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HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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SOP 5. NIH RESEARCH ACTIVITIES WITH HUMAN DATA/SPECIMENS

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SOP 5. NIH RESEARCH ACTIVITIES WITH HUMAN DATA/SPECIMENS

5.1 PURPOSE

This Standard Operating Procedure (SOP) sets forth NIH policies and procedures for research activities with human data/specimens that are covered by 45 CFR 46. (For activities regulated also by FDA, as applicable, please refer to SOP 15, "Research Regulated by the FDA".)

5.2 POLICY

NIH seeks to maintain the highest ethical standards when research is conducted with human specimens and data, following 45 CFR 46 requirements, and principles set forth in the Belmont report. The NIH Office of Human Subjects Research Protections (OHSRP) and/or NIH IRBs review research activities with human specimens and/or data, unless those activities are excluded from review by NIH policy. This SOP provides an overview of NIH requirements that pertain to NIH research activities with human specimens and data.

The requirements of this SOP do not apply to activities that involve only specimens and data from the sources set forth in Appendix 1. Consequently NIH activities that involve only these specimens and data found in Appendix 1 may proceed without any prior approval from an IRB or OHSRP.

5.3 DEFINITIONS

A. **Coded Specimens or Data**: For the purposes of these SOPs, Coded Data or Specimens mean that: 1. identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and 2. a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

B. **Data**: Information related to humans, including demographic, clinical, genetic and other individual information that may be derived from research with human subjects.

C. **Derivatives**: Materials produced by the modification of human specimens or isolation of a components(s) of specimen samples originally obtained from humans. Examples include human cell lines, recombinant DNA clones of human genes, and isolated infectious agents from humans.

D. **Human Subjects**: Means a living individual about whom an investigator (whether professional or student) conducting research obtains:

    1. Data through intervention or interaction with the individual, or

    2. Identifiable private information.

E. **Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

F. **Interaction** includes communication or interpersonal contact between investigator and subject.

G. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information provided for specific purposes by an individual, which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

H. **Individually Identifiable**: Individually identifiable means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information (45 CFR 46.102)

I. **Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable

knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program considered to be research for other purposes. For example, some demonstration and service programs may include research activities.

J. **Research repository**: A collection of specimens or data maintained for the overall purpose of sharing specimens and data for current and future research. Such research may be general and cover a wide array of diseases and topics, or may be more specific, focusing on a single disease or topic.

K. **Secondary use**: Research use of specimens or data other than the original research purpose(s) for which the specimens or data were initially collected through interaction or intervention with living individuals.

L. **Specimens**: A quantity of human tissue, blood, urine or other biologically derived material. A specimen can include everything from subcellular structures (DNA) to cells, tissue (bone, muscle, connective tissue), organs (e.g. liver, bladder, heart, kidney), blood, gametes (sperm and ova), and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta).

5.4 NIH POLICY FOR COMMON CATEGORIES OF RESEARCH ACTIVITIES WITH DATA/SPECIMENS

This SOP and SOP 6, “Determinations Made by the Office of Human Subjects Research Protections,” set forth NIH policies and procedures covering the most common categories of research activities with specimens and data. Those categories are set forth below with a reference to SOP sections that contain additional information about NIH policy for that particular research activity.

A. **Non-Exempt Research requiring IRB Review :**

1. Prospective collection of specimens and/or data through direct interventions or interactions with subjects or obtaining individually identifiable information for research: (Section 5.5): IRB review is required when NIH researchers prospectively collect data or specimens for non-exempt research through direct interventions or interactions with subjects or when a researcher obtains individually

identifiable information for research. This includes obtaining coded data or specimens (with or without the code) collected by others, e.g., a collaborator, through intervention or interaction with human subjects for the same research purpose

2. Secondary use of Identified or Coded specimens and/or data when NIH researchers can identify the subjects: (Section 5.6): IRB approval is also required for secondary non-exempt research use of specimens and/or data when NIH researchers or members of the research team can identify the subjects, e.g., through direct access to identifiers or when the research team has coded specimens or data with access to the key to the code.

3. Collaborative Research: When either party in collaborative research (see SOP 20) is engaged[1] in non-exempt human subjects research, the entire project must be approved by an IRB, either at the NIH and/or by an outside IRB. If the protocol is approved only at an outside IRB, there must be a reliance agreement for NIH to rely on the outside IRB (see SOP 20 A), unless the NIH collaborator will not be receiving any individually identifiable information. If the NIH is not interacting with human subjects or receiving any individually identifiable information during the collaboration, then OHSRP must review the collaboration and make an appropriate determination. Further, an agreement must be in place to ensure that individually identifiable information will not be shared.

B. **Research not requiring IRB Review**

1. NIH research activities with specimens and/or data that are not individually Identifiable when the NIH researchers cannot identify the subject, e.g., the NIH team does not have the key to the code (Section 5.7 and SOP 6): NIH research activities using only specimens and/or data which are either coded (without access to the key) or otherwise not individually identifiable may occur without IRB review if the use of specimens or data is a secondary use of existing specimens or data. (See OHRP “Guidance on Research

[1] See the OHRP Guidance on Engagement of Institutions in Human Subjects Research and the Human Subjects Regulations Decision Charts.

Involving Coded Private Information or Biological Specimens," 10/16/08). As explained in SOP 6, OHSRP must review the activity and make an appropriate determination prior to the initiation of the research.

2. NIH research activities with data/specimens that are "exempt" from requirements under 45 CFR 46.101 (Section 5.8 and SOP 6): Under 45 C.F.R. 46.101, some research activities with human subjects are "exempt" from IRB review and the Common Rule requirements. This means that a particular research activity with specimens/data is considered "human subjects research," under Part 46, but the requirements of 45 CFR 46 do not apply.

   These activities include, for example, research activities using only existing data, documents, pathological specimens, or diagnostic specimens that are publicly available, *or* if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to the subjects. Also see SOP 6 for a description of all research activities that are exempt from IRB review. As explained in SOP 6, OHSRP must review and make an appropriate determination prior to the initiation of the research activity.

3. Collaborative Research: If applicable, in collaborative projects involving human subjects research that is not exempt under 45 CFR 46, the analysis of "engagement in human subjects research" should occur. When the NIH research activity is not considered engagement in human subjects research, there is no requirement for IRB review at the NIH. However, OHSRP must review and make an appropriate determination prior to the initiation of the research activity (See SOP 6).

C. **Points to Consider When a Biospecimen Repository is Created at NIH: (Section 5.9)**

NIH researchers who collect and share specimens and/or data for research purposes (repositories or collections) must consider the ethical principles set forth in **Section 5.9**. These principles apply whether or not specimens contain identifiable data. Repositories that contain identifying information (including codes with the code key) must have IRB approval

and oversight for accepting specimens and data into the repository or distributing specimens and data for research use. OHSRP has authority to approve repository activities when the repositories do not contain identifiable specimens or data.

D. **Special research categories involving data/specimens: (Section 5.10)**

Research activities with specific types of data/specimens trigger other federal laws or NIH policy requirements. Those activities are set forth in **Section 5.10** of this SOP.

5.5 PROSPECTIVE COLLECTION OF SPECIMENS AND DATA FOR RESEARCH THROUGH DIRECT INTERVENTION OR INTERACTION WITH SUBJECTS OR NON-EXEMPT RESEARCH WITH IDENTIFIABLE PRIVATE INFORMATION

IRB review is required when NIH researchers prospectively collect data or specimens, for a research purpose, through direct interventions or interactions with subjects or when a researcher obtains individually identifiable information for research. This includes obtaining coded data or specimens (with or without the code) that were collected by a collaborator for the same research purpose. For example, when research collaborators at another site obtain specimens through intervention with a human subject, the NIH researchers are also engaged in human subjects research when working on the same research purpose (even if the specimens are coded). (In other circumstances as described in Section 5.7 and SOP 6, IRB review of NIH activities may not always be required.)

A. NIH researchers must follow all of the NIH policies and HRPP SOPs applicable to IRB review and approval of research protocols.

B. The protocol and consent should address which entities will have access to specimens or data, including researchers at other institutions. Per NIH policy, identifiers should be shared in only rare circumstances in which the research cannot reasonably be accomplished unless all collaborators have access to identifiers (See Paragraph F and G below).

C. NIH protocols should state how the samples, specimens and/or data will be stored, how they will be tracked, and what circumstances would prompt the PI to report to the IRB loss or destruction of samples. (Note if the loss

includes a Privacy Act breach, this must also be reported the applicable IC Privacy Act office.) See *Guidelines for Human Biospecimen Storage and Tracking with the NIH Intramural Research Program* (2013).

D. If applicable, the protocol and consent document must address whether specimens/data will be stored for future use.

E. If prospective collection involves repository activities with specimens and/or data, please consult the points to consider in **Section 5.9** of this SOP.

F. When sharing specimens or data with a collaborator:

1. Generally, if data or specimens under a prospective collection protocol will be shared with collaborators outside NIH, the NIH investigators should unlink or code the data or specimens before sending them to the collaborators and not release the key to the code. NIH policy is to share identifiers only when reasonably necessary for the collaborator to perform the research or comply with law; otherwise providing data/materials that are coded (without access to the key) or that are otherwise not individually identifiable is preferred.

2. If sharing identifiers: If the research collaboration requires that individually identified data/specimens be sent to a collaborator at another site, that site must first have a Federalwide Assurance (FWA) and IRB approval for the research activity. The Institution and its FWA number should be noted in the protocol or under a protocol amendment. Prospective subject consent may also be required for distribution of identifiers and/or the collaborator must agree to protect the data/samples as required in the Privacy Act.

3. NIH researchers must also follow the intramural technology transfer policy, requiring a Material Transfer Agreement (MTA) or other appropriate agreement when NIH specimens are sent outside NIH for research. See the IRP “Policy for the Transfer of Materials from NIH Intramural Laboratories” and consult an IC Technology Development Coordinator.

5.6 IRB REVIEW OF SECONDARY USE OF IDENTIFIABLE HUMAN DATA OR SPECIMENS

A. When researchers propose a new research study using previously collected specimens and/or data collected for a purpose other than the currently proposed research (e.g., it is a secondary use) and can identify the subjects who provided the specimens or data (that is, have access to individually identifiable information either directly or through coded information with a key to the code), a researcher must submit a written request (i.e., an amendment or new protocol) to an IRB that includes the following:

    1. The nature of the proposed research with a complete description of the samples or data;

    2. A justification for use of the identities or codes of the sources of samples or data, and, in the case of codes, a description of the ease or difficulty with which linkage can be made between the code and the source, and a description of who can make the linkage;

    3. A description of the extent to which confidentiality of research data will be maintained;

    4. The informed consent document which allows this use of the specimens and data, or a request for IRB waiver of informed consent (See Section B.).

    5. The protocol must state how the samples, specimens and/or data will be stored, how they will be tracked, and what circumstances would prompt the PI to report to the IRB loss or destruction of samples.

B. When research involves stored samples or data with identifiers previously collected, and/or for a purpose other than the currently proposed research, an important question is whether the NIH consent signed in the initial collection protocol is sufficient for the proposed research activity. The IRB should pay special attention to requests for waiver of informed consent. To waive informed consent for research, Federal regulations currently require that an IRB document in its minutes that the following four conditions have been met:

1. The research involves no more than minimal risk;

2. The waiver will not adversely affect the rights and welfare of the subjects

3. The research could not practicably be carried out without the waiver; and

4. Whenever appropriate, the subjects will be provided with the additional pertinent information derived from the new study.

Additionally, in those cases where a waiver of informed consent is sought, the protocol should contain a statement that the subject(s) who provided the specimens or data will not be contacted by anyone connected with the research without prior approval by the IRB.

If an NIH investigator(s) wishes to conduct a research collaboration in which he/she has identifiable specimens and data, but wants to send data or specimens that are either coded or otherwise not individually identifiable to collaborators outside NIH, the NIH investigator must obtain IRB approval of an amendment to the original protocol or IRB approval of a new protocol. See 5.5.F for information regarding collaboration and transfer agreements.

5.7 OHSRP REVIEW OF SECONDARY RESEARCH USES OF DATA OR SPECIMENS THAT ARE CODED (without the key) or FROM A DATABASE NOT PROVIDING IDENTIFIERS

When NIH research involves coded (without the key) data or specimens and the data or specimens were not collected specifically for the proposed research project through an interaction or intervention with living individual (e.g., it is a secondary use), such research cannot begin until the PI has obtained a formal determination from OHSRP that the activity is excluded from IRB review.
The policies and procedures governing these research activities are set forth in SOP 6, Section 6.4

5.8 OHSRP REVIEW OF ACTIVITIES WITH DATA/SPECIMENS THAT ARE EXEMPT FROM 45 CFR 46

Under 45 CFR 46, certain research activities with data/specimens are exempt from IRB review, i.e. do not require IRB review (45 CFR 46.101(b)). The complete list of "exempt" research activities is set forth in SOP 6 APPENDIX 2. That list includes research with only existing data, documents, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to the subjects.

At the NIH, OHSRP has sole authority to make a determination that an NIH research activity meets one of the six categories of human subjects research activities that are exempt from the DHHS requirement for IRB review. An NIH researcher does not have the authority to make his or her own exemption determination and must obtain OHSRP's approval prior to beginning any research activity. The applicable policies and procedures are set forth in SOP 6, Section 6.5.

5.9 POINTS TO CONSIDER WHEN A REPOSITORY IS CREATED AT NIH

An NIH IRB must approve and maintain oversight of specimen repositories that contain identifiable data or specimens (including coded information with a key to the code).

A. OHSRP must approve the creation and distribution of data and/or specimen repositories that do not contain identifiable data.

B. When creating repositories, NIH researchers should consider the following issues:

    1. How were data and specimens initially collected, i.e. clinical testing or research? If research, was the collection consistent with 45 CFR 46?

    2. Is there a link (a "code") to the subjects who are the source of the data or the specimens? If so, who retains the key to the code linking data to subjects?

3. Does the repository have standard operating procedures pertaining to collection of data/specimens, removal of data/specimens, access to information and distribution of specimens and/or data?

4. What protections exist to protect the confidentiality of the research subjects (i.e. what is the system for removing identifiable information)?

5. Could the research activity lead to possible identification of research subjects?

6. If data about subject identifiers are retained, do subjects have the opportunity to withdraw consent for the use of their identifiable specimens and/or data?

7. Is there a benefit for community or expert consultation for establishing repositories with samples from specific populations or groups? For example, does the local context need to be considered (See SOP 20B).

8. Does the repository have a data use agreement (DUA) or Human Material Transfer Agreement (hMTA) for deposit or removal of specimens/data from the repository? Typically these agreements focus on ensuring that: future researchers will not try to identify the subjects; the specimens will only be used for the approved research; if the specimens are coded, the code will not be shared with the receiving party; specimens or data will not be further distributed; notification and possible review will occur prior to publication. Also worth consideration is whether there will be future deposits (additions) to the repository by other researchers either from NIH or other institutions. There should be a standard DUA or hMTA for deposits or withdrawal of such data or specimens. For guidance on such agreements, contact your IC's Technology Development Coordinator

9. Does the repository have a system for tracking specimens/data? What is the preference for disposition of the material at the end of a research project?

10. If the collection or release of specimens and/or data involves researchers or materials originating from protocols or repositories in another country), are the SOPs of the NIH repository consistent with the HHS Human Subjects regulations (45 CFR 46)?

11. Do any other federal policies apply to repository research activities, such as the NIH policy for Genome-Wide Association Studies (GWAS)?

12. Is there a need for a standard transfer agreement for receiving specimens from another repository or researcher? May non-NIH researchers deposit and, if so, is there a standard deposit form? Contact an IC Technology Development Coordinator for guidance.

13. Has a NIH Privacy Act Officer performed a privacy impact assessment of the repository to determine what safety measures and policies apply to NIH storage and distribution of the specimens/data?

5.10 SPECIAL CATEGORIES OF RESEARCH WITH SPECIMENS AND DATA

Some NIH research activities trigger other federal requirements because of the type of specimens or data involved. Those special situations are set forth below:

A. **Fetal Tissue** – Federal law requires that: (a) no valuable consideration (a concept similar to profit) should be involved, (b) researchers should have no involvement in the termination of the pregnancy, and (c) the tissue must be obtained in accordance with state and local law. The governing Federal statutes are sections 498A and 498B of the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2.

   OHSRP staff will advise researchers about documentation required to conduct research with fetal tissue.

B. **Human Embryonic Stem Cells**– Researchers should refer to the NIH Intramural Sourcebook and other sources for additional requirements related to research with human embryonic stem cells (hESC), human

induced pluripotent stem cells (IPSC), and adult stem cells including the NIH Guidelines for Human Stem Cell Research

1. NIH Human Embryonic Stem Cell Registry (lines eligible for use with NIH funds) http://grants.nih.gov/stem_cells/registry/current.htm

2. NIH Guidelines for Human Stem Cell Research (the policy that applies to NIH-funded research using hESCs and iPSCs) http://stemcells.nih.gov/policy/pages/2009guidelines.aspx

3. NIH Stem Cell Website http://stemcells.nih.gov/Pages/Default.aspx (general info)

4. Stem Cell FAQs http://stemcells.nih.gov/research/pages/newcell_qa.aspx#consent

C. **Genome - Wide Association Studies (GWAS)** – Researchers must comply with the NIH GWAS policy as applicable (http://grants.nih.gov/grants/gwas/)

D. **Whole Exome and Whole Genome Sequencing** – Researchers should refer to the NIH sourcebook for applicable policies. (http://sourcebook.od.nih.gov/index.htm)

5.11 OTHER NIH REQUIREMENTS THAT MAY APPLY TO RESEARCH ACTIVITIES WITH SPECIMENS

A. **Human Material Transfer Agreements**: A written agreement with appropriate terms and Institute-authorized signatures is required to send human specimens out of the NIH intramural research program. Please refer to the NIH Office of Technology Transfer policy on this issue, http://www.ott.nih.gov/PDFs/Policy-for-the-Transfer-of-Materials.pdf and consult with your IC's Technology Development Coordinator http://www.ott.nih.gov/nih_staff/tdc.aspx. These personnel are available to assist in all phases of the process and to determine which technology transfer agreement is appropriate. They also serve as the Institutes and Centers (ICs) liaison with the Office of Technology Transfer and the Office of the General Counsel on technology transfer matters.

B. **The Privacy Act of 1974**: A system of records is a group of any records (paper or electronic) under the control of NIH from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual (such as SSN, date of birth, symbol, etc.). Such systems of Records are subject to the Privacy Act of 1974 (5 U.S.C. 552a). The Privacy Act regulates the collection, maintenance, use and dissemination of certain personal information held by the executive branch of the U.S. government. For guidance about Privacy Act requirements, NIH staff should consult with an IC Privacy Act coordinator, http://oma.od.nih.gov/about/contact/browse.asp?fa_id=3

C. OMB/Paperwork Reduction Act: The Project Clearance Branch (PCB) is the NIH control point for the OMB clearance process. This process provides clearance for many types of information collections (e.g., such as focus groups, usability testing, customer satisfaction surveys, comment cards, epidemiologic surveys, web surveys, etc..) Specific requests that fall under this clearance would be submitted by each IC to the PCB via the IC liaison: http://nih-extramural-intranet.od.nih.gov/nih/policies/project_clearance/pcllist.htm.

LIST OF APPENDICES

Appendix 1: Activities with Data and Specimens That Do Not Require IRB or OHSRP Approval

Appendix 2: DATA THAT MAY CONSTITUTE INDIVIDUALLY IDENTIFIABLE INFORMATION UNDER 45 CFR 46[2]

[2] Please note that this guidance does not address other legal standards (e.g., the Privacy Act) and should not be relied upon on for contexts other than the human subjects regulations at 45 CFR 46.

APPENDIX 1-- ACTIVITIES WITH DATA AND SPECIMENS THAT DO NOT REQUIRE IRB OR OHSRP APPROVAL

A. Research activities with certain types of data and specimens do NOT require approval from either an IRB or OHSRP, including research with:

1. Human specimens and data from deceased individuals (consult with your I/C privacy officer or OHSRP about whether identifiable information can be used).

2. Human specimens and data available from commercial repositories that do not contain information identifying the subjects providing the specimens and associated with the data.

3. Established cell lines that are available to qualified scientific investigators, provided the individual from whom the line was derived is not identifiable to NIH researchers and provided that NIH researchers do not have access to a code linking the cell line to that individual.

4. Derivatives of materials originally obtained from humans, if those materials are either (i) not identified as to the individual human source or (ii) coded but none of the NIH researchers will be given access to the key to the code.

B. Some activities with data and/or specimens are NOT research activities under 45 CFR 46, consequently 45 CFR 46 requirements do not apply. Activities in the this group include:

1. Use of specimens and data for diagnostic purposes only.

2. Single case reports, if the report is compiled by persons already involved in the patient' care, if the information is not individually identifiable, and if no changes were made in the patient's care or diagnostic testing for the sake of reportability. Case reports may constitute Human Subjects research if any of these three stipulations are not met or if more than a single case is analyzed for presentation.

3. Program evaluations in which the results of the evaluation are shared only with the program or entity in which the program

operates. For program evaluation, the data from the activity are produced by the program and returned to the program. They are not available to NIH researchers to use in future presentations, publications or research proposals. A program evaluation may constitute Human Subjects research if it evaluates new, modified or previously untested interventions or services, if it assigns program participants into groups to compare outcomes or if it compares standard and non-standard interventions. (Prior OHSRP or IRB approval is required if results from a program evaluation warrant dissemination to professionals or groups outside the organization or program being evaluated.)

Appendix 2: POINTS TO CONSIDER:

DATA THAT MAY CONSTITUTE INDIVIDUALLY IDENTIFIABLE INFORMATION UNDER 45 CFR 46[3]

The following (either individually or in combination) may constitute information that is individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information). The circumstances surrounding a research project may impact whether information is considered individually identifiable. For example, size and location of the research trial (if participants are from the same small town or zip code, age could be identifying); the disease or condition being studied, particularly if a rare disease; place of birth; nationality.

As a general rule, if gaining access to identifiable information is more involved than either using a key that links coded information to identifiers, or combining information that is either already in the possession of the investigator or easily accessible to the investigator, OHSRP may not consider the investigator to be in possession of individually identifiable information.

Brief examples:

A. Research Team A wants to conduct a study with a coded dataset for which they have a key. This dataset consists of only date of birth, medical condition, and length of hospital stay.

   Analysis: In this scenario, the data is may be considered individually identifiable to the researchers since they have access to the key and could presumably use the information in the dataset to readily identify participants.

B. Research Team B receives the same dataset from Research Team A, with Research Team A keeping the key to the code.

   Analysis: Because Research team B is not in possession of additional information about the participants, and this information is not readily

[3] Please note that this guidance does not address other legal standards (e.g., the Privacy Act) and should not be relied upon on for contexts other than the human subjects regulations at 45 CFR 46.

accessible to them, date of birth is not likely to be individually identifiable to the investigator.

The list below includes points to consider and is not intended to be exhaustive. Researchers should consult with OHSRP if they are unsure whether data in a particular research project would be considered individually identifiable.

A. Names or initials

B. Date of birth

C. Social security number

D. Street address

E. Telephone and fax numbers

F. Electronic mail addresses

G. Medical record number

H. Health plan identifier

I. Research study/protocol number

J. Account numbers

K. Certificate/license numbers

L. Vehicle identifiers and serial numbers, including license plate numbers

M. Identifying numbers related to devices, such as serial numbers

N. Internet protocol (IP) address numbers

O. Biometric identifiers, including finger and voice prints

P. Full face photographic images and any comparable images

Q. Pedigree – a diagram or text that indicates which individuals within a family express or carry a genetic trait or medical condition

R. Any other unique identifying number, characteristic, or code when a key to the identifier/characteristic/code is readily accessible to the investigator (see SOPs [5 “NIH Research Activities with Human Data/Specimens”] [and 6 “Determinations, Including Exemptions, Made by the Office of Human Subjects Research Protections (OHSRP) Under 45 CFR 46”] for additional discussions regarding the use of “Coded Specimens or Data” in research.)

S. Any other data or information which, in a given context or circumstance, can be used to make a participant identifiable to the researcher.