OSPA has currently used the language of this statement in some current contract negotiations.

The Office of Sponsored Programs Administration (OSPA) in conjunction with the Office of Health Information at MU issued an Institutional Statement (see page 2). This letter details the University’s position on 21 CFR 11 compliance and provides guidance with regards to our electronic health record (EHR) and its use in clinical investigations.

OSPA has currently used the language of this statement in some current contract negotiations. For further information regarding 21 CFR 11, please contact the OSPA Office at (573) 884-0508.

(continued on page 2)

Growing Knowledge:

Protected Health Information

The HIPAA Privacy Rule protects most “individually identifiable health information” held or transmitted by a covered entity or its business associate, in any form or medium, whether electronic, paper, or oral. The Privacy Rule calls this information protected health information (PHI). Protected health information is information, including demographic information, which relates to:

- The individual’s past, present, or future physical or mental health or condition,
- The provision of health care to the individual, or
- The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

For example, a medical record, laboratory report, or hospital bill would be PHI because each document would contain a patient’s name and/or other identifying information associated with the health data content.

By contrast, a health plan report that only noted the average age of health plan members was 45 years would not be PHI because that information, although developed by aggregating information from individual plan member records, does not identify any individual plan members and there is no reasonable basis to believe that it could be used to identify an individual.

The relationship with health information is fundamental. Identifying information alone, such as personal names, residential addresses, or phone numbers, would not necessarily be designated as PHI. For instance, if such information was reported as part of a publicly accessible data source, such as a phone book, then this information would not be PHI because it is not related to health data (see above). If such information was listed with health condition, health care provision or payment data, such as an indication that the individual was treated at a certain clinic, then this information would be PHI.

As per guidance from US Dept. of Health and Human services (HHS.gov)

Research Word Search:

Research Coordinator Institutional Review Information Compliance Principal Investigator Human Subjects Navigation

Health Sciences IRB is hosting an educational course on “Consent Types and Issues”
April 10, 2014 from 12-1 pm
Essential Conference Room / Room 1L03

Campus IRB is hosting an course on eIRB Navigation
April 15, 2014 from 1-3pm
101 East -Townsend Hall.

For details on how to sign up check out Upcoming Events at www.research.missouri.edu/irb
Spotlight on OSPA: 21 CFR 11 Compliance (continued)

UNIVERSITY OF MISSOURI
SCHOOL OF MEDICINE
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MU Health Care (MUCHC) has made the determination that we cannot provide the requested certification of our electronic records or electronic signatures or complete a questionnaire as it relates to 21 CFR Part 11 as these do not apply to the MUCHC records maintained for patient care purposes. The Food and Drug Administration (FDA) has confirmed this in the recently issued "Guidance for Industry: Electronic Source Data in Clinical Investigations" (found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM328693.pdf, page 8, section IV, Use and Description of Computerized Systems in Clinical Investigations.)

Records for patient care are maintained in accordance with other state and federal requirements but are not specifically in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act (the Act), Public Health Service Act (the PHS Act), or other FDA regulations. In addition, our patient records (electronic or paper) are not submitted to the FDA by our health care providers. However, data may be abstracted by researchers and then submitted to the FDA by the study sponsors by the principal investigators as a result of a research investigation. For this purpose we provide the following information.

MUHC provides the following electronic medical record system(s) that is also accounted for research and clinical studies:

- Cerner Millennium PowerChart

This system is not required to be compliant with the FDA regulations for research systems, but, as required, is in compliance with the HIPAA Privacy and Security Rules.

In addition, the Cerner system is certified for the purposes of the Meaningful Use Incentive program. Under the Meaningful Use requirements of the HITECH Act passed in 2009, electronic health record (EHR) technology must be tested and certified by an Office of the National Coordinator (ONC) Authorized Testing and Certification Body (ATCB). The Cerner system was tested and certified by the Certification Commission for Healthcare Information Technology (CCSHT), an ATCB, ensuring that the following requirements are being met:

- Provides the ability to produce a human-readable copy of data (which includes audit trails and the translation of coded data)
- Includes an audit trail that records date, time, and author of any data created, changed, or deleted
- Prevents new audit trail information from over-writing existing or previous information
- Provides the ability to create, maintain, and apply the roles, access permissions, and capabilities of each user that accesses the system so that users have access only to those system features and functions to which they have been granted access
  - Ensures that data used for clinical research source records are retained for the legal period

As specified in the HITECH legislation, in order for a provider or hospital to qualify for incentive payments, they must prove through an attestation process that the system has the specified capabilities and that they are being used. (Our health system) has completed this attestation of meaningful use. In addition to the above system features, the Chief Information Officer (CIO) has also attested to having or providing the following:

- Documented standard operating procedures
- Appropriation education and training for individuals who develop, maintain, and use the systems
- Data integrity due to appropriate lifecycle practices for both hardware and software from the standpoint of both the vendor and the IT Services department.

Thank you for the opportunity to provide this information.