APPENDIX C

Summary of Guidance on Creating Research Repositories

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Note: This is a general summary of the Guidance on Creating Research Repositories and does not contain all of the nuances in the policy. Investigators should consult the Guidance for more detailed information on when certain requirements attach. In addition, it is impossible to capture all factual circumstances in this summary chart; applicable requirements are determined by the IRB based on all relevant facts. In the event certain circumstances are unclear, please consult with the IRB to determine the appropriate process to follow. References to "data" below include both data standing alone in a Data Repository and also specimens in a Tissue Repository that have associated data.

1. Creation of Repository[i]

Method of Creating Repository		***Procedures***		
Source of Data[ii]	**Data to be Recorded in Repository**	**IRB Review?**	**Informed Consent?**	**HIPAA Authorization?**
Interaction with living individuals	Individually identifiable data (including coded information capable of being re-identified)	YES, approval required	YES	YES
	No direct identifiers, but includes one or more of the 18 HIPAA identifiers	YES, approval required	YES	YES
	Completely de-identified information	YES, approval required	YES	YES[iii]
Review of records containing individually identifiable information	Individually identifiable data (including coded information capable of being re-identified)	YES, approval required	YES (waiver criteria may be met given no interaction with living individuals) EXCEPTION: if data originally collected using research consent that covers this use, may not need new consent (IRB decides)	YES (waiver criteria may be met given no interaction with living individuals)
	No direct identifiers, but includes one or more of the 18 HIPAA identifiers	YES, but may qualify for exemption under 45 CFR 46.101(b)(4) (research on existing data if recorded in de-identified format; cannot be coded)	If not exempt – YES (waiver criteria may be met) If exempt – NO	YES (waiver criteria may be met)[iv]

	Completely de-identified information	YES, but may qualify for exemption under 45 CFR 46.101(b)(4) (research on existing data if recorded in de-identified format; cannot be coded)	If not exempt – YES (waiver criteria may be met) If exempt – NO	YES (waiver criteria may be met)[v]
Review of records that are not individually identifiable, but may contain one or more of the 18 HIPAA identifiers	No direct identifiers, but contains one or more of the 18 HIPAA identifiers	NO, not human subjects research	NO	YES (waiver criteria may be met)[vi] <u>EXCEPTION</u>: If the records to be reviewed constitute a limited data set, no authorization is required, but Data Use Agreement may need to be signed.
	Completely de-identified information	NO, not human subjects research	NO	YES (waiver criteria may be met)[vii] <u>EXCEPTION</u>: If the records to be reviewed constitute a limited data set, no authorization is required, but Data Use Agreement may need to be signed.
Receipt of coded information from a third party (not collected as part of the currently proposed research project)	Coded Information	YES; use of coded information may <u>not</u> be human subject research provided that the investigator is prohibited from accessing the key to the codes. However, the IRB must make this determination.[viii]	NO, as long as IRB determines the research does not involve human subjects.	YES, if PHI is included in data set (waiver criteria may be met) NO, if no PHI included, or if the only PHI included meets definition of Limited Data Set (but Data Use Agreement must be used)
Receipt of Limited Data Set from third party (not collected as part of the currently proposed research project)	Limited Data Set	May qualify for exemption under 45 CFR 46.101(b)(4) or may not constitute "human subjects research" depending on whether data are individually identifiable	If exempt or not "human subjects research" by definition – NO If non-exempt human subjects research – YES (waiver criteria may be met)	NO (but Data Use Agreement must be signed)
Receipt of completely de-identified information from third party (not collected as part of the currently proposed research project)	Completely de-identified information	NO	NO	NO

2. Uses of Data in Repository

Information to be Used or Made Available to Other Researchers	IRB Review?	Informed Consent?	HIPAA Authorization?
Individually identifiable data	YES	YES (waiver criteria may be met) EXCEPTION: if data originally collected using research consent that covers this specific use, may not need new consent (IRB decides)	YES (waiver criteria may be met)
Limited Data Set	YES, but may qualify for exemption under 45 CFR 46.101(b)(4) or may not constitute "human subjects research" depending on whether data are individually identifiable	If exempt or not "human subjects research" by definition – NO If non-exempt human subjects research – YES (waiver criteria may be met)	NO, but recipient must enter Data Use Agreement
Completely De-Identified Data Set	NO	NO	NO

[i] Research Repository is defined for purposes of the Guidance as the collection of health information either standing alone (Data Repository) or in association with collected biological materials such as tissue, blood, or other specimens (Tissue Repository) where the primary purpose is to compile data and/or specimens with associated data that may be used (for example, mining the data) or shared for research purposes.

[ii] These categories are not mutually exclusive. A specific repository research project may fall into more than one category.

[iii] Note that the act of de-identifying the data (e.g., stripping it of HIPAA's 18 identifiers) is not itself a "research" activity, it is considered to be part of the institution's "operations" and does not require separate authorization. Furthermore, the maintenance of data that are not individually identifiable, even if for research purposes, is not a human subjects research activity. However, the collection of information (or biological materials with associated information) directly from an individual for purposes of including it in a research repository is a research activity that likely requires a research authorization.

[iv] Even if the research is exempt under the Common Rule and therefore does not require informed consent, authorization may still be required under HIPAA and a waiver request should be made if the criteria are met.

[v] Even if the research is exempt under the Common Rule and therefore does not require informed consent, authorization may still be required under HIPAA and a waiver request should be made if the criteria are met.

[vi] Even if the research is exempt under the Common Rule and therefore does not require informed consent, authorization may still be required under HIPAA and a waiver request should be made if the criteria are met.

[vii] Even if the research is exempt under the Common Rule and therefore does not require informed consent, authorization may still be required under HIPAA and a waiver request should be made if the criteria are met.

[viii] It is theoretically possible that coded information that is completely de-identified by HIPAA standards may be considered individually identifiable, and thus human subjects research, if the standards for preventing the researcher from accessing the key to the code are not met.