NRDS Policy and Governance Working Group

Monday February 22, 2016

Meeting Minutes

Action Item	Who	By When
Review the definition for NRDS Content and Policy WGs (add examples)	Tina Taylor	2/29/16
Update the compliance review process to accommodate a paper document for changes	Tina Taylor	2/29/16

Agenda Topics

Introductions – Neesha Desai welcomed the callers and reviewed the current agenda.

NRDS Standard Policies – Tina Taylor reviewed the policies around the NRDS Standards proposed by the NRDS Policy and Governance WG.

- Judi: These are policies around formulating and using standard content.
- Jennifer: Would the style guide include italicizing comments?
    - Gwen: We have this posted on the Wiki, it covers capitation, italicizing text, individualize using HTML coding for specific items, etc.

NCTN and ETCTN Roles/Responsibilities – Tina Taylor reviewed the current roles and their responsibilities for NCTN and ETCTN

- Tina: There should always be representation from the Policy Working Group on the Content Working Group.
    - Mike: I agree. Also, when members would like to come up with a new item, they should go to the Content WG.
- Judi: We should provide a bit more details and maybe examples on what the NRDS Content vs Policy group is in charge of.
    - Tina and Neesha to review the definitions for the NRDS Content and Policy WG.
- Angela: In addition to creation of forms, will these roles include the additional review requirements?
    - Neesha: They will be there when the forms are built and the annual review. There will be a review process as the forms are built, a process when changes are required, and an annual review process.

NCTN/ETCTN Compliance Review Process – Tina Taylor walked through the proposed NCTN/ETCTN Compliance Review

- Mike: This is well thought out and makes sense
- Angela: Step 3, if I am the POC and I am sending my forms to the ALS Reviewer, am I doing that just at the beginning or every time I apply that to the global study.
    - Tina: No one has brought this up yet, my first thought is that it should not have to be reviewed each time but there may be times when something has happened and that is the only way to capture it.
- Angela: What is your thoughts of compliance? This implies it may be a form or form module type of thing. Is it the vision that the entire form would change or have standard and non-standard items?

  - Tina: This is something that the group will have to discuss
  - Mike: We are only focusing on the standard items
- Angela: To what extent can the OID names be changed after the caDSR or will it just be the field label that will be scrutinized?
  - Tina: We have not discussed this; my understanding is that if we had standards in the caDSR, that it would need to be used. I thought the long name would have to be used.
  - Mike: We are developing standards that will be back-filled in the caDSR.
- Angela: I assume the field name will need to remain the same that it is right now so one can compare on the form. Do you have any plans to standardize field OID (which is now a SWOG specific value for us).
  - Gwen: Once a name/OID has been decided upon, it should stay the same because the integrations will be based off of that.
  - Tina: The ALS template will be pushed to the LPOs, this will be what is used.
  - Judi: There was a slide of exactly which components will need to be standardized.
  - Neesha: There was a request to walk through the fields, one by one, to note something that should be allowed changed and the items that should not.
  - Angela: I would like to see a breakdown of fields that we would not be able to change from caDSR.
- Judi: It seems if a form is reviewed once for each LPO and it was compliant, it should not need to be reviewed more than annually. Any other deviations can be reviewed
  - Tina: I agree.
  - Mike: I would prefer we do the form once for all LPOs. The annual review was more to ensure the form(s) still made sense, but the review of newer items could also be reviewed.
  - Gwen: The compliance review is for the LPO (or group) would need to make a change to the form; this is by request only.
- Jennifer: This workflow suggests, a proposed change would need to be built into a study before it is reviewed. Is there a way to proactively suggest a change without building it in Rave?
  - Gwen: I would request the change with a paper copy, or a modified ALS, to request a change.
  - Jennifer: Perhaps the process can accommodate a paper form.
  - Gwen: I believe we can accommodate that.
- Mike: This one is how we would develop a standard. We may need an additional workflow to show how one would utilize it.
  - Tina: We may have added a little too many details for this level. There may be additional workflows needed for different circumstances.
  - Neesha: The point of the tracking log, we want to ensure we keep all changes documented to ensure all groups can see the process as it continues and changes.
  - Mike: Yes, we may need to just break this out further.
- Additional Workflow Suggestions, initially
  - Develop a CDE (completed)
  - Utilize/Modify a CDE (need to be completed)
  - Annual Review Process (completed)

NCTN/ETCTN Annual Standards Review Process – Tina Taylor reviewed the proposed NCTN / ETCTN Annual Standards Review Process.

Next Steps

- Break down the current workflows into 3 different workflows
- Mike: We will meet next week, since this was an off-week.

Attendance:

Name	Affiliation
Steven Jong	COG
Judi Manola	ECOG-ACRIN
Mike Montello	NCI
Tina Taylor	NCI
Gwen Dean	NCI
Janice Knable	NCI
Christina Warmington	NCI - Essex Management
Neesha Desai	NCI - Essex Management
Jennifer Thomas	NRG
Angela Smith	SWOG
Diana Vulih	Theradex