Marshfield Clinic

Guidance on the Approvability of HIPAA Authorization Waivers and Alterations

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. **Alteration** – Modification of the procedure for obtaining an authorization, such as waiver of some of the required elements of an authorization (which may include the requirement to obtain a signature on the authorization)

2.2. **Authorization** – A signed form granting permission to use an individual's PHI for the purposes described

2.3. **Minimal Risk** – The probability of harm and discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life of a health individual or during the performance of routine physical or psychological examinations or tests

2.4. **Not Practicable** – Not capable of being done with available means; infeasible

2.5. **Privacy Rule** – HIPAA, 45 CFR Part 164, Subparts A and E

2.6. **Protected Health Information (PHI)** – Information that is collected or held by a covered entity and relates to the past, present, or future physical or mental health or condition of an individual (including the provision of health care to an individual or payment for the provision of health care) which identifies the individual or to which there is a reasonable basis to believe the information can be used to identify the individual.

2.7. **Selection Bias** – Error due to systematic differences in the characteristics of those who are selected for study and those who are not

3. RESOURCE GUIDE BODY

This document outlines the circumstances under which the IRB may waive or alter the requirement to obtain HIPAA authorization. It focuses on the criterion related to practicability and describes situations in which waiver or alteration might be appropriate.

3.1. Background

a. Subparts A and E of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (the "Privacy Rule") established a set of safeguards protecting and restricting the use of identifiable health information for both research and clinical purposes. Note that fully de-identified research data are not subject to the Privacy Rule because they are not individually identifiable. A list of the 18 HIPAA identifiers follows:

- Name
- All geographic subdivisions smaller than a state (street address, city, county, precinct) Note: zip code or equivalents must be removed, but can retain first 3 digits of the geographic unit to which the zip code applies if the zip code area contains more than 20,000 people.
- For dates directly related to the individual, all elements of dates, except year (i.e., date of birth, admission date, discharge date, date of death)
- All ages over 89 or dates indicating such an age
- Telephone number
- Fax number
- Email address
- Social Security number
- Medical Record number
- Health Plan number
- Account numbers
- Certificate or license number
- Vehicle identification/serial numbers, including license plate numbers
- Device identification /serial number
- Universal Resource Locators (URLs)
- Internet protocol (IP) addresses
- Biometric identifiers, including finger or voice prints
- Full face photographs and comparable images
- Any other unique identifying number, characteristic or code

In many instances it is important to obtain access to identifiable PHI for research purposes. With limited exceptions, the Privacy Rule stipulates that a signed authorization is required of each research subject if their PHI will be used or disclosed for research purposes. When certain conditions are met an IRB or a Privacy Board is permitted to waive or alter this requirement. The criteria are (1) the use or disclosure of PHI must pose no more than minimal risk to the privacy of the subject, (2) the research could not practicably be conducted without the waiver or alteration, and; (3) the research could not be practicably conducted without access to and use of PHI.

The Privacy Rule does not define or offer any substantive guidance as to what factors might make it "not practicable" to conduct a given study. For this reason, MCRF IRB convened a subcommittee to discuss the issue and to formulate non-binding guidance for use by the IRB in reviewing requests to waive or alter the HIPAA requirement to obtain written authorization.

3.2. Guidance

a. Subcommittee Observations

The subcommittee offered the following observations on ways in which the Privacy Rule requirement that written authorizations be obtained can potentially prevent research from going forward:

- Failure to achieve full or at least representative participation in research by the targeted population (whatever the reason. Introduces selection bias into research results. This is more likely to occur in population-based studies that seek to understand epidemiologic phenomena such as incidence or prevalence. Requiring subjects to sign and return a written HIPAA authorization could have significant effect upon who decides to participate or not. Depending on the study goals and design, this bias could potentially compromise the ability to draw valid conclusions from the research.
- Minimal risk studies frequently qualify for a waiver of informed consent from the IRB. If data collected as part of such studies are subsequently coded or otherwise de-identified (i.e., no identifiable data is retained in the research records), the signed HIPAA authorization may be the only directly identifiable link connecting a subject with a particular study. This may represent a barrier to full participation for certain types of population based studies. Cultural factors may also prompt certain ethnic groups to avoid participation due to loss of anonymity.
- Practical experience suggests that it is often difficult to obtain a correctly signed HIPAA authorization from research subjects or their authorized representatives when conducting survey or questionnaire based research through the mail, or in any case when there is no direct person to person contact with the subjects as part of the research. Consequently, considerable resources of both personnel time and supplies are frequently expended in an effort to ensure documentation of HIPAA compliance. Generally, the expenses incurred will be proportional to the size of the population being studied, and the significance of those costs will depend on the size of the budget.

Members of the subcommittee described anecdotal adverse experience with each of these three factors. In addition, the potential for negative consequences of requiring a signed authorization (or consent form) from each research subject in certain types of research have been well documented (see references).

b. Operational

Based upon personal experience, a review of the relevant literature, including the federal regulations relevant to IRB waivers and/or alterations of HIPAA authorization, the subcommittee recommended the following operational guidance:

- As permitted by HIPAA, the IRB may grant a waiver of the requirement to obtain written authorization or may agree to alter the requirement for authorization. In altering the authorization requirements, the IRB may decide that core elements (e.g., signature) and required statements of an authorization may be eliminated. The alteration option permits the researcher to inform the subject of the intention to use and/or disclose PHI in research activity, while limiting the potentially adverse consequences associated with requiring a signature on a document.
- Regardless of whether a waiver or an alteration of the authorization requirement is requested, the IRB must determine and document that waiver criteria, as delineated in the Privacy Rule, are met. Specifically, the IRB must determine and document that:
  - The use and disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - An adequate plan to protect identifiers from improper use and disclosure
    - An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    - Adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the Privacy Rule
  - The research could not practicably be conducted without the waiver or alteration; and
  - The research could not practicably be conducted without access to and use of the PHI
- The waiver criteria are subjective, and the IRB is given the authority and responsibility to determine whether the waiver criteria are met on individual use and/or disclosure basis.

The following is an example of when the IRB may be more likely to consider granting a waiver of the requirement to obtain a written authorization:

- Retrospective research that does not otherwise require contact with human subjects may reasonably qualify for a waiver of the authorization requirement, since the majority of retrospective research would not move forward due to increased cost should there be requirement to contact subjects. In addition, the authorization may be the only directly identifiable document retained in the research records that would link the subject with the research, and it could be argued that the risk introduced is therefore no justified.

Retrospective research also frequently collects data from subjects who may no longer reside at the last address on record, or may even be deceased, making it not practicable or impossible to contact them or their legally authorized representative to obtain written permission to us or disclose PHI in the research.

Situations in which the IRB may be more likely to grant an alteration of the requirement to obtain a written authorization than waive authorization might include:

- Studies which depend on robust response rates from a target population in order to obtain accurate data (such as epidemiologic studies documenting prevalence or incidence) may qualify since it has been well documented that requiring a signed authorization interferes with response rates. This may in turn introduce selection bias into the results, compromising the research effort.
    - Comment: The IRB's decision on whether to allow a waiver on alteration may depend, in part on the amount of contact anticipated with the potential subjects
- Survey and questionnaire based studies. The added expense related to mailing and ensuring return of signed authorization forms may be prohibitive and precluding the study going forward.
    - Comment: Depending on the circumstances, the IRB may alter the authorization requirement by requiring a written information sheet containing applicable authorization elements but not requiring a signature. With this type of alteration, the subject is informed about the planned uses and disclosures of PHI and agrees to such us by returning the survey.
- Studies in which a cultural or personal desire for anonymity may limit participation, introducing bias that may affect the data due to incomplete response.
    - Comment: Depending on the amount of personal interaction with subjects, this situation may qualify for either a waiver or an alteration of authorization.

In summary, the Privacy Rule requirement for a signed authorization from each research participant must not be waived or the authorization altered solely for reasons of convenience. Rather, consideration must be given to each of the waiver criteria, and more specifically for purposes of this guidance, to whether or not it would be practicable to conduct the research without the waiver. In requesting a waiver or alteration, researchers should give thoughtful consideration to how the perspective of (1) introducing bias to the data collected (2) increasing the cost of the research, and/or (3) increasing the risk of identifying otherwise anonymous subjects, and whether such considerations would make it not practicable to conduct the research.

4. ADDITIONAL RESOURCES

4.1. References:

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- Bates, n. et al (2008). Privacy concerns, too busy, or just not interested: Using doorstep concerns to predict survey nonresponse. Journal of Official Statistics, 25(4), 591-612.
- Beebe, T. et al. (2007) The HIPAA authorization form and effects on survey response rates, nonresponse bias, and data quality. Medical Care, 45, 959-965.
- Bolcic-Jankovic, D. et al. (2007) Do characteristics of HIPAA consent forms affect the response rates? Medical Care, 45(1), 100-104.
- Bova, C. et al. (2012) Reframing the influence of the health insurance portability and accountability act on research. CHEST, 141 (3), 782-786. Doi: 10.1378/chest.11-2182
- Dunlop, A. et al. (2007). The impact of HIPAA authorization on willingness to participate in clinical research. Annuals of Epidemiology, 17 (11), 899-905. Doi: 10.1016/j.annepidem.2007.05.006
- Kho, M. et al. (2009). Written informed consent and selection bias in observational studies using medical records. British Medical Journal, 338(866), doi: 10.1136/bmj.b866
- Krousel-Wood, M. et al.(2006) Does waiver of written informed consent from the institution review board affect response rate in a low-risk research study?. Journal of Investigative Medicine, 54(4), 174-179. Doi: 10.2310/6650.2006.05031
- Marshfield Clinic Policy Use and Disclosure of PHI in Research, http://srdweb1.srd.local/clinic/policies/policy_detailsall.asp?recid+1320&rev=10&typeentity

- Nass, S. et al. Institute of Medicine (2009). Beyond the HIPAA privacy rule. Washington D.C.: The National Academies Press.
- Nelson, K. et al. (2002). Do patient consent procedures affect participation rates in health services research?. Medical Care, 40(4), 283-288.
- NIH Guidance Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, http://privacyruleandresearch.nih.gov/pr_02.asp
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- Tu, J. et al.(20040. Impracticability of informed consent in the registry of the Canadian stroke network. The New England Journal of Medicine, 350, 1414-21.
- Wipke-Tevis, D. et al.(2008). Impact of HIPAA on subject recruitment and retention. Western Journal Nursing Research, 30(1), 39-53
- Wolf, M. et al.(2005, 8 8). Local perspective of the impact of the HIPAA privacy rule on research. Communication, 474-479.

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library – Guidance #5111.1

2.0	[This is where revision changes are listed. List format, no bullets or numbers.] Updated to include new linked documents created Added paragraph on archiving (paragraph 3.4)
3.0	

6. DOCUMENT PROPERTIES

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