

## Quick Reference Guide on HIPAA Research Requirements

| <b>Research Examples</b>                                                                                                                                                                                                                                                | <b>Investigators should:</b>                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A clinical trial involving written informed consent.                                                                                                                                                                                                                    | Incorporate the required elements of the privacy authorization into the informed consent document, using the appropriate HSC consent template <sup>1</sup> .                                                                                                                                                                                                   |
| A clinical trial in which research personnel, who do not have a treatment relationship with the patients, will access medical records or lab results to screen for subjects.                                                                                            | <p>a. Incorporate the required elements of the privacy authorization into the informed consent document, using the HSC consent template</p> <p>b. Contact the HIPAA Compliance Office for an application for a Partial Waiver of Privacy Authorization for the recruitment activities. The waiver application should be included in the submission to HSC.</p> |
| Prospective use of clinical records or biological materials to create a database or specimen repository for future research.                                                                                                                                            | Submit the project to Human Subjects Committee for review. If informed consent is required by HSC, incorporate the required elements of the privacy authorization into the informed consent document.                                                                                                                                                          |
| A telephone survey for which written consent is not practicable.                                                                                                                                                                                                        | Submit the project to HSC; include an application for a Waiver of Privacy Authorization <sup>2</sup> .                                                                                                                                                                                                                                                         |
| Retrospective research, involving access to medical records or identifiable lab samples held by a health care provider.                                                                                                                                                 | Submit the project to HSC; include an application for a Waiver of the Privacy Authorization <sup>2</sup> .                                                                                                                                                                                                                                                     |
| A study in which the investigator receives a data set or tissue samples that have some identifiers removed, but not enough to meet HIPAA de-identification standards. (For example, research that requires dates of surgery, subject's zip code, or subject's initials) | Submit the project to HSC; include an application for a Limited Data Set <sup>2</sup> . Negotiate a Data Use Agreement <sup>2</sup> , in cooperation with the HIPAA Compliance Office.                                                                                                                                                                         |
| A project in which the researcher receives data or specimens that meet HIPAA de-identification standards.                                                                                                                                                               | Submit the project to HSC with an "Exempt" application; alternately, submit the project under a master plan for de-identified research (available in late Fall 2004)                                                                                                                                                                                           |
| Request for summary statistics on various diagnostic codes, in order to prepare a research protocol.                                                                                                                                                                    | Request information directly from Hospital Medical Records Department. No privacy or human subjects requirements apply.                                                                                                                                                                                                                                        |

<sup>1</sup> Available on the HSC website at: <http://www2.kumc.edu/researchcompliance/hscforms.htm>

<sup>2</sup> Available on the HIPAA Compliance Website at <http://www.kumc.edu/hipaa/forms/>  
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