

Tulane University

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APPROVED: April 1, 2003	REVISED:
EFFECTIVE DATE: April 14, 2003	POLICY NUMBER: GC-012

Tulane University Uses and Disclosures of PHI for Research

SCOPE OF POLICY

This policy applies to Tulane University Medical Group, its participating physicians and clinicians, and all University employees and business units who provide management, administrative, financial, legal, and operational support to or on behalf of Tulane University Medical Group and have been designated as part of the Tulane University HIPAA Health Care Component.

STATEMENT OF POLICY

Protected Health Information obtained by Tulane University Medical Group may not be used internally or disclosed to any persons or organizations outside Tulane University Medical Group for research purposes without the prior approval of the Institutional Review Board (I.R.B.) acting on behalf of Tulane University Medical Group. The I.R.B. will be responsible for ensuring that strict policies and procedures regarding access, use, and disclosure of protected health information for research purposes are followed.

IMPLEMENTATION OF POLICY

Certain requirements apply to the use and disclosure of protected health information in connection with research involving human subjects. As a rule, the I.R.B. may not authorize the use or disclosure of protected health information for research purposes except:

- For reviews preparatory to research;
- For research on the protected health information of a decedent;
- If Tulane University Medical Group has obtained the informed consent of the individual to participate in the research, or a waiver of such informed consent, prior to April 14, 2003 (this exception ceases to apply if informed consent is sought from the individual after April 14, 2003);
- If the information is completely "de-identified";
- If the information is partially de-identified into a "limited data set" and the recipient of the information signs a data use agreement to protect the privacy of such information;
- If Tulane University Medical Group has obtained a valid authorization from the individual subject of the information; or
- The I.R.B. approves a waiver of the individual authorization requirement.

The specific requirements for each of these exceptions are discussed below.

Special rules apply to the use and/or disclosure for research purposes of psychotherapy notes. Additional information on research involving psychotherapy notes can be found in Appendix E of this policy.

The I.R.B. must determine that one of the exceptions described below applies for permitting the use and disclosure of any protected health information for research purposes. The I.R.B. should require either an individual authorization or must grant a waiver of authorization if none of the other exceptions apply. All research activities must also comply with other applicable Tulane University Medical Group policies relating to research and with any additional requirements that apply to the specific types of information identified above as having special rules. Finally, to the extent that Tulane University

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Medical Group employees provide treatment to subjects as part of a research study, they must follow other policies to the extent those policies apply to the provision of health care to individuals.

1. Research Defined

For purposes of this policy, research includes any systematic investigation (including research development, testing, and evaluation) that has as its primary purpose the development of or contribution to generalizable knowledge.

- *Generalizable knowledge.* Knowledge may be generalizable even if a research study only uses protected health information held within Tulane University Medical Group and the results are generalizable only to the population served by Tulane University Medical Group. Research is therefore not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this policy.
- *Primary purpose.* The development or contribution to generalizable knowledge must be the primary purpose of the investigation for this policy to be applicable. In some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal hospital outcome evaluation, for example, may produce information that Tulane University Medical Group administration intends to generalize. If the purpose of a study changes and the results will be generalized, the investigator must document the change in status of the activity and obtain approval from the I.R.B.
- *Research authorization.* The subjects' permission to use and disclose PHI.

If an activity would be considered "research" under other applicable policies, it should be considered research for purposes of this policy. However, research that is exempt under the Common Rule may not be exempt under HIPAA and the procedures set forth in this policy must be followed with respect to such research.

2. General Prohibition and Exceptions

The I.R.B. may not authorize the use or disclosure of protected health information for research purposes unless at least one of the following exceptions applies:

Reviews Preparatory to Research. The I.R.B. may permit the use and disclosure of protected health information to develop a research protocol or for similar purposes preparatory to research (e.g., to determine whether Tulane University Medical Group has information about prospective research participants that would meet the eligibility criteria for enrollment in a research study). The preparatory research provision of the HIPAA Privacy Rule 45CFR 164.512(i)(1)(i) et seq. permits covered entities to use or disclose PHI as an aid to study recruitment, although it does not permit the researcher to remove PHI from the covered entity's site. The provision allows a researcher to identify prospective research participants for purposes of seeking authorization to use or disclose PHI for a research study.

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A researcher who is not part of the covered entity may not use the preparatory research provision to contact prospective research subjects. Rather, the outside researcher could obtain contact information through a partial waiver of authorization by the I.R.B. Actual contact would have to be made by someone who works as part of the covered entity and reasonably has access to the protected health information.

In order to permit the use or disclosure of protected health information under this exception, the I.R.B. must obtain representations from the researcher that:

- The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
- No researcher will remove any protected health information from Tulane University Medical Group's premises in the course of the review; and
- The protected health information for which use or access is sought is necessary for the research purposes.

During the preparatory review, those granted access may only record information in a form that is "de-identified." Appendix A describes the de-identified information. Appendix C includes a researcher certification form that would be signed by researchers seeking a waiver of authorization to access protected health information.

Research on the Protected Health Information of a Decedent. The I.R.B. may permit the use and disclosure of the protected health information of a decedent for research purposes. In order to permit such a use or disclosure, the I.R.B. must:

- Obtain representations from the principal investigator that the use or disclosure is sought solely for research on the protected health information of a decedent (*e.g.*, researchers may not request a decedent's medical history to obtain health information about a decedent's living relative); and/or
- Verify that the information for which use or disclosure is sought is necessary for the research purposes.

Informed Consents or Waivers of Informed Consent Obtained Prior to April 14, 2003.

The I.R.B. may approve the use or disclosure of protected health information for a specific research project provided that one of the three following requirements are met:

- Express Legal Permission for Use and Disclosure of Protected Health Information. If the researcher has obtained, prior to April 14, 2003, express legal permission from the individual that *specifically authorizes* a use or disclosure of protected health information for purposes of the research project, the I.R.B. may permit such use or disclosure for purposes of that project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored.
- General Informed Consent. If the researcher has obtained, prior to April 14, 2003, the individual's informed consent to participate in a specific research project, the I.R.B. may permit the use or disclosure for purposes of that project even though the informed consent does not specifically authorize the use or disclosure of protected health information for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.
- Waiver of Informed Consent. If the researcher has obtained, prior to April 14, 2003, an I.R.B. waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, the I.R.B. may permit a use or disclosure of the individual's protected health information for purposes of that project. However, if the researcher obtains an individual subject's informed consent at any time after April 14, 2003, the

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researcher will also be required to obtain the individual's Research Authorization (as provided in this policy) at that time.

Completely De-identified Information. The I.R.B. may allow completely de-identified information to be used and disclosed for research purposes without restriction. Information may only be considered completely de-identified when either (1) a qualified statistician documents his or her determination that the risk of identification is very small, or (2) the information meets the requirements described in Appendix A of this policy. If the I.R.B. has any doubts as to whether protected health information has been completely de-identified within the meaning of this policy, the information should be treated as though it were not completely de-identified and neither used nor disclosed for research purposes without meeting another exception.

Limited Data Set. The I.R.B. may allow the use and disclosure for research purposes of a limited data set including a partially de-identified subset of the individual's protected health information, provided that the person using or receiving the information has signed a Data Use Agreement through which he or she agrees to protect the privacy of the information received. Appendix B of this policy provides more information about the identifiers that must be removed from an individual's protected health information in order to create a limited data set.

Subject Authorization for Research. The I.R.B. may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization. Permissible uses and disclosures are limited to those described in the authorization, even though those permissible uses and disclosures may be more limited than what Tulane Medical Group Practice's Notice of Privacy Practices describes.

The Research Authorization must be completed by the principal investigator for the research subject's review and signature. It is the responsibility of the principal investigator to ensure that the Research Authorization covers the uses and disclosures necessary for the research study.

When obtaining a Research Authorization, an individual's ability to receive research-related treatment as part of a research study may be conditioned upon the individual's agreement to sign the Research Authorization form. However, in presenting the Research Authorization form to prospective subjects, researchers should never suggest that failure to sign the form will limit access to any treatment that may be available outside the study.

I.R.B. Approval of Waiver. The I.R.B. may allow the use and disclosure of protected health information for research purposes if the I.R.B. grants a partial or total waiver of the authorization requirement. If the I.R.B. grants only a partial waiver – that is, if it modifies or waives only some elements of the Research Authorization form – the I.R.B. must condition the use and/or disclosure of any protected health information for research purposes on compliance with any authorization requirements not waived and as modified. For example, if the I.R.B. grants a partial waiver of authorization to allow a researcher to obtain protected health information to recruit potential research participants, the researcher would still have to obtain Research Authorizations from the subjects to use and disclose protected health information to conduct the research study.

3. Individual Access

Individuals generally have a right to access all their protected health information maintained by Tulane University Medical Group or its business associates. Any patient requesting access to protected health information obtained in the course of research (including protected health information that may be contained in research records) should be directed to submit his or her request to the manager of the specific site for processing in accordance with Tulane University Medical Group's policy, GC-008 Patient Access to Protected Health Information, which provides detailed guidelines for responding to such requests.

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The manager of the specific site will determine, with assistance from the researcher and the Privacy Official, whether access to protected health information should be denied under any of the exceptions described in that policy.

4. Documentation

The I.R.B. must retain any writings or documentation required by this policy for six years from the date of its creation or the date when it last was in effect, whichever is later.

COMPLETE DE-IDENTIFICATION

Information is completely de-identified if none of the following 18 types of identifiers is contained in the information and if no one accessing the information has actual knowledge that the information could be used – alone or in combination with other information – to identify any individual who is the subject of the information. Note that this does not prohibit coding records so that they may later be re-identified, so long as the code does not contain information about the subject of the information (for example, the code may not be a derivative of the individual's Social Security Number) and is not used or disclosed for any other purpose, and so long as the re-linking mechanism (e.g., the subject log or coding algorithm) is not disclosed to any persons or organizations outside Tulane Medical Group Practice.

1. Names
2. All geographic subdivisions smaller than a State, including:
 - street address
 - city
 - county
 - precinct
 - zip codes 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: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. All elements of dates (except year) for dates related to an individual, including:
 - birth date
 - admission date
 - discharge date
 - date of death
 - 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
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
18. Any other unique identifying numbers, characteristics, or codes

APPENDIX B

CREATION OF LIMITED DATA SET

Tulane I.R.B. may approve the use and disclosure of a limited data set for research purposes if the person who would use or receive the information has signed a Data Use Agreement through which the person agrees to protect the privacy of the information received.

A limited data set may be created by removing from the individual's protected health information the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names;
2. Postal address information, other than town or city, state, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.

Note: Limited data sets may also be used and disclosed for Tulane University Medical Group's or the recipient's health care operations and for public health purposes, but requirements for the use and disclosure of a limited data set for these non-research purposes are set forth in the data use agreement. Any questions concerning use and disclosure of a limited data set for research or non-research purposes should be directed to Tulane University Medical Group's Privacy Official or his or her designee.

APPENDIX C

APPLICATION FOR I.R.B. WAIVER OR ALTERATION AUTHORIZATION

Project title: _____

Principal Investigator: _____

- 1) Describe the protected health information you plan to review and the purpose for your review. Protected health information may not be reused or disclosed to any other person or entity, except as required by law.

- 2) Describe or list sources of names of patients whose PHI will be included in this review (e.g. search of electronic records or lab database, review of physician's cases, review of departmental log or census).

- 3) If this review is to identify prospective research subjects, describe the plans for contacting prospective subjects. For reviews preparatory to research, protected health information may not be removed from the covered entity's site.

- 4) Describe the plans to protect subject identifiers from improper use and disclosure.

- 5) Describe plans to destroy the participant identifiers at the earliest opportunity consistent with the research unless retention is required for reasons of health, research, or law. Please explain when/if the participant identifiers will be stored or retained. If there is a health or research justification for retaining the identifiers, please explain.

- 6) Explain why the research could not practicably be conducted without the waiver.

- 7) Explain why the research could not be practicably conducted without access to and use of the PHI.

My research team and I will comply with the use and disclosure restrictions described above.

_____ (Signature) _____ (Date)

APPENDIX D

I.R.B. WAIVER PROCESS

I.R.B.'s may grant waivers of the research authorization requirement described in this policy. The purpose of this Appendix is to assist researchers in submitting waiver requests to an I.R.B. by providing a brief description of the role of the I.R.B. and explaining what the I.R.B. is required by federal law to consider when evaluating such requests. Tulane Medical Group Practice's affiliated I.R.B. will follow similar procedures. For more information, researchers should consult the operations manual of the I.R.B. from which a waiver is sought.

Composition of I.R.B.'s. To approve a waiver request under HIPAA, an I.R.B. must be established in accordance with the Common Rule 45CFR 46.107.

Criteria I.R.B. Must Consider. To grant a waiver of Research Authorization, an I.R.B. must find the following:

- The use or disclosure of patient health information involves no more than minimal risk to the individuals involved;
- There is an adequate plan to protect the "identifiers" from improper use and disclosure (Appendix A);
- There is an adequate plan to destroy the "identifiers" at the earliest opportunity, unless there is a health (*i.e.*, individual care) or research justification for retaining the identifiers or their retention is required by law;
- There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information is otherwise permissible under federal policy;
- 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 protected health information.

Review Procedures. If an investigator applies to an I.R.B. to grant a waiver of research as described above, the I.R.B. will follow the procedures as set forth in the Common Rule for full board review 45CFR 46.108 or expedited review 45CFR 46.110 as applicable.

APPENDIX E

USE AND DISCLOSURE OF PSYCHOTHERAPY NOTES FOR RESEARCH PURPOSES

Special restrictions apply to the use and disclosure of psychotherapy notes for research purposes. Psychotherapy notes are notes recorded (in any medium) by a mental health professional that (1) document or analyze the contents of conversation during a private counseling session or a group, joint, or family counseling session and (2) that are kept separately from the rest of the individual's medical record. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

In general, the use or disclosure of psychotherapy notes for research is permissible only if:

- The subject signs a Research Authorization, and
- The Research Authorization encompasses only psychotherapy notes and no other protected health information. Thus, if medical records are requested in addition to psychotherapy notes, two Research Authorizations will be required.

Because the rules for psychotherapy notes are more protective of privacy than the general HIPAA research rules, the following exceptions in the policy are not applicable to the use and disclosure of psychotherapy notes for research purposes:

- Reviews preparatory to research;
- Research on the protected health information of a decedent; and
- I.R.B. approval of waiver of authorization.

Note that the transition exceptions allowing continued use and disclosure of an individual's protected health information (including psychotherapy notes) are still applicable in this area. Thus, use and disclosure of such information for research purposes is permitted if an express legal permission, informed consent, or waiver of informed consent has been obtained from the individual prior to April 14, 2003 and the individual is not re-consented after April 14, 2003.

As explained in this University policy, individuals generally have a right to access all their protected health information maintained by Tulane Medical Group or its business associates. Individuals have no right, however, to access any psychotherapy notes.