

# Network Rave Data Standards (NRDS) Policy and Governance WG

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# Agenda

- NRDS Project Update
- NRDS Compliance Criteria
- NRDS Workflow Template Content
- Next Steps

# NRDS Project Update

- For all completed content

**Agreement to use the same question and answer set, formatted in the same way (i.e., text) for transmission to NCI.**

# NRDS Project Update

- **Completed Deliverables**

- OPEN Demography Content – Ready for implementation
- AE Content – Ready for implementation
- SAE Content – Pending CTSU Review
- Completed final review of the remaining CDUS Content
- Completed the final review of the additional OPEN Content forms
  - Screening/Pre-Registration Discussion
- Developed an implementation workflow for the OPEN content
  - 2 Pilot LPOs for implementation

# Compliance Criteria

- **Purpose**

- A set of rules for the ALS reviewer to use as a validation checklist
- Check will be used to ensure that the forms built in the Global Library are compliant with the new ALS.

- **Criteria**

- All Permissible Values (User Data String) are included with the associated Common Data Elements
- The Permissible Values (User Data String) have not been altered unless a formal exemption has been approved
- All Designated Question Text/Alternates are included with the associated Common Data Elements
- All Common Data Elements included in the ALS are on the form
  - Only the CDEs that are required for the study need to be included for the CDUS Reporting Content
- It is recommended that the NRDS Style Guide be used when developing the forms in the Global Library

# Intake Form

- **Workflows**

- Compliance Review
- Exemption Review

- **Purpose**

- Provide further information for the review

- **Fields**

- Point of Contact Name - free text
- Point of Contact Email – free text
- Point of Contact Phone Number – free text
- List of changes that have been made to the ALS – free text
- Type of intake review: Compliance or Exemption – radio button or drop down

# NRDS Standard Compliance Report

- **Workflows**

- Compliance Review
- Exemption Review

- **Purpose**

- Provide data on compliance numbers

- **Fields**

- Point of Contact Name - free text
- Point of Contact Email – free text
- Point of Contact Phone Number – free text
- Number of CDEs compliant – free text
- Number of CDEs non compliant – free text

# NRDS Compliance Tracking Log

- **Workflows**

- Compliance Review
- Standards Review

- **Purpose**

- Track the status of the compliance reviews

- **Fields**

- Point of Contact Name - free text
- Point of Contact Email – free text
- Point of Contact Phone Number – free text
- Compliance Status – not started, in review, completed
- Reason for non compliance



# Exemption Assignment Findings

- **Workflows**

- Exemption Review

- **Purpose**

- Track the status of the exemption reviews

- **Fields**

- Point of Contact Name - free text
- Point of Contact Email – free text
- Point of Contact Phone Number – free text
- Exemption Status – approved, not approved
- Reason for exemption – free text

# Impact Analysis

- **Workflows**

- Standards Review

- **Purpose**

- Provide a report on the changes needed and their impact on other activities. This is done by the NCI Curation Team.

- **Fields**

- Point of Contact Name who is completing the IA - free text
- Point of Contact Email who is completing the IA – free text
- Point of Contact Phone Number who is completing the IA – free text
- Impacted Systems– Drop Down
- Changes that need to be made – free text
- Other Impacts – Free Text

## Next Steps

- Review Roles/Responsibilities based on ISO standards
- Review drafted workflow templates

# Reference Information / Questions

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