# NRDS Policy and Governance Working Group
**Monday February 1, 2016**
**Meeting Minutes**

| Action Item | Who | By When |
|---|---|---|
| Put together some workflows to vet through for Governance and Policy | NCI-Co leads | 2/22/15 |

## Agenda Topics

**Introduction of members on the call** – Neesha Desai welcomed the callers and reviewed the current agenda.

**Recap/Project update** – Neesha Desai provided an overall NRDS Project update.

**Governance and Policy Discussion –** Dianne Reeves reviewed the short term and long-term policy options that were agreed upon. Dianne also provided some NRDS Policy discussion working categories (data sets, data elements, and waiver processes) for consideration and reviewed the NRDS Policy WG guidelines.

*Open Forum*
- Shauna: Your examples are not things that are being standardized; these do not seem to be in scope. I thought we are focusing on the standards related to integration.
  - Dianne: Yes, you are correct. These are just examples.
  - Shauna: There is almost an obvious governance for starting with standardized elements because they do not make sense unless you use them.
- Neesha: How often do we want to do reviews of the standards to ensure people are using them? Should we do all the studies prior to activation (and which ones)? Should we do a random sampling once or twice a year? Is there another way?
  - Judi: It is important for us to keep in mind that the two sets of CDEs are in OPEN, CDUS Integration, and the caAERS Integration. If we have to think about how those data elements get built and how could they deviate from the standard? We need to think about the process in order to answer this.
  - Shauna: Having a tool to identify deviations prior to activation would be ideal and would remove the need for migration later.
  - Angela: I agree and we should pursue that option until we get to a point where that is no longer an option (because of time).
  - Mike: An automated way is optimal but I am unsure if we can achieve that on day one. Until that point, how should we move forward? What if we check within 30 days of activation?
  - Angela: I am ok with the timeline spilling to after activation but I do not see why the process cannot start at least a month before activation. I would like to do it when the forms are stable.
  - Shauna: If we go the route we discussed, there really should not be a concern.
  - Angela; I am hoping that even a manual review should not be too time consuming.
  - Shauna: I lobby to give everyone time to get this data into their own global library.
  - Mike: That is a good policy issue; we need to build the timeline into the policy (possibly 3 months).
- Judi: Who will do compliance checking?
  - Mike: That would be the governance side.

- o Neesha: We will need to come up with a small workflow based on this. I will put something together for the next meeting.
  - o Shauna: Include a long term and short term goals
- Angela: Because the manual process starts with a standardized ALS, there may be a way to make the checks more efficient, it could be used as the long term goal.
- Neesha: Annual Review?
  - o Judi: There may be a need on a more immediate basis to make changes to standard data elements. If we make a change to a standard data element in between, is that redundant?
  - o Dianne: I would recommend a regular review but also an expedited process.
  - o Angela: Seems there needs to be a reactive way to change as needed prior to the annual review but also include an annual review to ensure we are still being consistent.
  - o Dianne: I would recommend (with the second part) to use a Wiki for people to post suggestions for improvement
  - o Shauna: Even if we think something needs to be changed, would we be able to change it more frequently than annually; I do not know how CTSU would be able to change anything more frequently than annually. We need to ensure the integrations are completed in a way that will last.
  - o Mike: We did make the system a little more flexible; if there is a change that needs to happen, we can work it out. If the government requires additional changes, we are capable to make changes. We should be able to update quick pick changes as needed.
- Mike: Previous times, we did not properly go through all of the policy and it caused more issues. Many of the policies will be very straight forward but we should still spell it out.
- Dianne: The Content Group would seem the best place to review requested changes to the content.
- Dianne: If we do this review and find issues, to whom would those issues be raised immediately?
  - o Angela: I would presume the ALS submitter
  - o Shauna: I believe anything you find are errors and not intentional deviations.
  - o Angela: If the user comes back and notes that the user did it intentionally, that is when it should be elevated. Then it would be reviewed to see if an exemption would be required or if it would need to be changed.
- Dianne: Who would receive a request for exemption?
  - o Mike: It would likely be Dianne and Mike but we would involve others that need to be involved.
- Dianne: There are times when people need something different but are still not out of alignment.
  - o Angela: I agree there may be exceptions made without hampering integration.
- Angela: Do you see this being very detailed?
  - o Mike: Yes, it will need to be sufficiently detailed.
  - o Shauna: The field label needs to be standardized but the SAS label may have flexibility. I think it would be helpful to walk through a build to note what is required and what is not
  - o Angela: I would also include screen shots.
  - o Dianne: This would be very helpful for training
- Shauna: Which group would go through architect and note the specific requirements? Whichever group it will be, I (and our global librarian) would like to be included.
  - o Mike: It would likely be the governance group.

- Judi: Will we need input from the integrations people?
- Angela: Will we retroactively apply this to previous studies?
  - Mike: Absolutely not, we will not be able to do that.

**Next Steps**
- Neesha to put together a workflow and review the constraints of possible updates.  Create a list of policies for the next meeting.

## Attendance:

| Name | Affiliation |
|---|---|
| Shauna Hillman | Alliance |
| Steven Jong | COG |
| Thalia Beeles | COG |
| Judi Manola | ECOG-ACRIN |
| Dianne Reeves | NCI |
| Gisele Sarosy | NCI |
| Mike Montello | NCI |
| Christina Warmington | NCI - Essex Management |
| Neesha Desai | NCI - Essex Management |
| Jennifer Thomas | NRG |
| Angela Smith | SWOG |
| Diana Vulih | Theradex |