As a reminder, HIPAA stipulates that a valid authorization form contain six elements and three required statements. The elements are:

Needed for a valid authorization form nee

1. The identification of who is providing the health information (i.e. the name of the hospital or doctor).
2. The identification of who is receiving the health information (i.e. the name of the researcher(s) or sponsor).
3. Specific identification of what health information is being requested (e.g. the entire medical records, x-ray reports, lab reports, etc.)
4. The expiration date of the authorization (e.g. the end of the research study, six months after signing, etc.) Please note the authorization form must have an expiration event (no expiration is not a recommended time period since you would need to keep the authorization form forever).
5. The signature of the subject, or their representative, and the date when signed.
6. The specific purpose of the use/disclosure (e.g. for research purposes of a specific study, etc.)

The three statements are:

1. The authorization can be revoked by writing to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(the person or group responsible for providing the health information).
2. The consequences of not signing the authorization. Regular treatment cannot be withheld; however, participation in the research can be restricted.
3. The health information may be disclosed after being released. This is because the researcher may not be covered under HIPAA if he/she is not providing health care. Other qualifiers may be added that reflect the privacy commitments in the informed consent.

These elements and statements must be included in the authorization form to be considered valid. A valid authorization agreement is fully completed and signed by the subject or their representative before any Protected Health Information (PHI) is used or disclosed (e.g. Electronic Medical Records). PHI cannot be disclosed prior to obtaining a valid authorization. To obtain protected health information from the covered entities, researchers must give the original signed authorization form to the covered entity to retain for six years after the expiration date. This must be done prior to accessing the medical records or health information for research purposes. Per the University best practice, the PI should retain a copy of the signed authorization form. A copy of the signed authorization form must be given to the subject.

For more information about HIPAA go to the Office of Civil Rights at <http://www.hhs.gov/ocr/hipaa>.

If you have questions, contact Judy McMillan at (517) 432-4502.