

MITRE Analysis of Advanced Notice of Proposed Rulemaking
Human Subjects Research Protections: Enhancing Protections for Research Subjects and
Reducing Burden, Delay, and Ambiguity for Investigators
August 1, 2011

On July 26, 2011, the Secretary of Department of Health and Human Services (HHS), in coordination with the Office of Science and Technology Policy (OSTP) published an Advanced Notice of Proposed Rulemaking (ANPRM) entitled, *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*. The purpose of the ANPRM is to request comments on how current regulations for protecting human subjects who participate in research might be modernized and revised to be more effective. Comments are due by September 26, 2011.

Basic regulations governing the protection of human subjects in research supported or conducted by HHS were first published in 1974. These regulations were updated in the late 1970s and early 1980s and are codified at 45 CFR Part 46, subparts A through E. In 1991, 14 other Federal departments and agencies joined HHS in adopting a uniform set of rules for the protection of human subjects. These regulations, known as the Common Rule, generally (1) require federally funded investigators in most instances to obtain and document the informed consent of research subjects, and (2) establish the requirements for Institutional Research Boards (IRB) that review and approve this research.

The rapid growth and expansion of human subjects research into such areas as national security, crime and crime prevention, using a wide array of methodologies, has led to many questions about whether the current regulatory framework is adequate and appropriate for the protection of human subjects in the 21st century. Overall, HHS and OSTP concluded that the existing rules requiring that research involving greater than minimal risk be reviewed by an IRB should not be changed. In addition, the ANPRM proposes changes to the following seven aspects of the current regulatory framework:

- Refinement of the existing risk-based regulatory framework to better calibrate oversight with a study's degree of risk,
- Utilization of a single IRB review of record for domestic sites of multi-site studies,
- Improvement of consent forms and the consent process for research,
- Establishment of mandatory data security and information protection standards for all studies that involve identifiable or potentially identifiable data,
- Establishment of an improved, more systemic approach for the collection and analysis of data on unanticipated problems and adverse events,
- Extension of Federal regulatory protection to all research conducted at institutions in the U.S. that receive funding from a Common rule agency for human subject research¹ and
- Improvement in the harmonization of regulations and related agency guidance.

We were asked to analyze the ANPRM to identify topics and issues related to health information technology (IT), on which the Privacy and Security Tiger Team, through the

¹ The ANPRM notes that this proposal will require legislation.

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HIT Policy Committee, may wish to comment. The related issues we identified are primarily associated with the topics of mandatory data security and information protection standards, including issues related to de-identified information and informed consent.

The analysis contained in the attached table identifies the specific proposals made in the ANPRM which correspond with these topics. The analysis includes summaries of the relevant Common Rule requirements, changes under consideration noted in the ANPRM, the specific questions on which HHS and OSTP are requesting comments and our analysis and related Tiger Team recommendations.

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| (1) Improving Informed Consent: | | | |
| <p>(1) (A) Improving Consent Forms:</p> <p>Generally, under the Common Rule and FDA regulations, investigators must obtain and document the subject's informed consent to participate in research. Consent forms are required to include at least eight specific items of information.</p> <p>Various aspects of the consent forms have been heavily criticized, as has the amount of time IRBs devote to editing and revising consent forms. Forms have become excessively long and legalistic, often stretching to 15 to 30 pages. Studies have shown that the reading level of many of these documents is above the 8th grade level.</p> | <p>The ANPRM proposes:</p> <p>(1) prescribing appropriate content that must be included in consent forms, with greater specificity than is provided in the current regulations;</p> <p>(2) restricting content that would be <i>inappropriate</i> to include in consent forms;</p> <p>(3) limiting the acceptable length of various sections of a consent form;</p> <p>(4) prescribing how information should be presented in consent forms;</p> <p>(5) reducing institutional "boilerplate" in consent forms; and</p> <p>(6) making available standardized consent form templates, the use of which could satisfy applicable regulatory provisions.</p> | <p>Q35: What factors contribute to the excessive length and complexity of informed consent forms, and how might they be addressed?</p> <p>Q36: What additional information, if any, should be required by the regulations to assure that consent forms appropriately describe to subjects, in concise and clear language, alternatives to participating in the research study and why it may or may not be in their best interests to participate? What modifications or deletions to the required elements would be appropriate?</p> <p>Q37: Would the contemplated modifications improve the quality of consent forms? If not, what changes would do so?</p> <p>Q38: Should the regulations require that, for certain types of studies, investigators assess how well potential research subjects comprehend the information provided to them before they are allowed to sign the consent form?</p> <p>Q39: If changes are made to the informed consent requirements of the Common Rule, would any conforming changes need to be made to the authorization requirements of the HIPAA Privacy Rule?</p> <p>Q40: Would informed consent be improved if the regulations included additional requirements regarding the consent process, and if so, what should be required? For example, should investigators be required to disclose in consent forms certain information about the financial relationships they have with study sponsors?</p> | <p>The principles underlying the Tiger Team's recommendation on meaningful patient consent may be useful to HHS in revising these regulations. Specifically, consent is meaningful when: it</p> <ul style="list-style-type: none"> • allows the individual advanced time and knowledge to make a decision, • is not compelled or used for discriminatory purposes, • provides full transparency and education, • commensurate with the circumstances, • is consistent with reasonable patient expectations for privacy, health, and safety, and • is revocable. <p><i>Notes/Observations:</i></p> <ul style="list-style-type: none"> • Regarding Q39, the Privacy Rule allows an authorization to be combined with an informed consent to participate in research;ⁱ the combined form must contain all the core elements and statements required by both.ⁱⁱ |
| <p>(1) (B) Waiver of Informed Consent or Documentation of Informed Consent in Primary Data Collection:</p> <p>IRBs may waive the requirements for obtaining informed consent under two sets of circumstances (45 C.F.R. 116 (c) or (d)). The most common set of circumstances permits an IRB to approve a consent</p> | <p>Waiver of Informed Consent or Documentation of Informed Consent in Primary Data Collection:</p> <p>The APRM offers no further specifics on this topic. See questions posed in following column.</p> | <p>Q 41: What changes to the regulations would clarify the current four criteria for waiver of informed consent and facilitate their consistent application?</p> <p>Q42: In circumstances where the regulations would permit oral consent, what information should investigators be required to provide to prospective subjects? Are all of the elements of informed consent included at 45 CFR 46.116 necessary to be conveyed,</p> | <p>The Tiger Team may wish to consider commenting on these questions based on the results of their previous deliberations on meaningful consent and transparency.</p> <p><i>Notes/Observations:</i></p> <ul style="list-style-type: none"> • Under the Privacy Rule, a covered entity may use or disclose protected health information (PHI) for |

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| <p>procedure which does not include, or which alters, some or all of the elements of informed consent or waives informed consent when:</p> <ul style="list-style-type: none"> • The research involves no more than minimal risk to the subjects; • The waiver or alteration will not adversely affect the rights and welfare of the subjects; • The research could not practicably be carried out without the waiver or alteration; and • Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (45 C.F.R. 116 (d)) <p>Many commentators have argued that conditions for waiver and consent are vague and applied haphazardly at different institutions.</p> <p>I IRBs may also waive the requirement for investigators to obtain a signed consent form. Concerns have been raised that such a waiver may not be flexible enough in dealing with certain circumstances, such as when federally-funded research is conducted in an international setting where for cultural or historical reasons signing a document may be viewed as problematic.</p> | | <p>or are some elements unnecessary? If some elements should not be required for oral consent, which ones are unnecessary?</p> <p>Q43: Are there additional circumstances under which it should be permissible to waive the usual requirements for obtaining or documenting informed consent?</p> <p>Q44: Are there types of research involving surveys, focus groups, or other similar procedures in which oral consent without documentation should not be permitted? What principles or criteria distinguish these cases?</p> | <p>research when it receives documentation that an IRB or a privacy board has approved a waiver of the authorization requirement based on specific criteria. These criteria are that the use and disclosure of PHI involves no more than minimal risk to privacy based on the presence of an adequate plan to protect identifiers and to destroy identifiers at the earliest opportunity; adequate written assurances that the PHI will not be improperly used or disclosed; and that the research could not be practicably conducted without the waiver and without the use of PHI.ⁱⁱⁱ</p> <ul style="list-style-type: none"> • The majority of the public does not support the procedure which allows an IRB to waive the requirements for individual authorization.^{iv} Numerous individuals who submitted comments to the proposed Privacy Rule expressed the belief that the waiver procedure abridges the individual’s right to decide whether or not to participate in research.^v |
| <p>(1) (C) Strengthening Consent Protections Related to Reuse or Additional Analysis of Existing Data and Biospecimens:</p> <p>Under both the Common Rule and the HIPAA Privacy Rule, if identifiers are removed, specimens and data that have been collected for purposes other than the proposed research can be used without any requirement for informed consent or a HIPAA authorization.</p> <p>When identifiers have not been removed, the Common Rule allows investigators, in certain</p> | <p>Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, would generally fall into the “excused²” category of research.</p> <p>Written general consent would be required for the research use of existing biospecimens after the effective date of the new rules.</p> <p>The ANPRM makes the following proposals with regard to researchers’ use of pre-existing data in the “excused” category of research:</p> <ul style="list-style-type: none"> • If the data was originally collected for non- | <p>Q45: Under what circumstances should future research use of data initially collected for non-research purposes require informed consent? Should consent requirements vary based on the likelihood of identifying a research subject? Are there other circumstances in which it should not be necessary to obtain additional consent for the research use of currently available data that were collected for a purpose other than currently proposed research?</p> <p>Q46: Under what circumstances should unanticipated future analysis of data that were collected for a different research purpose be permitted without consent? Should consent requirements vary based on</p> | <p>The Tiger Team has not yet addressed the use of protected health information for research purposes. The Tiger Team may wish to consider and comment on these questions.</p> <p><i>Notes/Observations:</i></p> <ul style="list-style-type: none"> • The ANPRM reiterates the current requirement in the Common Rule that if identifiers are removed, data that have been collected for purposes other than the proposed research can be used without any requirement for informed consent. The Tiger Team may wish to consider whether this requirement is currently consistent with public |

² ANPRM proposes to expand the current category of “exempted” studies to include all those that represent minimal risk. In addition, the ANPRM proposes that these studies be subject to uniform data security and information protections. This expanded category of “exempt” studies is to be renamed as “excused” to emphasize that these studies are not subject to IRB review but nonetheless, are subject to requirements designed for the protection of human subjects.

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| <p>situations, to obtain general consent for future research. Conversely, the HIPAA Privacy Rules has not been interpreted to permit general authorization for future unspecified research uses of health information.</p> | <p>research purposes, then, as is currently the rule, written consent is required only if the researcher obtains information that identifies the subjects.</p> <ul style="list-style-type: none"> • If the data was originally collected for research purposes, then consent would be required regardless of whether the researcher obtains identifiers. (<i>Note:</i> The allowable current practice of telling the subjects, during the initial research consent that the data they are providing will be used for one purpose, and then after stripping identifiers, allowing it to be used for a new purpose to which the subjects never consented, would not be allowed.) • These changes would be applied prospectively, not retrospectively. • There would be rules, to be determined that would allow for waiver of consent under specified circumstances. | <p>the likelihood of identifying a research subject?</p> <p>Q47: Should there be a change to the current practice of allowing research on biospecimens that have been collected outside of a research study (i.e. “left-over” tissue following surgery) without consent, as long as the subject’s identity is never disclosed to the investigator?</p> <p>Q48: What, if any, are the circumstances in which it would be appropriate to waive the requirement to obtain consent for additional analysis of biospecimens?</p> <p>Q49: Is it desirable to implement the use of a standardized, general consent form to permit future research on [biospecimens and] data? Are there other options that should be considered, such as a public education campaign combined with a notification and opt-out process?</p> <p>Q50: What is the best method for providing individuals with a meaningful opportunity to choose not to consent to certain types of future research that might pose particular concerns for substantial numbers of research subjects beyond those presented by the usual research involving biospecimens? How should the consent categories that might be contained in the standardized consent form be defined (e.g. an option to say yes-or-no to future research in general, as well as a more specific option to say yes-or-no to certain specified types of research)? Should individuals have the option of identifying their own categories of research that they would either permit or disallow?</p> <p>Q 51: If the requirement to obtain consent for all research uses of biospecimens is implemented, how should it be applied to biospecimens that are collected outside of the U.S. but are to be used in research supported by a Common Rule agency? Should there be different rules for that setting, and if so, what should they be? Should they be based on the relevant requirements in the countries where the biospecimens were collected?</p> <p>Q 52: Should the new consent rules be applied only</p> | <p>expectations.</p> |

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| | | <p>prospectively, that is, should previously existing [biospecimens] and data sets be “grandfathered” under the prior regulatory requirements? If so, what are the operational issues with doing so?</p> <p>Q 53: In cases in which consent for future research use is not obtained at the time of collection, should there be a presumption that obtaining consent for the secondary analysis of existing [biospecimens] or identifiable data would be deemed impracticable, such that consent could be waived, when more than a specified threshold number of individuals are involved? (SACHRP provided the Secretary with recommendations on this issue.) If so, what threshold number should constitute impracticability? Is the number of potential human subjects the only measure of impracticability?</p> | |
| <p>(2) Strengthening data protections to minimize information risks:</p> | | | |
| <p>(2) (A) Currently, the HIPAA Privacy Rule’s standards for identifiable and de-identified information are not aligned with what is considered human subject research under the Common Rule.</p> <p>The primary distinction between the Common rule and the Privacy Rule is the standard used to determine when information is no longer individually identifiable. The Common Rule does not apply to research if the identity of the subject is [not] or may [not] be readily ascertained by the investigator or associated with the information accessed by the researcher. For example, when a researcher accesses or receives data that has been coded and does not have access to the identifying key, the research is not considered human subject research and is not subject to the Common Rule’s requirements.</p> | <p>Consistently characterize information with respect to potential for identification:</p> <ul style="list-style-type: none"> • Adopt the HIPAA standards for purposes of the Common Rule regarding what constitutes individually identifiable information, a limited data set, and de-identified information, in order to address inconsistencies regarding these definitions and concepts between the HIPAA Privacy Rule and the Common Rule. • Evaluate the set of identifiers that must be removed for a data set to be considered “de-identified” under both human subjects regulations and the HIPAA Privacy Rule. | <p>Q54: Will use of the HIPAA Privacy Rule’s standards for identifiable and de-identified information, and limited data sets, facilitate the implementation of the data security and information protection provisions being considered? Are the HIPAA standards, which were designed for dealing with health information, appropriate for use in all types of research studies, including social and behavioral research? If the HIPAA standards are not appropriate for all studies, what standards would be more appropriate?</p> <p>Q55: What mechanism should be used to regularly evaluate and to recommend updates to what is considered de-identified information? Beyond the mere passage of time, should certain types of triggering events such as evolutions in technology or the development of new security risks also be used to demonstrate that it is appropriate to reevaluate what constitutes de-identified information?</p> <p>Q56: DNA extracted from de-identified biospecimens can be sequenced and analyzed in other ways, with the results sometimes being linked to other available data than may allow a researcher to identify the persons whose specimens were being studied. How</p> | <p>The Tiger Team has not yet considered the use of protected health information for research purposes or issues associated with de-identification. The Tiger Team may wish to consider and comment on these issues.</p> <p><i>Notes/Observations:</i></p> <ul style="list-style-type: none"> • The Privacy Rule imposes more stringent standards for de-identifying data and thus, may be more protective of the anonymity of the individual. The Privacy Rule restrictions also ensure that data is not re-identified using publicly available data bases while the Common Rule appears only to prohibit the researcher from obtaining the key code.^{vi} • Limited data sets in conjunction with data use agreements promote the use of information that is at least anonymized while providing some assurance that the individual will not suffer harm through re-identifications of their data.^{vii} |

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| | | <p>should Federal regulations manage the risks associated with the possibility of identification of such biospecimens? Should a human biospecimen be considered identifiable in and of itself? What are the advantages and disadvantages of considering all future research with biospecimens to be research with identifiable information?</p> <p>Q57: Should some types of genomic data be considered identifiable and, if so, which types (e.g., genome-wide SNP analyses or whole genome sequences)?</p> | |
| <p>(2) (B) Currently, IRBs are responsible for assessing the adequacy of each study’s procedures for protecting against informational risks.</p> | <p>Consider mandatory standards for data security and information protection whenever data are collected, generated, stored, or used:</p> <ul style="list-style-type: none"> • Research involving the collection and use of identifiable data, as well as data in limited data set form, could be required to adhere to data security standards modeled on the HIPAA Security Rule. These standards could require investigators to <ul style="list-style-type: none"> ○ use reasonable and appropriate encryption for data maintained or transmitted in electronic form, ○ use strong physical safeguards for information maintained in paper form, ○ use access controls that allow only authorized personnel to have access to the information, ○ establish audit trails, and ○ adhere to breach notification standards modeled on those applied to HIPAA covered entities. • For research using limited data sets or de-identified information, investigators would be strictly prohibited from attempting to re-identify the subjects of the information. • Data could be considered de-identified or in limited data set form even if investigators see the identifiers but do not record them in the permanent research file. • To strengthen enforcement mechanisms, consider providing for random retrospective audits and | <p>Q58: Should the new data security and information protection standards apply not just prospectively to data and biospecimens that are collected after the implementation of new rules, but instead to all data [and biospecimens]? Would the administrative burden of applying the rule to all data and biospecimens be substantially greater than applying it only prospectively to newly collected information and biospecimens? How should the new standards be enforced?</p> <p>Q59: Would study subjects be sufficiently protected from informational risks if investigators are required to adhere to a strict set of data security and information protection standards modeled on the HIPAA Rules? Are such standards appropriate not just for studies involving health information, but for all types of studies, including social and behavioral research? Or might a better system employ different standards for different types of research? (We note that the HIPAA Rules would allow subjects to authorize researchers to disclose the subjects’ identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition.)</p> <p>Q60: Is there a need for additional standardized data security and information protection requirements that would apply to the phase of research that involves data gathering through an interaction or intervention with an individual (e.g. during the administration of a survey)?</p> | <p>The Tiger Team may wish to provide comments on the additional privacy and security protections recommended by the HIT policy committee that go beyond HIPAA.</p> <p><i>Notes/Observations:</i></p> <ul style="list-style-type: none"> • While it is not completely clear what is meant by the term “modeled,” it should be noted that the HIPAA security rule is intended for application to an enterprise systems environment and thus, not all requirements may be applicable to the research environment. One example is the requirements for availability. • Data should be encrypted when the data is transmitted outside of the research entity. • Data at rest should be encrypted based on an analysis of the specific circumstances; encryption of data at rest can pose a risk of loss, particularly if the data is held for a long period of time. • The HIPAA Security Rule requires strong physical safeguards for information in both electronic and paper form. • It should be noted that use of access controls is an “addressable” requirement in the HIPAA Security Rule. • Regarding Q58, the benefits of applying these standards to all existing data are unclear; a case-by-case, risk-based analysis would be appropriate. In addition, it appears that the administrative burden of applying the rule to all data would be |

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| | <p>additional enforcement tools.</p> | <p>Q61: Are there additional data security and information protection standards that should be considered? Should such mandatory standards be modeled on those used by the Federal government (for instance, the National Institute of Standards and Technology recently issued a “Guide to Protecting the Confidentiality of Personally Identifiable Information.”)?</p> <p>Q62: If investigators are subject to data security and information protection requirements modeled on the HIPAA Rules, is it then acceptable for HIPAA covered entities to disclose limited data sets to investigators for research purposes without obtaining data use agreements?</p> <p>Q63: Given the concerns raised by some that even with the removal of the 18 HIPAA identifiers, re-identification of de-identified datasets is possible, should there be an absolute prohibition against re-identifying de-identified data?</p> <p>Q64: For research involving de-identified data, is the proposed prohibition against a researcher re-identifying such data a sufficient protection, or should there in some instances be requirements preventing the researcher from disclosing the de-identified data to, for example, third parties who might not be subject to these rules?</p> <p>Q65: Should registration with the institution be required for analysis of de-identified datasets, as was proposed in Section II (B) (3) for Excused research, so as to permit auditing for unauthorized re-identification?</p> <p>Q66: What entity or entities at an institution conducting research should be given the oversight authority to conduct the audits, and to make sure that these standards with regard to data security are being complied with? Should an institution have flexibility to determine which entity or entities will have this oversight responsibility for their institution?</p> | <p>substantially greater.</p> <ul style="list-style-type: none"> • Regarding, Q59, these standards may not be appropriate for all studies; it may be appropriate to apply them on a case by case basis. • Regarding Q61, additional standards for key management, remote access, and mobile devices may be worthy of consideration. In addition, the standards for disposal of data currently in the HIPAA Security Rule are also important to this environment. • Regarding Q62, without a change in the HIPAA Privacy Rule, covered entities would still be required to obtain data use agreements when disclosing limited data sets. • Regarding Q63, an absolute prohibition against re-identifying de-identified data may help mitigate the risk but may be difficult to enforce even with an audit requirement. • Regarding Q64, requirements preventing the disclosure of de-identified data would help mitigate the risks associated with disclosing de-identified data to third parties. |

ⁱ Modified Rule Preamble, *supra* note 197 at 53224-53225.

ⁱⁱ 45 C.F.R. 164.508.

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ⁱⁱⁱ 45 C.F.R. § 164.512(i)(2).

^{iv} Pritts, p. 42.

^v Final Rule Preamble, *supra* note 118 at 82694.

^{vi} Joy L. Pritts, JD, *The Importance and Value of Protecting the Privacy of Health Information: The Roles of the HIPAA Privacy Rule and the Common Rule in Health Research*, (Commissioned by the Institute of Medicine Committee on the HIPAA Privacy Rule and Research), (2008), <http://www.iom.edu/~media/Files/Activity%20Files/Research/HIPAAandResearch/PrittsPrivacyFinalDraftweb.pdf>, (accessed July 31, 2011).

^{vii} Pritts, p. 41.