

The Queen's Medical Center

HIPAA

Training Packet for Researchers

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HIPAA Training Packet for Researchers**

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Overview of HIPAA and Research

Facilities covered by the privacy rule can only share protected health information for research in certain circumstances. In addition to the permitted uses and requirements of HIPAA other existing state and federal laws continue to govern research participation requirements. Under HIPAA, subjects must authorize the use of their information for activities related to research. This is in addition to the current consent requirements. A facility may use or disclose patient information without first obtaining an authorization only if the RIRC grants a waiver of the authorization.

HIPAA protects the privacy of subject's information.

The RIRC is responsible for protecting the welfare of the subject.

Effective April 14, 2003:

**Access to Subject's
PHI for Research** = **RIRC Approved Consent
Form or Waiver of
Consent** + **HIPAA Authorization
by Patient or Waiver of
Authorization by RIRC**

HIPAA allows another method of obtaining subject information without an authorization (called Reviews Preparatory to Research), however, QMC will not be using this method.

The facility may disclose a limited data set to the researcher if a data use agreement exists between the facility and the researcher. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members. Contact the HPH privacy officer for further information.

Penalties for violations of HIPAA

Violations of the privacy rule could result in civil fines and/or criminal fines and jail time for the researcher. Violations could also result in private lawsuits being filed for malpractice, abandonment, negligence as well as a host of other alleged acts of wrongdoing. Even inadvertent violations can result in civil or criminal fines/jail time. For example:

- Inadvertent violations could mean fines up to \$100 for each violation of a requirement per individual.
- Criminal fines can range from \$50,000 to \$250,000 and/or 1-year to 10-year jail term.

Research With an Authorization

A privacy authorization signed by the patient permits the facility to allow a researcher to access, use and/or disclose patient information within the permissions and limitations defined by the actual document. Authorizations will be needed in most instances when access to a subject's protected health information for research is needed. Prospective research, such as a clinical trial, will generally require authorization. The authorization is different from the informed consent in that the authorization obtains specific permission to use and disclose protected health information for the research project. Until the subject signs the authorization, QMC and researcher may not use or disclose protected health information.

- Default Rule – A signed authorization must be obtained prior to using protected health information (PHI) for research.
- Need a waiver of authorization for recruitment purposes if access to protected health information will be needed (For example, you review the subject's chart or lab results in order to determine eligibility prior to obtaining their consent, or you plan to send pre-screening logs to a sponsor. This may also require the proper approvals to gain access to CliQ system.)

The authorizations must be study-specific. For projects that have sub-studies, a privacy authorization must also be obtained for the substudy.

The authorization must be written in plain language, and the subject must receive a signed copy of their authorization.

Minors who sign an assent form will not need to sign the authorization; only the parent or legal guardian will need to sign. HIPAA requires a legally authorized person to sign the authorization.

Authorizations must be retained for at least 6 years or as long as the study records are maintained, whichever is longer.

Required Elements of HIPAA/Privacy Authorization

1. Name of the person or class of persons authorized to release the information
2. Name of the patient whose records are to be released
3. Name of person or class of persons receiving the information
4. Description of the information to be released
5. Expiration date or event. Authorizations for research may have no expiration date or event, or the authorization continues until the “end of the research study”.
6. Description of the purpose(s) for which the information was requested
7. Signature of patient
8. If signed by the patient’s personal representative, a description of that person’s authority to sign on the patient’s behalf.
9. Date of signature
10. A statement of the patient’s right to revoke the authorization. [Research subjects may revoke their privacy authorization at any time during the research.]
11. A description of how the patient can revoke the authorization or a statement of any exceptions to the patient’s right to revoke the authorization. Revocation must be done in writing. If permission is revoked, the Privacy Rule allows continued use and disclosure of the information that was obtained prior to the revocation, as necessary, to preserve the integrity of the study. For example, to account for study withdrawals, to report adverse events to FDA, or to comply with study audits.]
12. A statement that information released may be subject to re-disclosure by the recipient and no longer protected by the privacy rule.
13. A statement that treatment, payment, continued enrollment in a health plan or eligibility for benefits will not be conditioned upon the individual’s provision of authorization (excepted as allowed by the federal and/or state law)
14. A statement that the access to PHI in study records will be temporarily held while study is in progress.
15. If authorization is for the purpose of marketing and the entity will receive direct or indirect remuneration from the marketing, a statement that remuneration is expected.

Transition Provisions:

Researchers may continue to use and disclose protected health information that was created or received for research, either before or after the compliance date, if the researcher obtained any one of the following prior to the compliance date:

- a. An authorization or other express legal permission from an individual to use or disclose protected health information for the research; or
- b. An informed consent of the individual to participate in the research; or
- c. A waiver of informed consent by the IRB in accordance with the Common Rule or an exception under FDA’s human subject protection regulations.

Separate authorization forms may be used initially during the transition period until such time that the consent form is amended or renewed for continuing renewal. At that time the elements of HIPAA authorization should be incorporated into the informed consent document. Both the separate authorization form (addendum to consent) template and a revised informed consent form template are available on the website. Investigators/sponsors may provide their version, however, it will be checked to make sure all elements are present.

Research Recruitment Under HIPAA

The requirements of the Privacy Rule impact the way in which potential subjects are identified and recruited for studies. According to the rule, health care providers involved in the treatment of an individual are allowed to talk with their patient about enrolling in a research study. This discussion would not require a privacy authorization. However, if the health care provider shares the patient's information with a researcher who is not involved in the patient's care, some form of privacy permission authorization to disclose must be in place, either through written authorization from the patient or an IRB waiver of authorization for the recruitment activity. The written permission or the waiver allows the researcher to view the patient's protected health information in order to make a determination about study eligibility.

Once a potential subject has been identified, research teams should follow appropriate ethical standards about contacting the patient. The initial contact should come from someone who is known to the patient as having legitimate knowledge of their health status, based on an established clinical relationship (i.e. attending physician).

Allowable Recruitment Practices

1. Health care providers who are conducting a study may talk with their own patients about the option of study enrollment.
2. Health care providers may use their own knowledge of the patient's condition and their knowledge about a colleague's study to inform their patients about a study. Three possibilities exist:
 - a. The provider gives the patient the researcher's contact information, and the patient initiates the contact; or
 - b. The patient signs an authorization so that the provider can give the patient's name to the researcher allowing the release of patient name and access to PHI.
 - c. Health care providers may release their patient records to a researcher without patient authorization, if the researcher has already obtained a waiver of authorization from the RIRC. Then the researcher can review the chart, determine eligibility, and work with the provider on contacting potential subjects.
3. The researcher posts RIRC-approved flyers or advertisements, and eligible patients directly contact the researcher.

Research Without an Authorization:

The researcher may access, use or disclose patient information without authorization only when the RIRC has granted a waiver of authorization. Some research projects may not need written authorization from the subject:

- for re-analysis,
- to provide access to PHI for the researcher to contact and recruit subjects into the study,
- medical record, data, or specimen review
- where obtaining authorization is not practicable.

Waivers must satisfy all the following criteria – which are similar to existing regulations:

1. The use and/or disclosure of protected health information involves no more than a minimal risk to the privacy of the subjects based on the following:
 - a. Investigator must provide an adequate plan to protect identifiers from improper use and disclosure;
 - b. Investigator must provide an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research described above, unless the investigator can give a health or research justification for retaining identifiers, or such retention is otherwise required by law; and
 - c. Investigator must provide 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 project referenced above, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.
2. The research could not practicably be conducted without the alteration or waiver; and
3. The research could not practicably be conducted without access to and use of identifiable health information (or PHI).

In addition:

4. The rights or welfare of the subject will not be adversely affected by the waiver.
5. The risks are reasonable in relation to the anticipated benefits of the research.

A separate letter which grants the waiver of authorization will be sent along with the RIRC approval letter. This letter must be kept with research records, and researchers may be asked to show proof of the waiver to medical records, and/or database gatekeepers.

Minimum Necessary Standards

In planning a project that employs a waiver of authorization, researchers should consider their responsibility to comply with the minimum necessary standards of the Privacy Rule. Only the minimum amount of protected health information should be used and disclosed, as necessary to accomplish the goals of the research. For example, date of birth should not be recorded if age will suffice.

Accounting procedures

The Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. This accounting must include disclosures of PHI that occurred during the six years prior to the individual's request for an accounting (on or after 4/14/03). An accounting of disclosure is not required for research made with a subject's authorization, or disclosures of a limited data set with a Data Use Agreement.

Examples of where accounting procedures will be needed:

- Subjects whose PHI are reviewed for prescreening/recruitment process:
 - Via notification through CliQ access system (Form 11), or
 - Via other methods (such patient request, attending physician request, etc.) through a waiver of authorization (Form 12)
 - *For either of the above methods, the researcher **must** enter information into CliQ system under “Accounting for Disclosure” menu. (More information will be provided when the system is fully complete.)*
- Record review. *The researchers are responsible for assisting the holder of the medical record in fulfilling their accounting duties.*
- Data Report requests. *Researchers must coordinate with the person providing the data report.*

For disclosures of PHI for research purposes without the individual’s authorization and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of disclosures. Covered entities may provide individuals with a list of all protocols, for which the patient’s protected health information may have been disclosed, as well as the researcher’s name and contact information. Other requirements may apply as well.

Databases

- HIPAA considers the creation of a database or repository to be research.
- Existing databases are grandfathered in IF you had some type of legal permission such as a consent form signed by the subject when the data was collected.
- Researcher will need a waiver or alteration of authorization for a new study using an existing database for a purpose other than that for which permission was granted.
- For reanalysis of the data a waiver or alteration of authorization may be appropriate.
- New databases require either an authorization or waiver of authorization.

Patient Rights

Patients have several new rights regarding their health information. The most relevant ones are:

1. Alternative means of communication – If a facility has agreed to an alternative means of communication with the patient, the facility has the obligation to make sure these are communicated to the researcher (e.g., no communication by email).
2. Accounting of disclosures – subjects have the right to know who the facility or researcher disclosed their information to for reasons other than treatment, payment or other health care operations, or that were made without the subject's authorization.
3. Individuals have the right to receive an accounting of disclosures that have occurred since April 14, 2003. They may request the accounting for up to 6 years. There are also other requirements.
4. Right to access health information – this right may or may not apply or may be temporarily suspended if the research records include information that is unique to the research record and the research involved treatment of the patient. Researchers should mention this in the informed consent/authorization document. Several other conditions may apply.

Business Associates

Facilities and researchers that qualify as covered entities under HIPAA are required to establish agreements with third parties that are given subjects' protected health information to do work for the covered entity. There are few instances where research will involve business associates. Sponsors are typically not a business associate unless they are involved with receiving subject information from the covered entity and then perform a service such as quality improvement analysis or data aggregation for the covered entity.

De-identifying Data

Removing the following 18 elements cause data to be considered “not individually identifiable” or “de-identified”.

1. Names;
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code;

This means that to qualify as de-identified data, all of the elements listed above must be removed. If data to be collected is completely de-identified, then project does not fall under Privacy rule (but it still falls under RIRC review.)

THE QUEEN'S MEDICAL CENTER

HIPAA Frequently Asked Questions

Q: What is the HIPAA Privacy Rule?

A: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law with multiple goals. It is best known as the law that established the right for individuals to maintain health insurance coverage when they move from job to job. Other portions of the law affect health care providers. The privacy section of HIPAA, called the Privacy Rule, imposes restrictions on the use and disclosure of patient information. It gives new rights to patients and requires health care providers to adopt safeguards that protect patient privacy.

Q: Whom does the Rule cover?

A: The law governs “covered entities” which include health plans, health care clearinghouses, and health providers who bill for their services electronically. The law also reaches to a provider’s business partners and vendors, since those partners must sign HIPAA-compliant contracts in which they agree to protect the health information they handle. HPH is applying HIPAA rules to all research.

Q: What information is covered?

A: The law covers Protected Health Information (PHI). HIPAA defines PHI as: individually-identifiable information created or received by a covered entity, that relates to the past, present, or future physical or mental health condition, the delivery of health care or payment for health care. The Privacy Rule applies not only to information maintained in electronic format, but also to any identifiable patient information on paper or transmitted verbally. It also includes all research information.

Q: Can I still use patient data for research?

A: HIPAA will affect the way researchers access patient data. If informed consent is being sought from the research subject, the subject must be informed of the planned uses and disclosures of their information through a privacy section in the consent form (or a separate authorization form). The new rules also affect the process of research recruitment. Different requirements exist for projects that do not involve informed consent, such as retrospective chart reviews. When informed consent is not required, the researcher must meet certain standards for protecting the privacy of the data, depending on the source of the research data and the nature of identifiers that are associated with the medical information being collected.

Q: Does the HIPAA Privacy Rule prohibit researchers from requiring participants in a research study to sign an authorization to use/disclose existing protected health information?

A: No. The Privacy Rule does not address conditions for enrollment in a research study. Therefore, the Privacy Rule does not prohibit researchers from requiring that participants who want to enroll in a research study sign an authorization for the use of pre-existing health information.

Q: Does the HIPAA Privacy Rule permit the creation of a database for research purposes through an Institutional Review Board (IRB) waiver of individual authorization?

A: Yes. A covered entity may use or disclose protected health information without individuals’ authorizations for the creation of a research database, provided the covered entity obtains documentation that an IRB has determined that the specified waiver criteria were satisfied. Protected

health information maintained by a covered entity in such a research database could be used or disclosed for future research studies as permitted by the Privacy Rule – that is, for future studies in which individual authorization has been obtained or where the Privacy Rule would permit research without an authorization, such as pursuant to an IRB waiver.

Q: Can researchers continue to access existing databases or repositories that are maintained by covered entities, even if those databases were created prior to the compliance date without patient permission or without a waiver of informed consent by an Institutional Review Board (IRB)?

A: Yes. Under the HIPAA Privacy Rule, covered entities may use or disclose protected health information from existing databases or repositories for research purposes either with individual authorization as required at 45 CFR 164.508, or with a waiver of individual authorization as permitted at 45 CFR 164.512(i).

Q: By establishing new waiver criteria and authorization requirements, hasn't the HIPAA Privacy Rule, in effect, modified the Common Rule?

A: No. Where both the Privacy Rule and the Common Rule apply, both regulations must be followed. The Privacy Rule regulates only the content and conditions of the documentation that covered entities must obtain before using or disclosing protected health information for research purposes.

Q: Is documentation of Institutional Review Board (IRB) and Privacy Board approval required by the HIPAA Privacy Rule before a covered entity would be permitted to disclose protected health information for research purposes without an individual's authorization?

A: No. The HIPAA Privacy Rule requires documentation of waiver approval by either an IRB *or* a Privacy Board, not both. At QMC, this will be the RIRC.

Q: What does the HIPAA Privacy Rule say about a research participant's right of access to research records or results?

A: With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about them that is maintained by a covered entity or its business associate in a "designated record set." A designated record set is basically a group of records which a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. While it may be unlikely that a researcher would be maintaining a designated record set, any research records or results that are actually maintained by the covered entity as part of a designated record set would be accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions applies to protected health information created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended *while the clinical trial is in progress*, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access protected health information will be reinstated at the conclusion of the clinical trial.

Q: Are the HIPAA Privacy Rule's requirements regarding patient access in harmony with the Clinical Laboratory Improvements Amendments of 1988 (CLIA)?

A: Yes. The Privacy Rule does not require clinical laboratories that are also covered health care

providers to provide an individual access to information if CLIA prohibits them from doing so. CLIA permits clinical laboratories to provide clinical laboratory test records and reports only to “authorized persons,” as defined primarily by State law. The individual who is the subject of the information is not always included as an authorized person. Therefore, the Privacy Rule includes an exception to individuals’ general right to access protected health information about themselves if providing an individual such access would be in conflict with CLIA.

In addition, for certain research laboratories that are exempt from the CLIA regulations, the Privacy Rule does not require such research laboratories, if they are also a covered health care provider, to provide individuals with access to protected health information because doing so may result in the research laboratory losing its CLIA exemption.

Q: Do the HIPAA Privacy Rule’s requirements for authorization and the Common Rule’s requirements for informed consent differ?

A: Yes. Under the Privacy Rule, a patient’s authorization is for the use and disclosure of protected health information for research purposes. In contrast, an individual’s informed consent, as required by the Common Rule and the Food and Drug Administration’s (FDA) human subjects regulations, is a consent to participate in the research study as a whole, not simply a consent for the research use or disclosure of protected health information. For this reason, there are important differences between the Privacy Rule’s requirements for individual authorization, and the Common Rule’s and FDA’s requirements for informed consent. However, the Privacy Rule’s authorization elements are compatible with the Common Rule’s informed consent elements. Thus, both sets of requirements can be met by use of a single, combined form, which is permitted by the Privacy Rule. For example, the Privacy Rule allows the research authorization to state that the authorization will be valid until the conclusion of the research study, or to state that the authorization will not have an expiration date or event. This is compatible with the Common Rule’s requirement for an explanation of the expected duration of the research subject’s participation in the study. It should be noted that where the Privacy Rule, the Common Rule, and/or FDA’s human subjects regulations are applicable, each of the applicable regulations will need to be followed.

Q: Who is responsible for accounting for research disclosures of protected health information (PHI)?

A: Patients have the right to receive an accounting of certain disclosures of their protected health information. The accounting process was established so that patients could learn about how their information was disclosed in cases where written permission was not required. Disclosures from a patient’s medical record that are made under a waiver of authorization, for activities preparatory to research, or for studies on decedents must be included in the accounting process. Researchers are responsible for assisting the holder of the medical record in fulfilling their accounting duties

Q: If a research subject revokes his or her authorization to have protected health information used or disclosed for research, does the HIPAA Privacy Rule permit a researcher/covered health care provider to continue using the protected health information already obtained prior to the time the individual revoked his or her authorization?

A: Covered entities may continue to use and disclose protected health information that was obtained prior to the time the individual revoked his or her authorization, as necessary to maintain the integrity of the research study. An individual may not revoke an authorization to the extent the covered entity has acted in reliance on the authorization. For research uses and disclosures, this reliance exception at 45 CFR 164.508(b)(5)(i) permits the continued use and disclosure of protected health information already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of

the research study. For example, the reliance exception would permit the continued use and disclosure of protected health information to account for a subject's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration, to conduct investigations of scientific misconduct, or to report adverse events.

However, the reliance exception would not permit a covered entity to continue disclosing additional protected health information to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.

Q: If research subjects' consent was obtained before the compliance date, but the Institutional Review Board (IRB) subsequently modifies the informed consent document after the compliance date and requires that subjects be re-consented, is authorization now required from these previously enrolled research subjects under the HIPAA Privacy Rule?

A: Yes. If re-consent (i.e., asked to sign a revised consent) is obtained from research subjects after April 14, 2003, the covered entity must obtain individual authorization as required at 45 CFR 164.508 for the use or disclosure of protected health information. The revised informed consent document may be combined with the authorization elements required by 45 CFR 164.508.

Q: Can covered entities continue to disclose adverse event reports that contain protected health information to the Department of Health and Human Services (HHS) Office for Human Research Protections?

A: Yes. The Office for Human Research Protections is a public health authority under the HIPAA Privacy Rule. Therefore, covered entities can continue to disclose protected health information to report adverse events to the Office for Human Research Protections either with patient authorization as provided at 45 CFR 164.508, or without patient authorization for public health activities as permitted at 45 CFR 164.512(b).

Q: Can covered entities continue to disclose protected health information to the HHS Office for Human Research Protections for purposes of determining compliance with the HHS regulations for the protection of human subjects (45 CFR Part 46)?

A.: Yes. The Office for Human Research Protections is a health oversight agency under the HIPAA Privacy Rule. Therefore, covered entities can continue to disclose protected health information to the Office for Human Research Protections for such compliance investigations either with patient authorization as provided at 45 CFR 164.508, or without patient authorization for health oversight activities as permitted at 45 CFR 164.512(d)..

Q: How long do records have to be retained under the HIPAA?

A: Researchers are responsible for appropriate record retention to meet HIPAA and other compliance requirements. The Privacy Rule requires that all documentation concerning patient privacy must be maintained for six years from the date it was last in effect. Clinical trial data should be retained for a minimum of six years, and longer if required by the sponsor and/or FDA.

THE QUEEN'S MEDICAL CENTER
HIPAA QUICK REFERENCE GUIDE FOR RESEARCH ACTIVITIES
AFTER APRIL 14, 2003

All projects must go through the usual RIRC process. In addition, there are requirements under HIPAA. This table is specific to the HIPAA application.

NEW RESEARCH STUDIES:	
Research Activity:	Investigators Must::
A new research study involving a consent form	Either incorporate the required elements of the authorization into the informed consent document or provide a separate document.
Research personnel accessing medical records or lab results to screen for subjects	<ul style="list-style-type: none"> a. Incorporate the required elements of authorization into the informed consent document. OR b. Apply for a Waiver of Authorization (Form 4, 12) for the recruitment activities of the study to be able to collect PHI, and must account for use and disclosure
Access to clinical records to create a database for future research	Submit application for a Waiver of Authorization (Form 4,12) <ul style="list-style-type: none"> a. For accessing information after discharge: use Medical Record Request form and work with medical records on accounting b. For accessing information on floor: account your use/disclosure in CliQ
Banking of biological materials for future research	<ul style="list-style-type: none"> a. Submit an application for a Waiver of Authorization (Form 4, 12) for the preparatory activities of the study (if needed) b. If informed consent is required by the RIRC, incorporate the required elements of the authorization into the informed consent document
Retrospective review, involving access to medical records or identifiable lab samples	Submit an application for a Waiver of Authorization (Form 4, 12) <ul style="list-style-type: none"> a. For medical records: Use Medical Record Request form and work with medical records for accounting your use b. For other information: Must account via CliQ
A project using de-identified (all 18 items are stripped) existing tissue/specimen/data	A waiver of authorization is not needed. (However, it must be reviewed by RIRC.)
Researcher accessing existing database for new research purpose	<ul style="list-style-type: none"> a. Submit an application for a Waiver of Authorization (Form 4, 12) b. If informed consent is required by the RIRC, incorporate the required elements of the authorization into the informed consent document c. Use Database Request Form, and work with data coordinator for accounting your use.

Updated: 4-11-03

NEW RESEARCH STUDIES (cont):	
Research Activity:	Investigators Must::
Access or use existing databases or repositories created prior to 4/14/03 without patient permission or without a waiver of informed consent by RIRC	<ul style="list-style-type: none"> a. Submit an application for a Waiver of Authorization (Form 4, 12) b. If informed consent is required by the RIRC, incorporate the required elements of the authorization into the informed consent document
Access data permitted in Limited Data Set Use Agreement	Contact Privacy Officer to establish limited data set agreement with facility AND submit application to RIRC

ONGOING ACTIVE RESEARCH STUDIES:	
Research Activity:	Investigators Must::
An ongoing research study still open to accrual of new subjects	Effective April 14, 2003, Authorization needs to be obtained from <u>new</u> subjects enrolled. Submit an Authorization form to the RIRC for review/approval. During the period of time that no changes are made to protocol or consent form, a separate authorization may be submitted. A template is available on QMC Research website for guidance.
An ongoing research study that was closed to accrual prior to April 14, 2003 and where informed consent was obtained	Authorization is not required, unless a modification is made to the consent form which requires re-consent of the subject. If so, an authorization needs to be obtained from the subjects enrolled. Submit an Authorization form to the RIRC for review/approval
Modification to a previously approved consent form that requires re-consent of the subject after April 14, 2003	Individual Authorization must be obtained. The revised consent form may be combined with the required authorization elements
An ongoing research study with a waiver of informed consent but informed consent is subsequently required after April 14, 2003	Individual Authorization must be obtained. The consent form may be combined with the required authorization element
An ongoing research study with a waiver of informed consent (i.e. record review, specimen study)	A Waiver of Authorization is not required unless the scope of the study is expanded or altered to require one.
An ongoing research study in the data analysis phase prior to April 14, 2003	Authorization is not required

Updated: 4-11-03

[*TEMPLATE*]
Addendum to Consent Form

Authorization to Use and Release Personal Health Information (PHI) for

Researchers/Investigators/Study Doctor: *[fill in]*

Study Title: *[fill in]*

The federal government has created a new privacy rule called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It gives you the right to decide who can use and release your personal health information (also called “protected health information” or PHI). This form, called an “Authorization”, explains your rights and how your health information will be used and released for this study.

Description and purpose of information to be released:

By signing this form, you will be allowing or “authorizing” the use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you as part of this study. Your personal health information is health information about you that could be used to identify you. This information may include information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

Who may receive, use or release information:

Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- *[Name of PI, and co-investigators]* and his/her research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

Who may receive the information by the above groups:

The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (*if applicable*)
- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health,
- *[Collaborators at other institutions]*
- *[Outside data analysts]*
- *[List any other class of persons or organizations not affiliated with QMC to whom the subject’s information might be disclosed]*

There is a possibility that your information may be released again by the sponsor of the study or governmental agencies described above and no longer covered by federal privacy rules.

You will not be identified by name in any published reports, or scientific publications, or meetings.

Right to Withdraw or Stop Taking Part in the Study

You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.

If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

Access to Your Information

You may not be allowed to see or get copies of certain information in your medical records collected as part of this research study while the research is going on. Once the research is completed, you will be able to access or get copies of the information.

There is no expiration date to this authorization.

You will get a signed copy of this consent form to keep.

Subject's Name (Print) Subject's Signature Date/ Time

If subject unable to sign:

Representative's Name (Print) Representative's Signature Date/ Time

If signed by a personal representative of the subject, a description of the representative's legal authority to act on behalf of the subject must be stated below:

Witness' Name (Print) Witness' Signature Date/ Time

I have explained this authorization to the above subject. In my judgment the subject is voluntarily and knowingly giving authorization and has the legal capacity to give authorization to take part in this research study.

Investigator's Name (Print) Investigator's Signature Date/ Time
(Individual obtaining Subject's consent)

Translator's Name (if appropriate) Translator's Signature Date/ Time
(Print)

Request for HIPAA Waiver of Authorization
For the use/disclosure of existing data OR for subject recruitment/prescreening

1. PROJECT TITLE:

2. PRINCIPAL INVESTIGATOR:

Check the appropriate box you are requesting:

- Use/disclosure of existing data. (for example, record review, specimen)
- For subject recruitment/prescreening

Check the box that describes what PHI will be used/disclosed for this study:

- | | |
|--|---|
| <input type="checkbox"/> Medical Records/personal health information | <input type="checkbox"/> Existing specimens/biologic material |
| <input type="checkbox"/> Diagnostic imaging | <input type="checkbox"/> Registry information |
| <input type="checkbox"/> Photographs | <input type="checkbox"/> Database information |
| <input type="checkbox"/> Other <input type="text"/> | |

3. Please complete the following:
Explain why research could not practicably be conducted without the waiver:

Explain why the research could not practicably be conducted without access to the protected health information (PHI).

Explain that rights or welfare of subject will not be adversely affected by the waiver.

5. I certify that the information provided above is correct and complete.

Signature of Principal Investigator

Date

HIPAA Packet for Researchers, Clinical Coordinators, and RIRC members

Acknowledgement of HIPAA Privacy Training for Research

Please sign and return this form to Research Regulatory Office

The Privacy Rule Standards in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) establishes the permitted uses of patient protected health information by health care providers and other parties covered by the law. As covered entities, users of protected health information (PHI) are required to abide by these standards. Violations can result in various penalties and/or fines.

1. I understand that QMC desires and has a legal responsibility to safeguard the privacy of all patients and to protect the confidentiality of their health information.
2. I acknowledge that I have received The Queen’s Medical Center HIPAA Training Packet for Researchers.
3. I understand that I am responsible for reading the information provided and complying with the Health Insurance Portability and Accountability Act (HIPAA) requirements for research, effective on April 14, 2003.
4. I agree that it is my responsibility to be familiar with the policies and procedures applicable to patient privacy.
5. I acknowledge that the federal law requires QMC to provide privacy and confidentiality training to me as a member of its workforce or as a research accessing QMC patient data.

Print Name

Date

Signature

If coordinator, which PI you work with

Please return this signed form to:
The Queen’s Medical Center
Research Regulatory Office
1301 Punchbowl Street, UT 505
Honolulu, HI 96813