E-SNAP Update

IRB & IACUC Approval Dates

Background

- E SNAP went "live" in November 2002 (FY2003 SNAP progress reports)
- Submission Statistics:
  - FY 2003 =   329
    FY 2004 = 2,854
    FY2005 To Date (as of 12/30/04) = 1180
- 247 Institutions now eSNAP enabled
- Self registration for eSNAP added to Commons Institutional Profile fall 2004
- One of the more significant business process changes implemented in eSNAP concerns the collection of the IRB and/or IACUC approval dates
- Participating grantees agree to provide retrospective data collection

Background (cont.)

- IRB & IACUC data review began February 2004
- E-mails sent to grantee officials with a spreadsheet attached for each grantee
- IRB & IACUC dates provided by grantee
- NIH staff (*a team of specialists across the NIH Institutes with an interest in compliance*) analyze data & follow up with grantees on any that appeared to be non-compliant
- Grantees provide explanations

Background (cont.)

- For those considered non- compliant, the Division of Grant Compliance and Oversight (DGCO), OPERA sends a letter to the organizational official requesting information concerning systems in place to assure proper stewardship of Federal $$$ when IRB and/or IACUC protocol reviews lapse
- To date, DGCO has been satisfied with all responses
- Some institutions have actually strengthened their procedures because of this exercise

Round 1
(Data Collected March 2004)

- Included all of FY2003 and 1st quarter of FY2004

- 488 out of 491 grants were compliant; i.e., 99.38%

- Three grants

- One Institution

- All IRB issues (no IACUC)

Round 2
(Data Collected May 2004)

- 357 out of 359 were compliant; i.e., 99.44%
- Two grants
- One Institution (*different from round 1*)
- All IRB issues (no IACUC)

Round 3
(Data Collected July 2004)

- 670 out of 679 compliant; i.e., 98.7%
- Nine grants
- Seven Institutions (*different from rounds 1 & 2—no repeat offenders*)
- Six IRB issues
- Three IACUC issues

Round 4
(Data Collected October 2004)

- 864 out of 876 were compliant; i.e., 98.63%
- 12 grants
- Eight Institutions
- Nine IRB issues
- Three IACUC issues
- Round 4 includes 2 repeat offenders

Issue to Resolve:
Repeat Offenders

- Options Being Considered
  - Require full reporting for a few rounds
  - Remove from E-SNAP and require hard copy submission
- Could be both as progressive actions

Issue to Resolve: Sampling Exercise

- Can no longer continue with 100% data collection and analysis

- Plan to switch to random sampling—*CWG thoughts on moving to a permanent random sampling*

- Also plan to pursue a contractor to permanently handle this activity

- Plan to approach OHRP & OLAW before implementing

Issues for Discussion

- Does random sampling provide adequate assurance of compliance?
- Are there other options for addressing non- compliant institutions?
- Does the data support a return to requiring dates at the time of submission?

- Note, at this time there are no plans to expand this beyond eSNAP. If continued, this will be a policy for electronic SNAP submissions only. Hard copy SNAPs will continue to require the data at time of submission.