This document summarizes changes in Policy 107 Privacy and Confidentiality (referred to as Policy 107 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.

The policy describes NIH privacy and confidentiality requirements and ensures that the Intramural Research Program (IRP) research activities comply with Federal standards for privacy and confidentiality in the collection, use and disclosure of research subjects' information.

NIH investigators are responsible for reviewing Policy 107 and complying with the requirements of the policy.

Note: Text from the policy and other policy titles are italicized.

Policy 107 Privacy and Confidentiality	**SOP Superseded by Policy 107**
***Policy 107 Privacy and Confidentiality* partially supersedes**	***SOP 18 Privacy and Confidentiality***
Applicability of Policy 107 - This policy applies to: • NIH Investigators • Non-NIH Investigators when they are otherwise subject to the NIH privacy and confidentiality standards (e.g., by agreement or through certain access to, or use of, NIH-protected data).	
Policy Requirement	**SOP Requirement**
Section C.1. – *It is the policy of the NIH Human Research Protection Program (HRPP) to maximize research subjects' privacy and to maintain the confidentiality of their personally identifiable information. In its human research and record-keeping activities, the NIH HRPP follows the requirements of the Privacy Act of 1974 (5 U.S.C. 552a).* AND **Section C.2.** – *The NIH follows federal law provided by the Privacy Act of 1974 (5 U.S.C. 552a). This Act includes procedures for: 1) Protecting records that can be retrieved by personal identifiers such as a name, social security number, or other identifying number or symbol, and 2) Persons to access their identifiable records and to request correction(s) of these records.* *a. In implementing the requirements of the Privacy Act, the NIH follows the Department of Health and Human Services (DHHS) Privacy Act Regulations, 45 C.F.R. Part 5b. Aside from the limited categories of disclosures permitted by 5 U.S.C. 552a(b), the Privacy Act prohibits*	**Section 18.2. –** *This policy establishes procedures for the NIH Human Research Protection Program (HRPP) to maximize research subjects' privacy and to maintain the confidentiality of their personally identifiable information. In its human research and record-keeping activities, the NIH HRPP follows the requirements of the Privacy Act, 5 U.S.C. 552a.*

disclosure of personally identifiable records without the written consent of the individual(s) to whom the records pertain. NIH Privacy Act System of Records Notices #09-25-0099 (Clinical Research: Patient Medical Records) and #09-25-0200 (Clinical, Basic and Population-based Research Studies of the National Institutes of Health), specify permissible uses and disclosures of the records covered by those systems. NIH has adopted Required NIH Language for inclusion in all NIH Institutional Review Board (IRB) approved consent documents that addresses research subjects' rights under the Privacy Act. See also **Section E.1.a.** This requirement remains unchanged from SOP 18. This policy describes requirements of the Privacy Act in the context of human subjects research. For example, in C.2.a. above we explain that consent is required prior to disclosure of personally identifiable records under the Privacy Act, including such information contained in research records and maintained in medical records. Further we explain that the NIH uses standardized required language to describe subjects' rights with regard to the Privacy Act. This required language must be included in all NIH informed consent documents approved by the NIH IRB (including those reviewed by IRBO when there is an external IRB). Neither NIH investigators, nor external IRBs can change this required language in NIH consents as described in Section E.1.e. below, and NIH PIs should consult with IRBO about any requests (or stipulations) to edit this language. When consent documentation has been waived by the IRB, then NIH investigators must provide a privacy notice instead.	
Section C.3. – *To further protect the privacy of research participants enrolled in research conducted by NIH investigators, or in collaboration with NIH investigators, the NIH IRP has been issued a Certificate of Confidentiality for applicable research pursuant to Section 301(d) of*	**Section 18.6.3.** – This section discussed the process for obtaining Certificates of Confidentiality (CoC). However, the procedures described in SOP 18 are no longer applicable.

the Public Health Service Act (42 U.S.C. 241(d)), as further explained in the DDIR Desk to Desk Memo regarding IRP implementation of Certificates of Confidentiality dated 10-13-2017 (Appendix 1 - DDIR Desk to Desk Memo regarding IRP implementation of Certificates of Confidentiality) and the NIH Policy on Issuance on Certificates of Confidentiality. NIH has adopted Required NIH Language for inclusion in all NIH IRB approved consent documents that explains the privacy protections afforded by the Certificate of Confidentiality. The obligations under the NIH Certificate of Confidentiality (CoC) have expanded under the Public Health Service Act. As mentioned in the next column, NIH investigators no longer need to seek a CoC on a protocol-by-protocol basis. In addition, the obligation to protect identifiable sensitive information (ISI) collected in the course of research extends to any research collaborators with whom NIH investigators share such information. OHSRP worked with Technology Transfer to ensure these obligations are described in tech transfer agreements, to aid research collaborators in understanding their responsibilities. Similar to Sections. C.1. and 2. above, the NIH uses standardized required language to describe privacy protections under the CoC. This required language must be included in all NIH informed consent documents approved by the NIH IRB (including those reviewed by IRBO when there is an external IRB). Neither NIH investigators, nor external IRBs can change this required language in NIH consents as described in Section E.1.e. below, and NIH PIs should consult with IRBO about any requests (or stipulations) to edit this language. When consent documentation has been waived by the IRB, then NIH investigators must provide a privacy notice instead.	The change in Policy 107 is based on the changes to the CoC due to the implementation in 2017 of new "21st Century Cures Act" requirements in the Public Health Service Act. One of the major changes is elimination of the requirement for investigators to seek an individual CoC for each applicable protocol. Instead a single CoC has been issued to cover the research activities of the NIH IRP. Another change to the CoC is the expansion of obligations under the Public Health Service Act to external recipients of data covered by the NIH CoC.
Section C.4. – *Secretary may exempt from disclosure under the Freedom of Information Act (FOIA) biomedical information about a research participant that is gathered or used during the*	**N/A** SOP 18 did not address release of information under FOIA.

course of biomedical research if, A) the participant is identified; or B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of a participant. Policy 107 was expanded to address how requests for release of information collected from subjects are managed under FOIA. Although SOP 18 did not address release of information under FOIA, the requirements and protections under FOIA have not changed.	
Section C.5. – *When the NIH is the Reviewing IRB it will ensure that the privacy and confidentiality protections outlined in the protocol and the informed consent document are consistent with 45 CFR 46 requirements.* The Common Rule (45 CFR 46) also specifies privacy protections for research subjects and the requirement to maintain the confidentiality of data. This requirement is unchanged from SOP 18.	**Section 18.5.4. –** This section described the IRB's responsibilities regarding ensuring protection of subject privacy when reviewing protocols and consents. **Section 18.6.2. –** This section described the IRB's responsibilities regarding ensuring confidentiality of subject data collected on the research.
Section C.6. – *Privacy Education – New NIH staff must complete required Privacy Awareness training before establishing NIH accounts. NIH staff are required to complete annual Privacy Refresher training, consistent with the requirements of the NIH Privacy Program.* The requirement for privacy education is not new at the NIH. However, this policy reiterates the importance of this training which is required by the NIH Privacy Program.	**NA** SOP 18 did not address privacy education.
Section C.7. – *The NIH is not subject to the HIPAA Privacy Rule. NIH Principal Investigators (PIs) should not agree to any HIPAA terms, including the execution of Business Associate Agreements, when collaborating with other institutions and should seek guidance from the NIH Office of the General Counsel in advance if such requests are posed to NIH PIs.* *a. When NIH is the Reviewing IRB, it may review protocols for institutions that are subject to HIPAA, however the NIH Reviewing IRB may not*	NA SOP 18 did not address multi-site research nor did it address HIPAA or Privacy Boards.

act as a Privacy Board, consistent with E.4.b.I. below. See also **Section E.4.b.** When the NIH IRB is the reviewing IRB, it will only apply the requirements under 45 CFR 46 and the privacy requirements that the NIH is subject to as a federal agency. The NIH IRB will not apply HIPAA, and it will not serve as a Privacy Board for another institution. This point is clearly spelled out in reliance agreements with other institutions, so that they are aware that the NIH will only serve as a Reviewing IRB when IRB review is ceded but will not serve as a HIPAA Privacy Board.	
Section E.1.b. – *The NIH Principal Investigator (PI), or as applicable, the NIH lead Associate Investigator (AI), is responsible to ensure that privacy and confidentiality protections are described in the protocol and research informed consent document when the research is being performed at an NIH site or the information will be entered into an NIH Privacy Act system.* AND **Section E.1.c.** – *NIH PIs/lead AIs will identify in the protocol and research informed consent document the procedures for protecting the privacy of research participants and the confidentiality of their data, consistent with this policy. This includes, for example, access to medical records for the purpose of subject identification (recruitment) or screening, collection of Personally Identifiable Information (PII)/Identifiable Sensitive Information (ISI) for the purposes of the research, and collection or use of human biospecimens with PII attached.* Although SOP 18 addressed privacy and confidentiality in their own sections respectively, these requirements are unchanged in Policy 107.	**Sections 18.5.b. Privacy and 18.6.1 Confidentiality –** Addressed these same requirements.
Section E.6. – *Investigators are responsible for following the plan described in the protocol for protecting the confidentiality of information and data provided by research subjects.*	**Section 18.61. –** *Investigators are responsible for following the plan described in the protocol for protecting the confidentiality of information and data provided by research subjects. The*

This requirement is unchanged from SOP 18.	*protections provided should be commensurate with the risk of harm from improper disclosure.*
Section E.1.e. – *For NIH consent forms: The terms of the Privacy Act of 1974 and the NIH Certificate is addressed in the Required NIH Language in the informed consent document (see Consent Form Templates for Required NIH Language). Neither PIs nor the IRB(s) will revise the Required NIH Language in the NIH informed consent document without prospective review and approval by OHSRP and the NIH Office of the General Counsel (OGC). This prospective review and approval is required even when a non-NIH IRB requests modifications to the Required NIH Language in the NIH consent form.* As stated above in Sections C.1., C.2. and C.3. NIH investigators must consult OHSRP or IRB immediately if any edits to NIH required language are requested.	**SOP 18** also specified that required privacy language in NIH informed consents could not be changed unless cleared by OHSRP and OGC. However, this policy includes the expanded CoC requirements under the Public Health Service Act (2017) and the use of consent form templates.