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Education
Healthcare
Life Sciences

NPRM Webinar Series: Research with Biospecimens and Identifiable Private Information

October 23, 2015

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A Bit About Our Speakers

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Agenda

- NPRM Overview
- Proposed Changes Related to Research with Biospecimens & Identifiable Private Information (IPI)
  - Definition of Human Subject
  - Compliance with Proposed Rule
  - Excluded Activities
  - Exemptions
  - Safeguards Requirements
  - Limited IRB Review
  - New Additional Elements of Informed Consent
  - Broad Consent
  - Waiver or Alteration of Consent, and Restrictions

Agenda, Continued

- Scenarios under Current and Proposed Rules
  - Scenario 1: Chart Review
  - Scenario 2: Storage of Specimens in a Repository
  - Scenario 3: Distribution of Samples from a Repository
  - Scenario 4: Development of Assay
  - Scenario 5: Secondary Research Use of Identifiable Private Information
- Discussion, Q&A

NPRM Overview

NPRM Overview

- On September 2, 2015, the Department of Health and Human Services (DHHS) and fifteen other Federal Departments and Agencies announced that a Notice of Proposed Rule Making (NPRM) was put on public display.
- The NPRM was published in the Federal Register on September 8, 2015: https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects.
- Included within the 519-page NPRM are approximately 45 major proposals to the Common Rule and 88 questions/requests for comment.
- Comments are due no later than 5 p.m. on December 7, 2015.

Proposed Changes Related to Research with Biospecimens and Identifiable Private Information

Definition of Human Subject

EXPANDING THE DEFINITION TO INCLUDE ALL BIOSPECIMENS

Current Definition at §_.102(f)	Proposed Definition at §_.102(e)(1)
Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: 1. data through intervention or interaction with the individual; 2. identifiable private information.	*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: i. Obtains data through intervention or interaction with the individual, and uses, studies, or analyzes the data; ii. Obtains, uses, studies, analyzes, or generates identifiable private information; or iii. Obtains, uses, studies, or analyzes biospecimens.

Definition of Human Subject

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS OR IPI

- Focus on “secondary research use” for biospecimens
- Goal of requiring informed consent for research involving biospecimens in all but a limited number of circumstances
- Response to public demand
- Not changing: definition of “identifiability”
- Two alternative proposals seek to narrow the types of applicable biospecimens through alternate definitions
  - Whole Genome Sequencing
  - Particular technologies

Compliance with the Proposed Rule

TRANSITION PROVISIONS AT §_.101(K)

§_.101(k)(1)

Research initiated prior to the compliance dates. Ongoing human subjects research in which human subjects (as defined by this policy) were involved prior to the compliance dates for the cited provisions need not comply with the additional requirements of this subpart at §§ __.101(a)(2), __.103(e), __.104(c) through (f), __.105, __.108(a)(2), __.109(f)(2), __.111(a)(7) and (8), __.114, __.115(a)(10) and (11), __.116, and __.117 that became effective on [*effective date of the final rule*].

Compliance with the Proposed Rule

TRANSITION PROVISIONS AT §_.101(K)

§_.101(k)(2)

Use of prior collections of biospecimens. Research involving the use of prior collections of biospecimens that meets both of the following criteria need not comply with the requirements of these regulations:

i. The biospecimens were collected for either research or non-research purposes before the compliance date for the additional requirements of this subpart at §__.102(e)(1)(iii), and
ii. Research use of the biospecimens occurs only after removal of any individually identifiable information associated with the biospecimens.

Compliance with the Proposed Rule

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- Biospecimens collected *prior to* the compliance date can be distributed for research use if stripped of identifiable private information
  - Many investigators and biorepositories already operate in this manner, so this may not require a change in practice
  - Distribution of biospecimens *with* identifiable private information would be subject to new informed consent provisions
- Biospecimens collected *after* the compliance date would be subject to the informed consent provisions of the new Rule
  - Investigators and biorepository managers will need to be able to distinguish between which biospecimens were collected *prior to* and *after* the compliance date

Excluded Activities

ACTIVITIES, RESEARCH OR NOT, TO WHICH THE PROPOSED RULE WOULD *NOT* APPLY

Many of these activities are either not discussed in the Current Rule or are *similar to* the Exemptions currently at §_.101(b).

Not Research, §_.101(b)(1)	Low-Risk Research, §_.101(b)(2)	Low-Risk and Does Not Meaningfully Diminish Subject Autonomy, §_.101(b)(3)
i. Internal Operational Monitoring ii. Oral Histories, etc. iii. Criminal Justice Activities iv. Quality Assurance Activities v. Public Health Activities vi. National Security Activities	*Does not apply to collection or analysis of biospecimens* i. Tests, Surveys, Interviews, Observations ii. "Existing" information iii. Certain Federal Research iv. HIPAA Research	i. Secondary research use of a non-identified biospecimen that is designed only to generate information about an individual that already is known

Excluded Activities

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- §_.101(b)(2)(ii) - similar to current exempt category 4, now this research would be excluded
  - "Research involving the collection or study of information that has been or will be acquired solely for non-research activities or was acquired for research studies other than the proposed research study when the sources are publicly available, or the information is recorded by the investigator in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects or otherwise conduct an analysis that could lead to creating individually identifiable private information"
- §_.101(b)(2)(iv) - research that involves the use of protected health information by a HIPAA covered entity for "health care operations," "public health activities" or "research" would now be excluded
  - This means that at institutions subject to the HIPAA regulations, projects where one is simply analyzing PHI from medical charts would not be required to undergo IRB review

Excluded Activities

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- Currently, secondary research utilizing coded or non-identified biospecimens could qualify as “Not Human Subjects Research”
  - The Common Rule generally does not apply to this research and informed consent generally is not required
- Under the proposed new definition of *human subject*, this would no longer be the case, so the Common Rule identifies an exclusion at §_.101(b)(3)
  - This exclusion is only for secondary research us of a non-identified specimen that is designed to generate only information about an individual that already is known, e.g., for a test/assay using a non-identified specimen for a disease that the person is already know to have
  - This likely accounts for only a small percentage of current secondary research use for non-identified specimens

Proposed Exemptions

RESEARCH THAT MAY INVOLVE SENSITIVE INFORMATION

§_.104(e)(2)

Secondary research use of identifiable private information that has been or will be acquired for non-research purposes, if the following criteria are met:

i. Prior notice has been given to the individuals to whom the identifiable private information pertains that such information may be used in research; and
ii. The identifiable private information is used only for purposes of the specific research for which the investigator or recipient entity requested access to the information.

Protection requirements at §_.105 apply to the above.

Proposed Exemptions

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- This proposed exemption is different than the current exemption at §_.101(b)(4):
  - "Research involving **the collection or study of existing data**, documents, records, 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 through identifiers linked to subjects**"
  - The proposed exemption is specific to identifiable private information that has been or will be acquired *for non-research purposes*
  - The proposed exemption allows for secondary research use of identifiable private information
  - The proposed exemption applies only for a specific study, not for all future use
  - The proposed exemption does not cover the collection of any data through a research interaction or intervention
  - There is some potential overlap with the exemption at §_.104(e)(2)

Proposed Exemptions

SECONDARY RESEARCH WITH BIOSPECIMENS & IPI

§_.104(f)(1)(i)

Storage or maintenance for secondary research use of biospecimens or identifiable private information that have been or will be acquired for research studies other than for the proposed research study, or for non-research purposes, if the following criteria are met:

A. Written consent for the storage, maintenance, and secondary research use of the information or biospecimens is obtained in accordance with §__.116(c) and (d)(2), and the template published by the Secretary of HHS in accordance with §__.116(d)(1) must be used. Oral consent, if obtained during the original data collection and in accordance with §__.116(c) and (d)(3), would be satisfactory for the research use of identifiable private information initially acquired in accordance with activities excluded from this policy under §__.101(b)(2)(i) or exempt from this policy in accordance with §__.104(d)(3) or (4), or §__.104(e)(1);
B. The reviewing IRB makes the determinations required by §__.111(a)(9).

Protection requirements at §_.105 apply. Informed consent and Limited IRB Review also.

Proposed Exemptions

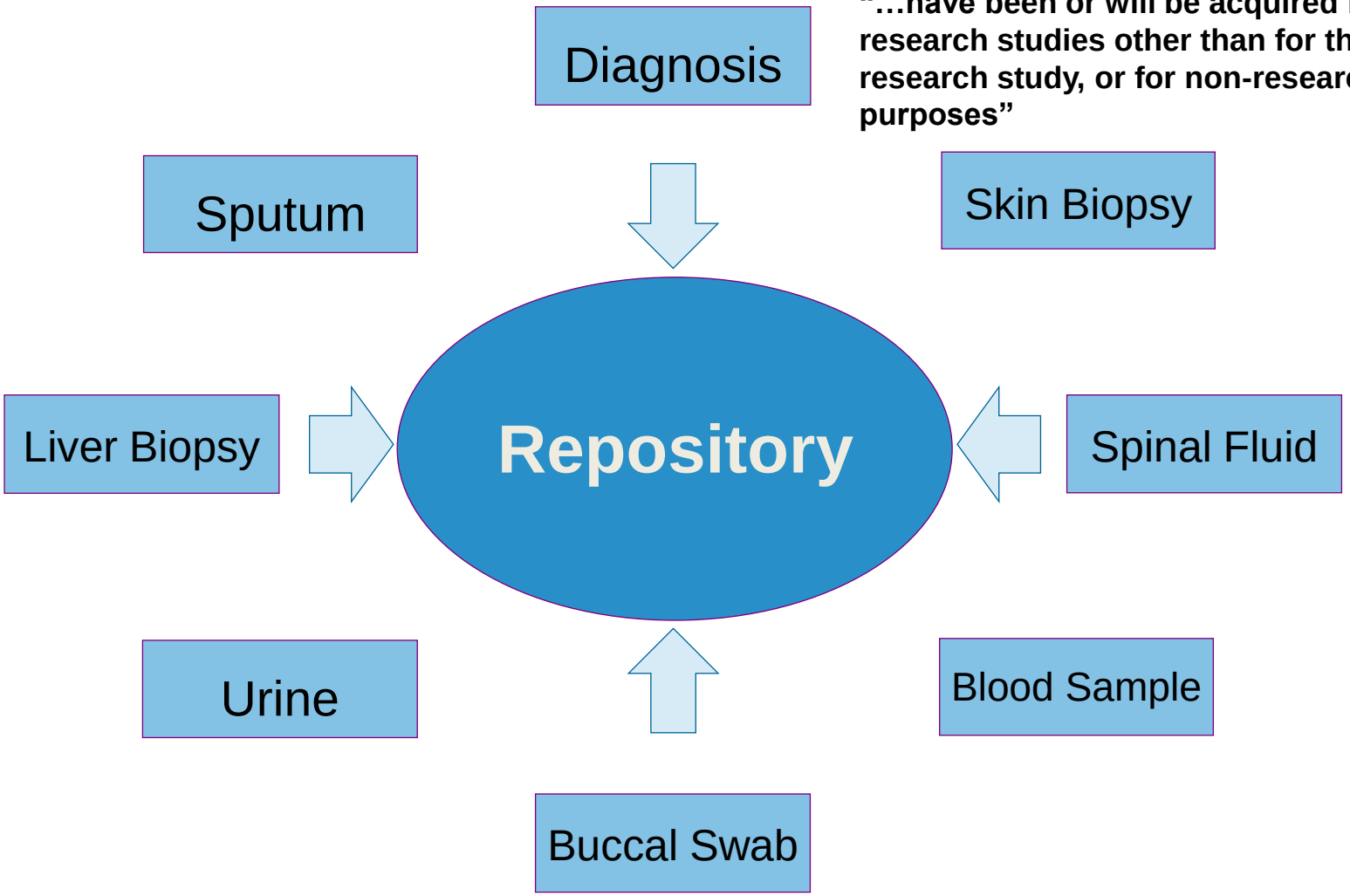
IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- This exemption does not cover the creation of any data or the actual new collection of any biospecimens or identifiable private information from a person through a research interaction or intervention
  - "Storage or maintenance for secondary research use of biospecimens or identifiable private information that **have been or will be acquired for research studies other than for the research study, or for non-research purposes**"
  - For example, if the proposed research activities involved creating a research repository of DNA samples that would be obtained from people through cheek swabs, the collection of the cheek swabs would mean that the creation of the research repository would require IRB review, and would not be exempt

Proposed Exemptions

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

"…have been or will be acquired for research studies other than for the research study, or for non-research purposes"



Proposed Exemptions

SECONDARY RESEARCH WITH BIOSPECIMENS & IPI

§_.104(f)(2)

i. Research involving the use of biospecimens or identifiable private information that have been stored or maintained for secondary research use, if consent for the storage, maintenance, and secondary research use of the information and biospecimens was obtained as detailed in paragraph (f)(1)(i)(A) of this section.

ii. If the investigator anticipates that individual research results will be provided to a research subject, the research may not be exempted under this provision and must be reviewed by the IRB and informed consent for the research must be obtained to the extent required by §__.116(a) and (b).

Protection requirements at §_.105 apply. Informed consent also.

Proposed Exemptions

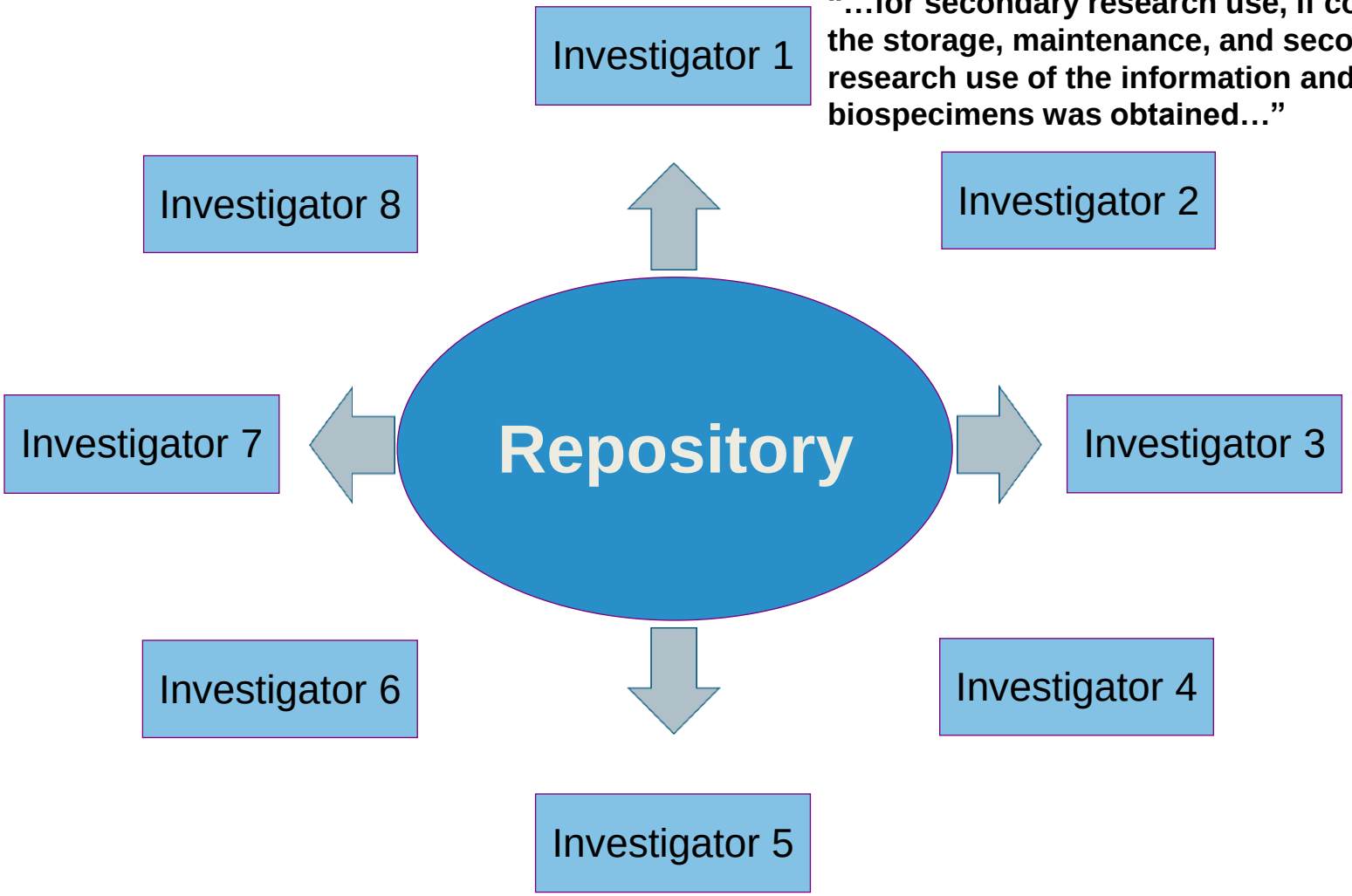
IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- This exemption covers activities that currently would not typically meet the definition of "human subjects research"
  - This exemption seems to have been added to account for the change in the definition of "human subject"
- For identifiable private information, this exemption overlaps with §_.104(e)(2) above, "Secondary research use of identifiable private information that has been or will be acquired for non-research purposes," in that this is for research involving the use of identifiable private information that has been acquired *for research or non-research purposes* and that has been stored or maintained for secondary research use

Proposed Exemptions

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

"…for secondary research use, if consent for the storage, maintenance, and secondary research use of the information and biospecimens was obtained…"



Safeguards Requirements

PROTECTION OF BIOSPECIMENS AND IPI

§_.105(a)

Institutions and investigators conducting research that is subject to this policy, or that is exempt from this policy under §__.104(e) or (f), involving the collection, storage, or use of biospecimens or identifiable private information, shall implement and maintain reasonable and appropriate safeguards as specified in paragraph (b) of this section to protect biospecimens or identifiable private information that they collect, obtain, receive, maintain, or transmit for research. The safeguards shall reasonably protect against anticipated threats or hazards to the security or integrity of the information or biospecimens, as well as reasonably protect the information and biospecimens from any intentional or unintentional use, release, or disclosure that is in violation of paragraph (c) of this section. IRB review of the safeguards required by this section is not required, except to the extent required by §__.104(f)(1).

Safeguards Requirements

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- §_.105(b) states that the Secretary's measures would satisfy protections requirements
- The Secretary's measures will be updated at least every 8 years
- Institutions are allowed to develop their own safeguards, provided that they meet or exceed HIPAA standards at 45 CFR 164.308, 164.310, 164.312, and 45 CFR 164.530(c)
- Researchers would be required to meet these requirements rather than the IRB being required to ask for and evaluate this information for each individual study

Limited IRB Review

REVIEW FOR EXEMPTIONS AT §__.104(F)

§_.111(a)(9)

For purposes of conducting the limited IRB review as required by §__.104(f)(1), the IRB need not make the determinations at paragraphs (a)(1) through (8) of this section, and shall determine that the following requirements are satisfied:

i. The procedures for obtaining broad consent for storage, maintenance, and secondary research use of biospecimens or identifiable private information will be conducted in accordance with the requirements of the first paragraph in §__.116.
ii. If there will be a change for research purposes in the way the biospecimens or information are stored or maintained, that the privacy and information protection standards at §__.105 are satisfied for the creation of any related storage database or repository.

Limited IRB Review

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- Limited IRB Review may be conducted under the expedited review procedure, as allowed by §__.110(b)(1)(iii)
- Although Limited IRB Review is required for the exemption at §_.104(f)(1), the NPRM does not intend for each particular study that qualifies for exemption under that category to undergo Limited IRB Review
  - "The purpose of this limited IRB review is to ensure that the process of obtaining consent will occur in an appropriate way, because there may be some circumstances (for example, when someone is admitted for emergency care), when the individual is not able to make an informed considered decision. This IRB review will, for many institutions, be essentially a "one-time" event (as opposed to being needed for specific research studies); the IRB would review an overall general institutional protocol for the manner in which people can provide broad consent for the maintenance or storage of their biospecimens for future secondary research." -p. 152 of the NPRM public inspection copy

New Elements of Informed Consent

NEW BASIC REQUIREMENT FOR FOR IPI

§_.116(a)(9)

One of the following statements about any research that involves the collection of identifiable private information:

i. A statement that identifiers might be removed from the data and the data that is not identifiable could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the representative, if this might be a possibility; or
ii. A statement that the subject's data collected as part of the research, from which identifiers are removed, will not be used or distributed for future research studies.

New Elements of Informed Consent

NEW ADDITIONAL ELEMENTS FOR BIOSPECIMENS & IPI

§_.116(b)(7), (8), & (9)

7. A statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. An option for the subject or the representative to consent, or refuse to consent, to investigators re-contacting the subject to seek additional information or biospecimens or to discuss participation in another research study.

New Elements of Informed Consent

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IPI

- The new additional element at §_.116(b)(8) clarifies an ambiguity in the current Rule regarding clinically relevant research
- Although future contact “opt out” clauses are regularly included in informed consent documents, tracking these decisions may be more complex considering the new frequency of inclusion of this additional element at §_.116(b)(9)

Broad Consent

STORAGE, MAINTENANCE, AND SECONDARY RESEARCH USE OF BIOSPECIMENS AND IPI

§_.116(c)(1)

If the subject or the representative will be asked to provide broad consent to the storage or maintenance of biospecimens or identifiable private information, collected for either research studies other than the proposed research or non-research purposes, and the secondary research use of this stored material, the information required in paragraphs (a)(2), (3), (5), and (7) and, if applicable, (b)(7) through (9) of this section, shall be provided to each subject, with the following additional information:

i. A general description of the types of research that may be conducted with information and biospecimens and the information that is expected to be generated from the research, the types of information or biospecimens that might be used in research, and the types of institutions that might conduct research with the biospecimens or information;

Broad Consent

STORAGE, MAINTENANCE, AND SECONDARY RESEARCH USE OF BIOSPECIMENS AND IPI

§_.116(c)(1), Continued

ii. A description of the scope of the informed consent must be provided, including:

A. A clear description of the types of biospecimens or information that were or will be collected and the period of time during which biospecimen or information collection will occur. This may include all biospecimens and information from the subject's medical record or other records existing at the institution at the time informed consent is sought; and

B. For purposes of paragraph (c)(1)(ii)(A) of this section, the period of time during which biospecimen or information collection will occur cannot exceed 10 years from the date of consent. For research involving children as subjects, that time period cannot exceed 10 years after parental permission is obtained or until the child reaches the legal age for consent to the treatments or procedures involved in the research, whichever time period is shorter. The time limitations described do not apply to biospecimens or information that initially will be collected for research purposes.

Broad Consent

STORAGE, MAINTENANCE, AND SECONDARY RESEARCH USE OF BIOSPECIMENS AND IPI

§_.116(c)(1), Continued

iii. A description of the period of time during which an investigator can continue to conduct research using the subject's biospecimens and information described in paragraph (c)(1)(ii)(A) of this section (e.g., a certain number of years, or indefinitely);

iv. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw consent, if feasible, for research use or distribution of the subject's information or biospecimens at any time without penalty or loss of benefits to which the subject is otherwise entitled, and information about whom to contact in order for the subject to withdraw consent. The statement must make clear that information or biospecimens that already have been distributed for research use may not be retrieved;

v. If applicable, a statement notifying the subject or the representative that the subject or the representative will not be informed of the details of any specific research studies that might be conducted, including the purposes of the research, that will use the subject's information and biospecimens;

Broad Consent

STORAGE, MAINTENANCE, AND SECONDARY RESEARCH USE OF BIOSPECIMENS AND IPI

§_.116(c)(1), Continued

vi. If applicable, a statement notifying the subject or the representative of the expectation that the subject's information and biospecimens are likely to be used by multiple investigators and institutions and shared broadly for many types of research studies in the future, and this information and the biospecimens might be identifiable when shared;

vii. The names of the institution or set of institutions at which the subject's biospecimens or information were or will be collected, to the extent possible (in recognition that institutions might change names or cease to exist); and

viii. If relevant, an option for an adult subject or the representative to consent, or refuse to consent, to the inclusion of the subject's data, with removal of the identifiers listed in 45 CFR 164.514(b)(2)(i)(A) through (Q), in a database that is publicly and openly accessible to anyone. This option must be prominently noted, and must include a description of risks of public access to the data.

Broad Consent

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IDENTIFIABLE PRIVATE INFORMATION

- Broad consent can be incorporated into another informed consent process and document in the *research* context
  - For investigators who plan to use biospecimens or identifiable private information for their own secondary uses or who plan to contribute the information or biospecimens to a data bank or repository, they will not be required to use a separate form.
- Broad consent in the *non-research* context would be limited to the following
  - Biospecimens or identifiable private information that exist at the time at which broad consent is sought;
  - Biospecimens or identifiable private information that will be collected up to 10 years after broad consent is obtained (or until a child reaches the legal age of consent, whichever comes first)

Waiver or Alteration of Informed Consent

ADDITIONAL CRITERIA FOR RESEARCH WITH BIOSPECIMENS & IPI

Current Criteria at §_.116(d)	Proposed Criteria at §_.116(f)(1)
1. The research involves no more than minimal risk to the subjects; 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects; 3. The research could not practicably be carried out without the waiver or alteration; and 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	i. The research involves no more than minimal risk to the subjects; ii. The research could not practicably be carried out without the requested waiver or alteration; iii. If the research involves accessing or using identifiable biospecimens or identifiable information, the research could not practicably be carried out without accessing or using identifiers; iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and v. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver or Alteration of Informed Consent

ADDITIONAL CRITERIA FOR RESEARCH WITH BIOSPECIMENS

§_.116(f)(2)

Additional criteria for waiver or alteration of consent for research involving biospecimens. For research involving the use of biospecimens, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the above requirements to obtain informed consent, provided the IRB finds and documents the criteria in paragraph (f)(1) of this section, and the following additional criteria:

i. There are compelling scientific reasons for the research use of the biospecimens; and
ii. The research could not be conducted with other biospecimens for which informed consent was obtained or could be obtained.

Waiver or Alteration of Informed Consent

ADDITIONAL CRITERIA FOR FOR RESEARCH WITH BIOSPECIMENS & IPI

§_.116(f)(3)

If an individual was asked to consent to the storage or maintenance for secondary research use of biospecimens or identifiable private information, in accordance with the requirements of paragraph (c) of this section, and refused to consent, an IRB cannot waive consent for either the storage or maintenance for secondary research use, or for the secondary research use, of those biospecimens or information.

Waiver or Alteration of Consent

IMPLICATIONS FOR RESEARCH WITH BIOSPECIMENS AND IDENTIFIABLE PRIVATE INFORMATION

- "Practicability" and "rights and welfare of subjects" remain as waiver criteria
  - The preamble to the NPRM stresses, consistent with the current Rule, that practicability applies to the ability to conduct research, not to the ability to obtain consent
  - "Rights and welfare" can refer to considerations beyond risk of harm or discomfort
- For §_.116(f)(2), the more stringent waiver conditions for research involving biospecimens , the NPRM states, "…the circumstances in which a waiver could be granted by an IRB should be extremely rare"
- An IRB cannot waive consent for storage/maintenance for secondary research use if an individual refused to consent to the "broad consent" form

Scenarios under Current and Proposed Rules

Scenario #1: Chart Review

Dr. Smith works at a covered entity and plans to access identifiable private information from subjects' health records at that entity in order to conduct research.

CURRENT RULE: 2 Options

- The research could likely be exempt under §_101(b)(4) if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
- The research could likely be reviewed under the expedited procedure at §_.110, category 5, likely with a waiver of consent at §_.116(d), if the investigator chooses to retain identifiable private information

Scenario #1: Chart Review

Dr. Smith works at a covered entity and plans to access identifiable private information from subjects' health records at that entity in order to conduct research.

PROPOSED RULE:

- The research could likely be excluded under §_101(b)(2)(iv); however, HIPAA waiver criteria would likely need to be evaluated
- The research would not require review by an IRB; therefore, expedited review and waiver of consent would be irrelevant

Scenario #2: Storage of Specimens in a Repository

Dr. Bechert develops a repository protocol that includes (a) obtaining specimens (and associated identifiable private information) that were previously collected for other purposes and (b) storing or maintaining those specimens for future secondary research use; the specimens are coded and only coded or non-identified specimens are released to researchers for secondary research use.

CURRENT RULE:

- Storage or maintenance of identifiable specimens is considered human subjects research
- IRB review and informed consent (or waiver of informed consent) storage or maintenance of specimens for secondary research would be required in this scenario

Scenario #2: Storage of Specimens in a Repository

Dr. Bechert develops a repository protocol that includes (a) obtaining specimens (and associated identifiable private information) that were previously collected for other purposes and (b) storing or maintaining those specimens for future secondary research use; the specimens are coded and only coded or non-identified specimens are released to researchers for secondary research use.

PROPOSED RULE:

- Storage or maintenance of identifiable specimens is considered human subjects research, but could be exempt under §_104(f)(1)
- Informed consent must have been obtained previously whether specific to a research activity or under broad consent

Scenario #3: Distribution of Specimens from a Repository

Dr. Bechert develops a repository protocol that includes (a) collecting specimens and (b) obtaining informed consent directly from subjects; the protocol is reviewed and approved by the IRB; the specimens are coded and only coded or non-identified specimens are released to Dr. Conte for secondary research use.

CURRENT RULE:

- Dr. Conte's secondary research use of coded or non-identified specimens would typically not meet the definition of human subjects research
- IRB review and informed consent (or waiver of informed consent) for distribution of specimens for secondary research would not be required in this scenario

Scenario #3: Distribution of Specimens from a Repository

Dr. Bechert develops a repository protocol that includes (a) collecting specimens and (b) obtaining informed consent from subjects; the protocol is reviewed and approved by the IRB; the specimens are coded and only coded or non-identified specimens are released to Dr. Conte for secondary research use.

PROPOSED RULE:

- Dr. Conte's secondary research use of coded or non-identified specimens would meet the definition of human subjects research
- Secondary research use of coded or non-identified specimens would likely qualify for exemption under §_104(f)(2)

Scenario #4: Development of Assay

Dr. Williams is conducting research on diabetes. She wants to develop an assay to screen for the presence of a biomarker that is linked to Type 2 diabetes. She will obtain blood samples and associated non-identified private information from a diabetes repository and will use those samples to develop the assay.

CURRENT RULE:

- Dr. Williams' development work would not meet the definition of "human subjects research" under the current Rule
- Note that Dr. Williams' work could be considered a "clinical investigation" under FDA regulations if it will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit

Scenario #4: Development of Assay

Dr. Williams is conducting research on diabetes. She wants to develop an assay to screen for the presence of a biomarker that is linked to Type 2 diabetes. She will obtain blood samples and associated non-identified private information from a diabetes repository and will use those samples to develop the assay.

PROPOSED RULE:

- Dr. Williams' development work would meet the definition of "human subjects research" under the proposed Rule, but could be excluded under §_.101(b)(3)
- FDA considerations would still apply in this scenario

Scenario #5: Secondary Research Use of IPI

Dr. Rohrbach maintains a database with several thousand records containing identifiable private information relating to behavioral and educational outcomes for individuals with autism. Dr. Hunter asks for Dr. Rohrbach to share information pertaining to children ages 10-15 for a research study he is conducting. The number of records totals over 800

CURRENT RULE: 2 Options

- If Dr. Rohrbach shares coded or non-identified information from the database, then Dr. Hunter's activities would not be considered "human subjects research"
- If Dr. Hunter insists on receiving IPI, then his activities would be "human subjects research" for which IRB review would be required; a waiver of consent may be appropriate

Scenario #5: Secondary Research Use of IPI

Dr. Rohrbach maintains a database with several thousand records containing identifiable private information relating to behavioral and educational outcomes for individuals with autism. Dr. Hunter asks for Dr. Rohrbach to share information pertaining to children ages 10-15 for a research study he is conducting. The number of records totals over 800

PROPOSED RULE: 2 Options

- If Dr. Rohrbach shares coded or non-identified information from the database, then Dr. Hunter's activities would still not be considered "human subjects research"
- If Dr. Hunter insists on receiving IPI, then his activities would be "human subjects research"; requirements for IRB review and waiver of consent would depend on a variety of factors

Discussion

Additional NPRM Resources

- OHRP Website
- Federal Register
- 9/15/2015 PRIM&R NPRM Webinar
- 9/16/2015 OHRP Research Community Forum, Cleveland
- 10/14/2015 OHRP Workshop at 2015 NIH Regional Seminar, San Diego
- Past Huron Webinars:
  - 4/15/2015: Get Prepared: External IRBs Are in Our Future
  - 9/18/2015: An Overview of the NPRM
- Upcoming Huron NPRM Webinars:
  - 11/4/2015: Proposed Changes to Reduce Administrative Burden

THANK YOU!

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