

# Changes in the IRB Processes – Coming Now and in the Future

CRRO Seminar Series

October 22, 2014

IRB Staff

# Intro: Who we are

- John Ennever – Director
- Lucas Breen – Associate Director
- Katie Jones – Sr. Analyst, Blue Panel
- Khaled Khattar – Application Administrator
- Jamie Merrill – Sr. Analyst, Blue Panel
- Matthew Ogrodnik – Sr. Analyst, Expedited/Orange Panel
- Debora Perez – Sr. Analyst, Purple Panel
- Pattie Pierre – Sr. Analyst, Green Panel
- Roz Schomer – IRB Coordinator
- Erin Schrader – Sr. Analyst, Green Panel
- Annette Wingard – Administrative Secretary

# Intro: Organization of the Boards

- Panels
  - Green (Colin Marchant, chair) – principal biomed
  - Blue (Jim Feldman, chair) – principal non-biomed
  - Orange (David Kaufman, chair) – genetics
  - Purple (Sanford Auerbach, chair) – continuing review

# Intro: Volumes

October 1, 2013 – September 30, 2014

- Initial Submissions
  - Full Board 133
  - Expedited 178
  - Exempt 335
- Amendments
  - Full Board 135
  - Expedited 870
- Continuing Review
  - Full Board 180
  - Expedited 1,003

2,386 done by staff vs. 448 by the Boards

# Changes Now In Effect

- Expiration dates:
  - For new studies that were conditionally approved, the expiration date is one year from when the stipulations were determined to be fulfilled, not from the date the Board conditionally approved the study
  - For continuing reviews, the expiration date is one year from the previous expiration date, when the review is done within 30 days of the previous expiration date

# Changes Now In Effect (cont.)

- Modifications to the protocol cannot be processed with Continuing Reviews
  - They can be submitted at the same time, just using a separate submission
- Consent forms are no longer stamped with an expiration date
- Recruitment materials will be stamped
- We request that continuing reviews be submitted 4 to 6 weeks prior to study expiration

# Changes Coming Soon

- New (improved) version of INSPIR
  - Easier Navigation
    - Use of external IRB (WIRB, NCI CIRB, cede review)
    - Not Human Subject Determination
    - Exempt Determination
  - Elimination of read-only sections from INSPIR I
  - Simplified Continuing Review application

# Wish-list of Changes

- For non-federally funded, minimal risk research, new policies embracing flexibility, see: <https://oprs.usc.edu/initiatives/flex/>
- Examples:
  - 2 or 3 year approvals for minimal risk research
  - New categories of “exempt” research
  - Expanded list of minimal risk procedures that can be approved via expedited review

# Wish-list of Changes (cont.)

- A comprehensive how-to manual
- More use of central IRBs and reliance agreements
- AAHRPP accreditation

# Your wish list of changes

- Let us hear them now: