JOHNS HOPKINS
UNIVERSITY

Center for Clinical Trials

Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

(Mon) 15 October 2012

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: On the magic of transforming human subject research data to non human subject research data

Coded private information, in the parlance of the Office for Human Research Protections (OHRP), is information (data) or biological specimens pertaining to a research subject identified by letter, symbol, or combination thereof instead of name or other unique personal identifiers (See Guidance on Research Involving Coded Private Information or Biological Specimens; dated 16 October 2008; http://www.hhs.gov/ohrp/policy/cdebiol.html).

The persons or parties transmitting coded private information and persons or parties receiving coded private information are exempt from IRB regulations if the transmitting persons or parties do not have the means of identifying persons by name or commit to not supplying recipients with codes linking Id codes to names. The OHRP considers data not linkable to persons as data not involving human research subjects.

If the party providing coded private information collaborates or has interest in the research to be done by the recipient, the transmitting party is considered to be involved in the research and, hence, subject to regulations governing research on human beings.

The OHRP recommends that institutions have policies serving to designate the individual or entity authorized to determine whether research involving coded private information or specimens constitutes human subjects research and that investigators not be allowed to make the determination.

Observations

The OHRP's definitional footwork has been driven by pressure to deal with data sharing mandates of the NIH. On the surface, the footwork makes life easier for coordinating centers with responsibilities for data sharing. The transformation of human research data to data not regarded as human research data allows coordinating centers to data share without IRB approval, but there is a catch. Investigators do not have authority to make the determination. Therefore, the operational implication is that one would have to submit proposals to supply coded private information to one's IRB or some other body for clearance to proceed with such transmissions. So much for life made easier.

It is evident that deidentification under the OHRP guidance is minimal compared to that required under HIPAA regulations for data sharing. The question is whether investigators are willing to data share under the OHRP guideline, given HIPAA requirements for deidentification.