Introductions & Announcements

- New Coordinators since last meeting
- Reminder – give me email address changes if your moving to Nebraska Medicine or to UNMC
- Introducing Cassie Cruz-Montes – Research Billing Sr. Associate
  - Overview of research billing
  - Monitoring and consolidating the matrices
  - Works with you on billing problems
  - Does not move charges

Matrices Updated

- 120 studies have been closed in One Chart
- 800+ Matrices being reviewed for complete subject list (260+ remain)
- Random auditing of matrix and patient billing monthly
- Archiving duplicates of the matrices – only the current working copy should be in the folder

EXAMPLE:
Scope of Practice

- Meeting is set for January 5, 2015
- Wittson Hall
- 1 pm
- Room 3034

Registries and Matrices

It is important to have an updated subject list in the matrix for registry studies that have billable items!

For Registries with NO billable items
- Maintaining the matrix subject list is NOT necessary

For Registries with ONE billable item
- Maintaining the matrix subject list is NOT necessary
- Scan in the consent form and add a note that patient was enrolled in the registry for a one time blood draw etc.
- Add the date of consent & date of blood draw
- When complete change status to "Follow-Up" in One Chart
- Maintain the matrix subject list as with any other study

IRB Updates

Sue Legsdon, MS, CIP
IRB Administrator/Compliance Coordinator

Jenny Kucera, MS, CIP
IRB Administrator/Education Coordinator
RSS

- New “Forms” function
- Justification when no changes have been made
- Personnel changes
- Old applications/forms
  - Put “TRASH” as title name
  - List IRB Administrator as Lead Coordinator

IRB Education

- AMA Category 1 Credit for IRB Education Series
- 2015 IRB Education Series TBA
- Need training?

Contact Information

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Updating the Enrollment Status

• Using Patient Research Enrollment, the following should occur
  • Update the enrollment status as the patient is completed, in follow-up or any other status
  • Assist with Billing
  • Add Active End date
Updating the Enrollment Status

- **Completed**: No further interventions or data collection
- **Follow-up**: No further interventions but continued data collection
  - Long-term Oncology survivorship
  - Registries after blood collection

Updating the Study Build Status

- **Closed**:
  - No further interventions or billing
  - Closed to accrual
  - May continue to collect data
IRB Order Set/ Smart Set
• Approved workflow includes a standard Order Set or Smart Set for each Study

IRB Order Set/ Smart Set
• Oncology
  • This requirement is satisfied by Treatment plan build and Smart Sets
  • Continue to contact Jill Kestel and Meg Peters

IRB Order Set/ Smart Set
• Non-Oncology
  • All studies need to have Smart Sets built.
  • Will be sending out Template and contacting individual coordinators.
Pend Orders
• CC charts to PI IN-basket
• Allows PI to locate Encounter quickly
• PI can sign the Pended Orders

Pend Orders
• Oncology
  • Send Chart

Pend Orders
• Non-Oncology
Pend Orders
PI In- Basket

New NIH Biosketch Format

Biosketch Update
• Timing
• Guidance
• Changes
• Sample Biosketches
• Tools
• Next Steps
New NIH Biosketch/ New Timing

- NIH has been testing a new format through
  - Request for information
  - Series of pilot FOAs
- Following a November Notice of implementation (NOT-OD-15-024), NIH released a second Notice (NOT-OD-15-032)
- Bottom Line: Effective date for implementation has moved from January 25 to May 25, 2015

NIH Guidance

- Encourages researchers to use new format
- Allows researchers to use current or new format until effective date
- New format is required on or after May 25, 2015

Format Change

Allows researchers to . . .

- Use 5 page
  - Moves from 4 to 5 pages
- Identify up to 4 publications that specifically highlight the researcher’s qualifications for the current project
  - See the Personal Statement section
- Describe up to 5 of their most significant contributions to science
  - See new Contribution to Science section
  - Replaces the “Selected Peer-Reviewed Publications” section
- Provide a link to a full list of their published work as found in a publicly available digital database
  - See the Contribution to Science section
PDF Sample Biosketches

Sample biosketches can be found on the SF424 (R&R Application and Electronic Submission Information forms) page:
- 'Old format' Samples (may be used prior to May 25, 2015)
  - General
  - Fellowship
- 'New format' Samples (must be used on/after May 25, 2015)
  - General
  - Fellowship - Predoctoral
  - Fellowship – Postdoctoral

Caution: Those are fillable-PDF forms which will cause an error in the electronic submission of an SF424 (R&R) application.

SciENcv: Biosketch Tool

SciENcv (Science Experts Network Curriculum Vitae)
- Serves as an interagency system designed to create biosketches for multiple federal agencies
- Supports the current NIH and NSF biosketch formats
- Support for NIH's new format is expected in late December
- Will also provide a dataset that will highlight federal investments in science
  - A YouTube video provides instructions for using SciENcv

Next Steps

- We have 4 months to learn the new systems
- VCR office and SPA
  - will host workshops to introduced the new biosketch and tools
  - are partnering with Library and experienced departmental experts
- NIH, VCR and SPA encourage early use of new biosketch
Uniform Guidance

A Federal Update
Deborah K. Vetter, Director
Sponsored Programs Administration

Uniform Guidance

- Grant Reform
- Timelines
- Changes
- Next Steps

Uniform Guidance

Initial Names
- Super-circular
- Omni-circular
- 2 CFR 200
- A-81

Actual Name
- Uniform Guidance or UG
UG: Grant Reform

- Designed to harmonize and streamline OMB guidance on grants from **eight** documents into **one**
- Consolidates OMB Circulars A-21, A-110, A-133
- Described as an extreme make-over

| OMB A-21 | = Universities |
| OMB A-110 | = Agencies |
| OMB A-133 | = Auditors |

UG: Significant Change

- the most significant change to federal regulations in 50 years
  - 1947 Negotiated first formal set of cost principles
  - 1958 Codified principles in A-21
  - 1966 Committed to reimburse “fair share” of research costs
  - 1979 Introduced concept of MTDC
  - 1991 Revised A-21 significantly (term “indirect cost” changed to F&A)
  - 2014 Released Uniform Guidance

UG: Legislated Timelines

- June 26, 2014—Federal Agencies
- December 26, 2014—Non-federal Entities
UG: Post December 26, 2014

- Awards and UG
  - New Awards = UG
  - Continuations = Agency names regs
  - 1 award could have 2 regulations

UG: Timelines

April 2012
  - OMB issued advance notice of proposed guidance
  - UNMC submitted comments

May 2013
  - OMB issued proposed guidance
  - UNMC submitted comments

UG: Timelines

December 2013
  - OMB issued final guidance
  - UNMC formed working groups to study UG

June 2014
  - Federal awarding agencies submitted implementation plans to OMB
  - University of Nebraska-wide working groups began to meet
UG: Terminology

Interesting language use

- 46 Times = “internal control”
- 66 Times = “written”
- 66 Times = “prior approval”

Source: Maximus

Uniform Guidance: Next Steps

December 2014 and beyond . . .

- OMB releases agency policies
- Agency implementation begins
- Changes to UNMC policies and procedures

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