



HIPAA Privacy Procedure #15

Effective Date: April 14, 2003
 Reviewed Date: February, 2011
 Revised Date: February, 2011
 Scope: Radiation Oncology

Use of Disclosure of PHI in Research

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Policy Expectation:

Washington University (WU) has adopted a policy that provides guidelines and instructions on the appropriate use and handling of Protected Health Information (PHI) in research. In most cases the prior review and approval of the IRB will be required.

Why is this important?

The policy to which this procedure relates, covers all PHI which is or may be created, used or disclosed by, through or during research activities. It applies to all faculty and staff who conduct research, assist in the performance of research or otherwise use or disclose PHI in connection with research. This includes students, student employees, residents, post-doctoral fellows, visiting, courtesy, affiliate and adjunct faculty, industrial personnel, administrative fellows and similar others.

Failure to comply may result in WU being liable for civil and criminal penalties under the HIPAA regulations.

What do you need:

- HIPAA Privacy Policy #15, Use or Disclosure of PHI in Research
- HIPAA Glossary of Terms, <http://hipaa.wustl.edu>
- HSC web site, <http://medicine.wustl.edu/~hsc/>
- WU HIPAA website, <http://hipaa.wustl.edu>

IMPORTANT NOTES ON HOW TO USE THIS PROCEDURE:

This procedure is meaningful only if the reader is familiar with the web site of the WUMC Human Studies Committee. Forms referenced may be found on the web sites above. The HSC forms are not provided as Exhibits in this procedure due to updates being made to the forms from time to time. Radiation Oncology specific forms are attached as Exhibits.

Steps:	Additional Information
1. Principal investigators should insure that a HIPAA compliance form and consent form adapted for HIPAA have been filed with the HSC for studies that will accession patients or re-consent patients on or after April 14, 2003. Contact the Siteman Clinical Trials Office, Carol Rush.	Carol Rush 747-8068 crush@wustl.edu
2. All cancer-related Consent for Research Forms must include the Siteman Cancer Center statement.	See HSC Web Site.

<p>3. The following data collection for research does not require review by HSC:</p> <ul style="list-style-type: none"> • preparatory to research • decedent research • limited data sets with data use agreements • de-identified data 	
<p>4. Preparatory Research</p> <ul style="list-style-type: none"> • Document that the researcher will Use PHI solely for the purpose of developing a research protocol and that no PHI will be recorded or removed from the source or used in the actual research project. • PHI sought is to conduct preparatory research; the researcher may review PHI but the researcher may not record or remove PHI. The researcher may record aggregate data (e.g., 50 patients in 6 months). • PHI sought is to identify prospective research participants in order to seek an authorization. • Provide documentation that the above criteria are met to the data custodian. 	<p>An Authorization or Waiver is not required for preparatory research. However, if identifying research participants to seek an Authorization, the researcher needs a Partial Waiver.</p> <p>The PHI sought is subject to the WU HIPAA Procedure #11, Minimum Necessary Request, Use or Disclosure of Protected Health Information.</p>
<p>5. Decedent Research</p> <ul style="list-style-type: none"> • Document that the researcher plans to Use or Disclose decedent PHI including: <ul style="list-style-type: none"> • The Use will be solely for research on the PHI of the decedent. • The death of the Individual about whom the PHI is being sought has been documented by the researcher. • The PHI sought is necessary for the purposes of research. • Provide documentation that the above criteria are met to the data custodian. • A researcher may use and disclose a decedent’s PHI for research without an Authorization or IRB waiver, provided: <ol style="list-style-type: none"> 1. Solely for research on decedent PHI 2. Researcher has documentation of death of individual 	<p>The PHI sought is subject to the WU HIPAA Procedure #11, Minimum Necessary Request, Use or Disclosure of Protected Health Information.</p>

<p>6. De-Identified Health Information</p> <ul style="list-style-type: none"> • Determine whether to pursue de-identification of health information related to the usefulness of the end result to the research project. • The decision to pursue de-identification renders the remaining information exempt from HIPAA rules. Therefore, neither an Authorization nor a Waiver is required. • Select the method to be used to de-identify the PHI and report the selected method to the IRB using the appropriate IRB form. <ul style="list-style-type: none"> • Removal of all HIPAA identifiers, or • Statistical method administered by an independent qualified statistician. • If the Statistical Method is selected, provide documentation through the submission of a Statistical Certification to the IRB that two criteria are met: <ul style="list-style-type: none"> • The risk of re-identification of the data, along or in combination with other data, is very small, and • Methods and results of the de-identification process are made known. • Determine if and how a Re-identification Code will be used to permit the information to be re-identified as necessary. • Use the Code Access Agreement available on the IRB web site to document that the individual requesting the data will not have access to the Re-identification Code. <p>NOTE: For researchers submitting to the medical school IRB: Use the Code Access Agreement available at the WUMC Human Studies Committee web site to document that the person requesting the data will not have access to the Re-Identification Code.</p> <ul style="list-style-type: none"> • Submit studies using de-identified data to the IRB for review under the Common Rule that all human subject research, regardless of sponsorship, will comply with the Federal Policy for the Protection of Human Subjects. 	<p>De-identification means the removal of all identifiers designated by HIPAA as a means for revealing the identity of an Individual. Refer to the HIPAA Glossary of Terms for a listing of the identifier data elements.</p> <p>The researcher must receive the data de-identified. The research team cannot perform the de-identification process.</p> <p>While no internal or external experts have been identified by WU at the time of this writing, the potential for this statistical method still remains.</p> <p>The expert administering the statistical method may not be the researcher or anyone directly involved in the research study.</p> <p>The Re-Identification Code may be affixed to the research record provided the key to such a code is not accessible to the researcher requesting to Use or Disclose the de-identified health information.</p>

<p>7. Limited Data Set</p> <ul style="list-style-type: none"> • Determine whether to pursue the use of a Limited Data Set related to the usefulness of the end result to the research project. <p>The decision to pursue the use of a Limited Data Set eliminates the need for an Authorization or a Waiver.</p> <ul style="list-style-type: none"> • Exercise caution in making a decision related to a Limited Data Set. Just because the number of PHI identifiers in a research study will be limited (small), that small number of elements does not necessarily qualify as a Limited Data Set. • Execute a Data Use Agreement (available on the IRB web site) between the parties who will be sharing the PHI in the Limited Data Set. • The researcher may use or disclose a limited data set without an Authorization or Waiver of Authorization. 	<p>Limited Data Set is defined as PHI that may include only the following elements: town, city, State, zip code and dates directly related to an Individual about whom the PHI is being sought such as date of birth, admission, discharge or death.</p> <p>Refer to the HIPAA Glossary of Terms for a more detailed definition.</p> <p>Caution: A researcher using his/her own records cannot use a Limited Data Set.</p> <p>A Data Use Agreement must be in place between WU custodian and recipient of limited data set.</p>
<p>8. Research Authorization to Use or Disclose PHI</p> <ul style="list-style-type: none"> • <i>As a general rule, obtain an Authorization from all participants in research prior to the internal Use or external Disclosure of PHI for any related purpose.</i> • Obtain a valid signature on the Authorization. See HIPAA Policy #15 regarding adults and minors who may sign the Authorization. • Refer to the HIPAA Procedure #13, Uses and Disclosures of Protected Health Information without Verbal or Written Authorization for situations in which researchers are permitted or required to Use or Disclose PHI without authorization. Examples include legal authorities and public health oversight agencies. • Ensure the Authorization is reviewed and approved by the IRB prior to enrolling subjects or conducting research. 	<p>Authorization language has been integrated into the consent forms. Templates are available on the appropriate IRB web site with instructions on completion and links to other important materials.</p> <p>Only research personnel may execute a research Authorization.</p> <p>The Principal Investigator should obtain a Certificate of Confidentiality as directed by the appropriate IRB to protect the data from subpoena.</p>

<ul style="list-style-type: none"> • Provide a copy of the completed and signed Authorization to the research subject at time of signing. • Authorizations should be filed in the research file along with the consent. A copy of any approved Waiver of Authorization should be kept in participant’s record. Waivers of authorization are not signed by participants. Waivers are granted by IRB for a study. <p>A Notice of Privacy Practices must be provided to a research participant when an Authorization is obtained</p>	<p>See Consent Form/ Authorization Form on HSC web site http://www.medicine.wustl.edu/~hsc/hipaa/</p> <p>See Notice of Privacy Policy</p>
<p>9. Recruiting Potential Research Participants</p> <ul style="list-style-type: none"> • Ensure all recruitment techniques are reviewed and approved by the IRB prior to implementation. • Use one of the following acceptable recruitment methods: <ul style="list-style-type: none"> • PI/collaborators recruit his/her/their own patients • PI sends an HSC approved letter to colleagues asking for referrals of eligible patients. The treating physician makes initial patient contact. If the patient is interested, the patient contacts the PI or (with permission of the patient) the treating physician invites the PI to talk with the patient about enrollment. • PI sends an HSC approved letter to colleagues asking the physician to send out HSC approved general “Dear Patient” letters describing the research study. The PI may draft the letter with the treating physicians’ signature, but may not have access to the patient names or addresses for mailing. If the PI wants the letters to be personalized (Dear Mr. Doe), the personal information would have to be entered by the treating physician. • Advertisements/media. All materials must have HSC approval. Please note: <i>Multi-site studies providing a central 1-800 number for interested individuals must get an authorization before conducting a screening interview. However, without prior authorization the operator may ask for a zip code in order to refer the caller to the appropriate research center. Likewise, a self screening method may be used without prior authorization.</i> • Volunteer for Health (VFH) database. • Patient Education Newsletter System (PENS). Newsletter articles must be HSC approved, contact Jacqueline Stack at 747-6542 for more information. 	<p>Recruitment of study participants, like many other human research activities, is now subject to both IRB and HIPAA regulations and policies.</p> <p>Potential subjects should be introduced to a study by someone familiar to them (i.e., someone directly involved in their clinical care.)</p> <p>Exceptions: Using the self-screening method or the screening does not include PHI.</p>

<ul style="list-style-type: none"> • Access to a shared database to determine eligibility and contact potential participants. This option is reserved for small groups that share patient care responsibilities as well as records. To use this option the researcher will need to explain: a) the nature of the database, b) how many people will have access to the database, c) the connection between the PI and the potential participants, d) how the research will be presented to potential participants. • Use of a Partial Waiver of Authorization for Recruitment Purposes, A Form K5 must be submitted to the IRB. • <i>At a minimum, provide the name of the principal investigator and description of the study to persons responding to a study advertisement prior to obtaining an Authorization.</i> • Do not administer any screening questions to persons expressing interest in a study without first securing an Authorization from the Individual. 	
<p>10. Individual's Access to Research Information</p> <ul style="list-style-type: none"> • Refer to WU HIPAA Procedure #2, Access by Individuals to Protected Health Information, which establishes the right of an Individual to his/her own PHI but restricts the access to such information contained in the "Designated Medical Record". • Discuss level of access in the research Authorization process even if the subject will not be allowed access to the research record. • Provide access to research information that is contained in the Designated Medical Record using the standard request forms and response templates in HIPAA Procedure #2 referenced above. • At the discretion of the researcher, deny access to research information that is NOT contained in the Designated Medical Record provided that: <ul style="list-style-type: none"> • PHI is/was obtained in the course of the research • Individual agreed to the denial of access in the Authorization/Consent, or • Research remains in progress. • Use the standard forms for denial of access available in HIPAA Procedure #2 referenced above by checking the appropriate box related to research. 	<p>This raises the question of where research information resides related to the definition of the "Designated Medical Record" and the extent to which research information is used to make clinical decisions as in the case of clinical trials.</p> <p>If the research record is part of the Designated Medical Record, Individuals have the right of access to such research record.</p> <p>If the research record is not part of the Designated Record Set (maintained separately), the researcher may determine the level of subject access.</p> <p>The researcher will use due diligence in ensuring placing research information in the incorrect Designated Medical Record in error does not occur.</p>
<p>11. Waiver of Authorization by IRB</p> <ul style="list-style-type: none"> • Determine whether to pursue a Full or Partial Waiver of Authorization. 	<p>Physicians may contact their own patients for purposes of recruiting them to participate in a research study without and Authorization.</p>

<ul style="list-style-type: none"> • For a Full Waiver, complete Form K1 on the IRB web site to show that the research project meets all the criteria are satisfied. • For Partial Waiver, complete Form K5 on the IRB web site to show that the Use or Disclosure of PHI will be limited to the following: <ul style="list-style-type: none"> • To screen or recruit participants • Determining which Individuals are candidates for the study • To contact potential participants • Submit the completed request to the IRB for Full or Partial Waiver of Authorization for review and approval prior to taking any further action related to the research. • Refer to and comply with WU HIPAA Privacy Procedure #11, Minimum Necessary Request, Use or Disclosure of Protected Health Information. 	<p>Full Waiver is only appropriate in those situations when consent will also be waived.</p> <p>Partial Waiver means that an authorization is waived for screening or recruiting purposes, but the consent and Authorization must be completed by the study subject upon decision to participate.</p> <p>Only collect the amount and type of PHI essential to the study and record as few identifiers of subjects as possible.</p>
<p>12. Individual's Revocation of Research Authorization</p> <ul style="list-style-type: none"> • Facilitate a request by an Individual to revoke his/her Research Authorization by presenting and requesting the completion of the Withdrawal Letter available on the IRB web site. • Forward a copy of the Withdrawal Letter to the RO Privacy Liaison since this process is part of HIPAA compliance. • Incorporate the Revocation in a report to the IRB at the time of continuing review. • Implement the subject's Revocation of the Authorization and terminate research on the subject under the specified protocol. • Continue to Use or Disclose PHI collected about the Individual within the parameters of a valid Withdrawal Letter. • The researcher will send the Individual notification in writing that his/her Revocation request was received. Requests for Revocation of Authorization should be kept in participant's research file. 	<p>RO Privacy Liaison Kevin Sharkey Tel 314-286-1076 Fax 314-362-8521 Campus Box 8224 mailto:ksharkey@radonc.wustl.edu</p> <p>Refer to WU HIPAA Privacy Procedure #16, Restrictions on Use or Disclosure of Protected Health Information. While Individuals have the right to request restrictions on how PHI is Used or Disclosed, WU researchers have no obligation to comply with the request due to administrative complexity. Since the research Authorization outlines how PHI will be Used or Disclosed, an Individual desiring restrictions should simply revoke the Authorization.</p> <p>See Sample Revocation on HSC web site.</p>

13. Accounting for Uses and Disclosures of PHI in Research

If Radiation Oncology uses or discloses PHI for reasons other than treatment, payment or health care operations (TPO) or as specifically authorized by the Individual, Radiation Oncology is required to keep records of such Uses or Disclosures for six (6) years and be able to produce such records upon request by the Individual.

- *Disclosure* is to parties external to Washington University.
- *Use* means the internal sharing, employment, application, utilization, examination or analysis of such information maintained by WU.
- *Workforce* means employees, volunteers, trainees and other persons whose conduct in the performance of work for WU, is under the direct control of WU, whether or not paid by WU.
- The researcher will assist Individuals in making their requests for an Accounting in writing, either through completion of a Request form or in a letter.
- Uses and Disclosures should be tracked at the time they occur; otherwise the PI will have to go through all research records used to find each individual activity. This may be impossible within the time constraints to respond to request for Accounting.
- Researcher will use the Tracking Tool for PHI Custodians for Uses and Disclosures form to record Disclosure of PHI.
- The researcher shall maintain an accounting of all Disclosures of PHI, *unless disclosure was made pursuant to Authorization or as part of a limited data set or is specifically authorized by Individual in Consent/Authorization form.*

The researcher must keep records of all disclosures of PHI created during a research project for 6 years from latest date records were accessed and provide to the Individual upon request:

- where disclosed with no authorization
- pursuant to IRB waiver
- used in preparation of research protocol
- decedent's PHI used for research

Disclosure of PHI to sponsors should be made only if there is an authorization from Individual or a Waiver from the HSC.

- Researcher will send a copy of the paper Disclosure Form to Department Privacy Liaison. Researcher may keep a copy for own file. Privacy Liaison will enter Disclosure in Electronic Disclosure Log on WU Web Site and will retain the paper form in file.

See Exhibit D and Exhibit G

RO Privacy Liaison
Kevin Sharkey
Tel 314-286-1076
Fax 314-362-8521
Campus Box 8224
<mailto:ksharkey@radonc.wustl.edu>

<ul style="list-style-type: none"> • Researcher will amend the Authorization or Waiver if the research team changes and submit the amendment to the IRB. Otherwise, new persons receiving PHI will constitute a Disclosure. Therefore, make sure the team is broad enough in the Authorization or Waiver. • Data custodians are accountable for tracking and reporting an accounting when requested by an Individual to include reasons for Disclosure, to whom Disclosed, the protocol, purpose of the study and when Disclosed. • Researcher will use a simplified accounting process if the research Disclosure involves the PHI of more than 50 people by indicating: The research activities in which the Individual’s PHI may have been Disclosed, Description of the purpose of the study, The type of PHI Disclosed, and The timeframe during which such Disclosures occurred. • Researcher will use the Tracking Tool for PHI Custodians for Uses and Disclosures form to record Uses of PHI in research, in order to show that the rules related to internal uses are being followed. These records should be retained in the researcher’s files, and be available for compliance audit. No copy need be sent to the Department Privacy Liaison. 	
<p>14. Notice of Privacy Practices (Notice) Refer to WU HIPAA Privacy Procedure #12, Notice of Privacy Practices for an outline of the Notice and its intended purpose.</p> <ul style="list-style-type: none"> • It is NOT necessary to distribute a Notice or secure an acknowledgement for studies that have been given an exception by the IRB to this provision. The exception is based upon information from the PI in the HIPAA application to the IRB that states there is no treatment involved in the study and none of the participants in the study are “patients”. The exception will have to be given by the IRB to the entire study or not at all. If there is a mix of “patients” and non-patient study subjects, the Notice must be distributed and the acknowledgement secured at the first point of contact. • Research taking place outside of the US is NOT covered by HIPAA policies at this time. Once the data reaches the US, it becomes subject to HIPAA. • Data normally considered to be subject to HIPAA and shared internationally remain subject to HIPAA since the “ownership” and decision making occur in the US. 	<p>There are four versions of Notices.</p> <ul style="list-style-type: none"> • Summary version of a Joint Notice with BJH, SLCH and WU to be distributed when subjects will be seen on the medical campus. • Summary version of a WU only Notice to be distributed when subjects will be seen elsewhere. • Long versions of both the Joint Notice and the WU only Notice available to Individuals upon request. <p>Web site: WUPhysicians.wustl.edu</p>

<ul style="list-style-type: none"> All Radiation Oncology patients are given a Privacy Notice on their first visit to the department by the BJH Registrar. This is documented by the Registrar entering “Yes” in the BPIN hospital system. BJH Hospital requires Notice to be given only one time. <p>Include the WU Summary Notice in mailed surveys. A note, as outlined below, should accompany the Notice to explain to the recipient why they are receiving the Notice.</p> <p>“Your informed consent and authorization document tells you how we will deal with your information for the purposes of this study. However, we are required by federal regulation to inform you of how our institution generally deals with protected health information. The enclosed brochure gives you that general information.”</p> <p>Offer the Notice in the introductory phase of a telephone interview. Assist the Individual in deciding on the use of the mail, fax, review on the WU Physicians web site, or to be picked up by the Individual upon first face-to-face encounter with the researcher as applicable. Document the offer at the same time and in the same place that the informed consent for telephone interviews is documented.</p>	<p>Acknowledgment is not required for mailed surveys.</p> <p>For telephone interviews, document acknowledgment on, Exhibit 3, Sample Log.</p>
<p>15. Business Associate Agreements</p> <ul style="list-style-type: none"> Secure a Business Associate Agreement for any vendor providing administrative or infrastructure services on behalf of the research study. Examples include information system support services provided by persons not part of the WU workforce, consultants and accreditation bodies with whom PHI is shared. Refer to WU HIPAA Privacy Procedure #6, Use or Disclosure of Protected Health Information with Business Associates for details on how to execute such an agreement. 	<p>Business Associate Agreements are not required for activities directly associated with and documented in the research Authorization.</p> <p>A Business Associate Agreement is not a substitute for the research Authorization, a Waiver or a Sub-award Contract.</p>
<p>16. Other</p> <ul style="list-style-type: none"> Research Information Related to Media Refer to WU HIPAA Privacy Procedure #10, Use or Disclosure of Protected Health Information in Media Relations. Communications with Individuals that include PHI Refer to WU HIPAA Privacy Procedure #7, Appropriate Methods of Communicating Protected Health Information. Fundraising Related to Research Refer to WU HIPAA Privacy Procedure #8, Use or Disclosure of Protected Health Information in Fundraising. 	

<ul style="list-style-type: none"> • Marketing Related to Research Refer to WU HIPAA Privacy Procedure #9, Use or Disclosure of Protected Health Information in Marketing. • Registration of Research Databases Refer to WU HIPAA Privacy Procedure #17-2, Identification of Electronic Repositories with Protected Health Information. • Access to Research Databases Refer to WU HIPAA Privacy Procedure #17-3, Access to Electronic Protected Health Information. • Passwords Refer to WU HIPAA Privacy Procedure #17-4, Passwords. The researcher will maintain two-key security of research records. • Amendment of Research Information Refer to WU HIPAA Privacy Procedure #4, Amendment of Protected Health Information. 	<p>Ensure a comprehensive inventory of all persons who need access.</p> <p>See Privacy Procedures 17-2, 17-3, 17-4.</p> <p>Amendment of PHI will only apply to research information contained in the Designated Medical Record.</p>
<p>17. PHI used in research should be disposed of properly by shredding the data, clearing the hard drive, destroying diskettes, strip data of all identifiers, etc.</p>	
<p>18. When the researcher leaves WU, additional steps may be required.</p>	<p>See Exhibit I.</p>

Exhibit A

**Request for
Accounting of Disclosures of
Protected Health Information in Research**

Request Date: _____

Individual Name: _____

Date of Birth: _____ SSN: _____

Individual Address: _____

Telephone Number: (H) _____ (W) _____

Study # : _____

Period Requested for Accounting of Disclosures: (May not exceed the 6 year period prior to your request.)

Beginning: _____ Ending: _____

Is this your first request for an accounting of the disclosure of your medical information within the last 12 months? ____ Yes ____ No

NOTE: If you have made additional requests within the last 12 months, Washington University may impose a reasonable cost-based fee for each additional request. Please check with _____ to receive the cost of your request.

Patient and/or Patient's Representative

Date

For Washington University Use Only:

Accounting has been: _____ Provided _____ Date of Response: _____
_____ Extension Requested: _____ Date: _____
(Attach Form)

Signature of Staff Person _____ Date _____

Print Name & Title

Exhibit B

Accounting of Disclosures of Protected Health Information in Research

Request Date: _____

Individual Name: _____

Individual Address: _____

Telephone Number: (H) _____ (W) _____

Study Record #: _____

Requested Period Requested for Accounting:

Beginning: _____ Ending: _____

Reason for Disclosure:

- Waiver of Authorization
- Preparation for research
- Decedent
- Authorization is required and one was not obtained
- Public health activities
- By Business Associates

<i>Date of Disclosure or Timeframe</i>	<i>Person or Entity & Address Receiving PHI</i>	<i>Type of PHI</i>	<i>Name or List of Protocol(s)</i>	<i>Purpose of Study</i>

Signature of Staff
Person _____

Response Date _____

Print Name & Title _____

EXHIBIT C

Request for Extension of Time To Respond to Request for Accounting in Research

To [Individual]:

We have received your request for an Accounting of the disclosures of Protected Health Information in Research and are in process of responding to your request.

Federal regulations require us to respond to your request within 60 days of our receipt of the request. If we are unable to respond within such time, we may receive a one-time extension of 30 days within which we will provide you with a response to your requested accounting. Currently, we are experiencing delays in our processing of the review of your request due to [INSERT REASON FOR DELAY] and will require an additional 30 days to respond to your request. We appreciate your patience in this matter and will provide you with a response to your requested amendment by [INSERT DATE THAT IS NOT GREATER THAN 90 DAYS FROM THE RECEIPT DATE].

If you have questions concerning your request, please contact [INSERT NAME OR TITLE OF PERSON] at Washington University [INSERT CONTACT INFORMATION].

Sincerely,

EXHIBIT D

Tracking Tool for PHI Custodians For Uses and Disclosures

(Electronic or Medical Records)
[Not to be used for Patient Access - See Procedure #2]

Date of Request: _____

Department of Person Requesting PHI: _____

Method of Identity of Person Requesting PHI:

ID Badge: _____

Other (specify): _____

Covered Entity Affiliation:

WU _____

BJH _____

SLCH _____

Patient Name: _____ MRN or SSN _____

or

Data List: _____

What is being requested: _____

Purpose of Request: _____

Research

No IRB Review Required

Preparatory Research (No information can be copied or removed)

Decedent Research

With IRB Authorization Letter: Compliant with:

Authorization - Full Access (attach copy)

Limited Data Set - Dates/Zip Codes (attach copy of Data Use Agreement)

Waiver - Full Access (attach copy)

Waiver - Partial Access (attach copy)

Other

Authorization is required and one was not obtained

Public Health Activities

Business Associates unrelated to TPO

EXHIBIT D (Cont.)

Describe PHI released

Number of Records Released (attach a list if available) _____

Requesting Party Signature _____

PHI Custodian Signature _____

Date of Release _____

EXHIBIT E

Examples of Disclosures in an Accounting

1. To Health Oversight Agencies
2. For certain research, including disclosures pursuant to a waiver of an authorization for research
3. When an authorization is required and one was not obtained
4. For public health activities
5. By business associates for purposes other than for treatment, payment or health care operations

Examples Not Subject to Accounting Requirement

1. Disclosures made to carry out treatment, payment and health care operations
2. Disclosures made to individuals of their own PHI
3. Disclosures made to persons involved in the individual's care or for purposes of notifying such person of an individual's condition or status (see Policy on Verbal/Inferred Agreement to Use or Disclose Protected Health Information)
4. Disclosures made for national security or intelligence purposes
5. Disclosures made to correctional institutions or to law enforcement officials having lawful custody of an inmate
6. Disclosures that occurred prior to April 14, 2003
7. Disclosures of de-identified PHI
8. Disclosures made to law enforcement officials or health oversight agencies when such officials or agencies have made a request to suspend an accounting
9. Disclosures of Limited Data Sets related to research, covered by Data Use Agreement
10. Disclosures that are incidental to TPO (such as overhead conversations containing PHI)
11. Disclosures made pursuant to the individual's authorization
12. Disclosures by or to a Business Associate for purposes of TPO

EXHIBIT F

When You Leave Radiation Oncology

The following policies have been put in effect in Radiation Oncology to be compliant with the Health Insurance Portability and Accountability Act (HIPAA).

1. A resident leaving the Medical Center cannot take PHI. Residents may take de-identified, aggregate data only.
2. A staff physician leaving the employ of Washington University cannot take PHI without the approval of the Chairman of the department and authorization of the patients.
3. A current physician employee can contact a physician who has left, FAX records containing PHI to that physician and consult with that physician about the treatment of a patient who was seen by the physician who has left. All of these activities fall under TPO (treatment, payment, healthcare operations) and can be accomplished by permission of the patient's original treatment consent.
4. A researcher who leaves Washington University can request of the Chairman of the department to copy research records containing PHI in his/her research study, if the researcher agrees that PHI will be protected consistent with HIPAA regulations. The originals of the records remain at Washington University.

If research materials are contained within a patient medical record, the department physician must obtain the appropriate patient authorization before copies of those research materials can be transferred.

Exhibit G

Guidelines for Researchers Disclosures of PHI

If Radiation Oncology uses or discloses PHI for reasons other than TPO or as specifically authorized by the Individual, Radiation Oncology is required to keep records of such Uses and Disclosures for six (6) years and be able to produce such records for the Individual upon request.

Disclosure is to parties external to Washington University.

Use means the internal sharing, employment, application, utilization, examination or analysis of such information maintained by WU.

Workforce means employees, volunteers, trainees and other persons whose conduct in the performance of work for WU, is under the direct control of WU, whether or not paid by WU.

Requesting Person/ Entity	Amount of PHI to be disclosed	Individual Authorization Required	Disclosure Permitted /Required (No auth)	Review by Privacy Office, or Risk Mgt or Legal Counsel Required before release	Researcher Tracking Tool Required	Researcher Accounting Required if Requested
Individual (i.e., the patient) or Parents/Guardians	If the research record is part of the Designated Medical Records, Individuals have the right of access to such research record. If the research record is not part of the Designated Record Set (maintained separately), the researcher may determine the level of subject access.	No	Yes	No	Yes	No
Researchers	To extent allowed by IRB or be-identified	Research authorization from Individual	Yes	No	Yes	Yes where waiver of research; yes where no authorization; yes if used in preparation of research protocol; yes if decedent's PHI used for research; no if data use agreement.
PHI located in multiple departments		Yes	After review	Yes	Yes	Yes
Dept. Health & Human Services		No	After review	Yes	Yes	Yes

Requesting Person/ Entity	Amount of PHI to be disclosed	Individual Authorization Required	Disclosure Permitted /Required (no auth)	Review by Privacy Office, or Risk Mgt or Legal Counsel Required before release	Researcher Tracking Tool Required	Researcher Accounting Required
Medicare inquiry outside of normal payment inquiry		No	After review	Yes	Yes	Yes
Subpoenas		No	After review	Yes	Yes	Yes. See policies on Permitted and Required disclosures. Refer all subpoenas to Risk Management
Attorney	PHI within scope of subpoena or individual's authorization	-	After review	Yes	Yes	Yes
Disclosures otherwise required by law	All requested PHI necessary to comply with/enforce the relevant law.	No	After review	Yes	Yes	Yes
Law enforcement officials	All requested PHI within the scope of the individual's authorization, subpoena, or court order.	-	After review	Yes	Yes	Yes

EXHIBIT H

PREPARED FOR RADIATION ONCOLOGY FACULTY

HIPAA AND IRB REQUIREMENTS FOR RESEARCH EFFECTIVE 4/14/03

Please contact Anna Eccher re completion of these documents
SCC Clinical Trials office, 747-8068, ecchera@ccadmin.wustl.edu

WU HSC web site, <http://medicine.wustl.edu/~hsc/>
WU HIPAA web site, <http://hipaa.wustl.edu>

RESEARCH PROJECT

TO BE HIPAA/IRB COMPLIANT

Will you be enrolling subjects after 4/14/03?

Submit to HSC a HIPAA Compliance Application and Authorization.

Is this a retrospective study?

Submit to HSC a HIPAA Compliance Application and K1 (full waiver request) or K5 (partial waiver request).

Do you have a research database?

Submit to HSC Form 24 if database is essentially its own entity and used to support future research or if conglomerate of data from several studies.

Does your study involve cancer?

Submit HSC forms to PRMC first before IRB.

Are you collecting data with a Waiver of Consent currently?

Submit to HSC a HIPAA Compliance Application and K1 or K5 waiver application.

