# VA Portland Health Care System (VAPORHCS) –

# Research & Development Committee & Institutional Review Board

# IRQ Appendix J – HIPAA: STATISTICAL ANALYSIS DE-IDENTIFICATION CERTIFICATION FORM

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

**This appendix should be completed if this study requires Expert Determination for the statistical analysis of de-identified data/information.**

*Requirements of the HIPAA Privacy Rule for de-identification using Expert Determination are outlined in VHA Directive 1605.01 located at:* [*https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub\_Number*](https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number)

*For questions, please contact a VAPORHCS Privacy Officer.*

***NOTE:*** *Analysis of de-identified genetic information must follow the requirements of the HIPAA Privacy Rule for de-identification using Expert Determination as outlined in VHA Directive 1605.01 Appendix A. The Expert Determination must be documented in writing and contain all of the elements required HIPAA Privacy Rule. The definitions for genetic information, genetic testing and genetic services are below. Genetic information cannot be de-identification under Safe Harbor (removing 18 identifiers).*

***Genetic Information:*** *Genetic information, with respect to an individual, means information about: (1) the individual’s genetic tests, (2) the genetic tests of the individual’s family members, (3) the manifestation of a disease or disorder in the individual’s family members, or (4) any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any of the individual’s family members. Genetic information is health information.*

***Genetic Service:*** *Genetic services means: (1) A genetic test; (2) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or (3) Genetic education.*

***Genetic Test:*** *Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.*

*In addition, genetic sequencing fits into the definitions provided by the HIPAA Privacy Rule around genetic information, genetic testing and genetic services (see above definitions). Genetic sequences, as genetic information, cannot be of de-identified under Safe Harbor as well.*

1. This certification applies to the information used by, shared with or disclosed to the following:

***NOTE:*** *If this certification is for this study to continue with de-identified data analysis of genetic information* ***AFTER*** *IRB finalization/closure, please**describe the genetic information to be analyzed and include who will conduct the analysis.*

**B. As the principal investigator for this study, I certify the following:**

1. The **statistical expert** (insert name),, is a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable and he/she has completed the following:

**a.** [ ]  Determined that the risk that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information is very small; **AND**

**b.** [ ]  Documented the methods and results of the analysis that justify such determination.

1. The following documentation must be submitted with this form:
	* 1. Documentation, e.g., curriculum vitae or other professional credentials, that demonstrates that the person listed in B.1. has the requisite knowledge and experience; **AND**
		2. Documentation that justifies the determination, as required by B.1.b.

 **c.** Data use agreement entered into with any individual(s) and/or sponsor(s) outside the VHA covered entity to which this statistically de-identified information will be used and/or disclosed.

**Investigator’s Assurances**

1. If I assign a code or other means of record identification, in order to allow information de-identified to be re-identified,

a. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, and

 b. I will not use or disclose the code or other means of record identification for any purpose other than re-identification, and

 c. I will not disclose the mechanism (algorithm or other tool) for re-identification.

1. Before I allow a code to be used to re-identify this information,

 a. If the purpose of the re-identification is within the scope of the original research protocol, I will obtain approval of an amendment from the IRB and comply with the requirements of HIPAA; or

 b. If the purpose of the re-identification is outside the scope of the original protocol, I will submit a full New Study Application, obtain IRB approval, and comply with the requirements of HIPAA.

1. I have completed and attached a data use agreement entered into with any individual(s) and/or sponsor(s) outside the VHA covered entity to which this statistically de-identified information will be used and/or disclosed.
2. I understand that the code or other means of record identification must not be disclosed to non-VHA entities.

Principal Investigator/Responsible Investigator (if applicable) Date