Email-Based Informed Consent: Innovative Method for Reaching Large Numbers of Subjects for Data Mining Research

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ABSTRACT

Since the 2010 NASA authorization to make the Life Sciences Data Archive (LSDA) and Lifetime Surveillance of Astronaut Health (LSAH) data archives more accessible by the research and operational communities, demand for data has greatly increased. Correspondingly, both the number and scope of requests have increased, from 142 requests fulfilled in 2011 to 224 in 2014, and with some datasets comprising up to 1 million data points. To meet the demand, the LSAH and LSDA Repositories project was launched, which allows active and retired astronauts to authorize full, partial, or no access to their data for research without individual, study-specific informed consent. A one-on-one personal informed consent briefing is required to fully communicate the implications of the several tiers of consent.

Due to the need for personal contact to conduct Repositories consent meetings, the rate of consenting has not kept up with demand for individualized, possibly attributable data. As a result, other methods had to be implemented to allow the release of large datasets, such as release of only de-identified data. However the compilation of large, de-identified data sets places a significant resource burden on LSAH and LSDA and may result in diminished scientific usefulness of the dataset.

As a result, LSAH and LSDA worked with the JSC Institutional Review Board Chair, Astronaut Office physicians, and NASA Office of General Counsel personnel to develop a “Remote Consenting” process for retrospective data mining studies. This is particularly useful since the majority of the astronaut cohort is retired from the agency and living outside the Houston area. Originally planned as a method to send informed consent briefing slides and consent forms only by mail, Remote Consenting has evolved into a means to accept crewmember decisions on individual studies via their method of choice: email [1,2,3] or paper copy by mail. To date, 100 emails have been sent to request participation in eight HRP-funded studies.

The development of the Remote Consent process, the laws allowing transmission of consent via electronic means, total metrics to date, and remaining challenges (e.g., response issues, use of International Partner data, biospecimens/genetic data) for the research use of LSAH/LSDA data will be described.

REFERENCES

[1] Uniform Electronic Transactions Act. (http://www.ncsl.org/research/telecommunications-and-information-technology/uniform-electronic-transactions-acts.aspx)

[2] The E-Sign Act, PL #106-229, June 20, 2000. (http://www.gpo.gov/fdsys/pkg/PLAW-106publ229/pdf/PLAW-106publ229.pdf)

[3] Department of Human Health Services, Office of Human Research Protections, guidance on use of electronic signatures to document consent: OHRP guidance on electronic signatures to document consent. (http://answers.hhs.gov/ohrp/questions/7260)