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Education
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NPRM Webinar Series:
NPRM Proposals to Reduce IRB Administrative Burden

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A Bit About Our Speakers

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Agenda

- NPRM Overview
- Previous Webinars and Additional Resources
- Proposed Changes to Reduce Administrative Burden
  - II.A. Proposed Changes to the Scope and Applicability of the Regulations
  - II.E. Cooperative Research
  - II.F. Changes to Promote Effectiveness and Efficiency in IRB Operations
  - II.G. Proposed Changes to IRB Operational Requirements
  - II.H. Other Proposed Changes

Agenda, continued

- Scenarios under Current and Proposed Rules
  - Scenario 1: Exemption/Exclusion
  - Scenario 2: Chart Review
  - Scenario 3: Research with Sensitive 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

Previous Webinars and Additional Resources

- Huron hosted 2 previous webinars focused on the NPRM:
  - Overview of the NPRM (September 18, 2015)
  - Biospecimen & Consent Changes (October 23, 2015)
- Additional Huron resources include:
  - Huron's Clinical Research Management Briefing
  - Client Alerts

Recordings of previous webinars, documents and subscriptions to future information are available at:

http://www.huronconsultinggroup.com/Insights

II. A. Proposed Changes to the Scope and Applicability of the Regulations

Exclusions

Explicit Exclusion of Activities from the Common Rule *§__.101(b)*

- Simply, exclusions are a mechanism to assist with not research/not human subject research determinations
- Unlike "exempt" research, excluded research is **not expected to undergo any type of review to determine this "excluded" status**
  - Investigators would independently make these determinations with little to no IRB involvement
- There is no alteration to the fact that activities that do not meet the criteria for being subject to the Common Rule remain outside the scope of the rule (i.e., Not Research, Not Human Subject Research)
- Eleven specific "excluded" activities broken into three subcategories
- It is proposed that all of the exclusion categories apply to research that is subject to subpart B and subpart C, and therefore the **requirements imposed by subpart B and subpart C would not need to be met**
- Research involving children is not eligible for exclusion, *except* for research where the investigator has no interaction with subjects

Explicit Exclusion of Activities from the Common Rule

Current Rule	Proposed Rule
(1) activities that do not meet the definition of research (§__.102(d) of the current Rule);	(1) activities that do not meet the definition of research (§__.102(d) of the current Rule);
(2) activities that are not described as research subject to regulation (§__.102(e) of the current Rule); and	(2) activities that are not described as research subject to regulation (§__.102(e) of the current Rule);
(3) activities that do not involve a human subject (§__.102(f) of the current Rule).	(3) activities that do not involve a human subject (§__.102(f) of the current Rule); and
	(4) activities specifically described as excluded (§__.101(b)(1) – (b)(3) of the proposed Rule).

Explicit Exclusion of Activities from the Common Rule
§__.101(b)(1) – Activities Determined Not To Be Research

1. Program improvement activities

- Data collection and analysis, including the use of biospecimens, for an institution's own **internal operational monitoring and program improvement purposes,** if the data collection and analysis is limited to the use of data or biospecimens originally **collected for any purpose other than the currently proposed activity, or is obtained through oral or written communications with individuals (e.g., surveys or interviews)**
  - These activities are not designed to produce generalizable knowledge

2. Certain oral history, journalism, biography, and historical scholarship activities

- Projects that focus directly on the specific individuals about whom the information is collected

3. Quality assurance or improvement activities

- Implementation of an accepted practice to improve the **delivery** or **quality** of care or services (including, but not limited to, education, training, and changing procedures related to care or services) if the purposes are limited to altering the **utilization of the accepted practice** and collecting data or biospecimens to evaluate the effects on the utilization of the practice
- Also includes quality improvement activities that are not related to delivery of patient care, but rather involve the delivery or quality of other public benefit or social services
  - This exclusion does not cover the evaluation of an accepted practice itself

Explicit Exclusion of Activities from the Common Rule
§__.101(b)(2) – Low-Risk Activities

- These activities are sufficiently low-risk and nonintrusive that the protections provided by the regulations are an unnecessary use of time and resources;
- These activities are considered low-risk either in themselves or because appropriate safeguards are already in place independent of the Common Rule

Explicit Exclusion of Activities from the Common Rule
§__.101(b)(2) – Low-Risk Activities

Revised version of current Exempt Category 2:

- Research involving educational, survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) uninfluenced by the investigators if at least one of the following is met:
  - Current requirements (recording information in a manner that subjects cannot be identified OR any disclosure outside of the research would not reasonably place subjects at risk (criminal or civil liability, financial standing, employability, educational advancement, or reputation), OR
  - The research will involve a collection of information subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq., research information will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-government Act of 2002, 44 U.S.C. 3501 note, and all of the information collected, used, or generated as part of the research will be maintained in a system or systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a
    - NPRM indicates that research that meets the above-required regulations have comparable, if not stronger privacy protections than the result of IRB review.
    - The exclusion does not include research activities in which any sort of intervention is used, in addition to the specified methods of information collection.
  - This proposed exclusion does not include the first element in the current exemption category at §__.101(b)(3)(i), which is the element related to elected or appointed public officials or candidates for public office.

Explicit Exclusion of Activities from the Common Rule
§__.101(b)(2) – Low-Risk Activities

Revised version of current Exempt Category 4

- Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, but only if the sources are publicly available or if the information is recorded by investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to them.
  - 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.
  - Does not include secondary research use of biospecimens.
  - Does not require that the data exist as of the time that the study commences, but rather is expanded to include the secondary research use of data collected in the future for research or non-research purposes.

Explicit Exclusion of Activities from the Common Rule
§__.101(b)(2) – Low-Risk Activities

- Certain research involving the use of protected health information regulated elsewhere under HIPAA
  - The exclusion is limited to ensure that it only applies to research studies and information that are already subject to independent privacy, confidentiality, and security protections.
  - These are activities whose **risks relate only to privacy and confidentiality**, and are already subject to protections provided by HIPAA.
  - Research that involves the use of protected health information by a HIPAA covered entity for **"health care operations," "public health activities," or "research,"** as those three terms are defined under the HIPAA Rules, would be excluded from the Common Rule.
  - This proposed exclusion would **not** apply if the investigator that receives and uses individually identifiable health information for a research study was not covered by the HIPAA Rules, even if the entity disclosing the individually identifiable health information to the investigator was covered by the HIPAA Rules.

Explicit Exclusion of Activities from the Common Rule *§__.101(b)(3)*

Excluded Category 3: Low-risk human subjects research activities that do not meaningfully diminish subject autonomy

- The secondary research use of non-identified biospecimens that is designed only to generate information about an individual that already is known
  - Applies to research subjects to this policy and to research subject to the additional requirements of 45 CFR part 46, subparts B, C, or D

Explicit Exclusion of Activities from the Common Rule
Research by Federal Agencies

§__.*101(b)(1) iii.* Criminal justice activities

Collection and analysis of data, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. The activities excluded are necessary for the operation and implementation of the criminal justice system.

§__.*101(b)(1) v.* Public health surveillance

When a public health authority conducts public health surveillance activities to fulfill its legal mandate to protect and maintain the health and welfare of the populations it oversees.

§__.*101(b)(1) vi.* Intelligence surveillance activities

Research involving surveys, interviews, surveillance activities and related analyses, or the collection and use of biospecimens where these activities are conducted by a defense, national security, or homeland security authority solely for authorized intelligence, homeland security, defense, or other national security purposes.

§__.*101(b)(2) iii.* Certain federal government-conducted research using government generated/collected information obtained for non-research purposes

This exclusion is proposed for situations in which both the original data collection and the subsequent (secondary) analysis are subject to data security, participant privacy, and notice requirements associated with the named federal statutes and regulations. As such, it does not seem that the delay imposed by obtaining a determination as “exempt” or “expedited” is likely to increase the protections provided to those who have already provided the government with information for other purposes.

Proposed Changes to Exemptions

Proposed Exemptions

§__.104(c) Making Exempt Research Determinations

This proposal would change the way we think about exemptions. It would no longer be a binary decision because it would no longer mean that the research is exempt from review.

- Eight exemptions divided into three categories according to the kind of risk and what protections are called for:
  - **Category 1**: Low-risk interventions that do not require application of standards for privacy safeguards and biospecimen protection
  - **Category 2:** Research that may involve sensitive information that requires application of standards for privacy safeguards and biospecimen protection
  - **Category 3:** Secondary research involving biospecimens and identifiable private information that requires application of privacy safeguards, broad consent and limited IRB review.

Proposed Exemptions

§__.104(c) Making Exempt Research Determinations

- Federal departments and agencies shall develop a “decision tool” to assist in the documentation of exemption determinations. If the decision tool is used, further assessment or evaluation of the exemption determination is not required (“safe harbor”).
- An institution or, when appropriate, the IRB, must maintain records of exemption determinations made for human subject research.
- Note that for FDA-regulated device studies IRB review is required by statute.

Category 1: Low Risk Interventions

Do not require application of privacy standards or biospecimen protection

- One new exemption – Research involving benign interventions in conjunction with the collection of data from an adult subject (§__.104(d)(3))
- Revised version of exemption category 1 in the current Common Rule (research conducted in established or commonly accepted educational settings) (§__.104(d)(1))
- Revised version of the current exemption category 5 (research and demonstration projects) (§__.104(d)(2))
- Not changing: Exemption category 6 in the current Common Rule (taste and food quality evaluation) (§__.104(d)(4))

Category 1: Low Risk Interventions

Do not require application of privacy standards or biospecimen protection

- **New exemption** – Research involving benign interventions in conjunction with the collection of data from an adult subject (via verbal, written responses or video recording) if subject prospectively agrees and at least one of the following is met:
  - Information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects; or
  - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Category 1: Low Risk Interventions

Do not require application of privacy standards or biospecimen protection

- **Revised** version of exemption category 1 in the current Common Rule (research conducted in established or commonly accepted educational settings):
  - The goal is to retain an exemption for a considerable portion of education research, but to provide for review if the research might adversely affect students' opportunity to learn required educational content, or the assessment of educators.

Category 1: Low Risk Interventions

Do not require application of privacy standards or biospecimen protection

- **Revised** version of the current exemption category 5 (research and demonstration projects):
  - Each federal department or agency conducting or supporting the research and demonstration projects would be required to establish, on a publicly accessible federal website or in such other manner as the department or agency head may prescribe, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision.
  - The research or demonstration project would be required to be published on this list prior to or upon commencement of the research.
  - The language in this exemption clarifies the original language to say that a federally conducted project examining any aspect of a public benefit or service program would qualify for the exemption.

Category 2: Research that may involve Sensitive Information

Requires application of privacy safeguards and biospecimen protection

- Revised version of exemption category 2 – Research Involving Educational Tests, Surveys, Interviews, or Observation of Public Behavior if the Information is Recorded with Identifiers and even if the Information is Sensitive (§__.104(e)(1))
- Variation of current expedited category 5 – Secondary Research Use of Identifiable Private Information (§__.104(e)(2))

Category 2: Research that may involve Sensitive Information

Requires application of privacy safeguards and biospecimen protection

- **Revised** version of current exemption category 2 – Research Involving Educational Tests, Surveys, Interviews, or Observation of Public Behavior if the Information is Recorded with Identifiers and even if the Information is Sensitive
  - Does not include interventions
  - Includes visual or auditory recording
  - Allows for research to be exempt where sensitive identifiable private information is collected and the release of that information could pose some measure of risk.
- **Unlike the new exclusion** that is also a revised version of current Exempt Category 2, this exemption criteria allows identifiers and does not exclude activities when disclosure outside of the research could possibly place subjects at risk (criminal or civil liability, financial standing, employability, educational advancement, or reputation).

Category 2: Research that may involve Sensitive Information

Requires application of privacy safeguards and biospecimen protection

- Variation of expedited category #5 – Secondary Research Use of Identifiable Private Information that has been or will be acquired for non-research purposes, if the following are met:
  - Prior notice has been given to the individuals to whom the identifiable private information pertains that such information may be used in research
  - The privacy safeguards are required, and
  - Data will be used only for purposes of the specific research proposed in the exemption request, not for any further secondary research use

Category 2: Research that may involve Sensitive Information

Requires application of privacy safeguards and biospecimen protection

Alternative scopes for this secondary use provision are also proposed for consideration:

- A narrower scope could be envisioned that would limit the exemption to data generated by the Federal Government for which a privacy impact assessment has been conducted pursuant to section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3601 et seq, that fully describes the ways that the information will be accessed, used, maintained, disseminated, and protected, and there is a formal written agreement between the investigator and the federal agency that requires the investigator to apply the same practices and safeguards as those addressed in the privacy impact assessment. Such a narrower interpretation might be easier to implement, and the line between §__.104(e)(2) and (f)(2) would be clearer.
- Alternatively, it could be broadened to allow additional research uses of the information beyond the specific research for which the investigator or recipient entity obtained the information.

Categories 2 & 3: Application of Standards for Privacy Safeguards

Research That May Involve Sensitive Information

The proposed Application of Standards for Privacy Safeguards offers three avenues to meeting the data security and privacy protection requirements for these two proposed exemptions:

- The investigator is required by law to comply with, or voluntarily complies with, the HIPAA Rules;
- The activity is conducted by federal departments and agencies, and the activity is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and the research will involve a collection of information subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.; or
- The investigator complies with the privacy safeguards promulgated by the Secretary of HHS

Category 3: Additional Requirements – Broad Consent

Requires privacy safeguards, broad consent, and limited IRB review

- We've just discussed the privacy safeguards within Category 2
- **Broad Consent** – When identifiable private information is collected for research purposes, consent would be required to notify subjects if their non-identified information could be utilized for future research studies without additional consent. Written consent for the storage, maintenance, and secondary research use of the information or biospecimens could be obtained using the broad consent template that the Secretary of HHS will develop
  - There would be at least two broad consent templates developed: one for information and biospecimens originally collected in the research context, and another for information and biospecimens originally collected in the non-research context
  - If templates not used, protocol will require IRB review which may include review of the original data/specimen collection protocol

Category 3: Additional Requirements – Limited IRB Review

Requires privacy safeguards, broad consent, and limited IRB review

- **Limited IRB Review** - The reviewing IRB conducts a limited IRB review of the process through which broad consent will be sought, and, in some cases, of the adequacy of the privacy safeguards described in §__.105.
  - (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

Category 3: Secondary Research with Biospecimens

Requires privacy safeguards, broad consent, and limited IRB review

Exemptions for secondary research involving biospecimens and identifiable private information that requires application of privacy safeguards, broad consent, and limited IRB review (§__.105, §__.116(c), §__.111(a)(9))

- Exemption for the Storage or Maintenance of Biospecimens or Identifiable Private Information for Secondary Research Use (§__.104(f)(1))
- Exemption for Secondary Research Use of Biospecimens or Identifiable Private Information where Broad Consent has been Sought and Obtained (§__.104(f)(2))

Category 3: Secondary Research with Biospecimens

Requires privacy safeguards, broad consent, and limited IRB review

- Exemption for the Storage or Maintenance of Biospecimens or Identifiable Private Information for Secondary Research Use – This exemption allows the 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 study, or for non-research purposes, if the following criteria are met:
  - Written consent for the storage, maintenance, and secondary use is obtained using the broad consent template the Secretary of HHS will develop. Oral consent, if obtained during the original data collection and in accordance with the elements of broad consent would be satisfactory for the research use of identifiable private information initially acquired in accordance with activities meeting exclusion or exempt criteria; and
  - The reviewing IRB conducts a limited IRB review of the process through which broad consent will be sought, and, in some cases, of the adequacy of the privacy safeguards

Category 3: Secondary Research with Biospecimens

Requires privacy safeguards, broad consent, and limited IRB review

- Exemption for Secondary Research Use of Biospecimens or Identifiable Private Information where Broad Consent has been Sought and Obtained
  - For the actual secondary research studies that will be conducted using biospecimens or identifiable private information that have been stored for unspecified secondary research studies
  - 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 must be obtained

Proposed Changes to Expedited Review

Proposed Changes to Expedited Review

It is anticipated that with the following changes, more studies that involve no more than minimal risk would undergo expedited review, rather than full review, which would relieve burden on IRB.

- Evaluation of the list of expedited review categories would occur every 8 years, followed by publication in the Federal Register and solicitation of public comment (§__.110(a)).
- The Secretary of HHS will create and publish and maintain a list of activities that should be considered minimal risk, and this list will be evaluated every 8 years (§__.102(j)).
- Expedited review can occur for studies on the Secretary's list unless the reviewer(s) determine(s) that the study involves more than minimal risk (§__.115(a)(9)).
- IRBs will be required to document their rationale when they override the presumption that studies on the Secretary's expedited review list involve greater than minimal risk.
- The NPRM proposes at §__.109(f) eliminating continuing review for many minimal risk studies (namely those that qualify for expedited review), unless the reviewer documents why continuing review should take place (as would be required by §__.115(a)(8)).

II. E. Cooperative Research (NPRM and Current Rule at §__.114) and Proposal to Cover Unaffiliated IRBs Not Operated by an Institution Holding a Federalwide Assurance

Cooperative Research §__.114 (b)(1)

Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be selected by the Federal department or agency supporting or conducting the research or, if there is no funding agency, by the lead institution conducting the research.

- Would not apply:
  - Research not supported or conducted by a federal agency or department;
  - When more than single IRB review is required by law (e.g., FDA-regulated devices); or
  - If the Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate

Cooperative Research

- New provision at §__.101(a) that would explicitly give Common Rule departments and agencies the authority to enforce compliance directly against unaffiliated IRBs that are not operated by an assured institution
  - This provision addresses OHRP's current practice of enforcing compliance through the institution engaged in human research, even in circumstances when the regulatory violation is directly related to the responsibilities of an external IRB
  - Compliance actions could be taken directly against the IRB responsible for the flawed review, rather than the institutions that relied on that review

Cooperative Research

- New provision at §__.103(e) that the institution and the IRB of record should establish and follow written procedures identifying the compliance responsibilities of each entity (applies to US only)
  - These procedures should be set forth in an agreement between the institution and the IRB specifying the responsibilities of each entity in ensuring compliance.
  - This policy would apply regardless of whether the study underwent convened or expedited review
  - This policy would not relieve any site of its other obligations under the regulations to protect human subjects. Nor would it prohibit institutions from choosing to conduct additional internal IRB reviews, however, such reviews would no longer have any regulatory status in terms of compliance with the Common Rule
    - Even though a local IRB may conduct its own additional internal review, such a review would not be binding on the local site if not adopted by the single IRB, and the terms of it would not be enforced by ORHP

Cooperative Research

- Relevant local contextual issues (e.g., investigator competence, site suitability) pertinent to most studies can be addressed through mechanisms other than local IRB review
  - The evaluation of a study's social value, scientific validity, and risks and benefits, and the adequacy of the informed consent form and process generally do not require the unique perspective of a local IRB
- See Huron's April 2015 Webinar for additional considerations on single IRB review of multi-site research

II. F. Changes to Promote Effectiveness and Efficiency in IRB Operations

Continuing Review of Research
§__.109(f)

- CR eliminated for all studies that undergo expedited review, **unless** the reviewer **documents** justification for why continuing review would enhance protection of research subjects.
- CR eliminated for certain studies initially reviewed by a convened IRB, once certain specified procedures are all that remain for the study, unless specifically mandated by the IRB, specifically (1) **analyzing data** (even if it is identifiable private information), or (2) **accessing follow-up clinical data** from procedures that subjects would undergo as part of standard care for their medical condition or disease.
- CR not required for secondary research using information and biospecimens that requires limited IRB review under new exemption §__.104(f)(1)
- **Annual confirmation** that research is ongoing and that no changes have been made that would require the IRB to conduct continuing review is required.
- Investigators would continue to be required to **submit changes** to the protocol to the IRB.

II. G. Proposed Changes to IRB Operational Requirements

Proposed Criteria for IRB Approval of Research §___.111

When considering criteria for approval #3 (equitable selection of subjects), added emphasis on issues related to "coercion or undue influence" for research with vulnerable populations

- Adds emphasis on issues related to "coercion or undue influence" when considering IRB member expertise and applying the regulatory criteria for approval in the review of research involving a vulnerable category of subjects
  - IRBs should focus on coercion or undue influence, not other considerations related to vulnerability
- "Economically or educationally disadvantaged persons" now included as an example of a vulnerable category of subjects, requiring an IRB to give consideration to membership expertise in this area.
- Adds "physically disabled persons" to list of populations potentially vulnerable to coercion or undue influence (§__.111(a)(3) and §__.111(b))

II. H. Other Proposed Changes

Changes to the Assurance Process

- Eliminate the following requirements:
  - that an institution provide a statement of ethical principles with which it will abide as part of the assurance process
  - that an institution designate one or more IRBs on its FWA established in accordance with the Common Rule
  - that an up-to-date list of the IRB members and their qualifications be included in an institution's assurance
  - that a department or agency head's evaluation of an assurance will take into consideration various factors related to the adequacy of the program
  - **the current option of "checking the box" on an FWA**
  - **that grant applications undergo IRB review for the purposes of certification**
- Add requirement for institutions to have and follow procedures for documenting the institution's reliance on any unaffiliated IRB and the respective responsibilities of each entity.

Scenarios under Current and Proposed Rules

Scenario #1: Exemption/Exclusion

Dr. Smith proposes a study where she will survey students at Huron State University, and conduct interviews with them about their shopping habits. Identifiable information will be collected in order to potentially re-contact subjects for further questions.

CURRENT RULE:
The research could likely be exempt under §_101(b)(2)

Scenario #1: Exemption/Exclusion

Dr. Smith proposes a study where she will survey students at Huron State University, and conduct interviews with them about their shopping habits. Identifiable information will be collected in order to potentially re-contact subjects for further questions.

PROPOSED RULE:

- The research could likely be excluded under §_101(b)(2)(i);
- No IRB review necessary

Scenario #2: Chart Review

Dr. Williams 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 #2: Chart Review

Dr. Williams 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 #3: Research with Sensitive Information

Dr. Garcia would like to conduct a survey with patients in his practice's waiting room. He will be collecting identifiable information, and some of the questions will inquire about past drug or alcohol abuse.

CURRENT RULE: Options

- The research will likely not be eligible for exemption under current exemption category 2 §_.101(b)(2) because identifiers are maintained and one could argue that the responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- The research could be reviewed under the current expedited procedure at §_.110, category 7, possibly with a waiver of documentation of consent at §_.117(c), since the investigator chose to collect and retain identifiable private information.

Scenario #3: Research with Sensitive Information

Dr. Garcia would like to conduct a survey with patients in his practice's waiting room. He will be collecting identifiable information, and some of the questions will inquire about past drug or alcohol abuse.

PROPOSED RULE:

- The research could likely be exempted under §__.104(e)(1) because this revised category allows for research to be exempt where sensitive identifiable private information is collected and the release of that information could pose some measure of risk; however, this will require the application of the privacy standards that we discussed.

Discussion

Additional NPRM Resources

- OHRP Website
- Federal Register
- 9/15/2015 PRIM&R NPRM Webinar
- Past Huron Webinars:
  - 4/15/2015: Get Prepared: External IRBs Are in Our Future
  - 9/18/2015: An Overview of the NPRM
  - 10/23/2015: Research with Biospecimens and Identifiable Private Information

Conclusions

Summary

- A number of NPRM proposals are proposed to increase IRB efficiency, and reduce administrative burden on both the IRB and researchers.
  - Exclusions will clarify and add items to the current not human subjects/not research determinations
  - Exemptions will be categorized into three groups according to level of risk and required protections
  - Expedited review regulations would provide specific guidance on which activities are deemed minimal risk
  - Relaxed requirement for annual review of minimal risk research
  - Cooperative Research will require use of a single IRB for federally funded, multi-site research activities with certain exceptions
  - Revised assurance (FWA) process will decrease administrative tasks and reporting to OHRP, and potentially increase flexibility for unfunded research

Thank you!

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