HARVARD UNIVERSITY
Information Technology

Research Administration and Compliance Systems Project Agreements-DUA

January 2019

Agenda

- Data Use Agreement

  – Definition & Guidance

  – System

- Research Administration and Compliance Systems Project

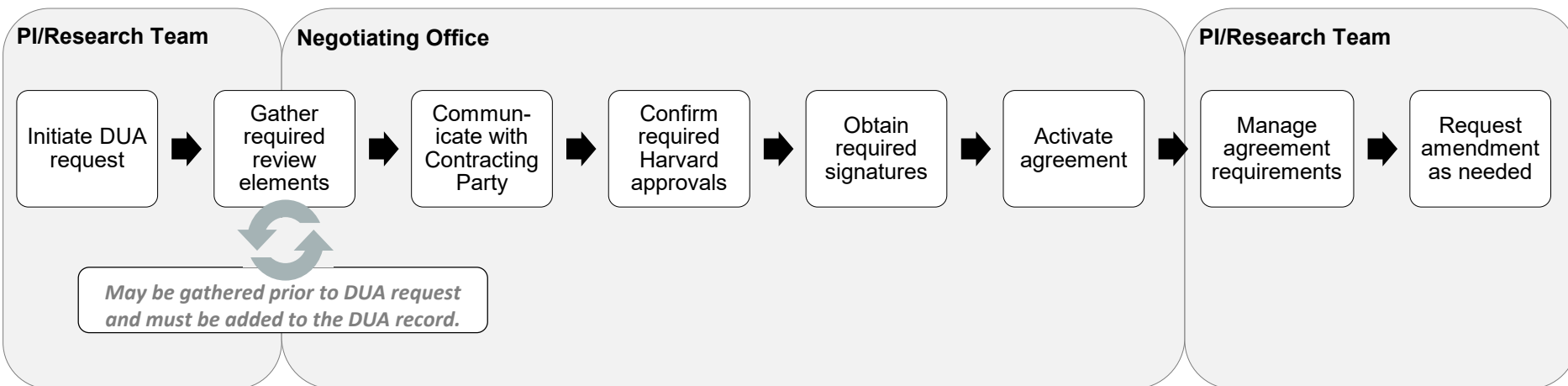# What is a Data Use Agreement (DUA)?

- A Data Use Agreement (DUA) is a binding contract governing access to and treatment of nonpublic data between two or more parties.

- A DUA may provide for data to be received by Harvard and/or for Harvard data to be disclosed to another organization.

- DUA terms and conditions vary depending on the laws and regulations governing the particular type of data, as well as the policies and/or requirements of the data provider.

- DUA terms may address:

    - Restrictions on how the data can be used

    - Specific security requirements for transferring and storing the data

    - Publication guidelines

    - Liability for claims arising from the improper use of the data

    - Privacy regulations applicable to the data (e.g. HIPAA, FERPA, GDPR)

History of DUAs at Harvard

- All DUAs at Harvard are to be reviewed and signed by the appropriate sponsored research office (OSP, HMS ORA, SPH ORA).

- Efforts to funnel DUAs to the appropriate offices have included:

    – Dedicated e-mail Inbox

    – ADAMS

    – Qualtrics Intake form

    – General training/outreach

- The number of DUAs received by the sponsored research offices has increased over the past several years
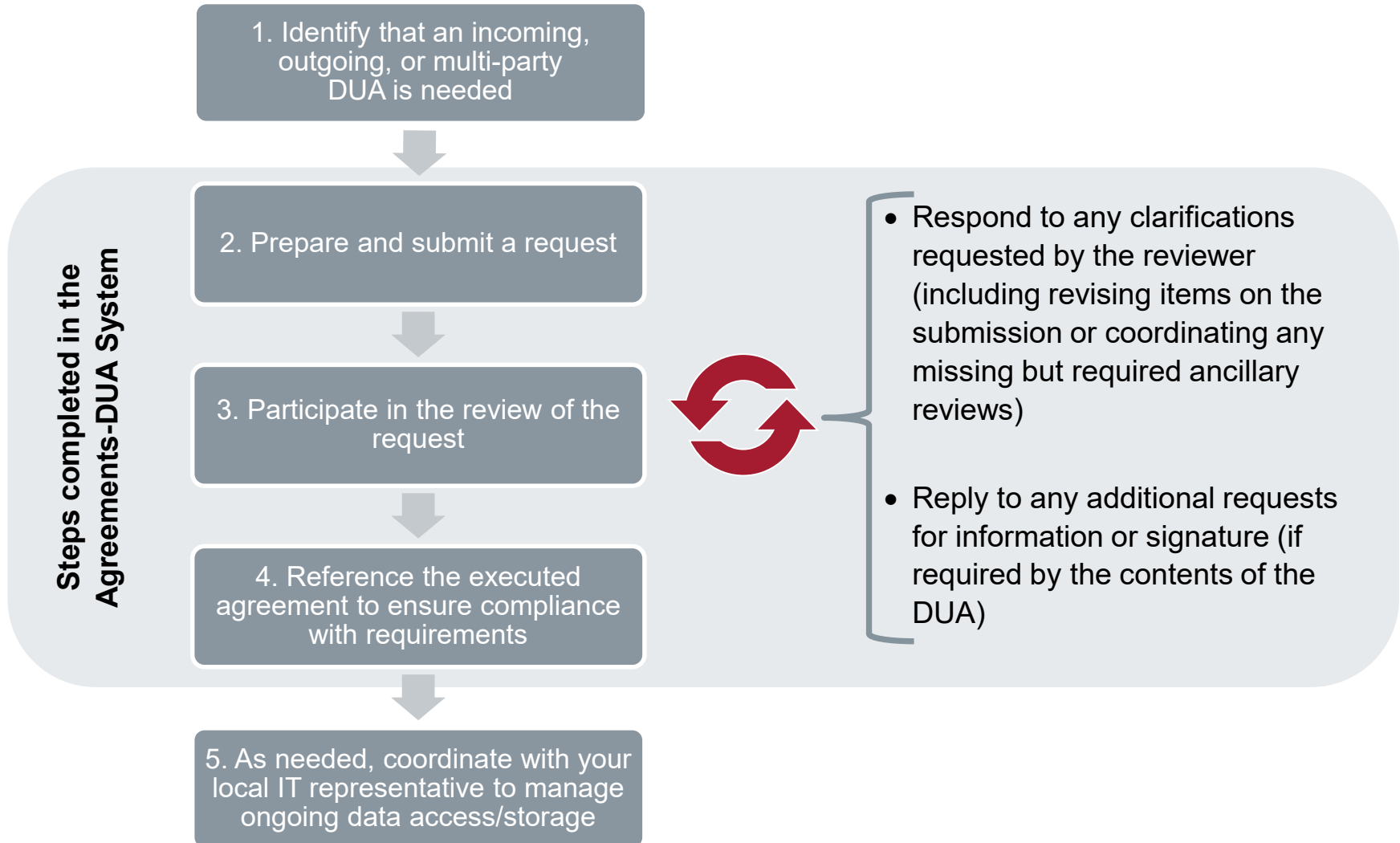
    Ex: In 2016, 198 DUAs were entered into OSP's assignment queue for review. In 2018, 255 DUAs were received by OSP for review.

- Process lacked standardization and transparency both for researchers, and across reviewing offices.

- Volume necessitated an improved system for managing intake, addressing compliance issues, and providing a central repository for agreement management.

- DUA Guidance: https://vpr.harvard.edu/files/dua_guidance.pdf

DUA Review Process

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┌─ PI/Research Team ──┐  ┌─ Negotiating Office ─────────────────────────────────────────────────────┐  ┌─ PI/Research Team ────────┐
│                     │  │                                                                          │  │                           │
│  [Initiate DUA   → ]│  │ [Gather   → ] [Commun-  → ] [Confirm   → ] [Obtain   → ] [Activate    → ]│  │ [Manage      → ] [Request ]│
│  [request        ]  │  │ [required    ] [icate with ] [required    ] [required    ] [agreement   ]│  │ [agreement      ] [amendment]│
│                     │  │ [review      ] [Contracting] [Harvard     ] [signatures  ]               │  │ [requirements   ] [as needed]│
│                     │  │ [elements    ] [Party       ] [approvals   ]                             │  │                           │
│                     │  │                                                                          │  │                           │
│                     │  │       ↻                                                                  │  │                           │
│                     │  │  [May be gathered prior to DUA request                                   │  │                           │
│                     │  │   and must be added to the DUA record.]                                  │  │                           │
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- DUA review request initiated by PI/researcher.
- Agreement and supporting documentation are reviewed by negotiating office (OSP/ORA). Clarifications are requested as needed.
- Comments/revisions to the draft are sent to the data provider for review.
- Once all required approvals (e.g. IRB, HUIT) have been collected and DUA terms negotiated, the negotiating office executes the final agreement on behalf of Harvard.
- PI/Research Team are responsible for managing the data in compliance with the DUA, and consulting with OSP/ORA on any amendment requests (e.g., term extension).

Agreements-DUA System

Steps completed in the Agreements-DUA System

1. Identify that an incoming, outgoing, or multi-party DUA is needed

2. Prepare and submit a request

3. Participate in the review of the request

4. Reference the executed agreement to ensure compliance with requirements

5. As needed, coordinate with your local IT representative to manage ongoing data access/storage

- Respond to any clarifications requested by the reviewer (including revising items on the submission or coordinating any missing but required ancillary reviews)

- Reply to any additional requests for information or signature (if required by the contents of the DUA)

Agreements-DUA System

- Provides basic data entry, approval workflow, and document repositories.

- Supports multiple agreement types; we are starting with DUAs.
  Additional agreement types are under discussion for addition to the system.

- Look-and-feel is similar to other administrative systems
  (like ecrt and ESTR-IRB)

Research Administration & Compliance Systems Project

Agreements-DUA is part of a larger project at Harvard.

- Programmatic approach; delivering a collection of projects tied together, in service to the research community
- Three-year ITCRB investment spanning a variety of compliance areas
- Main objectives:
  - Improving faculty experience
  - Enhancing compliance
  - Reduction of administration burden

Questions?