A (Very) Simplified View of the NIH Grants Pipeline

Application Submitted → Review → Just-in-Time

Award Made → Progress Reports (RPPR) → Closeout
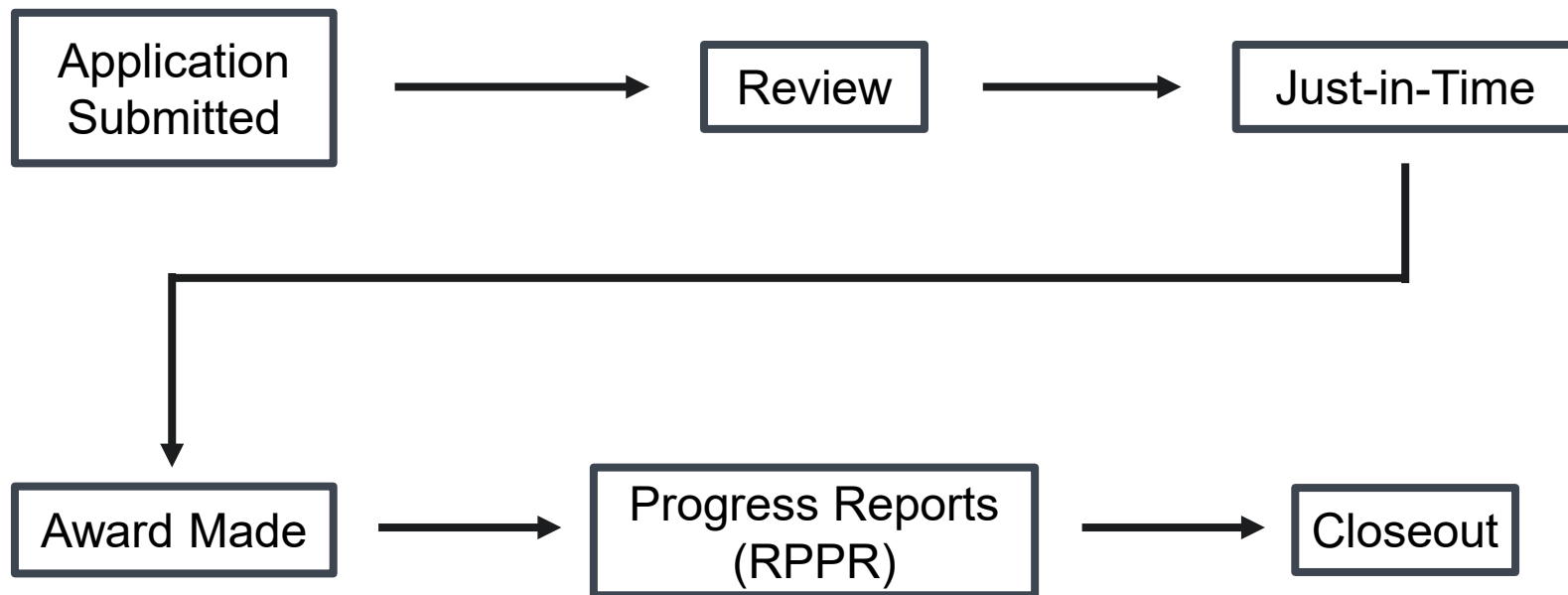
Considerations for Data Sharing are Made Throughout the Grant Pipeline

Write DMS Plan

Modify DMS Plan with PD

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┌──────────────┐        ┌──────────┐        ┌──────────────┐
│ Application  │───────▶│  Review  │───────▶│ Just-in-Time │
│  Submitted   │        │          │        │              │
└──────────────┘        └──────────┘        └──────────────┘
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┌──────────────┐        ┌──────────────────┐        ┌──────────┐
│  Award Made  │───────▶│ Progress Reports │───────▶│ Closeout │
│              │        │     (RPPR)       │        │          │
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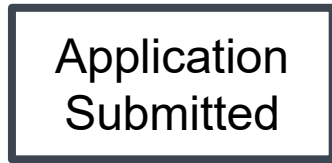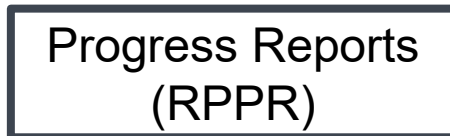
Execute DMS Plan & Modify (if necessary)

Assess Data Sharing

Data Sharing Considerations Post-Award

Write DMS Plan

| Application Submitted |

→

| Review |

→

Modify DMS Plan with PD

| Just-in-Time |

| Award Made |

You Are Here

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| Progress Reports (RPPR) |

Execute DMS Plan & Modify (if necessary)

→

| Closeout |

Assess Data Sharing
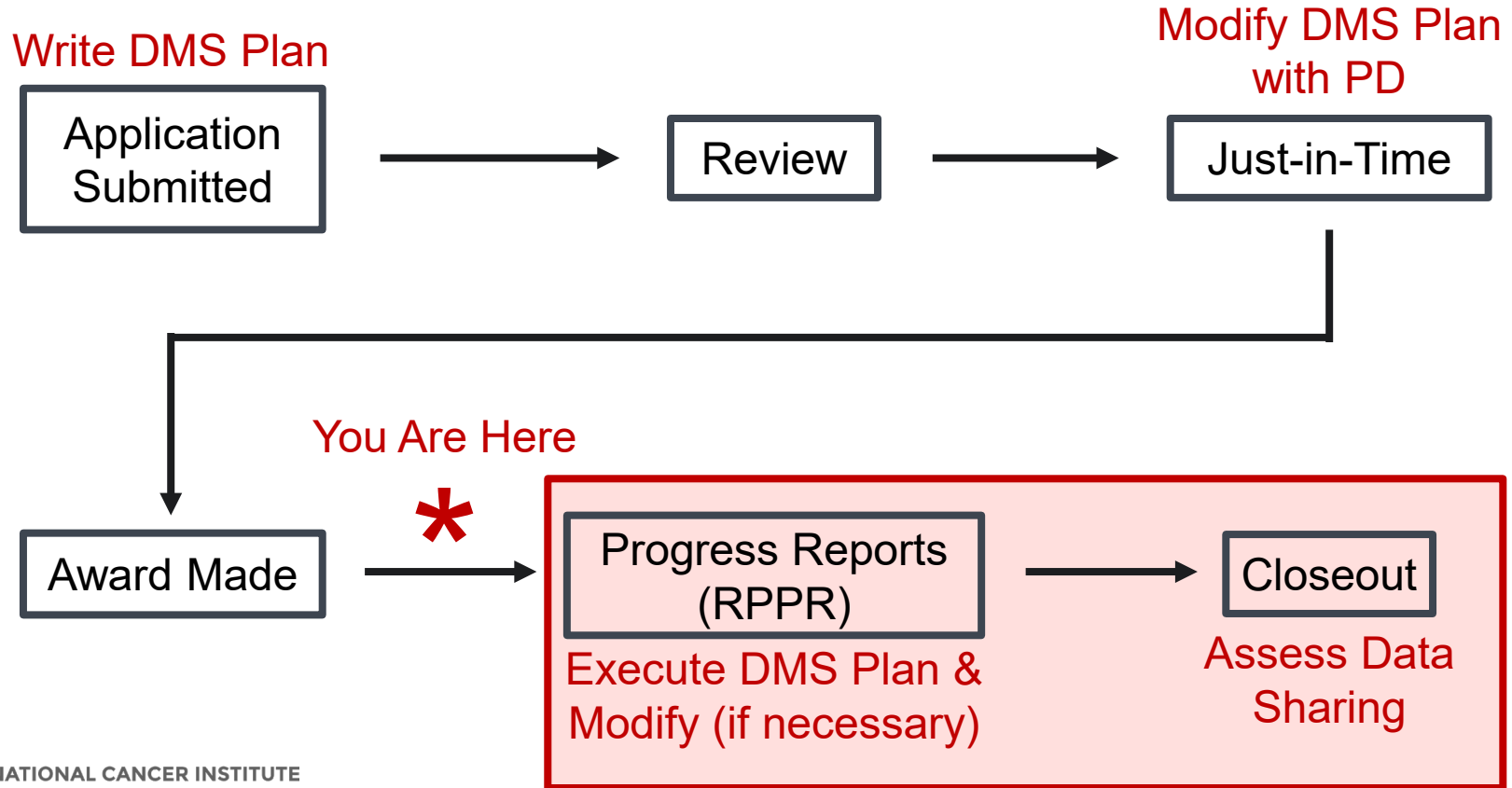
NIH Data Sharing Policies: Applicability and Requirements

- **Data Management & Sharing (DMS) Policy (2023)**
  - Applies to all grants generating "scientific data"—all R01s & equivalent
  - PI must write & execute a DMS Plan with input from Program Director

- **Genomic Data Sharing (GDS) Policy (2014)**
  - Applies to grants generating "large-scale" genomic data
  - PI must specify restrictions on data sharing of human genomic data consistent with consent
  - Data must be deposited in an NIH-sponsored repository (dbGaP)

Post-Award DMS Policy Considerations

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Making Changes to the DMS Plan Post-Award

- The DMS Policy **allows modifications** to DMS plans post-award when plans change:

  - New data types being generated

  - New samples with specific data sharing restrictions

- Send modifications to your Program Director *proactively* to avoid delays or other issues

- RPPRs will also include a question about changes to your DMS Plan

- Your PD will assess whether changes are appropriate and may ask clarifying questions

Reporting Data Sharing in Progress Reports (RPPRs)

- Annual progress reports now include a tabular section to report data generation, deposition, and release

- Your Program Director will review & determine whether your DMS plan is being followed and may reach out for more details

Data Type ▲		Has data been generated to date? ⇕	Has the data been shared? ⇕	Status of Data Sharing ⇕	Repository ⇕	Unique Identifiers/Digital Object Identifier ⇕
array-derived geno-type data	•••	Y	Y	Shared	Data Hub	ABC1234
Demographic Data	•••	Y	N	Data not yet published will share in future	Not Applicable	Not Applicable
Phenotypic and clini-cal data	•••	N	N	Not yet expected to be shared	Not Applicable	Not Applicable

*If data has not been generated and/or shared as outlined in the approved Plan, describe why, and identify any corrective actions that have or will be taken to comply with the approved plan.

Post-Award GDS Policy Considerations

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Transition to GDS Applicability: Genomic Data Thresholds

- While reviewing an RPPR, your Program Director may reach out for details to determine whether a threshold for "large-scale" genomic data has been surpassed—*even if your award was not initially subject to the GDS Policy*

- A "specimen" in this context depends on the technology used—*for single-cell techniques, each cell constitutes a specimen*

Data Type	# of Specimens (Human)	# of Specimens (Nonhuman)
GWAS	1000	500
<100 genes	1000	500
≥100 genes	100	50
Genome-wide	100	50
ChIP-seq	100	50
Metagenome	100	50

More details on cancer.gov

GDS-Applicable Awardees Generating Human Data Must Provide an Institutional Certification (IC) Form

- Blank IC Forms can be found on the [NIH Data Sharing website](#) and come in three variants:

  - Samples collected *before* Jan 25, 2015, with *and* without consent

  - Samples collected *after* Jan 25, 2015

- IC Forms specify restrictions on sharing of *human* genomic data consistent with consent, and must be signed by an institutional signing official

  - This applies even if proposed research is *not* human subjects research (i.e., human cell lines, PDXs, etc.)

dbGaP: An NIH Repository for Controlled-Access Data
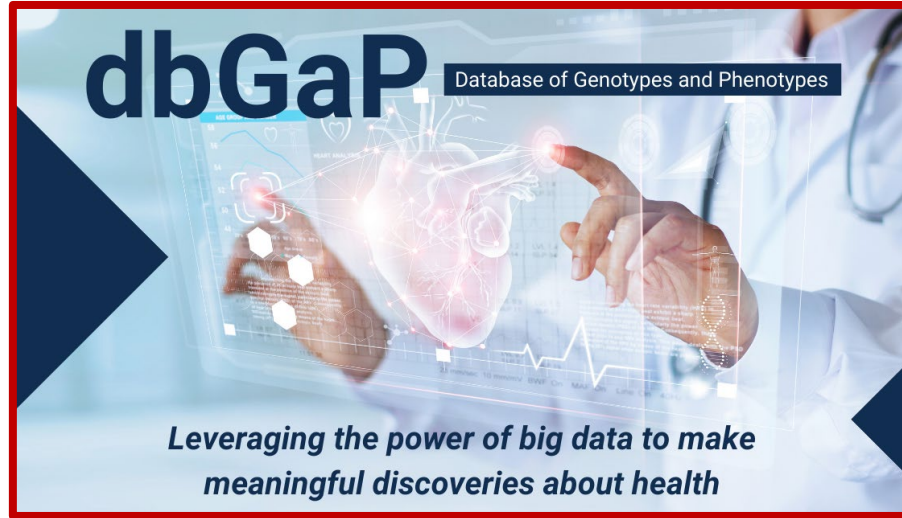
- The **D**ata**b**ase of **G**enotypes **a**nd **P**henotypes (dbGaP): NIH-managed repository for genomic data

- Common controlled-access repository for human genomic data—required for human data subject to the GDS policy

Initiating Data Deposition into dbGaP

1. Contact your **Program Director** and indicate that you'd like to deposit data to dbGaP

2. Your PD will put you in contact with the appropriate **Genomic Program Administrator** (for DCB, that's me!)

3. The GPA will register your study and send a link to begin data submission

4. After depositing study metadata (in collaboration with dbGaP staff), you'll receive an accession number for your study

DCB Resources for Data Sharing Questions

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2024 NIH Public Access Policy

- Applies to manuscripts accepted for publication ***on or after December 31, 2025***

- All NIH-funded publications ***must be submitted to PubMed Central*** for public availability ***without embargo*** upon the official date of publication

- This does ***not*** require payment of an article-processing charge (APC)

- PIs/institutions may upload the accepted manuscript directly to PubMed Central

Thank you!

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