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| University of Washington Human Subjects DIvision | **WORKSHEET Genomic Data Sharing Certification** |

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| **PURPOSE AND APPLICABILITY** |

This worksheet is used by the IRB for determining if the [NIH Genomic Data Sharing (GDS) Policy](https://sharing.nih.gov/genomic-data-sharing-policy/about-genomic-data-sharing/gds-policy-overview) requirements have been met for [institutional certification](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form#step-1) of genomic and linked phenotypic data submission to the [NIH-designated repositories](https://sharing.nih.gov/genomic-data-sharing-policy/submitting-genomic-data/where-to-submit-genomic-data). This worksheet should also be used for assessing non-NIH funded studies that plan to share genomic data through NIH-designated repositories. Researchers can use this worksheet for informational purposes, particularly with regard to identifying applicable consent requirements.

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| **INSTRUCTIONS** |

This worksheet is intended to be used with HSD’s [Genomic Data Sharing Guidance.](https://www.washington.edu/research/hsd/guidance/ancillary/gds/) Links to additional relevant information in the guidance have been included throughout the document.

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| 1. **MAIN CRITERIA** |

The IRB must find that all criteria below are met for data to be certified for submission to NIH repositories.

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| **GDS CERTIFICATION CRITERIA** | **Met** |
| **1.1** The data submission is consistent as appropriate with all applicable national, tribal, and state laws and regulations, as well as relevant institutional policies. ([Consistency with Applicable Laws](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#3)) |  |
| **1.2** The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR 46. ([Consistent with 45 CFR 56](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#4)) |  |
| **1.3** The identities of research participants will not be disclosed to NIH-designated data repositories. ([Confidentiality](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#6)) |  |
| * 1. The investigator’s plan for de-identifying data sets is consistent with the standards outlined in the policy ([Confidentiality](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#6)):  1. The identities of data subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users, AND 2. The identifiers enumerated at section 164.514(b)(2) of the HIPAA Privacy Rule are removed |  |
| **1.5** Consideration was given to risks to individual participants and their families associated with submitting data to the NIH-designated data repositories and subsequent sharing. ([Consideration of Risks](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#5)) |  |
| **1.7** To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated repositories and subsequent sharing. ([Consideration of Risks](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#5)) |  |
| **1.4** The submission of data to NIH-designated repositories and subsequent sharing for research purposes are consistent with the informed consent of the study participants from whom the data were obtained. ([*Use section 2 below to determine if consent requirements are met*](#CONSENT_REQUIREMENTS)) |  |
| **1.5** Any limitations on research use of the data, as expressed in the consent documents, are delineated. ([*Use section 3 below to identify data use limitations*](#RESTRICTIONS_AND_USE_LIMITATIONS)) |  |

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| 1. **GENOMIC DATA SHARING CONSENT REQUIREMENTS** |

Use this section to identify applicable consent requirements and determine if the requirements are met. Additional considerations may apply when consent was obtained from the parent of a minor or from a legally authorized representative. If consent requirements are not met, the data cannot be certified. However, the researcher may be able to obtain an exception from the NIH institute or center funding the research. ([Consent](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#7))

Note: As of January 25, 2021, [NHGRI expects](https://www.genome.gov/about-nhgri/Policies-Guidance/Data-Sharing-Policies-and-Expectations/NHGRI-specific-GDS-Policy-FAQs#explicit-consent) that all genomic data generated by NHGRI-funded or supported research will have explicit consent for future research use and broad data sharing. Apply the requirements described in **2.1** regardless of when specimens were collected.

**2.1 Genomic data from specimens collected ON or AFTER 1/25/2015 (effective date of policy).**

***Refer to HSD’s Designing Consent webpage for*** [***consent language about sharing data through NIH repositories***](https://www.washington.edu/research/hsd/guidance/consent/design/#sharing)***.***

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| **REQUIREMENTS** | **Met** |
| **GDS Policy. *These elements must be included in the consent form.***   * Consent must be explicitly obtained for research with specimens. * Consent must be explicitly obtained for generating genomic and phenotypic data. * Consent must be explicitly obtained for future research use of data. * Consent must be explicitly obtained for broad sharing of data (e.g. with large research communities, through a public access repository). * Consent must be explicitly obtained for sharing data through an [unrestricted or public access](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#9) repository unless the data will be shared through [controlled](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#9) access repositories. |  |
| **GDS guidance expectations.**  ***HSD Policy.* *These elements must be included in the consent form due to increasing risk of re-identification as a result of advances in technology.***   * A statement that confidentiality cannot be guaranteed. * A statement that it may be possible to re-identify the data. * A statement that there may be unknown risks associated with re-identification of the data. |  |
| **GDS guidance expectations.**  ***HSD Policy:*** ***These consent elements are only required when applicable.***   * A statement that re-identified data could potentially be used to discriminate against or stigmatize subjects, their families, or groups (e.g. data related to the risk of developing particular diseases or conditions, information about family relationships or ancestry). * A statement that data can be withdrawn upon request, though already distributed data cannot be retrieved. [Note: applies when researcher will retain link to identifiers and plans to provide option for withdrawal.] * Return of results is described as a rare occurrence. [Note: applies if results will be returned.] |  |

**2.2 Genomic data from specimens collected BEFORE 1/25/2015, and IDENTIFIABLE at time of collection.**

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| **REQUIREMENTS** | **Met** |
| **GDS Policy.**   1. **If consent was obtained for research with specimens,** **the language in the consent form cannot be inconsistent with (or preclude) any of the following*:***  * generating genomic and phenotypic data * future research use of data * broad sharing of data (e.g. with large research communities, through a public access repository). * sharing data through [unrestricted or public access](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#9) repository unless the data will be shared through [controlled](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#9) access repositories.      1. **If consent was not obtained for research with specimens, GDS policy permits data sharing. However,** [**NIH strongly encourages**](https://sharing.nih.gov/faqs#/genomic-data-sharing-policy.htm?anchor=56637) **researchers to transition to using specimens with explicit consent.**   ***HSD policy: genomic data sharing is permitted when the following criteria are met:***   * + There are compelling reasons why it is not now possible to obtain consent.   + The broad sharing of genomic data (e.g. with large research communities, through a public access repository) will not adversely affect the rights and welfare of the subjects.   + There are compelling scientific reasons why the genomic and phenotypic data should be broadly shared and used for future research.   + The scientific benefits clearly outweigh any additional risks introduced by the absence of consent to subjects, families, and groups (after taking into account the protections in place.) |  |

**2.3 Genomic data from specimens collected BEFORE 1/25/2015, and DE-IDENTIFIED at the time of collection.**

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| **REQUIREMENTS** | **Met** |
| **GDS Policy. Data sharing permitted even If consent was not obtained for research with specimens. However,** [**NIH strongly encourages**](https://sharing.nih.gov/faqs#/genomic-data-sharing-policy.htm?anchor=56637) **researchers to transition to using specimens with explicit consent.**  ***HSD Policy:* *genomic data sharing is permitted when the following criteria are met:***   * The broad sharing of genomic data will not adversely affect the rights and welfare of the subjects. * There are compelling scientific reasons why the genomic and phenotypic data should be broadly shared and used for future research. * The scientific benefits clearly outweigh any additional risks introduced by the absence of consent to subjects, families, and groups (after taking into account the protections in place.) |  |

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| 1. **RESTRICTIONS AND DATA USE LIMITATIONS** |

Identify the applicable [consent group specifications and data use limitations](https://www.washington.edu/research/hsd/guidance/ancillary/gds/#8) from the consent form.

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| **3.1 CONSENT GROUP SPECIFICATIONS** | **APPLIES** |
| Participants have consented to return of results |  |
| The use of aggregate-level data for general research is consistent with the consent form |  |
| The data are to be made available through unrestricted access repositories |  |
| The data are to be made available through controlled access repositories |  |
| The [genomic summary results are *sensitive*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) |  |

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| **3.1 MAIN USE LIMITATIONS** | **APPLIES** |
| **General Research Use:** Use of data for unspecified research is permitted. |  |
| **Health/Medical/Biomedical:** Use of data is limited to health/medical/biomedical purposes (excludes study of population origins or ancestry). |  |
| **Disease specific**: Use of the data must be related to the specified disease |  |
| **Other:** Use limitation that is not covered by the above categories. |  |

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| **3.3 MODIFIERS** | **APPLIES** |
| **Genetic studies only:** Data can be used only for genetic studies. |  |
| **Methods:** Data can be used for statistical methods research and development |  |
| **Not-for-profit use only**: Data can be used only for not-for-profit organizations and should not be made available to commercial entities. |  |
| **Publication required:** Data can be used only if the secondary investigator will disseminate the study findings to the larger scientific community. |  |
| **IRB approval required:** Data can only be used with IRB approval from the secondary investigator’s institution. |  |
| **Collaboration required:** Data can only be used for collaborative research with the primary study investigator(s). A letter of collaboration must be submitted with the request for data. |  |

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| **RELATED MATERIALS** |

[SUPPLEMENT Genomic Data Sharing](https://www.washington.edu/research/forms-and-templates/supplement-genomic-data-sharing/)

[GUIDANCE Genomic Data Sharing](https://www.washington.edu/research/hsd/guidance/gds/)

[SOP Request for Genomic Data Sharing – Investigators](https://www.washington.edu/research/policies/sop-request-for-genomic-data-sharing-certification-investigators-2/)

SOP Genomic Data Sharing – HSD Procedures [HSD internal access only]

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| **REFERENCES** |

[NIH Genomic Data Sharing (GDS) Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-111.html)

[NIH GDS FAQs](https://sharing.nih.gov/faqs" \l "/genomic-data-sharing-policy.htm)

[NIH Guidance on Consent for Future Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy](https://sharing.nih.gov/sites/default/files/flmngr/NIH_Guidance_on_Elements_of_Consent_under_the_GDS_Policy_07-13-2015.pdf)

[NIH Points to Consider for Institutions and Institutional Review Boards in Submission and Secondary Use of Human Genomic Data under the National Institutions of Health Genomic Data Sharing Policy](https://sharing.nih.gov/sites/default/files/flmngr/GDS_Points_to_Consider_for_Institutions_and_IRBs.pdf)

[NIH Standard Data Use Limitations](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form" \l "step-5)

[NIH Points to Consider in Developing Effective Data Use Limitations Statements](https://sharing.nih.gov/sites/default/files/flmngr/NIH_PTC_in_Developing_DUL_Statements.pdf)

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.0 | 03.28.2024 | 03.28.2024 | Convert from PDF to Word; retire GDS consent worksheet and move relevant content to this worksheet; remove consent requirements for NIH GWAS policy which is superseded by NIH GDS policy; remove separate consent requirements for unfunded research; remove HSD policy to grant exceptions – exceptions can only be granted by NIH; add note about more stringent NHGRI consent requirements |
| 1.4 | 05.12.2017 | 05.12.2017 | Updated links |
| 1.3 | 02.07.2017 | 02.07.2017 | Forgot to updated title from Checklist to Worksheet on 12.30.2016 |
| 1.2 | 12.30.2016 | 12.30.2016 | Updated from Checklist to Worksheet; no version saved |
| 1.1 | 08.17.2016 | 08.17.2016 | Fixed JavaScript errors |
| Previous versions |  |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu). |

**Keywords:** Ancillary review; GDS; Results