Network Rave Data Standards (NRDS) Policy and Governance WG

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Agenda

- NRDS Policy and Governance Suggestions and Responses
- NRDS Policy and Governance Roles/Responsibilities
- NRDS Policy and Governance Workflows
- Next Steps

NRDS Policy and Governance Suggestions and Responses

- **Define what is in scope and out of scope for the NRDS Policies**
  - Included a description with the set of policies that states:

"These policies apply to the formulation and utilization of NRDS approved Standards in Rave for the NCTN and ETCTN."

NRDS Policy and Governance Suggestions and Responses

- **What can an LPO submit for a review, ALS or CRF?**
  - The standard question text can-NOT be changed except if pre-approved by NRDS WG (exception NOT the rule).
  - A response CAN be eliminated if it is not appropriate for a specific study.
  - Additional responses can-NOT be added to a pick list.
  - Responses can-NOT be merged.
  - The question and answer sets MUST follow the style guide recommendations.
  - Coded values specific to each group can be used in their own systems but NOT in Rave.
  - An ALS **must** be submitted to document an **implemented** change.
  - A CRF can be submitted with supporting evidence for a **proposed** change to a NRDS Standard CDE.

NRDS Policy and Governance Suggestions and Responses

- **Which components of the ALS can be changed by the LPOs?**

- **What happens when CTSU provides the final ALS to the groups and the LPOs want to use their own Short Name (OIDs), etc?**
  - **Working on a response for this group**

NRDS Policy and Governance Roles/Responsibilities

- **Clearly define the roles between NRDS Content and Policy WG**
  - NRDS Content WG
    - The committee established to identify and manage the NRDS approved Standards for use in Rave by NCTN and ETCTN.
      - Identify proposed NRDS Standards
      - Review and approve updates to NRDS approved Standards
      - Collaborate with the NRDS Policy and Governance WG to manage the NRDS approved Standards
      - Collaborate with the caDSR Registry Steward when utilizing the NRDS Standards
      - Verify the use of NRDS approved Standards in CTSU prepared ALS files during the initial stages

NRDS Policy and Governance Suggestions and Responses

- **Clearly define the roles between NRDS Content and Policy WG**
  - NRDS Policy and Governance WG
    - Identify and govern the decisions on the adoption and usage of the NRDS Standards in Rave by NCTN and ETCTN.
      - Review the recommended updates to existing NRDS Standards for compliance to the NCTN and ETCTN Governance Framework
      - Enforce approved policies and governance
      - Define an escalation strategy

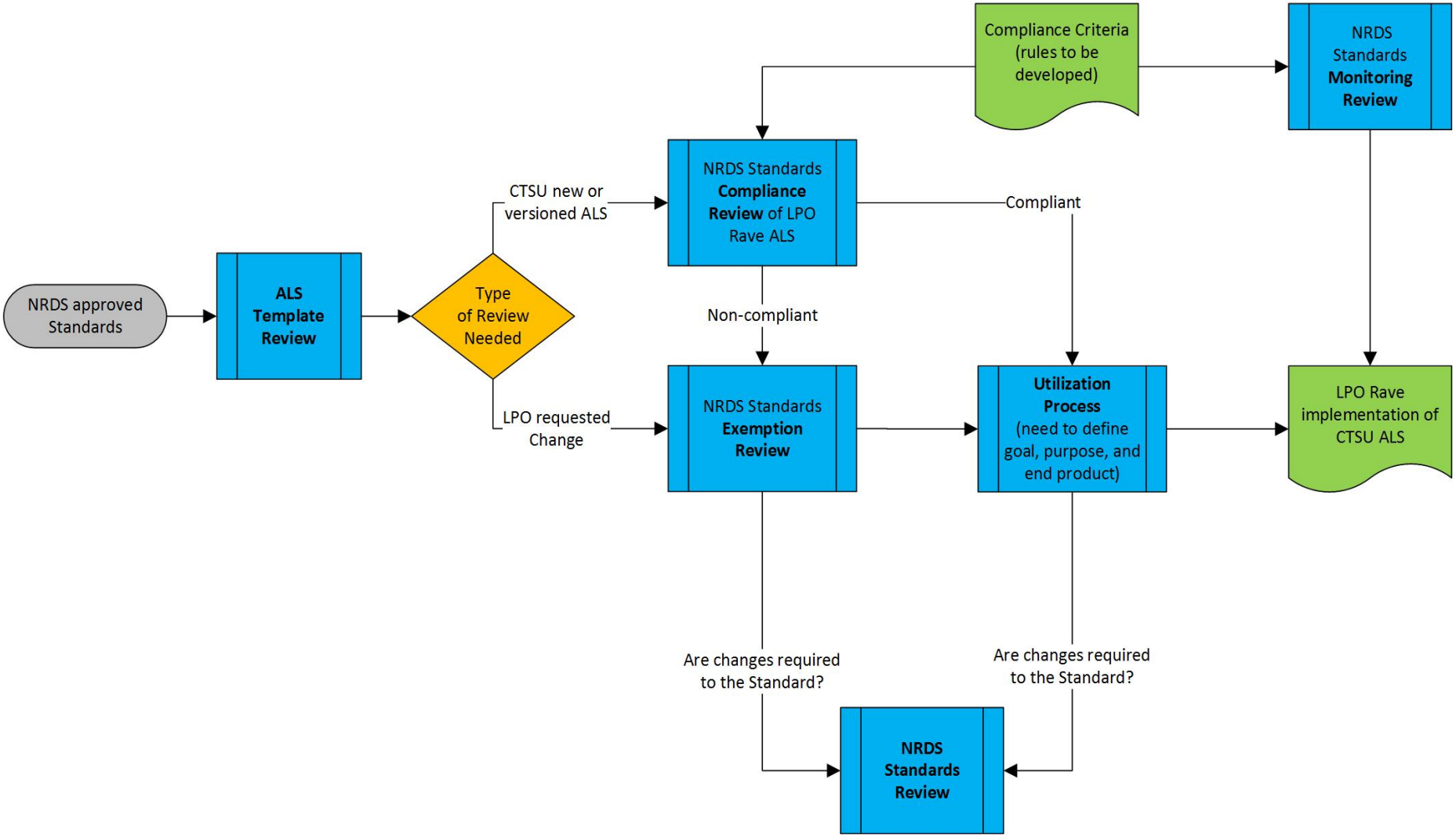
NRDS Policy and Governance Workflows

- NRDS Standards Process
  - **Trigger**: NRDS Content WG provides NRDS approved standards
  - **Goal**: To produce a high level workflow of the NRDS Policy and Governance Workflows
- ALS Template Review
  - **Trigger**: CTSU releases a new version of an ALS template
  - **Goal**: To produce an ALS template that uses the NRDS approved Standards correctly
  - **Deliverable**: Report for CTSU to make changes to the ALS template as needed
- NRDS Standards Compliance Review
  - **Trigger**: An LPO is building a study using a new or versioned ALS template
  - **Goal**: To ensure the LPOs ALS file is in compliance with the CTSU ALS template
  - **Deliverable**: Compliance Report back to the submitting LPO

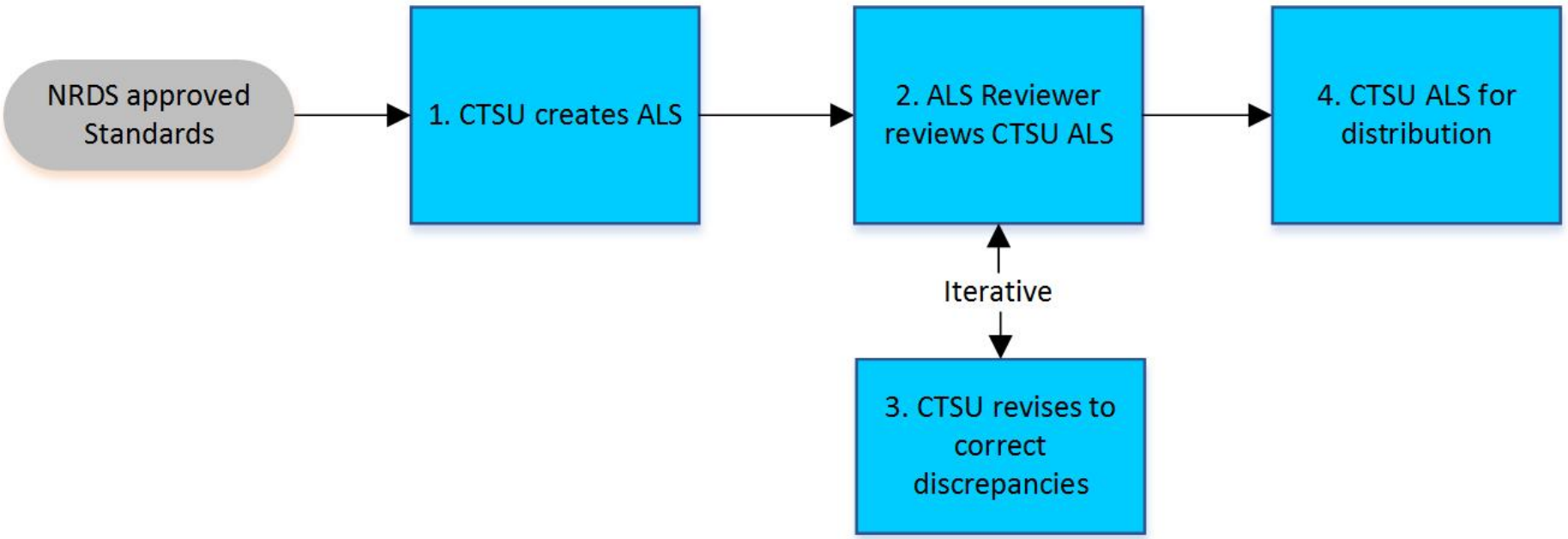
NRDS Policy and Governance Workflows

- NRDS Standards Exemption Review
  - **Trigger**: LPO submits a change request or an ALS is found to be non-compliant
  - **Goal**: Assessment of an LPO change request or non-compliant ALS
  - **Deliverable**: Report of the exemption assessment findings
- NRDS Standards Monitoring Review
  - **Goal**: Ongoing surveillance to ensure compliance with NRDS Standards
  - **Deliverable**: Monitoring Metrics Report
- NRDS Standards Review
  - **Trigger**: Based on the needs of the NRDS Community
  - **Goal**: Ensure NRDS Standards meet the needs of the NRDS Community
  - **Deliverable**: Report delivered to the NRDS Content WG for disposition

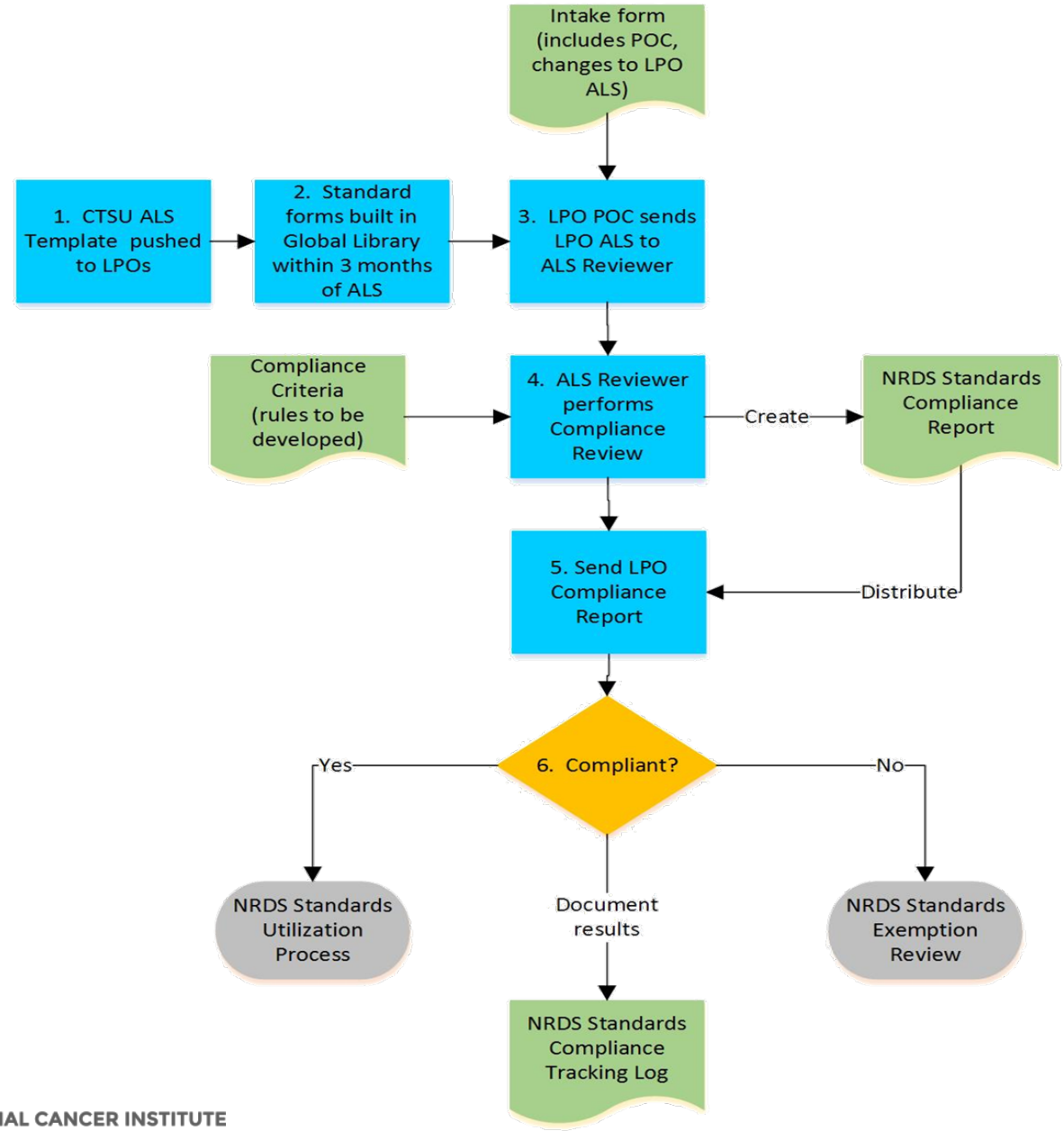
NRDS Standards Process



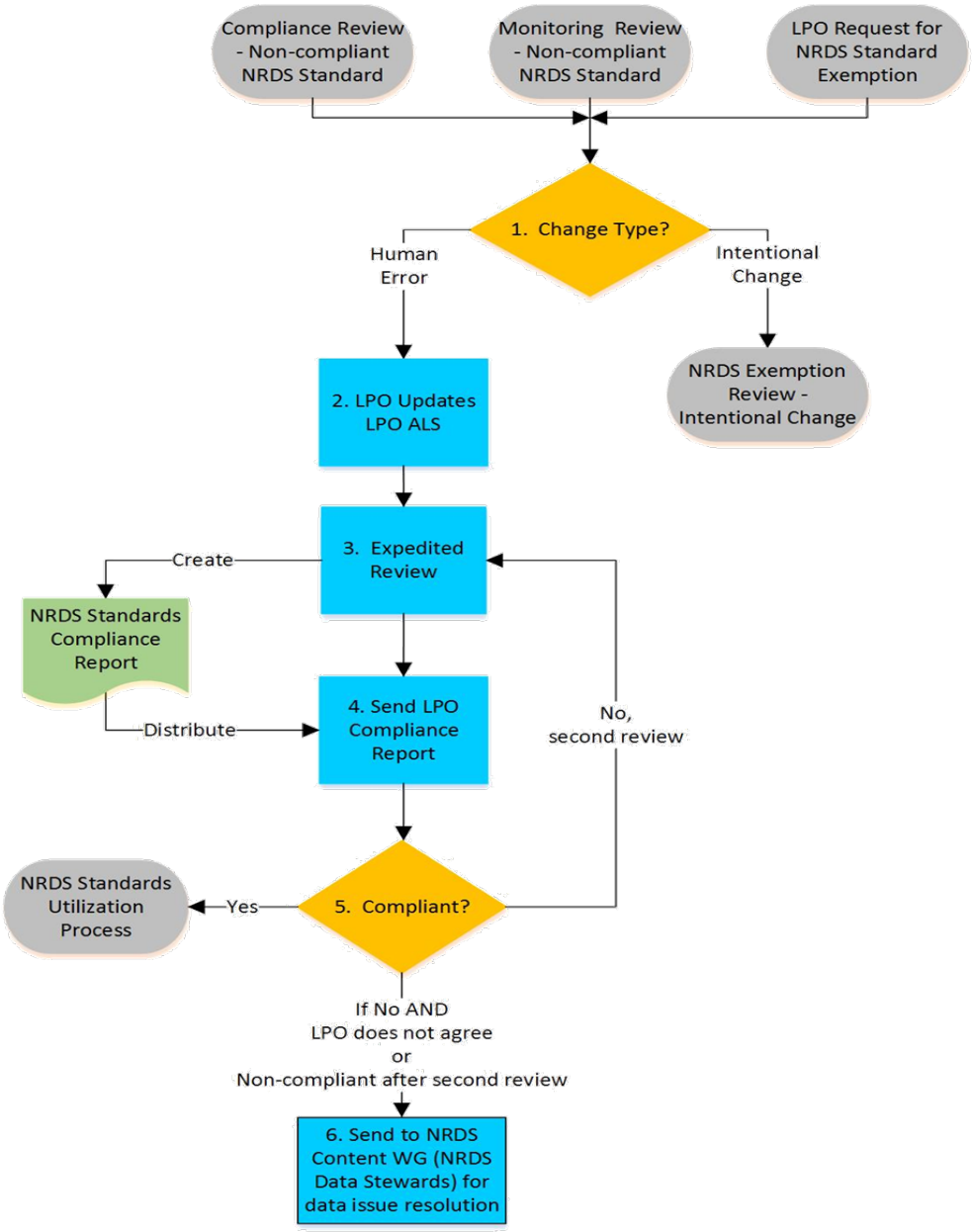
ALS Template Review



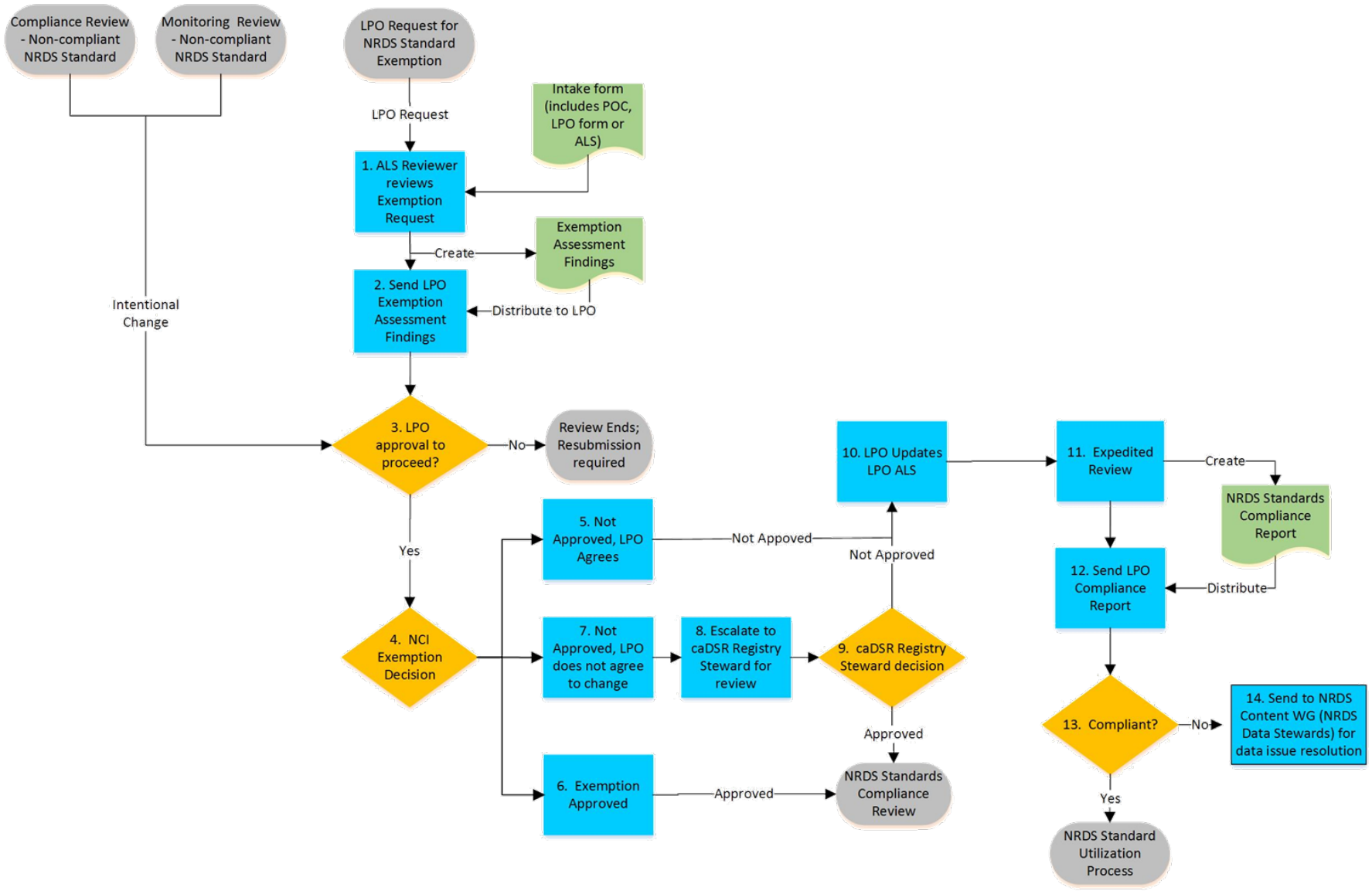
NRDS Standards Compliance Review



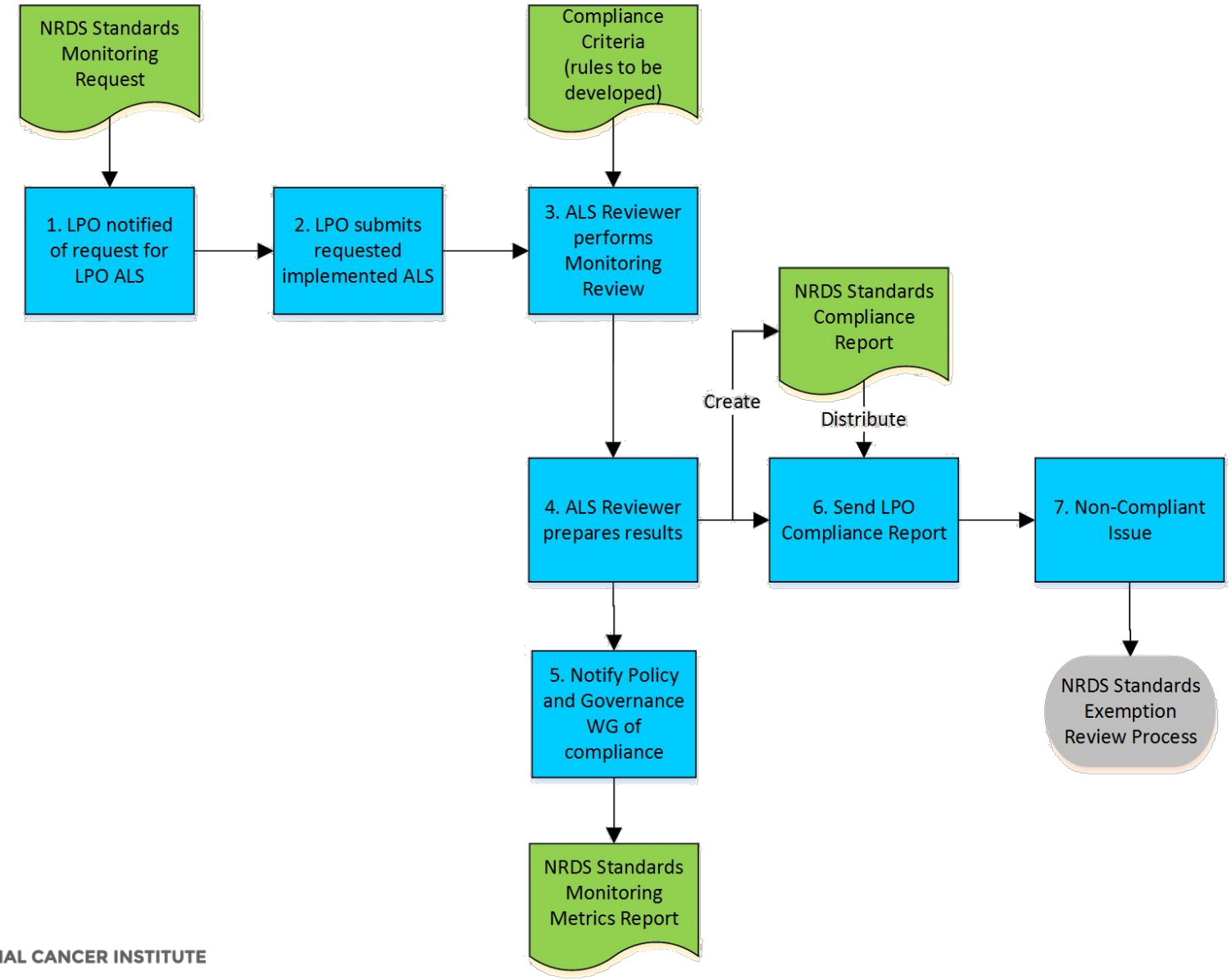
NRDS Standards Exemption Review – Human Error



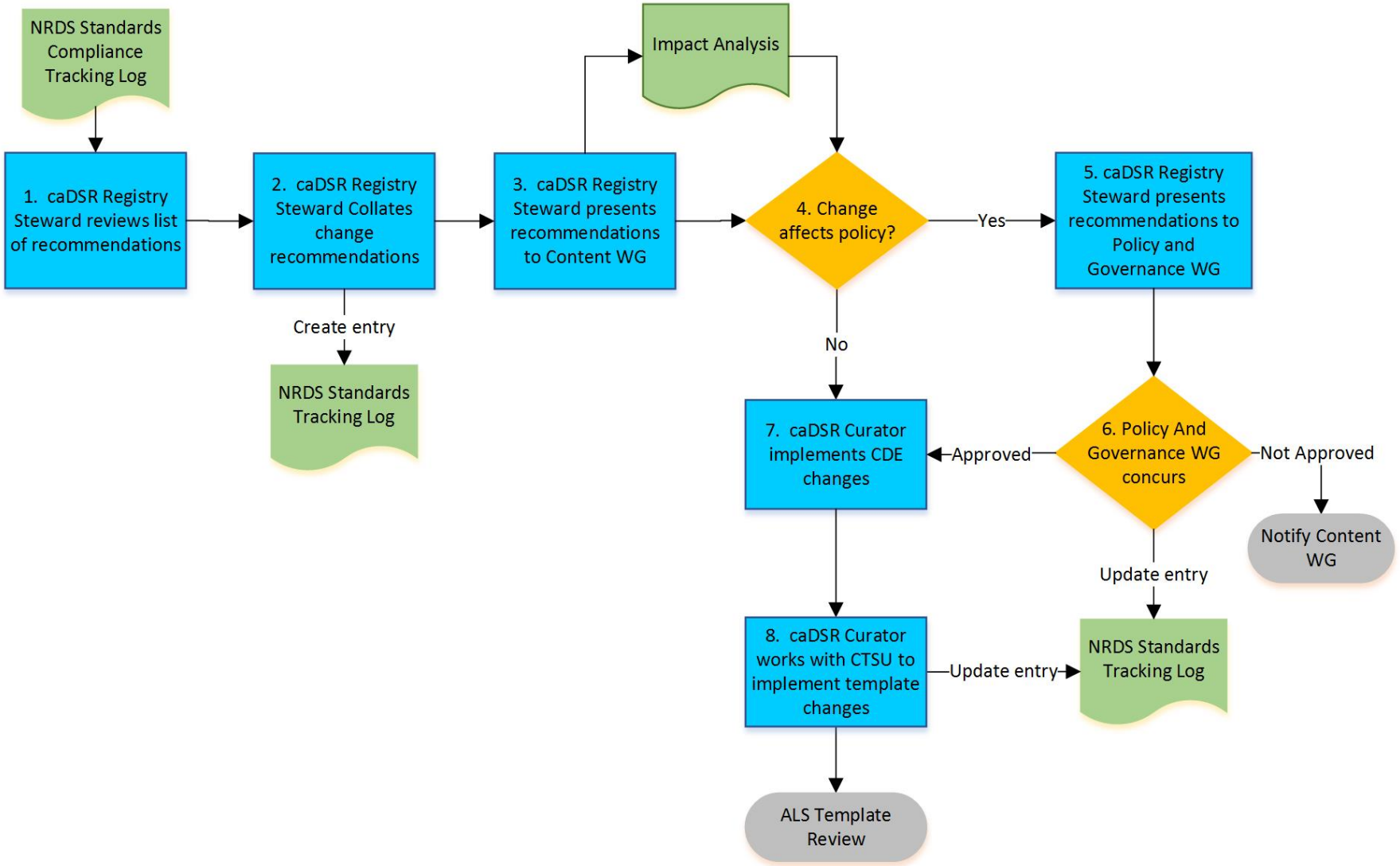
NRDS Standards Exemption Review – Intentional Change



NRDS Standards Monitoring Review



NRDS Standards Review



Next Steps

- Continue defining governance and policies

Reference Information / Questions

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