use of urine and serum but DNA more available

# Access to Biospecimens

---

- ❖ Application forms will be posted on OAI Online web site

<http://www.oai.ucsf.edu/datarelease/>

- ❖ Review criteria include statistical design, characteristics of proposed biomarker, efficient use of specimens, etc.
- ❖ Requirements for data generated to be made public within 6-12 months after analyses completed

# Other NIAMS OAI Related Efforts

---

- Possible OAI-related Meetings
  - OA and knee imaging
    - Imaging Based Measures in OA meeting
      - *Summer 2008 in Boston, MA USA*
  - Exploration of Risk Factor Data from OAI & Other Recent OA Studies
    - Small workshop to evaluate risk factors
    - Precedes CDC/AF meeting in 2008/9
  - Workshop on Genetics of OA
    - Need for and design of OA genetic cohorts
    - Tentative plans for 2009