NEW!

NIH Policy for
Data Management & Sharing

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Data Stewardship Goals

- **Advance rigorous and reproducible research**
  - Enable validation of research results
  - Make high-value datasets accessible
  - Accelerate future research directions
  - Increase opportunities for citation and collaboration

- **Promote public trust in research**
  - Foster transparency and accountability
  - Demonstrate stewardship over taxpayer funds
  - Maximize research participants' contributions
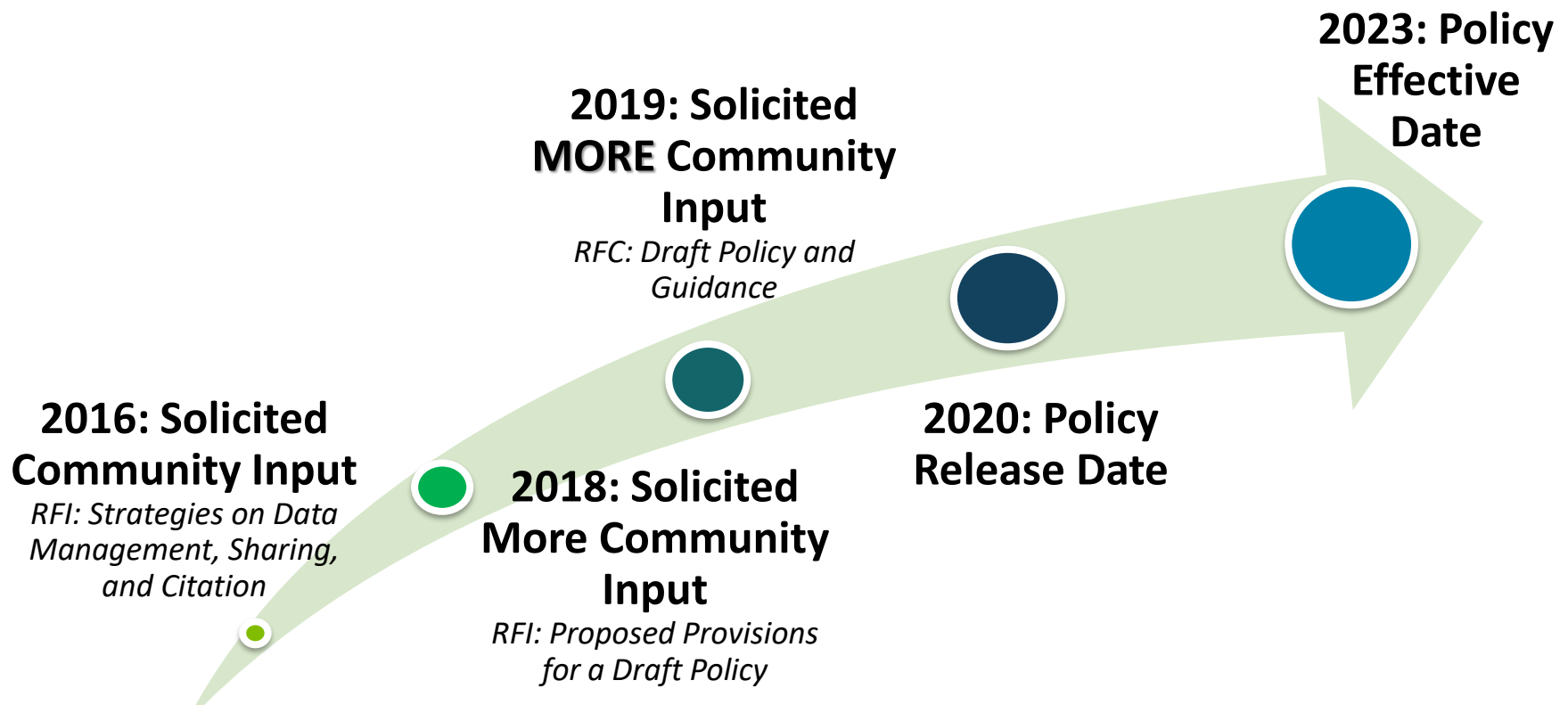 - Support appropriate protections of research participants' data

NIH Policy for Data Management and Sharing

- **Submission of Data Management & Sharing Plan for all NIH-funded research** *(how/where/when)*

- **Compliance with the ICO-approved Plan** *(may affect future funding)*

- **Effective January 25, 2023** *(replaces 2003 Data Sharing Policy)*

- **Supplemental info available to assist**

- **Aims to foster data stewardship**

An Iterative Policy Development Process

- Sought public comment repeatedly

- Tribal Consultation*
  *Details provided in "NIH Tribal Consultation Report: NIH Draft Policy for Data Management and Sharing"

- Intersection with other government agencies & Secretary's Advisory Committee for Human Research Protections

2023: Policy Effective Date

2019: Solicited MORE Community Input
RFC: Draft Policy and Guidance

2020: Policy Release Date

2016: Solicited Community Input
RFI: Strategies on Data Management, Sharing, and Citation

2018: Solicited More Community Input
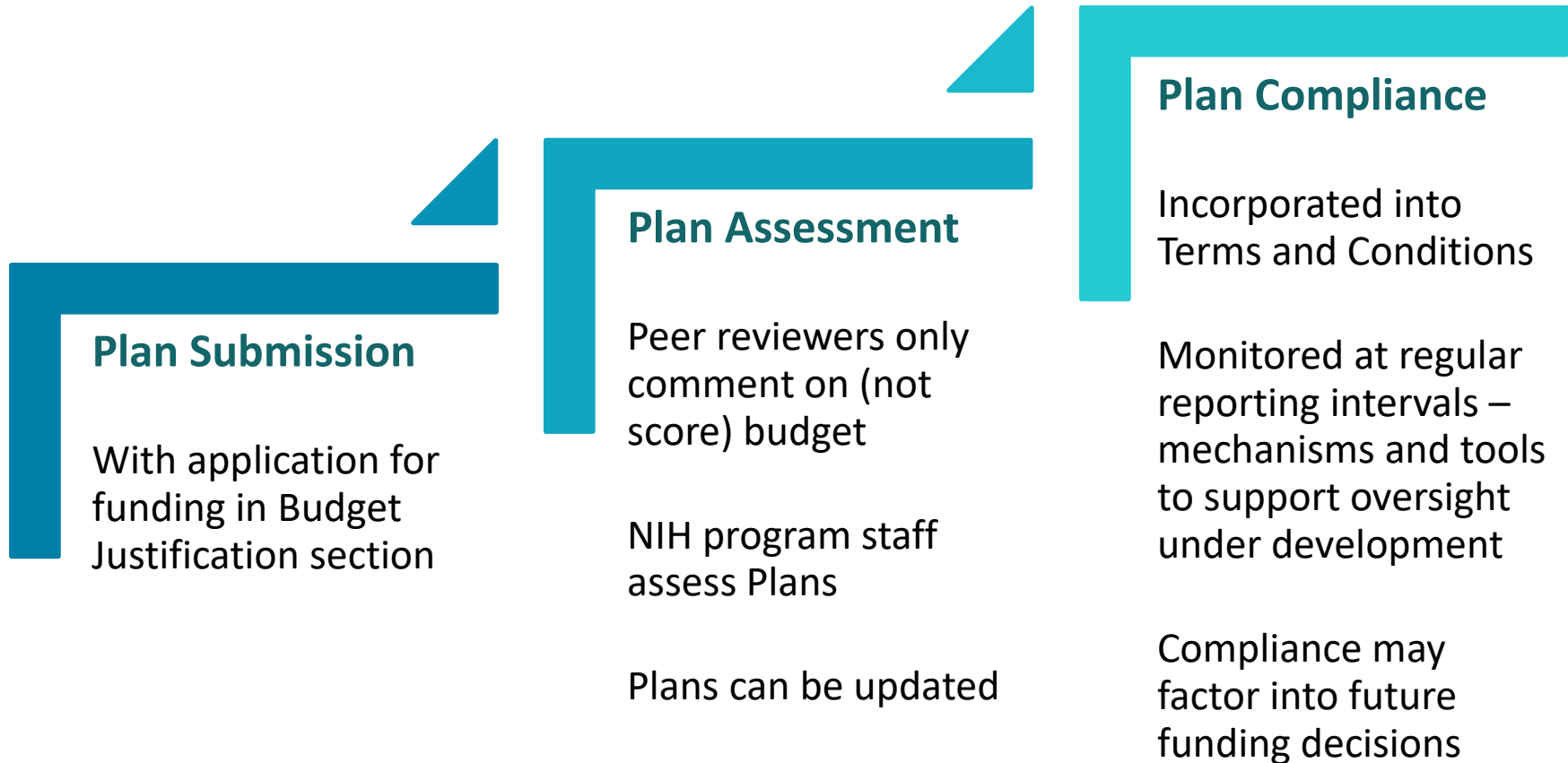*RFI: Proposed Provisions for a Draft Policy*

The Devil is in the Details…

- **Scope:** All NIH-supported research generating *scientific data*

- **SHARING SHOULD BE …**

  - **The default practice**

    - Maximize appropriate data sharing; Plans may justify exceptions (i.e., ethical, legal, technical factors)

  - **Responsibly implemented**

    - Plans should outline protection of privacy, rights, and confidentiality

    - Existing laws, regulations, and policies continue to apply

  - **Timely**

    - **When to share data?** No later than <u>publication</u> or <u>end of award</u> (if unpublished); other relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames

'Which brings us to my next point.'

Plan Submission and Review

Extramural Grant Awards*

Plan Submission

With application for funding in Budget Justification section

Plan Assessment

Peer reviewers only comment on (not score) budget

NIH program staff assess Plans

Plans can be updated

Plan Compliance

Incorporated into Terms and Conditions

Monitored at regular reporting intervals – mechanisms and tools to support oversight under development

Compliance may factor into future funding decisions

Analogous requirements for contracts, OTAs, IRP

Supplemental Info to the Policy: Allowable Costs

- **Reasonable costs allowed in budget requests**
  - Curating data/developing supporting documentation
  - Preserving/sharing data through repositories
  - Local data management considerations

- <u>**NOT**</u> **considered data sharing costs**
  - Infrastructure costs typically included in indirect costs
  - Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

Supplemental Info to the Policy: Repository Selection

- **Encourages use of established repositories**

- **Helps investigators identify appropriate data repositories**
  - e.g., use of persistent unique identifiers, attached metadata, facilitates quality assurance

- **NIH ICs may designate specific data repository(ies)**

Resources for Implementation

What's Next?

- **Outreach and engagement** – additional supplemental information to come (including tribal-specific considerations)

- **Develop tools** for estimating data management and sharing costs (e.g., [2020 NASEM report on forecasting costs](#) & [April 2021 NASEM workshop on the culture of data management & sharing](#))

- **Develop mechanisms, tools, and approaches** for incentivizing good data sharing practices

- **Clarify interactions** with other NIH-wide (e.g., GDS Policy) and ICO-specific data sharing policies

- **Developing FAQs and other resources** to aid policy implementation

˜*2-year implementation window!*

Thank You!

- OSP Data Management and Sharing Website

- NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing

- NOT-OD-21-014 – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan

- NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing

- NOT-OD-21-016 – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

Questions? sciencepolicy@mail.nih.gov