1. Introduction

In administering access to archival holdings, the role of the archivist is to uphold legal rights to privacy along with legal rights to public disclosure. Archivists must develop and implement policies on access and use of holdings that promote open intellectual inquiry while meeting compliance requirements of the law. Over the past twenty years, archivists have had an especially challenging job keeping pace with the rise of new laws and regulations governing access to records from the health fields. However, the enactment of HIPAA has had a greater impact on access and use of archival holdings than any of the previous laws for the following reasons:

• The HIPAA Privacy Rule does not apply equally to all archives with collections documenting the history of the health fields. It applies only to archives within entities covered under this rule. Some institutions with covered entities have chosen to place their archival and special collections programs outside the covered entities of their institutions. The Privacy Rule does not apply to the archival repositories of the United States government. Throughout the country there are many other types of public and private archives with records documenting the health fields which are not subject to the compliance requirements of the Privacy Rule. As a result there are many disparities between archives that are covered by the Privacy Rule and those that are not covered. Archives within covered entities have to follow strict limitations on access and use of their holdings. Archives not subject to the Privacy Rule do not have to follow these same limitations. As a result, archival patrons throughout the country face significant inequities in how they may access and utilize archival holdings at covered entities.

• The HIPAA Privacy Rule is one of the first rules to apply to identifiable health information in general in any format and in any medium. Previous laws and regulations relating to privacy of health records have applied specifically to records of patients and records of research subjects in hard-copy formats. At
archival repositories fragments of incidental health information not related to patients and human subjects may be found throughout all types of holdings from minutes of governing boards and committee records to correspondence files, diaries, photograph collections, etc. Having to limit access to the incidental health information of all decedents presents enormous challenges to archivists. Principles of archival theory and organization are based upon types of records and not upon the various kinds of information that may be embedded in a record. The only way to limit access to fragments of incidental health information embedded in this wide spectrum of general, non-patient holdings, is to limit access to the broad spectrum of records or undertake the laborious task of redacting the fragments of embedded incidental health information. Such limitations on access to the broad holdings of an archival repository create major impediments for patrons and are complex and labor-intensive for archival staff to administer.

The HIPAA Privacy Rule contains no principle for passage of time. It is one of the first laws or regulations to assign rights of privacy to the deceased in perpetuity. Under previous laws and regulations, an individual’s right to privacy ceased at death. Until the Privacy Rule went in effect archival repositories throughout the country had allowed open access to the incidental health information of decedents that is found in general correspondence files, diaries, and other types of documents. Most repositories with collections of patient records of the deceased have had special policies and procedures in place for access and use of these patient records and provisions in place for protecting the privacy of patients. Under the Privacy Rule archival repositories at covered entities must now limit reference access to all incidental health information of decedents in general holdings that had previously been open and accessible for research while archival repositories that are not part of covered entities may continue to grant open access to incidental health information of decedents in their general holdings.

2. The Impact of the HIPAA Privacy Rule on the Medical Archives at Johns Hopkins

To operate in compliance with the Privacy Rule, it has been necessary to re-organize reference and research services and to transfer additional staffing from other divisions of the Medical Archives to assist in the operation of reference and research services. As a result, work in other areas such as processing, cataloging, exhibitions, publications, and public outreach has been severely constrained. Since the Privacy Rule is an unfunded mandate, the Medical Archives did not receive any additional funding from the government or Johns Hopkins for managing the compliance requirements of the Privacy Rule. All staff members must now participate to some extent in the operation of reference and research services in order to meet the highly labor-intensive compliance requirements of the Privacy Rule. The interpretation of the Privacy Rule and the implementation of policies and procedures for reference and research services at the Medical Archives have evolved as follows:
Interpretation of the Privacy Rule - Since the Privacy Rule does not contain specific guidelines for the operation of archives at covered entities, legal counsel for Johns Hopkins Medicine and outside legal experts studied implications of the Privacy Rule for the operation of archival programs within covered entities. The consensus of opinion was that the Privacy Rule applied to all types of information and records taken in and managed by the covered entity, that the definition of Protected Health Information (PHI) referred to health information about all individuals, not just information about patients and human subjects, and that there was no distinction between the PHI of the living and the deceased. Guidelines for the operation of the Medical Archives evolved out of this interpretation of the Privacy Rule. See Addendum A. “The Alan Mason Chesney Medical Archives and HIPAA” by Joanne E. Pollak, Vice President and General Counsel, Johns Hopkins Medicine, 26 June 2003.

Implementation of Policies and Procedures - The major challenge in revising reference policies to comply with the Johns Hopkins interpretation of the Privacy Rule is that materials that had been previously open and accessible for general reference must now be restricted and the incidental health information of decedents and non-decedents must be screened and redacted before showing documents to patrons. The Privacy Rule now limits general reference access and use of nearly 95% of the holdings of the Medical Archives. Only health information that has previously been disclosed through publication may be provided without redaction. However, the Privacy Rule does allow broad access to archival holdings for the purpose of research. It defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” and offers guidelines for adjudicating requests for access to holdings to conduct research. Rules for research on decedents are less rigorous than those for non-decedents. To conduct research in a collection that contains health information of non-decedents, the patron must apply to the Privacy Board of the Johns Hopkins Medical Institutions for a waiver of authorization to conduct the research. Although this broader access for research is helpful, it does not cover general reference access which is a large part of activity in the archives.

Whereas the Privacy Rule’s compliance requirements for conduct of research are in keeping with regulations that had already been in place at the Medical Archives, the major challenge has been how to handle requests for provision of reference information and copies of documents. To comply with the institutional interpretation of PHI under the Privacy Rule and to be able to provide basic reference information to patrons, the staff must first screen the files requested for presence of incidental health information. When there is incidental health information embedded in a document, a staff member must first photocopy that document and redact the incidental health information before showing it to the patron. Screening and redacting incidental health information from individual documents for general reference purposes is an enormously labor-intensive and
frustrating procedure for staff to manage. Having to expend valuable staff time to screen and redact incidental health information from documents that would be freely accessible at archives not designated as covered entities is a significant drain on the program’s resources. The requirement for redaction of incidental health information of decedents results in a major disparity for archival patrons who could have open access to the same type of information at repositories not subject to the Privacy Rule.

See Addendum B. “Accessing the Holdings of the Alan Mason Chesney Medical Archives” by Andrew Harrison, Marjorie Kehoe, Phoebe Evans Letocha, Nancy McCall, Michael Miers, Gerard Shorb, and Kate Ugarte. Edited by Michael Miers.

3. The Impact of the HIPAA Privacy Rule on Patrons of the Medical Archives at Johns Hopkins

Archival patrons are primarily frustrated by (a) limitations on access to archival holdings that had been previously accessible for general reference; (b) the bureaucratic requirements for registration for general reference services and the length of time it takes to screen and redact documents; and (c) the Johns Hopkins’ interpretation of the Privacy Rule differs from that of some other repositories. Since the Privacy Rule does not contain specific guidelines for archives, archival repositories within covered entities have made individual interpretations of the Privacy Rule to define the scope of PHI and to administer the archival repositories at their respective institutions.

Patrons who are conducting research which they wish to publish are especially frustrated by the Privacy Rule. If they receive a waiver of authorization from the Privacy Board of the Johns Hopkins Medical Institutions to conduct archival research, they are still not free to publish the PHI of deceased individuals which they may encounter in their research at the Medical Archives. The Privacy Rule requires that they obtain authorization from the legal representatives of the deceased in order to publish PHI from a covered entity. In instances when the deceased have no legal representatives, we believe the only option is for the patron to obtain a ruling from a judge. That the Privacy Rule treats all types of health information equally and makes no provisions for ranges of sensitivity poses major impediments for patrons wishing to publish. Incidental health information found in personal correspondence about conditions not considered to be highly sensitive such as colds and fractures is regarded the same as information about conditions considered to be highly sensitive such as psychiatric illnesses and sexually transmitted diseases.

Archival patrons who are conducting research on topics where significant documentation on that particular topic is located at several other archival repositories complain about having to submit to significantly different policies on access and use of health information of decedents at these various repositories. For instance, if someone wishes to conduct research for a biography of John Shaw Billings who was the principal planner for the Johns Hopkins Hospital, the National Library of Medicine, and the New York Public Library, that individual would have to consult the Billings materials in the archives at these three institutions. In order to publish the identifiable health information found in a personal letter at Johns Hopkins from Billings to his wife about
falling and fracturing his foot while on a trip to Europe, the biographer would have to obtain authorization from a legal representative of Billings who died in 1913. If the biographer found the same information in Billings’ correspondence at the New York Public Library or the National Library of Medicine, he or she would be free to publish it without having to obtain authorization from a legal representative or a ruling from a judge if a legal representative could not be found.

The staff of the Medical Archives finds the policies and procedures for provision of general reference services imposed by the Privacy Rule to be complex and time-consuming to administer. They find it especially frustrating for general reference requests to have to screen and redact incidental health information that had been previously accessible before the Privacy Rule, and continues to be accessible at repositories not covered by the Privacy Rule and at repositories with different interpretations of the Privacy Rule. Since the new policies and procedures went into effect on 14 April 2003, the staff has made a continued and concerted effort to clarify the language of forms and to improve the flow of procedures for patrons. Despite all of their efforts to improve the quality of services to patrons, the major obstacles created by the Privacy Rule remain. The major obstacles to archival patrons may be summarized as follows:

- There is no uniform interpretation of the Privacy Rule for archival practice at covered entities. A uniform interpretation of the Privacy Rule for archival reference services at covered entities would normalize these services and save valuable staff time now being expended on the development of policies and procedures which are based on different interpretations of the Privacy Rule.

- There is no consensus on the definition and scope of PHI at archival repositories within covered entities.

4. Revising the Privacy Rule to Accommodate Archival Reference and Research.

Action should be taken to address problems that the Privacy Rule has imposed on archival reference services at covered entities. If the following clarifications were to be made, archival programs within covered entities would be able to offer patrons access to and the ability to publish the same kinds of incidental health information of decedents that is accessible at archival repositories outside covered entities.

- Limit the scope of PHI to apply to information from records of patients and human subjects (living and deceased) and allow access to incidental health information for the purpose of general reference.

- Introduce principles for passage of time. Restrictions for reference use of incidental health information of decedents found in correspondence files, diaries, that are hundreds of years old should be eased when the possibility of offense to living descendants is minimal. Documents containing health information from antiquity, the Middle Ages, the Renaissance, and the eighteenth and early
nineteenth century should be open and accessible for archival reference and research whenever possible.

- Define and adopt standards for sensitivity of identifiable health information in archival holdings. Incidental health information may be categorized by ranges of sensitivity. Restrictions for access and use of incidental health information of decedents that refers to common conditions not considered to be highly sensitive and embarrassing to descendants if disclosed should be eased.

- Allow the publication of the incidental health information. The need to promote knowledge through publication should be taken into greater consideration. Archival patrons who wish to publish less sensitive incidental health information of decedents that appears outside patient records in professional and personal correspondence should not be encumbered by requirements to locate a legal representative or to obtain a court ruling to publish less sensitive incidental health information that appears outside patient records in professional and personal correspondence. At a minimum, publication of incidental health information about decedents should be allowed.

Other recommendations for changes may be found in Addendum C “Presentation to the Secretary’s Advisory Committee on Human Research Protections” by Joanne E. Pollak, Vice President and General Counsel, Johns Hopkins Medicine, 30 March 2004.

5. Conclusion.

That the Privacy Rule applies only to archival repositories within covered entities creates major disparities for the administration and operation of these archives. Varied interpretations of the Privacy Rule at archival programs within covered entities have resulted in widely assorted policies on access and use of archival holdings at these repositories. Ultimately there is much confusion over what constitutes the protected health information in archival holdings at covered entities. Some archival programs at covered entities have made the interpretation that Protected Health Information (PHI) refers only to patient information and not to the fragments of incidental health information that are found in correspondence files, diaries, and photographs. Other archival programs have interpreted Protected Health Information to include the fragments of incidental health information found in professional and personal correspondence files as well as the identifiable health information in patient records. As a result there are varying definitions of the scope of PHI at these archival repositories and how that PHI may be utilized for purposes of reference and publication.

Extending privacy rights to all types of incidental health information in perpetuity is unprecedented in archival practice and limits the ability of students, scholars, writers, artists, film-makers, the media, and others to access archival sources at covered entities for general reference and to publish from these archival sources when the same kind of information is easily accessible at repositories not covered by the Privacy Rule. It greatly constrains open intellectual inquiry and the ability to document facts and events and the telling of biography and history.
Whereas the Privacy Rule introduced much needed measures for protecting health information of living and deceased patients, it now needs to be adjusted to make incidental health information of all individuals, not patients, accessible for archival reference and publication. The Privacy Rule should be revised to extend the same opportunities for archival reference that exist at archival repositories outside covered entities to archival repositories within covered entities.

Addendum A. “The Alan Mason Chesney Medical Archives and HIPAA” by Joanne E. Pollak, Vice President and General Counsel, Johns Hopkins Medicine, 26 June 2003

Addendum B. “Accessing the Holdings of the Alan Mason Chesney Medical Archives” by Andrew Harrison, Marjorie Kehoe, Phoebe Evans Letocha, Nancy McCall, Michael Miers, Gerard Shorb, and Kate Ugarte. Edited by Michael Miers.

Addendum C. “Presentation to the Secretary’s Advisory Committee on Human Research Protections” by Joanne E. Pollak, Vice President and General Counsel, Johns Hopkins Medicine, 30 March 2004
ADDENDA
ADDENDUM A
The Alan Mason Chesney Medical Archives

And

HIPAA

Joanne E. Pollak
Vice President & General Counsel
Johns Hopkins Medicine
June 26, 2003
What is HIPAA?

- “HIPAA” is a federal law adopted in 1996

THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

- Privacy Regulations adopted under HIPAA the (“Privacy Rule”) require covered entities to protect identifiable health information or “protected health information” (“PHI”) they create or receive.
Why Does HIPAA Apply to the Archives?

 Hornets: HIPAA applies to the Archives because the Archives is part of the School of Medicine, which is a part of the covered entity portion of the Johns Hopkins University.

 Hornets: HIPAA also applies to the Archives because it receives PHI from other schools within the University that are parts of the covered entity portion of the University.
What is PHI?

PHI is information that is created or received by a covered entity that

 יכולה Relates to the health of an individual or the provision of or payment for health care to an individual, and

Identifies the individual or reasonably may be used to identify the individual
What Information is Covered Under HIPAA?

 בצורה של קבוצת התחומים הבאות:

- PHI about living persons
- PHI about deceased persons
What Must The Archives Do To Protect PHI?

❑ Staff must assure, to the extent possible, that only those authorized to see PHI have access to PHI

❑ Both the Open and Closed Collections contain PHI

❑ If a person is authorized to access PHI, staff does not need to block or remove PHI from the material

❑ If a person is not authorized to access PHI, staff must block or remove PHI from the material to the extent reasonably possible
How Can a Person be Authorized to Have Access to PHI?

Access for Johns Hopkins “health care operations” purposes (quality assurance, safety, etc.)

Access for research on information on decedents (much of the Archives materials will fall into this category)

Access for reviews preparatory to research (testing out a theory or idea)

Access for Research

- with an individual’s authorization or their representative’s authorization

- with a waiver of authorization
What is a Waiver of Authorization And Why is the Privacy Board Needed?

🔗 When an individual or his/her representative is not available to consent to access, a Privacy Board may waive the individual’s consent if certain criteria are met

🔗 Under the Privacy Rule, only a Privacy Board or Institutional Review Board may grant the waiver

🔗 Waivers are only needed if the PHI relates to a living person or to a mixture of living and deceased persons
What is the Role of the Privacy Board?

- Oversee the HIPAA policies of the Archives

- In cases where access to PHI of living persons is sought, but it is not possible or practical to obtain consent for access, the Privacy Board may review and approve requests for a waiver of authorization
  
  - many requests will be for access to information only about deceased individuals, in which case only certain research representations are required and a waiver of authorization is not required
  
  - some requests will be for access to information about a mixture of deceased and live individuals or all live individuals, and in these cases, a waiver of authorization is required
What are the Criteria for Waiver of Authorization?

• The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the following elements:

  - The requestor has an adequate plan to protect the identifiers from improper use and disclosure.

  - The requestor has a plan to destroy the PHI at the earliest opportunity appropriate to the research, subject to any health or research justification for retaining the PHI or unless the retention is required by law.

  - The requestor has provided written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study.

• The research could not practicably be conducted without the waiver; and

• The research could not practicably be conducted without access to and use of the described PHI.
What is Research?

• The Privacy Rule and Common Rule definitions are the same.

• *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
What are the Requirements For the Privacy Board?

• Must have at least two members.

• Members should have varying professional backgrounds and collectively have competency to review the effect of a research protocol on an individual’s privacy rights and interests.

• Must have one independent member who has no affiliation with Johns Hopkins

  - if the independent member has an affiliation with any entity applying for a specific waiver of authorization, another independent member must be added to the Board for review of that request
ADDENDUM B
Accessing Archival Holdings

The Alan Mason Chesney Medical Archives is the official archival repository of The Johns Hopkins Medical Institutions. Our mission is to advance knowledge in the health fields by supporting the current activities of the Medical Institutions, to commemorate the role of Johns Hopkins in the history of medicine, nursing, and public health, and to provide primary source material for research, and tools for education and training whenever legal, regulatory, and ethical conditions permit. We hope you will take the time to explore the resources available here, and to learn more about our new initiatives.

For all requests, the first step is to submit a Registration form.

Registration Form

This is the only step necessary for access to archival holdings that have been screened and redacted of any restricted information, and for access to published materials.

The Medical Archives encourages patrons to apply for access to all of its holdings. However, while some materials held in the Medical Archives are freely accessible, consultation of certain types of records or information is restricted. When requesting access to restricted materials, you will need to complete an additional application which will then be reviewed and adjudicated within the context of the applicable laws.

Once you have registered, Medical Archives staff will inform you of any restrictions that may apply to the materials you have requested and, when necessary, will assist you in completing any additional steps that are required.

Accessing Archival Holdings with Restrictions

Planning an On-Site Visit

Research Services

Reproductions/Permissions

Forms
Accessing Archival Holdings with Restrictions

Various laws restrict open access to certain types of records and information held in the Medical Archives. Some of these laws contain provisions which allow special terms of access for particular types of research. The Medical Archives invites patrons to apply for access to holdings with legal restrictions when provisions of the law allow research. Applications are reviewed and adjudicated within the context of applicable laws.

Access for research on information on decedents
To apply for access to holdings that may contain personally identifiable health information when all individuals are presumed deceased, complete and return Form B below.

Application for Access for Research on Decedents, Form B

To apply for access to student records of deceased individuals, complete and return Form E below.

Application for Access to Student Records, Form E

Access for reviews preparatory to research.
To request access solely to prepare for a research activity or for similar purposes preparatory to research, complete and return Form C below

Application for Access for Reviews Preparatory to Research, Form C

Access for Johns Hopkins institutional operations.
Members of the Johns Hopkins workforce only. To request access for operational purposes, complete and return Form A below.

Healthcare Operations, Form A
General access for Research

If the type of research you are doing or the type of information you are seeking does not fall into one of the specific categories above, there are two other ways of gaining access to restricted materials.

1. You may request the authorization of each individual subject of the restricted information, or their personal representative, by having each complete the D-1 form below.

   Individual Privacy Authorization, Form D-1

2. If it is not practicable to obtain the authorization of each subject, you may request a waiver of individual authorization by completing the D-2 form below and submitting it to the JHMI Privacy Board, a review board which will consider and adjudicate your request within the context of applicable laws.

   Application for Waiver of Authorization from the Privacy Board, Form D-2
Registration for Research and Request for Access
(Please type or print)

Name of Patron ____________________________________________

Position ____________________________________________

Johns Hopkins Affiliation: SOM ___ SON ___ SOPH ___ JHH ___ Bayview ___ Homewood ___

☐ Other Institutional Affiliation ______________________________________________________

☐ Independent Researcher

Please indicate sponsoring party and/or name the individuals or entities with which information will be shared: ____________________________________________________________

________________________________________________________________________________

If you are acting on behalf of another party or you intend to share this information with additional parties, they must submit a completed Registration Application, and have approval for access before this information can be shared.

Your Contact Information:
Street ____________________________________________
City, State, Mail Code, Country ________________________________
Phone ___________________________ Cell Phone ________________________________
Fax ____________________________________________
E-mail ____________________________________________
Web Site ____________________________________________

How will the information provided by Archives be used? (Check all that apply and specify use)
☐ Research for publication, broadcast, distribution, or exhibition ________________________
☐ Research for legal purposes ______________________________________________________
☐ Research for educational purposes ________________________________________________
☐ Other _________________________________________________________________________

Describe and state the purpose of your inquiry in detail: (Please type or print.)
________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________
Agreement with Respect to Rights, Regulations, and Procedures

Name of Patron___________________

Part 1: Rights to Privacy

I understand that the materials to which I have requested access may contain protected health information (“PHI”) as defined under Privacy Regulations issued under the Health Insurance Portability and Accountability Act (“HIPAA Privacy Rule”). If I encounter PHI in my access to the materials, I agree to make no notes or other recordation of the PHI and agree not to re-disclose the PHI to any other party for any purpose without the express permission of the Alan Mason Chesney Medical Archives (“Archives”).

I understand that the materials to which I have requested access may contain confidential information, which is otherwise protected under federal or state law or regulation or Johns Hopkins policies. I agree to make no notes or other recordation of confidential materials and agree not to re-disclose the confidential material to any other party for any purpose without the express permission of the Archives.

I understand that if I request copies of materials in the Archives, any PHI or confidential information will be redacted unless I have specific authorization to copy the materials or other specific exceptions apply.

Part 2: Rights to Intellectual Property

The Johns Hopkins University and The Johns Hopkins Hospital hold intellectual property rights to some, but not all, materials in the Archives. Some material to which you have requested access may still be protected by copyright and by the intellectual property laws of the United States and the Berne Convention. You are solely responsible for obtaining permission for use from the holder (the institution, the author, heirs, legatees, or literary executors) of the intellectual property. After release to you of the materials, The Johns Hopkins University and The Johns Hopkins Hospital assume no responsibility for any infraction of intellectual property laws or for any other improper or illegal use that may arise from your utilization of materials from the Archives.

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1 Protected Health Information means “individually identifiable health information, held or maintained by a covered entity [such as the Alan Mason Chesney Medical Archives] or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium [...]. This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse”. Reference: U.S. Department of Health and Human Services, National Institutes of Health; HIPAA Privacy Rule, Information for Researchers web site. Address: http://privacyruleandresearch.nih.gov/pr_07.asp

2 The copyright law of the United States (Title 17, USC) governs the making of photocopies or other reproductions of copyrighted material. Under certain conditions specified in the law, archives and libraries are authorized to furnish a photocopy or reproduction. One of these specified conditions is that the photocopy or reproduction is not to be “used for any purpose other than private study, scholarship or research.” If a user makes a request for, or later uses, a photocopy or reproduction for purposes in excess of “fair use,” that user may be liable for copyright infringement. This institution reserves the right to refuse a copying order if, in its judgment, fulfillment of the order would involve violation of copyright law. For more information please refer to U.S. Copyright Office: http://www.copyright.gov/title17/

3 The Berne Convention is an international copyright treaty signed by 96 countries. The United States became a member of the Berne Convention on March 1, 1989. The regulations of The Berne Convention are more far-reaching than US Copyright Law. For more information please refer to U.S. Copyright Office: http://www.copyright.gov/fls/fl100.html; http://www.copyright.gov/title17/circ92.pdf

Revised 09.02.04
Part 3: Rules and Regulations for use of the Alan Mason Chesney Archives

1. Research visits are by appointment only.
2. All patrons, on site or remote, must complete the Registration for Research and Request for Access application, and the Agreement with Respect to Rights, Regulations, and Procedures.
3. Patrons may take only paper, pencils, and laptop computers into the Reference Room.
4. Patrons visiting the archives must check all backpacks, briefcases, coats.
5. Patrons may not use cell phones, digital cameras, scanners, or voice dictation equipment in the Reference Room.
6. Patrons may not bring any food or beverages into the Reference Room.
7. All materials must be used in the Reference Room, and may not be removed for any reason.
8. Patrons may work with one box at a time. Please remove only one folder at a time from the box. After viewing the folder, replace it in the box, preserving the existing order, and initial the Call Slip indicating materials reviewed.
9. Patrons should exercise care in the handling of materials.
10. Reproductions will be made at the discretion of the reference staff. They will show you how to request items for reproductions. The cost of services is available from the reference staff or at: http://www.medicalarchives.jhmi.edu/forms/FeeSchedules%20reproduction%201-1-04.pdf.

I understand that it is my obligation and responsibility to maintain the confidentiality of any PHI or confidential information that I may encounter. Improper re-disclosure of this information is a breach of confidentiality which could result in the loss of my access to the Archives. I also understand that improper re-disclosure of this information may constitute a violation of the Privacy Rule or other federal or state laws that could result in fines or other legal penalties.

I understand that it is my obligation and responsibility to obtain authorization for the use of information and materials from the owners/licensees of intellectual property and persons of interest with respect to private information that is protected by law. I hereby waive any claim against The Johns Hopkins University and The Johns Hopkins Hospital for any liability should my use of materials from the Archives violate any state or federal laws concerning intellectual property or privacy. I also agree to indemnify and hold harmless the University and the Hospital for any liability resulting from any disclosure by me or redisclosure to others of the materials from the Archives.

I understand that the Archives does not waive any proprietary rights to the materials being used, and that the Archives reserves the right to restrict access to any and all materials in its holdings.

I agree to abide by the Rules and Regulations of the Archives.

_________________________   ______________________
Signature           Date

(For each subsequent visit, please sign and date below.)
Certification of Access to Materials
for the Purpose of Johns Hopkins Medical Institutions Healthcare Operations

The Privacy Regulations issued under the Health Insurance Portability and Accountability Act (the “Privacy Rule”) allow access to materials at the Alan Mason Chesney Archives (the “Archives”) to members of the Johns Hopkins Medical Institutions workforce and its business associates for valid operational purposes. These purposes include, but are not limited to, quality assurance inquiries, medical education, utilization review activities, planning activities, accreditation activities, audit or compliance activities.

I certify that I am:

☐ a member of the Johns Hopkins Medical Institutions workforce holding the position of: ____________

☐ a business associate of Johns Hopkins Medicine performing services on behalf of Johns Hopkins Medicine. Attached is a copy of the business associate agreement.

I am requesting access to the following materials: ______________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

I require access to Archives materials for the following purpose: __________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

_______________________________________________________    ____________________
Signature of Requestor         Date

(Please print or type name)

Archives Action:

Based upon the description of the purpose provided by the Requestor, and in reliance upon the Requestor’s certification, the request for access is:

☐ Approved for the stated purpose.

☐ Denied for the stated purpose.

_______________________________________________________    ____________________
Signature of Archives Reviewer         Date
Application for Access to the Alan Mason Chesney Medical Archives for Research on Decedents

I, the undersigned, wish to access the Alan Mason Chesney Medical Archives (“Archives”) materials in order to conduct research on decedents. These materials do or may contain protected health information (“PHI”) as defined in the privacy regulations issued under the Health Insurance Portability and Accountability Act (the “Privacy Rule”). In connection with the request, I offer the following information and make the following representations:

Purpose of the research: (please describe) _________________________________________________________________
____________________________________________________________________________________________________
____________________________________________________________________________________________________

Name(s) of decedent(s) or class of decedents whose materials are needed for this research: ______________________
____________________________________________________________________________________________________
____________________________________________________________________________________________________

Person(s) other than myself who will have access to the health information: ___________________________________
____________________________________________________________________________________________________
____________________________________________________________________________________________________

I make the following representations to the Archives:

- My use of Archives materials is solely for the purpose of conducting the research described above on the decedent(s) or the class of decedents named above.
- I understand that I may not request a decedent's medical history to obtain information about another living person such as a decedent's living relative.
- I affirm that access to materials that may contain PHI is necessary for my research purposes.
- I agree to provide, upon request, documentation of the death of the decedent(s) whose PHI I am requesting or accessing.
- I understand that I am responsible to document any disclosures of PHI including the date of each disclosure, the name and contact information for the organization or person to whom it was disclosed, a brief description of the information disclosed, and the reason for the disclosure.

Signature of Applicant ___________________________ Date ________________

Please type or print name ____________________________

Archives Action:  
☐ Approved  
☐ Other action

Signature ___________________________ Date ________________

1 The personal representative of an individual whose PHI you obtain may request an “accounting of disclosures” under the federal Privacy Rule. The individual may ask for an accounting for the six-year period prior to the request or since the applicable compliance date. An accounting for disclosures of identifiable health information is not required when PHI is shared with a researcher who is a workforce member of a Johns Hopkins covered entity.
Application for Access to the Alan Mason Chesney Medical Archives
for Reviews Preparatory to Research

I, the undersigned, wish to access materials that do or may contain protected health information
(“PHI”) as defined in the privacy regulations issued under the Health Insurance Portability and
Accountability Act (the “Privacy Rule”).

Purpose of the review: _____________________________________________________________
________________________________________________________________________________
________________________________________________________________________________

Persons with whom health information will be shared: _________________________________
________________________________________________________________________________
________________________________________________________________________________

Persons other than myself who will conduct the review: ________________________________
________________________________________________________________________________
________________________________________________________________________________

I make the following representations to the Archives:

• I seek access to the materials described in the Registration solely to prepare a research activity
  or for similar purposes preparatory to research.
• I will not remove any protected health information.
• I affirm that access to the requested materials is necessary for my research purposes.
• I understand that during my review preparatory to research I may not record any information
  that could be used to identify the subjects of that information

_________________________________________________  ______________________
Signature of Requestor                                                                                     Date

_________________________________________________
Please type or print name

Note to Researcher: If the request for review preparatory to research is approved by the Archives, it is your responsibility to keep
an accounting of those to whom you disclose PHI at any time during the review preparatory to research. Under the Privacy Rule,
an individual whose PHI you obtain may request an “accounting of disclosures” for the six-year period prior to the request or
since the applicable compliance date. An accounting for disclosures of identifiable health information is not required when PHI is
shared with a researcher who is an employee or workforce member of a Johns Hopkins covered entity.

Archives Action:

☑  Approved
☐  Other Action______________________________________________________________

________________________________________  ______________________
Signature                                                                                     Date

Revised 12.01.04
Other Action:

For the reasons described below, the Archives has determined that the Registration and this Attachment C do not satisfy the requirements of the Privacy Rule. The researcher may apply to the Privacy Board for a waiver of Privacy Authorization (Attachment D-2) or contact the Archives staff for guidance in revising the Registration and this Attachment C for resubmission.

Findings and recommendations: ______________________________________________________________
___________________________________________________________________________________________
___________________________________________________________________________________________

Signature of Archives Representative                              Date
Authorization to Allow Access
to Information in The Alan Mason Chesney
Medical Archives

I have been asked to give my consent to allow researchers to access materials in the Alan Mason Chesney Medical Archives (the “Archives”) that contain health information or other private information about me. By signing this form, I give my consent to the access as described in this form.

1. **Describe the types of information to be used and disclosed by the researcher.** *(For example, “medical records from Johns Hopkins Hospital” or “physician notes of Dr. X for 1974”):*

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________

2. **What is the purpose of the research activity? How will the information be used?**

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________

3. **Give the names of anyone who will be given access to the information:**

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________

4. **Give the names of anyone with whom the researchers may share the information and for what purpose:**

   ________________________________________________________________

   ________________________________________________________________

   ________________________________________________________________
5. By authorizing disclosure of the information, I acknowledge that, while the researcher will make every effort to assure that the information is used only for the purpose of the research activity, there is a risk of re-disclosure whenever information is disclosed and that, once my information is disclosed, it may no longer be protected by federal and state privacy laws.

6. I understand that I am not required to sign this form and that no care or other activity at Johns Hopkins will be affected if I do not sign this form.

7. I understand that this authorization has no end date, but that I may cancel the authorization at any time. If I cancel this authorization, the cancellation will only affect future use and disclosure of my information. Beginning on the date the authorization ends, no new health information will be used, but any health information that was shared before the cancellation will continue to be used.

8. I will receive a copy of this form.

________________________________________________    ______________
Signature          Date

________________________________________________
Please type or print your name

________________________________________________
If a personal representative, list authority for the person
Application for a Waiver of Authorization for Research Use or Disclosure of Protected Health Information (PHI) and Other Personal Information that is Protected by Law

The policies of the Johns Hopkins Medical Institutions foster open intellectual inquiry within the context of the law and the ethics of the health professions. Research of records, data, and information held by the Medical Institutions may be conducted when it is legally possible to permit access to and use of these materials. The Privacy Board of the Johns Hopkins Medical Institutions reviews applications to conduct research of institutional records and data that contain information that is protected by law. It is the charge of the Privacy Board to allow research of these institutional materials whenever it is legally possible and ethically responsible to do so.

Guidelines for Submission of Application

1. The application to the Privacy Board includes the attached D-2 and the following supporting documents:
   - A project abstract which includes a summary of the materials at the Johns Hopkins Medical Institutions that you wish to access
   - Curriculum Vitae
   - A letter of reference. Letters of reference may be waived for faculty and staff of The Johns Hopkins Medical Institutions.

2. Applications will be considered once a completed D-2 and all supporting documents have been received. Contact the Privacy Board staff for dates of scheduled meetings.

3. In preparing your application, please clearly define the measures you intend to take to safeguard any personal information protected by law that you may encounter in your research. See the attached summary of laws protecting personal information. In reviewing applications, the Privacy Board is required to evaluate the following factors:
   - Your intended use of the protected information, and the degree to which that information is necessary to your proposed research;
   - The specific legal terms of access that apply to the various types of protected information to which you seek access;
   - The degree to which your use or disclosure of the information may jeopardize the right to privacy of the subjects of that information;
   - Your plan for disposing of the protected information at the conclusion of your research;
   - The degree to which a waiver of individual authorization is necessary to your research;
   - The degree of risk of unlawful, unauthorized, or unethical use or disclosure, reuse or redisclosure of the private information of individuals.

Please contact the Privacy Board staff if you have questions or need assistance in the preparation of your application.
Application for a Waiver of Authorization for Research Use or Disclosure of Protected Health Information (PHI) and Other Personal Information that is Protected by Law

Name of Applicant: _____________________________________________________________

1. In order for the Privacy Board to grant a waiver of authorization, you must demonstrate that your research cannot practically be conducted without access to the material and that your research cannot be practically conducted without the waiver.

   a) Indicate why the materials that you wish to access are necessary to your proposed research: ________________________________________________________________

      __________________________________________________________________________

      __________________________________________________________________________

   b) Indicate why the study cannot be conducted without the waiver of authorization. Check all that apply.

      ❑ It would be difficult or impossible to find the persons whose personal information may be included.
      ❑ Materials contain information of both living and deceased individuals.
      ❑ Until I review the information I will not know whose personal information may be included.
      ❑ Other reasons: ____________________________________________________________

      __________________________________________________________________________

      __________________________________________________________________________

2. The materials you access may contain the confidential information of many individuals. Explain why your use of PHI/Confidential Information poses no more than a minimal risk to the subjects of that information: ____________________________________________

      __________________________________________________________________________

      __________________________________________________________________________

      __________________________________________________________________________

      __________________________________________________________________________
3. List those persons/entities with whom, for research purposes, you will need to share the PHI/Confidential Information:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

4. Following are examples of elements included in a typical plan to protect confidential information. Please check all those that are included in your plan and add any other privacy protections that you intend to utilize.

- Only those persons indicated in this application will be granted access.
- All paper files will be stored within a secured storage system to which only you and those persons indicated above will have access.
- All electronic data will be password protected.
- Passwords and system IDs will not be shared.
- Passwords will be changed on a regular basis.
- Additional protections: _____________________________________________
  __________________________________________________________________
  __________________________________________________________________

5. Indicate how you will protect the PHI/Confidential Information you encounter if publications and/or oral presentations result from this research. Check all that apply.

- Omission of information from publication
- Redaction of information
- Modification of identifiers
- Other methods:________________________________________________________
  __________________________________________________________________
  __________________________________________________________________

6. Please indicate the procedures that you will follow to destroy your notes and data containing PHI/Confidential Information.

- Physical and/or electronic data will be shredded or deleted.
- Other methods:________________________________________________________
  __________________________________________________________________
Statement of Principal Investigator

As Applicant, I make the following assurances to the Privacy Board:

- The information that I have provided in this request for a Waiver of Authorization is complete and accurate.
- I will access only the minimum amount of PHI/Confidential Information necessary to accomplish the research described in this application.
- I will not reuse the PHI/Confidential Information or disclose it to any person or entity other than those indicated in this application, except:
  1) as required by law,
  2) for authorized oversight of the research,
  3) in connection with other research for which the HIPAA Privacy Rule permits PHI to be used or disclosed.
- If at any time I wish to reuse this information for other purposes or disclose the information to other individuals or entities I will seek approval by the Privacy Board.
- I understand that I am ultimately responsible for protecting the private information of individuals.

_________________________________________ ________________________________
Signature of Principal Investigator   Additional Investigator            Date

______________________________________  ________________________________
Please type or print name     Additional Investigator         Date

_________________________________  ________________________________
Date         Additional Investigator         Date

Note to Applicant:

If the Privacy Board or its Designee approves a waiver of authorization, it is your responsibility to keep an accounting of those to whom you disclose PHI at any time during the research activity. Under the Privacy Rule, an individual whose PHI you obtain may request an “accounting of disclosures” for the six-year period prior to the request or since the applicable compliance date. An accounting for disclosures of identifiable health information is not required when PHI is shared with a researcher who is an employee or workforce member of a Johns Hopkins covered entity.
Summary of the Laws that Protect Personal Information


HIPAA Privacy Rule – Under HIPAA, the Privacy Rule went into effect on April 14, 2003. The purpose of the Privacy Rule is to establish minimum Federal standards for safeguarding the privacy of individually identifiable health information. The Privacy Rule allows access to protected health information (PHI) for research purposes under limited circumstances, and only when that research corresponds to the Rule’s definition of research.

Research - Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

In most circumstances, the researcher must obtain authorization from the individual whose PHI he wishes to use or disclose. However, a Privacy Board or Institutional Review Board may grant a waiver of the required individual authorization to use or disclose PHI. In order to be considered for this waiver, the researcher must demonstrate to the Privacy Board or IRB that his plan of research meets, in whole or in part, the following criteria:

- The use or disclosure of PHI involves no more than a **minimal risk** to the privacy of individuals, based on, at least, the presence of the following elements:
  1. An adequate plan to protect the PHI from improper use and disclosure.
  2. An adequate plan to destroy the PHI at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the protected health information or such retention is otherwise required by law.
  3. Adequate written assurances 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 HIPAA.

- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to the materials that may contain PHI.
Minimal Risk – The Privacy Rule adopts the definition of “minimal risk” that was established under the Common Rule. By this definition, “minimal risk” means “that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

PHI (Protected Health Information) is defined as “individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium [...]. This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse”. This definition applies to living and deceased individuals.

Thus in protecting the privacy of individuals, the following 18 identifiers may not be revealed: names; geographic subdivisions smaller than a state; all elements of dates (except year); telephone numbers; facsimile numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers; full-face photographic images; Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

For more information on the HIPAA Privacy Rule (45 CFR 160, 164), and the Common Rule (45 CFR 46 Subpart A) visit the following websites:

U.S. Department of Health and Human Services, National Institutes of Health; HIPAA Privacy Rule Information for Researchers:
http://privacyruleandresearch.nih.gov/

Details on the 18 identifiers may be found at:
http://privacyruleandresearch.nih.gov/pr_08.asp#8a

National Institute of Health, Office of Human Subjects Research; Code of Federal Regulations:
http://ohsr.od.nih.gov/guidelines/45cfr46.html
FERPA - The Family Educational Rights and Privacy Act (commonly referred to as the Buckley/Pell Amendment, 20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of the education records of living individuals.

Confidential Education Records - As defined in FERPA, Confidential Education Records are “those records that are
1) directly related to a student; and
2) maintained by an educational agency or institution or by a party acting for the agency or institution.”

The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. Under this Act, confidential education information may be disclosed without the authorization of the subject of that information under only a very limited number of circumstances. Disclosure is allowed for limited research uses:

- To develop, validate, or administer predictive tests;
- To administer student aid programs; or
- To improve instruction

This disclosure is only allowed, however, under the following conditions:

- Personally identifiable information is not shared;
- Personally identifiable information is not redisclosed;
- The information is used only for the reason for which it was disclosed;
- The information is destroyed when no longer needed for research.

While FERPA only restricts disclosure of the educational records of living individuals, it is the policy of the Johns Hopkins Medical Institutions to not disclose grades or any evaluative information of all individuals, living or deceased.

For information on FERPA, visit the following websites:

United States Code, Title 20:
http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=90598411836+1+0+0&WAISaction=retrieve
Code of Federal Regulations:
http://www.access.gpo.gov/nara/cfr/waisidx_03/34cfr99_03.html

Common law and institutional policy - While HIPAA protects health information and FERPA protects student information, common law protects other types of private information when that information is of a kind that

1) would be highly offensive to a reasonable person, and
2) is not of legitimate concern to the public
(See Second Restatement of Torts at §§ 652A – 652I).

Finally, it should be noted that the privacy policies of the Johns Hopkins Medical Institutions supplement all of the above-noted federal laws and regulations and that the policies of The Johns Hopkins Medical Institutions may be stricter, concerning certain aspects of privacy protection, than federal or state laws or regulations. The Privacy Board of The Johns Hopkins Medical Institutions reserves the right to refuse access to any information in all cases where it finds that such access may jeopardize the privacy of any individual.
Application for Access to the Alan Mason Chesney Medical Archives for Personnel, Student, or Proprietary Records of Deceased Individuals

The records or subject of records to which I seek access:
____________________________________________________________________________________________
____________________________________________________________________________________________

My authority for access:
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

The following person(s) will access the records:
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

The purpose of my request for access to these records:
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

I understand that federal law, state law and/or Johns Hopkins policies limit access to these records. I also understand that the Archives reserves the right to grant or deny access to any materials in its holdings.

Signature of Applicant                      Date
(Please print or type name)

Archives Action:
Based upon the description of the purpose provided by the Requestor, and in reliance upon the Requestor's certification, the Staff of the Archives have determined as follows:

☑ The request for access is **approved** for the stated purpose.
☑ The request for access is **denied** for the stated purpose.

Signature of Archives Reviewer                      Date
ADDENDUM C
Presentation to
the Secretary’s Advisory Committee
on Human Research Protections

Joanne E. Pollak
Vice President & General Counsel
Johns Hopkins Medicine
March 30, 2004
## ISSUE: Application of the HIPAA Privacy Regulations to Medical Archives

<table>
<thead>
<tr>
<th><strong>Current Situation</strong></th>
<th><strong>Consequences of Current Situation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Archives that are part of a covered entity must comply with the HIPAA Privacy Regulations</td>
<td>Archives that are part of covered entities generally have created Privacy Boards to review research requests</td>
</tr>
<tr>
<td>Individually Identifiable Health Information is health information collected from an individual and which is created or received by a health care provider</td>
<td>However, many requests are not classic “research”, e.g., press, interested family members, historians, biographers, lay people wanting to read about famous or educationally important people</td>
</tr>
<tr>
<td>Protected Health Information (PHI) is Individually Identifiable Health Information that is maintained by the covered entity in any form or medium</td>
<td>Whereas access to medical records held in Archives has traditionally been quite limited, access to general archival materials has not been so limited</td>
</tr>
<tr>
<td>Archival materials held by covered entities contain PHI. These materials include medical records but also include historical documents which “incidentally” include PHI, such as, letters, notes, studies, etc.</td>
<td>- “incidental PHI” is everywhere</td>
</tr>
<tr>
<td>Archives obtain documents from outside the covered entity as well as receive transfers of documents from within the covered entity</td>
<td>- staff must review materials and mask it for non-research requests</td>
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<td>- for research requests, “minimum necessary” is very difficult</td>
</tr>
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<td>HIPAA requires authorization of person to publish, but finding the authorized representative is difficult</td>
</tr>
<tr>
<td></td>
<td>- de-identification is difficult</td>
</tr>
<tr>
<td></td>
<td>- publication of educational dissertations may be impossible (to publish, the student needs permission of each person - but many cannot be found without much work or not at all)</td>
</tr>
<tr>
<td></td>
<td>Donations to Archives within covered entities are being negatively affected</td>
</tr>
</tbody>
</table>

### Proposed Change

- Clarify that only PHI in the “designated record set” held by Archives within a covered entity is subject to the HIPAA Privacy Regulations.
- Clarify that PHI used in bonafide educational dissertations may be published if the minimum necessary standard is applied and the document is reviewed and approved by an IRB or Privacy Board.
## ISSUE: Authorization for Future Unspecified Research

<table>
<thead>
<tr>
<th>Current Situation</th>
<th>Consequences of Current Situation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Under the Common Rule a participant may give Informed Consent to the</td>
<td>• Confusion - An Example:</td>
</tr>
<tr>
<td>contribution of their data/specimens to a database to be used for future</td>
<td>- A participant signs an Informed Consent to put his/her tissue in a</td>
</tr>
<tr>
<td>unspecified research</td>
<td>tissue bank for cancer research</td>
</tr>
<tr>
<td>- Common Rule standard is that description of future research must be</td>
<td>- If it is practicable, the person would be sent a new HIPAA Authorization form for each new protocol.</td>
</tr>
<tr>
<td>explained with as much specificity as possible</td>
<td>Yet the person would not be given a new Informed Consent form, nor would they be “enrolled”</td>
</tr>
<tr>
<td>- Exs. “for future research related to colon cancer”; “for future research</td>
<td>in the new study - yet they would be expected to read and understand</td>
</tr>
<tr>
<td>related to immune deficiency and related diseases”</td>
<td>a HIPAA Authorization for each new study. This is confusing to participants</td>
</tr>
<tr>
<td>• Under HHS’s interpretation of the HIPAA Privacy Rule’s Authorization</td>
<td>- For each new protocol the burden is on the researcher to</td>
</tr>
<tr>
<td>requirements, a participant must sign a new Authorization at the time of the</td>
<td>• locate all those who provided data for the database and get their Authorization, if it is</td>
</tr>
<tr>
<td>subsequent research use or disclosure on the premise that the participant does</td>
<td>practicable to do so, or</td>
</tr>
<tr>
<td>not have enough information now to provide an authorization for unspecified future</td>
<td>• request a waiver of Authorization from the IRB — yet the IRB would be waiving</td>
</tr>
<tr>
<td>uses</td>
<td>Authorization in a situation where the participant gave</td>
</tr>
<tr>
<td></td>
<td>their Informed Consent for research. This is confusing to IRB members</td>
</tr>
<tr>
<td></td>
<td>• Administrative Burden</td>
</tr>
<tr>
<td></td>
<td>- Need to get new Authorization/waiver</td>
</tr>
<tr>
<td></td>
<td>- Waiver triggers accounting requirements which should be unnecessary</td>
</tr>
<tr>
<td></td>
<td>since person gave their Informed Consent to the research</td>
</tr>
</tbody>
</table>

## Proposed Change

- Align the HIPAA Privacy Rule’s requirement for the need for future Authorization with the Common Rule requirements for the need for future Informed Consent, i.e., no future Authorization needed.
- If the future research cannot be described with sufficient specificity to meet the Common Rule test, both an Informed Consent and Authorization will be needed for the future research.
- The HIPAA Privacy Rule does not appear to require amendment in order to make this interpretation; rather, HHS would need to change its guidance as to its interpretation of the Rule.
**ISSUE:** The Need for a Dual Process for Authorization/Informed Consent

<table>
<thead>
<tr>
<th>Current Situation</th>
<th>Consequences of Current Situation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A researcher must obtain Informed Consent for research under the Office of Human Research Protection (OHRP) and Food and Drug Administration (FDA) Regulations.</td>
<td>• A participant must sign a privacy Authorization for the use of their PHI in a study as well as an Informed Consent to participate in the study.</td>
</tr>
<tr>
<td>• OHRP Regulations only cover research funded by federal authorities.</td>
<td>- Although these are separate approvals, if the researcher does not have the privacy Authorization, the researcher may not use or disclose the PHI for the research, <em>i.e.</em>, the participant cannot participate in the research.</td>
</tr>
<tr>
<td>• FDA Regulations only cover research involving certain drugs, substances and devices.</td>
<td>• HHS has clarified that the IRB does not need to approve the privacy Authorization — even for FDA studies.</td>
</tr>
<tr>
<td>• The HIPAA Privacy Regulations cover all protected health information (PHI) created or maintained by covered entities in connection with research, regardless of the funding source or agency involved.</td>
<td>- HHS is ignoring the legal reality that the privacy Authorization and the Informed Consent are legally linked</td>
</tr>
<tr>
<td>• The OHRP and FDA rules are comprehensive and protect participant privacy. For those covered entities already subject to OHRP and FDA rules, adding a second layer of privacy requirements is complex, administratively burdensome, confusing to researchers and confusing to participants, with virtually no added privacy protection.</td>
<td>- Decoupling the processes does not decouple their legal interdependence</td>
</tr>
<tr>
<td></td>
<td>- Separate forms leave everyone confused</td>
</tr>
<tr>
<td></td>
<td>- Various NIH Institutes now are demanding that the forms be separate.</td>
</tr>
</tbody>
</table>

**Proposed Change**

• Amend the Privacy Regulations to provide that PHI may be used in research if either of the following is met:
  (i) compliance by the covered entity with federal OHRP and FDA regulations for all research conducted at the covered entity, or
  (ii) compliance by the covered entity with the Privacy Regulations.

• This alternative would protect all PHI in research carried on by covered entities. For those under OHRP/FDA rules, privacy protection would be required under those rules. For those not under OHRP/FDA rules, privacy protection would be required under HIPAA rules.

• OHRP could provide guidance/new rule that use and disclosure of health information in research should be expressly addressed in the Informed Consent.