DEVELOPER USE STATEMENT

SECTION A and **SECTION B** should be filled out by all Lead Developers and Developer Partners requesting access to controlled data or involved in the management or establishment of a controlled-access data repository. For **SECTIONS C-E**, please refer to their headings for instructions and applicability. For more information on the developer access pathway see: NOT-OD-24-157.

Date (MM/DD/YYYY):

Lead Developer or Developer Partner:

Lead Developer or Developer Partner's Institution:

Award, Contract, or OTA number (if applicable):

Program Officer/Program Director (if applicable):

SECTION A: General Information and Justification of Data Access

Please indicate which of the following best describes you:

- ○ Extramurally-funded Lead Developer: Principal Investigator (PI) listed as the Project Director (PD) or PI on the funding application

- ○ Federal Lead Developer: Lead Developer (e.g., team lead) at the managing NIH Institute, Center, or Office (ICO) repository or other federal agency

- ○ Developer Partner: developer not directly funded by NIH or the federal government (e.g., sub-awardee) partnering with an extramurally-funded or federal Lead Developer

IMPORTANT: Developer Partners must enter into a contract with the Lead Developer prior to gaining access to data. For more information see *Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy* (NOT-OD-24-157).

Please name the repository or access system you are managing, establishing, or requesting data access from:

Provide a justification of why developer access for controlled-access human genomic data is needed and describe the intended developer activities and data use.

Please indicate if you are using a Third-Party IT System and/or Cloud Service Provider (CSP) (check one):

- ○ **Yes**

- ○ **No**

If yes, please provide the name of Third-Party IT System and/or CSP:

SECTION B: Affirmation of DMI Reporting and Security Attestations

Affirmation of Data Management Incidents (DMI) Reporting

By selecting Yes, I, _____, as Lead Developer or Developer Partner, affirm to notify the NIH of any actual or suspected violations of the Terms and Conditions for developer access, the NIH Genomic Data Sharing Policy, or any additional ICO-specific requirements to the NIH Developer Data Access Committee (DAC) (DeveloperAccessDAC@od.nih.gov) within 24 hours of when the incident is identified.

- ○ **Yes**

- ○ **No**

Attestation of Compliance to Security Best Practices

I, _____, as Lead Developer or Developer Partner, attest to complying with (check one):

- ○ NIH Security Best Practices for Controlled-Access Data Repositories.

- ○ NIH Security Best Practices for Users of Controlled-Access Data

IMPORTANT: Lead Developers or Developer Partners should determine whether they are managing a repository (e.g., performing activities such as repository maintenance and infrastructure development). If so, the Lead Developer is expected to adhere to the NIH Security Best Practices for Controlled-Access Data Repositories.

Please indicate what standard you are applying (check one):

- ○ NIST SP 800-53, latest revision, Moderate Baseline or above

- ○ FedRamp Moderate Baseline or above

- ○ FISMA Moderate Baseline or above

- ○ NIST SP 800-171, latest revision

- ○ ISO/IEC 27001/27002

- ○ Other, including prior revisions of the above standards

If other was selected, please describe the standard the Lead Developer is applying:

```
[                                                              ]
[                                                              ]
[                                                              ]
[                                                              ]
[                                                              ]
```

Attestation of Third-Party Compliance

I,   **, as Lead Developer or Developer Partner,**

attest that   **is complying with (check one)**

- ○ NIH Security Best Practices for Controlled-Access Data Repositories
- ○ NIH Security Best Practices for Users of Controlled-Access Data
- ○ I am not working with a of Third-Party IT System and/or CSP

If applicable, please indicate the standards the Third-Party IT System and/or CSP is applying (check one):

- ○ NIST SP 800-53, latest revision, Moderate Baseline or above
- ○ FedRamp Moderate Baseline or above
- ○ FISMA Moderate Baseline or above
- ○ NIST SP 800-171, latest revision
- ○ ISO/IEC 27001/27002
- ○ Other, including prior revisions of the above standards

If other was selected, please describe the standard the third-party and/or CSP is applying:

SECTION C: Information on Developer Partnerships

IMPORTANT**:** Extramurally-funded or Federal Lead Developers must complete this section.

Please indicate if you seek to work with a Developer Partner not directly funded by NIH or the federal government that will need access to NIH controlled-access data (check one):

- ○ Yes

- ○ No

If yes, please provide the following information for each applicable Developer Partner:

Name of Developer Partner(s):

Name of Developer Partner's Institution(s):

Name of Developer Partner program manager:

Please indicate if you have entered into a contract with the Developer Partner containing the developer terms of access (check one):

- ○ Yes

- ○ No

IMPORTANT: Developer Partners have additional obligations, including submission of their own DUS, and must enter into a contract with the Lead Developer prior to gaining data access. For additional information on responsibilities see *Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy* (NOT-OD-24-157).

SECTION D: Developer Partner Information

IMPORTANT**:** Developer Partners must complete this section.

Please Provide the following information:

Developer Partner Program Manager: [   ]

Developer Partner IT Director: [   ]

Please indicate if you have entered into a contract with the Lead Developer containing the developer terms of access (check one):

○ Yes

○ No

IMPORTANT: Developer Partners must enter into a contract with the Lead Developer prior to gaining data access.

Please provide the following information:

Name of Lead Developer: [   ]

Name of Lead Developer's Institution: [   ]

Lead Developer Award Information, if applicable: [   ]

SECTION E: Federal Lead Developer Work with Extramural Developers

IMPORTANT**:** Federal Lead Developers must complete this section.

Please indicate if you are working with an extramural developer funded by an award, contract, or OTA.

○ Yes

○ No

If you are a Federal Developer working with an extramural developer, please provide their award, contract, or OTA number:

[   ]

IMPORTANT**:** Extramural developers funded via an award, contract, or OTA must fill out their own DUS.

Developer Use Statement Signature Page

Signatories to this document agree to adhere to the developer terms of access contained within the Data Use Agreement (DUA, see appendix) or in the term and condition of award and any additional NIH program or ICO-specific requirements and agree that role-based training on the NIH Security Awareness Course has been reviewed.

Submitted and Agreed to By:

> **Lead Developer or Developer Partner:**

Name: [   ]

Title: [   ]

Signature: [   ]

Date: [   ]

IMPORTANT: Only Federal Lead Developers and Developer Partners need to complete the following:

Institutional Signing Official:

> **By signing below, I, on behalf of (Name of Institution) acknowledge that the (Name of Institution), the Lead Developer or Developer Partner, and those that they directly supervise will adhere to the developer terms of access (i.e., DUA, see appendix) and any NIH program or ICO-specific requirements for NIH controlled access.**

Name: [   ]

Title: [   ]

Signature: [   ]

Date: [   ]