NCI's National Clinical Trials Network and NCI's Experimental Therapeutics Clinical Trials Network Standards Policy and Governance Plan

Status:	**Draft**
Version No.:	
Effective Date:	
Last Modified Date:	
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Note: Before using this document, make sure it is the latest revision. The Network Rave Data Standards (NRDS) Policy and Governance Document can be accessed on the NRDS Policy and Governance Wiki.

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Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	5/24/ 2016	Neesha Desai	Created original document	

NCTN and ETCTN Standards Policy and Governance Plan

1. Summary

The Network Rave Data Standards (NRDS) Policy and Governance Document establishes framework, responsibilities and requirements for development, maintenance and implementation of Rave Data Standards within the NCI's National Clinical Trials Network (NCTN) and the NCI's Experimental Therapeutics Clinical Trials Network (ETCTN).

2. Purpose

A well implemented Network Rave Data Standards Policy and Governance Document supports management of standardized data related resources and reduces risks associated with compliance, security, privacy, and data sharing.

The audience for this document includes the NCTN and ETCTN as well as other stakeholders who create and use NCI data resources in Rave

3. Scope

This NRDS Policy and Governance Document applies to the creation, modification and use of Network Standard Rave data elements and NRDS-approved Standards for the NCTN and ETCTN. In particular, NCI organizations, Information Technology (IT) project managers, application developers, contracting officers and their technical representatives as well as grantees, contractors and others working on behalf of who design, develops, compile, manipulate or maintain the NCTN and ETCTN NRDS standards.

4. Introduction

Wikipedia defines Data Governance (E) as a "discipline that embodies a convergence of data quality, data management, data policies, business process management and risk management surrounding the handling of data in an organization. Through data governance, organizations can exercise positive control over the processes and methods used by their data stewards and data custodians to handle data." The Data Governance Institute defines Data Governance (F) as "a system of decision rights and accountabilities for information-related processes, executed according to agreed-upon models which describe who can take what actions, with what information, and when, under what circumstances, using what methods." Managing an organization's adopted standards for data collection and management will lead to better quality data and fewer issues throughout the whole business process. Business rules and best practices can be adopted to define specific requirements for parts of the business process and these can become part of the overall governance plan.

The definition that is chosen for Standards Governance should be based on what a program is trying to accomplish in order to clearly articulate policies, processes and procedures to the user community. A Standards Governance policy should complement

an organization's Data Management and IT policies. Effective Governance will require input and support from data managers, subject matter experts and data stewards.

Principles for NCTN/ETCTN/Theradex Standards

NCI CBIIT is responsible for many programs and projects that collect, maintain and store data related to the search for a cure for cancer. This data must be treated as an asset by defining data collection methodology, data quality, data provenance, data ownership and data security so that this resource can be utilized, not only by the original generator, but that it will be of value to other researchers. The Office of the National Coordinator prepared a governance framework (May 2013) for electronic health information that could be used as a framework for a NCI CBIIT standards and data governance program (B). A similar document has been prepared by the Data Governance Institute (F). There are a number of principles to be considered:

a. Organizational Principles
    - Operate with transparency and openness.
    - Adhere to applicable federal policies and practices.
    - Promote inclusive participation and adequate stakeholder representation in development of policies and procedures.
    - Ensure consistent and equitable oversight.
    - Provide due process to the stakeholders to which it provides oversight.
    - Enable better decision-making and reduce operational friction.
    - Train management and staff to adopt common approaches to issues.
    - Reduce costs and increase effectiveness through coordination of efforts.

b. Trust Principles
    - Provide public access to any governance policies and any modifications to those policies.
    - Protect and manage personally identifiable information when it is accessed or exchanged.

c. Business Principles
    - Set participation standards that promote collaboration and avoid implementation of policies that prevent electronic interchange.
    - Enable integration of data and assure data integrity.
    - Promote more efficient and effective use of data by users of commonly defined data from disparate sources.
    - Maximize use/reuse of resources.
    - Provide open access to exchange services for sharing with partners.
    - Publish statistics on use of the data resources.
    - Maintain up-to-date information about compliance with relevant statutory and regulatory requirements.

d. Technical Principles

- Ensure technology supports the trust and business principles.
- Prioritize the exclusive use of federal vocabulary, content, transport and security standards.
- Encourage the use of standards adopted by voluntary consensus standards developing organizations.
- Lead engagement for development of new and improved standards.
- Develop standards for specific use cases, if warranted.
- Actively participate in development and implementation of conformance assessments and testing to measure compliance with federal standards.
- Communicate with managers and stakeholders as part of any standards development process.

5. Roles and Responsibilities

The following is a list of Roles and Responsibilities for the NTCN and ETCTN and staff that oversee the governance of standard CDEs.

1. **NCI Leadership Committee** - An oversight committee that provides strategic guidance and direction on the NRDS Project activities that align with NCI's vision and goals.
2. **NCTN and ETCTN** - NRDS Project stakeholders that provide subject matter expertise for content standardization.
3. **Lead Protocol Organization (LPO)** – NCTN and ETCTN organizations that develop and conduct NCI Clinical Trials.
4. **NRDS Content WG** – The committee established to identify and manage the NRDS approved Standards for use in Rave by NCTN and ETCTN.
   a. Identify proposed NRDS Standards
   b. Review and approve updates to NRDS approved Standards
   c. Collaborate with the NRDS Policy and Governance WG to manage the NRDS approved Standards
   d. Collaborate with the caDSR Registry Steward when utilizing the NRDS Standards
   e. Verify the use of NRDS approved Standards in new or updated CTSU prepared ALS
5. **NRDS Policy and Governance Working Group** – A committee established to identify and govern the decisions on the adoption and usage of the NRDS Standards in Rave by the NCTN and ETCTN.
   a. Review the recommended updates to existing NRDS Standards for compliance to the NCTN and ETCTN Governance Framework
   b. Enforce approved policies and governance
   c. Define an escalation strategy for the NRDS community
6. **ALS Submitter** - A person who distributes the ALS documentation and any changes to the ALS Reviewer.

7. **ALS Reviewer** - The caDSR curation team designee who reviews ALS documents to ensure they comply with the NRDS Standards.
8. **caDSR Registry Steward** – NCI representative who reviews and analyzes change recommendations provided by the NRDS stakeholders.
9. **caDSR Curator** – The caDSR curator(s) who implements approved content as identified by the caDSR Registry Steward.

6. Exemptions for Data Standard Usage

1. Types of Exemptions
   a. *Temporary Exemption***:** Exemption with a designated expiration date. A temporary exemption enables the system managers to wait until an appropriate time in the systems life cycle (e.g., modernization) or project to incorporate a new data standard.
   b. *Permanent Exemption***:** Exemptions granted for the life of the system or project.
2. Determination of Need
   a. The validation workflows will help determine whether the NCTN or ETCTN will have problems complying with a relevant data standard.
   b. Both NRDS Policy and Governance WG and the NRDS Content WG are consulted for compliance review and/or assistance. Every effort shall be made to achieve compliance.
   c. An exemption is required if a data element within a new study is not in compliance with the new version by the required implementation date.
      - New study: A study that is opened after the data standard is implemented.
   d. An exemption is data standard specific. A separate exemption must be issued for each data standard to which the application or project does not comply.
3. Submission of an Exemption Request
   a. The party responsible for the application or project submits the exemption request in writing to NCI CBIIT. An email request to neesha.desai@nih.gov is acceptable. The request will be posted within 2 business days on the NRDS Wiki with the following attributes.
      - Requestor Name
      - Requestor Organization
      - Date Requested
      - Request Title
      - Standard
      - Description
4. Disposition of Exemption Request.
   a. The NRDS Policy and Governance WG, NRDS Content WG, requesting party, CTSU and NCI Leadership (if it is appropriate or there is a dispute), evaluate applications and makes recommendations.

b. Exemption evaluation includes
   - Impact to integrations
   - Resources required to make the change
   - Other competing priorities
   - Requirements imposed by agency mandating data submission

c. NCI Leadership notifies the applicant in writing of the disposition of the request within **5 business** days of receipt.

5. Posting of Exemption Information.

a. The requesting party must record the exemption information in all relevant system life cycle documentation. This includes a tracking long on the NRDS Wiki.

7. NCTN and ETCTN Standards Usage Policies

1. The standard question text can-NOT be changed unless pre-approved by NRDS WG (exception is NOT the rule)
   a. The standard question text is the field label in Rave
2. A response CAN be eliminated if it is not appropriate for a specific study.
3. Additional responses can-NOT be added to a pick list.
4. Responses can-NOT be merged.
5. The question and answer sets should follow the style guide recommendations.
   a. Answer sets are composed of permissible values and value meaning
   b. Answer Set is the Dictionary in RAVE which is composed of PV/VM (coded values/user data string). The OCI gives users the option of choosing whether the coded value or user data string is displayed for the public to view.
   c. Permissible values can be coded values or user text strings in Rave
6. Group specific codes for standard data elements can-NOT be used in Rave.
7. An ALS **must** be submitted to document an **implemented** change.
8. A Case Report Form (CRF) can be submitted with supporting evidence for a **proposed** change to a NRDS Standard Common Data Element (CDE).
9. All approved NRDS standards will be implemented prospectively. The NCTN and ETCTN will not be required to retro-fit the older studies to the new standard initially or for changes in the future unless it is NCI mandated.

8. Compliance Criteria

1. Purpose
   a. A set of rules for the ALS reviewer to use as a validation checklist
   b. Checks will be used to ensure that the forms built in the Global Library are compliant with the new ALS.
2. Criteria
   a. All responses are included with the associated Common Data Elements

b. All NRDS approved Question Text/Alternates appropriate for modality (Field Label) are included with the associated Common Data Elements

c. All Common Data Elements that are required for the form are included in the ALS for the form

    - Only the CDEs that are required for the study need to be included for the Clinical Data Update System (CDUS) Reporting Content

d. Group specific codes for standard coded data values can-NOT be used in Rave.

e. Changes to the NRDS Approved Permissible Values and Question Text/Alternates (Field Label) cannot be made unless a formal exemption has been approved
    - Answer Set is the Dictionary in RAVE which is composed of PV/VM (coded values/user data string).
    - Permissible values can be coded values or user text strings in Rave

f. It is recommended that the NRDS Style Guide be used when developing the forms in the Global Library

9. Validation Workflows

The NRDS Policy and Governance Working Group developed a set of workflows to monitor the use of the NRDS standards. The workflows ensure the proper use and validation of the standards by NCTN and ETCTN.

1. NRDS Standards High Level Process
    a. The goal of this workflow is to produce a high-level representation of how the NRDS Policy and Governance workflows tie in together.

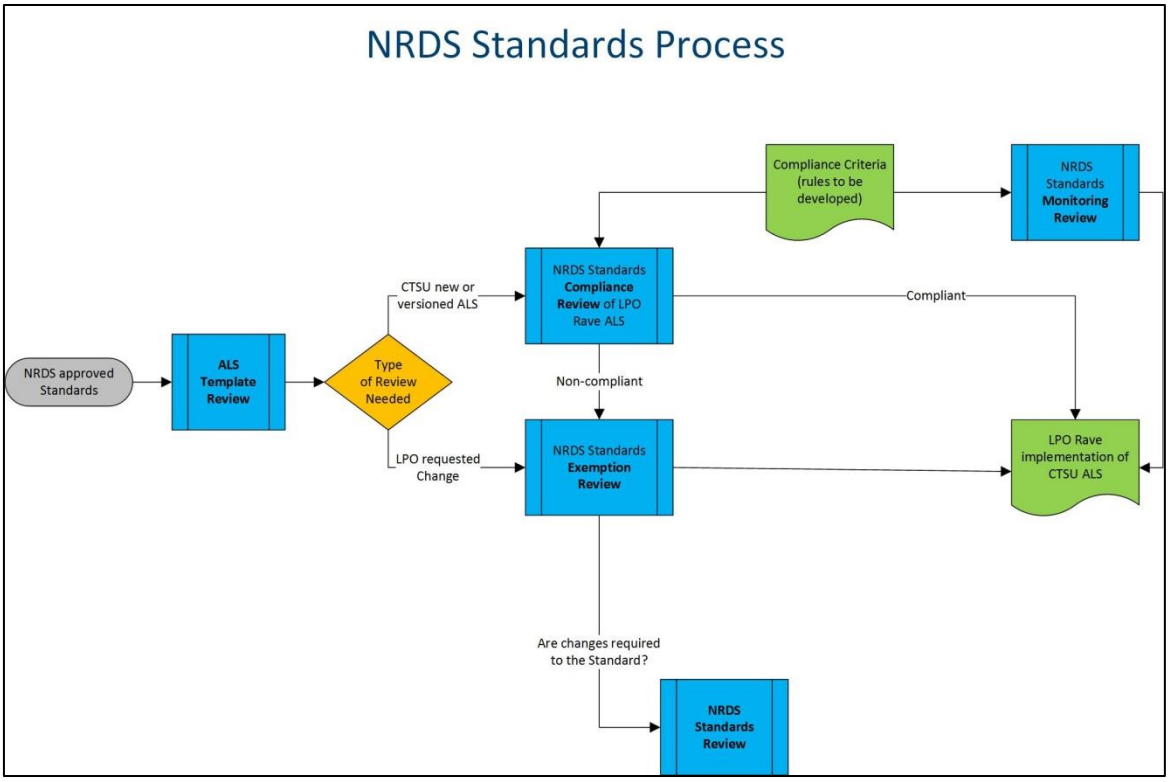

Figure 1: NRDS Standards Process

2. ALS Template Review
    a. The workflow is initiated when CTSU releases a new version of the ALS template. The goal of this workflow is to produce an ALS template that uses the NRDS approved Standards correctly. The outcome of this workflow is a report to CTSU to make changes to the ALS template as needed.

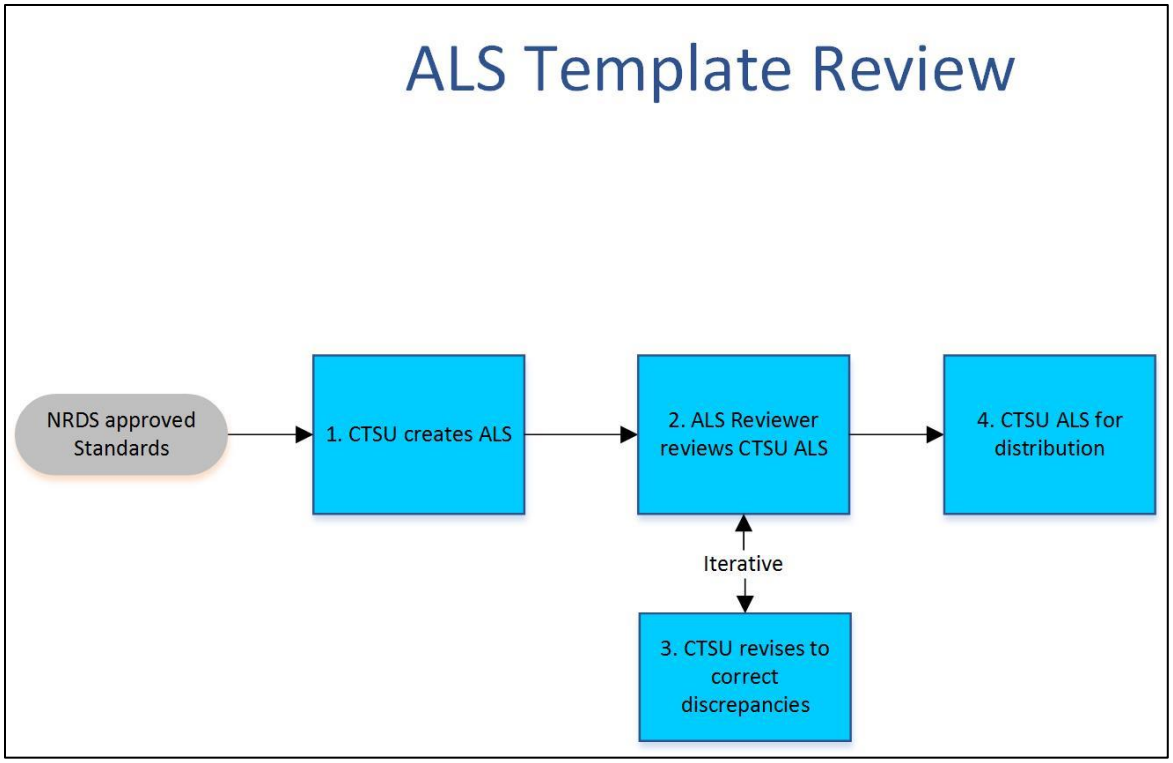

Figure 2: ALS Template Review

3. NRDS Standards Compliance Review
   a. The workflow is initiated when an LPO is building a study using a new or versioned ALS template. The goal of this workflow is to ensure the LPOs ALS file is in compliance with the CTSU ALS template. The outcome of this workflow is a compliance report back to the submitting LPO with a status notification emailed to NCI Leadership and the NRDS Policy and Governance Working Group.

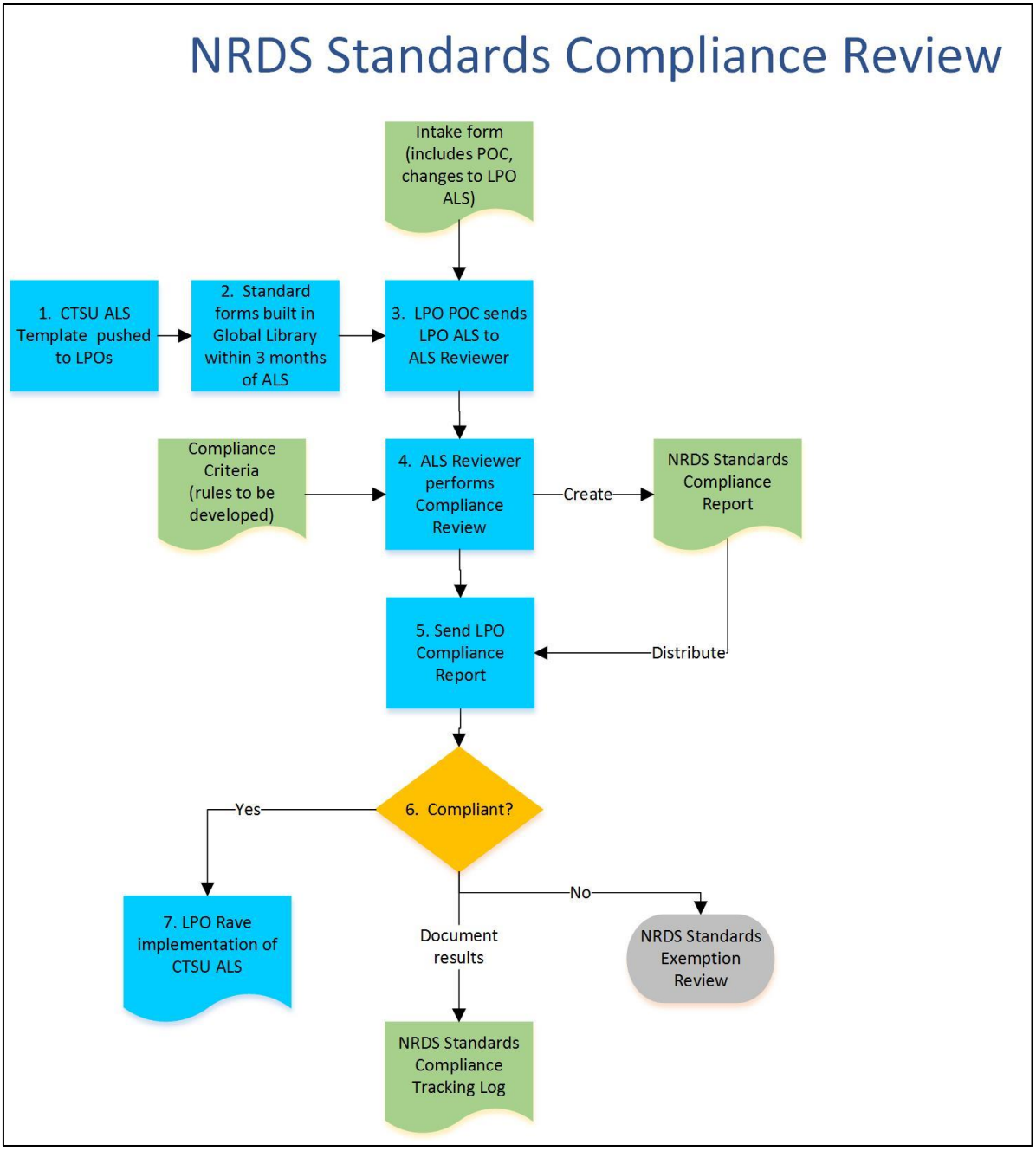

Figure 3: NRDS Standards Compliance Review

4. NRDS Standards Exemption Review
   a. The workflow is initiated when the LPO submits a change request or an ALS is found to be non-compliance. The goal of this workflow is to provide an assessment of an LPO change request or non-compliant ALS. The outcome of this workflow is a report of the exemption assessment findings emailed to the LPO, the NRDS Policy and Governance Working Group and to NCI Leadership.

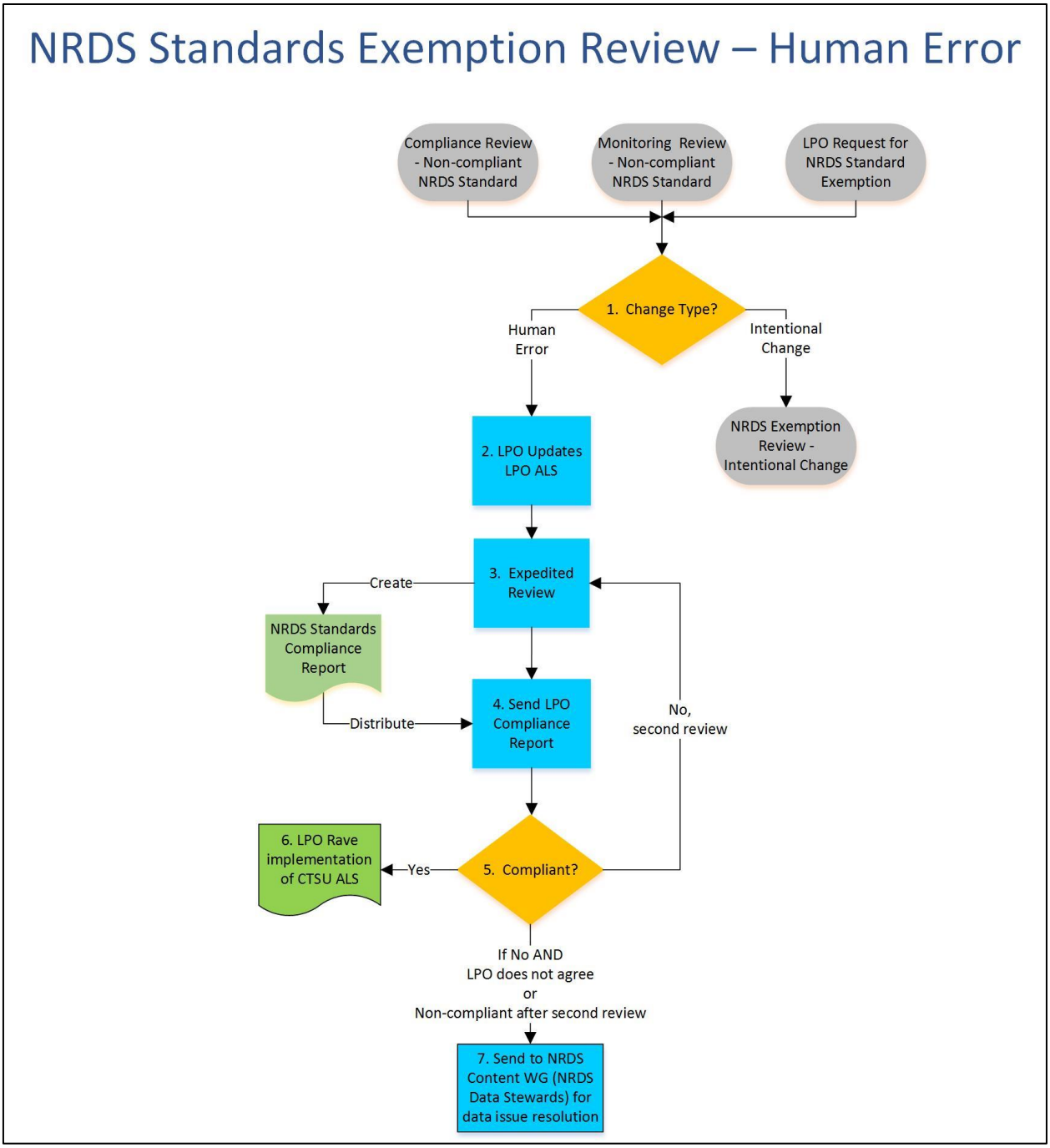

Figure 4: NRDS Exemption Review - Human Error

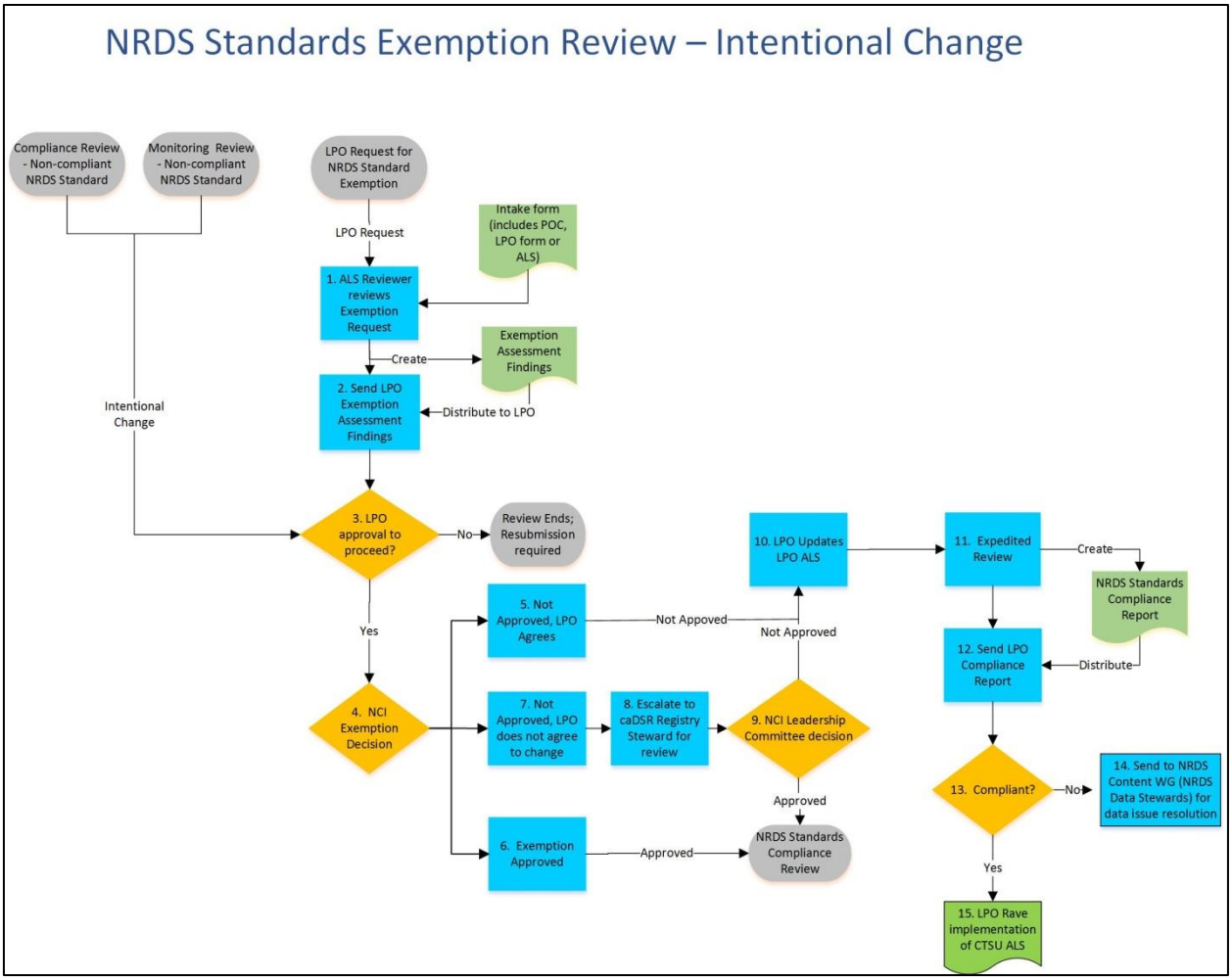

Figure 5: NRDS Standards Exemption Review - Intentional Change

5. NRDS Standards Review
   a. The workflow is initiated based on the needs of the NRDS Community. The goal of this workflow is to ensure NRDS Standards meet the needs of the NRDS Community. The outcome of this workflow is a report delivered to the NRDS Content WG for disposition.

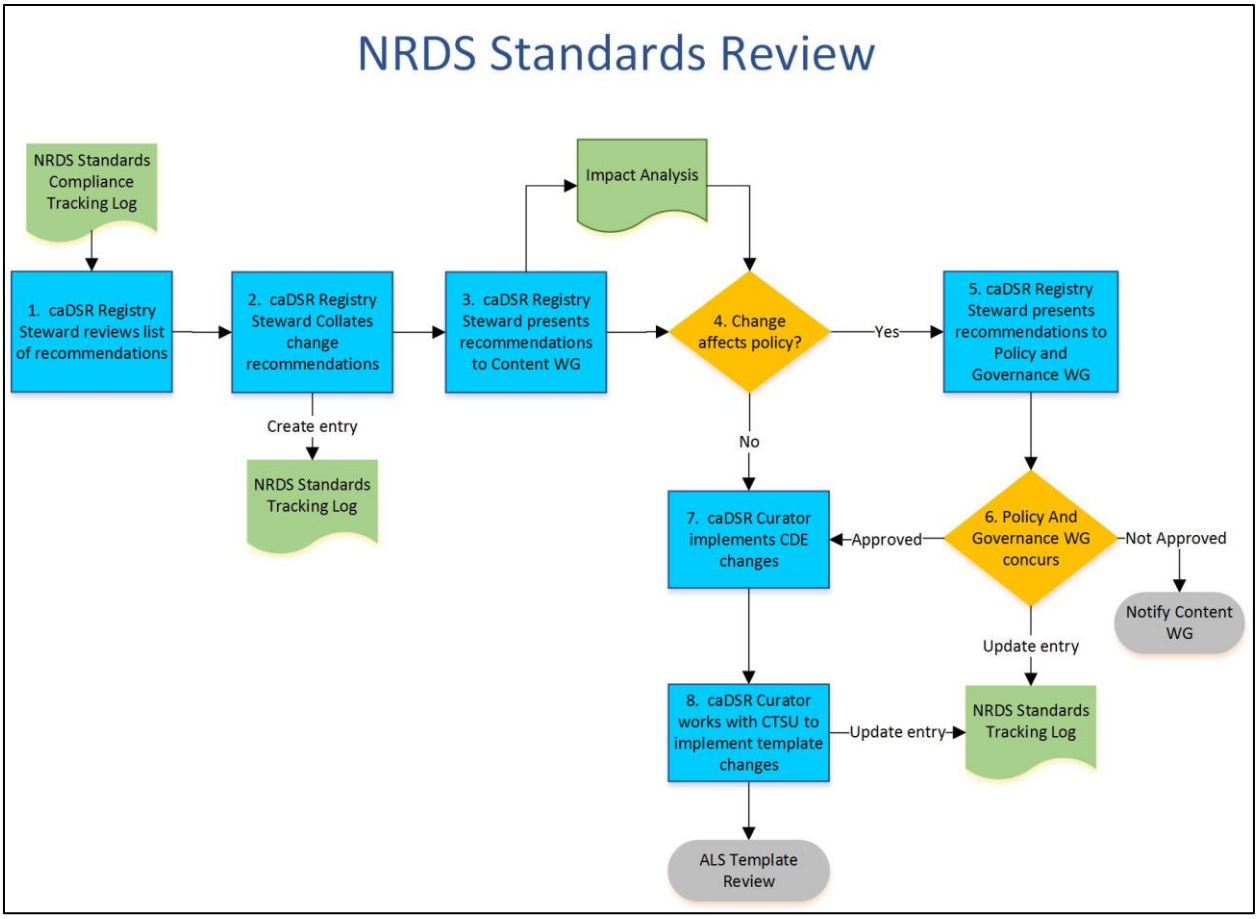

Figure 6: NRDS Standards Review

10. Frequently Asked Questions

1. **Which components of the ALS can be changed by the LPOs**?
   a. Regarding all CTSU Integrations:
      - CANNOT BE CHANGED: NRDS approved Permissible Values (User Data String), NRDS approved Question Text/Alternates (Field Label), Field & Form OIDs, Dictionaries & Dictionary LOVs (User Data String) and coded data and user data strings unless an alternate compliant solution has been agreed upon.
      - CAN BE CHANGED: Field Label, Header text and Form Instructions
      - CAN BE ADDED: Edit checks/custom functions involving these forms, Statistical Analysis System (SAS) labels, etc.

   b. Regarding the CTSU Oncology Patient Enrollment Network (OPEN)-Rave Forms Integration:
      - The above items, *plus…*
      - CAN BE ADDED: LPOs can create/ add additional Edit Checks (ECs) and Custom Functions (CFs) for the OPEN-Rave Integration forms to verify or populate data in LPO-specific forms.

2. **What happens when CTSU provides the final ALS to the groups and the LPOs want to use their own Short Name (Other IDs-OIDs), etc?**
   a. Regarding *all* CTSU Integrations:
      - If OIDs or dictionaries are changed, the integrations will break, unless an alternate compliant solution has been agreed upon.

3. **How does this (LPO customization) impact integrations?**
   a. Regarding all CTSU Integrations:
      - The allowable LPO customization should have no impact on the CTSU integration activities, provided the LPOs do not change the OIDs and dictionaries, unless an alternate compliant solution has been agreed upon

4. **Can the HTML tags in the field label be changed?**
   a. HTML tags can be changed as long as the content has not been altered.

5. **Can instruction text be added with the content?**
   a. Instructional text can be added as long as the format is in italics and in parenthesis. Refer to the NRDS Style Guide for more information.

11. Master Glossary

Administered Item - A registry item for which administrative information (begin date, end date, Identifier, version, more) is recorded in an Administrative Record. Examples include: Classification Scheme, Conceptual Domain, Context, Data Element, Data Element Concept, Object Class, Property, Representation Class, and Value Domain.

Best Practice - Guidance outlining the preferred and recommended way of creating/maintaining metadata.

Business Rules - Rules developed for implementation of a data standard in a specific system/application or organizational unit.

caDSR (cancer Data Standards Registry and Repository): A metadata repository used to record information about data and data standards.

CBIIT -Center for Biomedical Informatics and Information Technology

Common Data Element (CDE) - Within the caBIG context, used interchangeably with Data Element (DE) to capture a unit of data for which the definition, identification, representation and permissible values are specified by means of a set of attributes. Synonym - Data Element (DE).

Community of Interest - A group that can be defined by their common interests, needs or goals, e.g., a group of scientists, database designers, analysts, librarians with a common interest in drinking water monitoring data.

Compliance - An assessment of the accuracy and completeness of an implementation of a data standard according to data standard specifications and the guidance implementation document.

Conceptual Domain – A set of valid Value Meanings.

Control Committee – The organizational unit of the Registration Authority that is constituted to provide technical direction and harmonization of Administered Items for the metadata register. (Source: ISO/IEC 11179)

Data Element Concept (DEC) - An idea that can be represented in the form of a data element, described independently of any particular representation. Often conceptualized as the 'question' portion of a CDE.

Data Standard – A documented consensus-based agreement on the format and definition of common data.

Datatype - A set of distinct values, characterized by properties of those values and by operations on those values.

Implementation Guidance - General guidance for implementation of a data standard for all systems/applications. It may contain common business rules applicable to all systems/applications.

Long Name - A readable and descriptive phrase describing an administered item.

Major Data Standards Revision: A revision of the data standard which will have an impact on systems/application implementation. For example, the addition, deletion or change of a data element(s) or data element definition(s), or a change in the choice of a mandatory code set.

Minor Data Standards Revision - A revision of the data standard which will not have an impact on its implementation. For example, editorial corrections of spelling or syntax errors, a change in format to make consistent with new data standards, or to correct a minor error.

Object Class - A set of ideas, abstractions, or things in the real world that are identified with explicit boundaries and meaning and whose properties and behavior follow the same rules.

Permissible Value (PV) - The exact names, codes, or text that can be entered and stored in a data field in an information management system.

Property - A characteristic common to all members of an Object Class.

Qualifier - A term used in conjunction with a primary term that helps define and render a concept unique.

Read-only Users – An organizational unit or individual that is approved to review the contents of the metadata register. (Source: ISO/IEC 11179)

Registrar – An organizational unit within the Registration Authority, expert in registration processes, responsible for facilitating the registration of Administered Items and making those Administered Items widely accessible and available to the community. (ISO/IEC 11179)

Registration Authority – An organizational unit that desires to operate and manage a Metadata Registry based upon the ISO/IEC 11179 Metadata Registry standard. (Source: ISO/IEC 11179)

Representation - The representation is composed of a value domain, data type, units of measure (if necessary), and representation class (optionally) and defines how instance data will be recorded.

Required Implementation Date - The date, stated in the data standard, by which the data standard must be incorporated into all applicable agency systems (directly or by mapping system/application data elements to the standardized data elements.)

Responsible Organization – The organization, or part thereof, that is responsible for the integrity and accuracy of the attributes values of the metadata; e.g., the semantics of Administered Items maintained and controlled by a Registration Authority. (Source: ISO/IEC 11179)

Retirement Date - The date upon which a version of a data standard has been superseded by a new version. The old version should no longer be used unless an exemption is obtained and recorded.

Short Name - An abbreviated representation of the long name of an administered item.

Steward – An organizational unit of the Metadata Registry community responsible for the accuracy, reliability, and currency of descriptive metadata at a registration status level of "Qualified" or above within an assigned area. (Source: ISO/IEC 11179)

Submitter – An organizational unit, approved by a process defined by the Registration Authority, authorized to identify and report Administered Items suitable for registration. (Source: ISO/IEC 11179)

Submitting Organization – An organizational unit wishing to register metadata in accordance with procedures prescribed by ISO/IEC 11179 and the Registration Authority. (Source: ISO/IEC 11179)

Value Domain (VD) – A set of attributes describing representational characteristics of instance data with or without enumerated permissible values.

Value Meaning (VM) – The reusable metadata attribute that defines a single permissible value; the meaning or semantic content of a data value.

Value Meaning Description/Definition (VMD) - The definition or description of the value meaning.

Exemption - An official approval issued by the NCI which exempts a system from the requirement to conform to a data standard.

Wiki - A NCI wiki where all developers and users of data standards can find information about NCI data standards and guidance on their implementation; and, collaborate on development, revision of data standards and/or implementation issues.

Workgroup - A team of subject matter experts that develops or modifies a data standard and/or data standard implementation guidance document.

Workgroup Charter - Developed by the workgroup to define the scope and the level of effort needed for the development of a proposed data standard.

12. Acronyms

1. ALS – Architect Loader Spreadsheet
2. NCI's National Clinical Trials Network (NCTN)
3. NCI's Experimental Therapeutics Clinical Trials Network (ETCTN)
4. Network Rave Data Standards (NRDS)
5. National Cancer Institute – NCI
6. Information Technology (IT)
7. Center for Biomedical Informatics and Information Technology (CBIIT)
8. Architect Loader Specification (ALS)
9. Cancer Trials Support Unit (CTSU)
10. Lead Protocol Organization (LPO)
11. Working Group (WG)
12. Cancer Data Standards Registry and Repository caDSR
13. Case Report Form (CRF)
14. Common Data Element (CDE)
15. Clinical Data Update System (CDUS)
16. Statistical Analysis System (SAS)
17. Oncology Patient Enrollment Network (OPEN)
18. Edit Checks (ECs)
19. Custom Functions (CFs)
20. Other IDs-OIDs
21. Permissible Value (PV)
22. Value Domain (VD)
23. Value Meaning (VM)
24. Value Meaning Description/Definition (VMD)

13. References

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2. Data Standards Policy, EPA Classification No: CIO 2133.0, 06/28/2007 - Data Standards Development; Data Standards Implementation; Data Standards Maintenance; Requesting Data Standards Conformance Exemption
3. Governance Framework for Trusted Electronic Health Information Exchange, Office of the National Coordinator, May 2013, http://www.healthit.gov/sites/default/files/GovernanceFrameworkTrustedEHIE_Final.pdf
4. The IBM Data Governance Unified Process, Sunil Soares, http://www-01.ibm.com/common/ssi/cgi-bin/ssialias?htmlfid=IMM14074USEN&appname=wwwsearch , pdf download available
5. Office of the National Coordinator, Healthit.gov, Policy Making, Regulation and Strategy, http://www.healthit.gov/policy-researchers-implementers/health-information-exchange-governance
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7. Wikipedia – Data Governance, http://en.wikipedia.org/wiki/Data_governance