Icahn School of Medicine at Mount Sinai

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REQUEST FOR WAIVER OF AUTHORIZATION TO RELEASE PHI FOR RESEARCH PURPOSES

An investigator may request a waiver of authorization for the release of protected health information (PHI) for research purposes. PHI is defined as individually identifiable health information. The Code of Federal Regulations Title 45, Part 164.512 (i) permits the IRB to approve a waiver, if very specific criteria are met. Your request will be considered on a case-by-case basis by the IRB. To determine if your request meets of these criteria, you must answer the following series of questions.

I am requesting awaiver of authorization.

Please provide a brief description of the research being conducted.
Left ventricular hypertrophy (LVH) is enlargement and thickening of the walls of the heart's main pumping chamber (the left ventricle). It develops in response to a number of systemic conditions including high blood pressure and other heart disease. LVH is a risk factor for a number of serious conditions including congestive heart failure, heart attack, and stroke. LVH is most easily diagnosed using echocardiograpy (ultrasound of the heart), however this imaging modality is relatively expensive and requires the expertise of a cardiologist to interpret. Electrocardiography (ECG, measurement of impulses through the heart's electrical conducting system) can be easily performed by any medical practitioner, and can be used to diagnose LVH. Several criteria have been developed to diagnose presence of LVH by ECG, however these have suffered from poor sensitivity and specificity. We aim to develop an improved method to diagnose both the presence and degree of LVH by ECG. This will be done by performing a retrospective electronic database analysis of echocardiograms, electrocardiograms, and cardiac MRIs performed at Mount Sinai Hospital during a 1.5 year period. Electrocardiographic measurements will be correlated with left ventricular size on echocardiograms and cardiac MRIs, and using statistic methods including logistic and linear regression a formula to more accurately predict presence of left ventricular hypertrophy and left ventricular size will be developed using ECG will be developed.

A. What Identifiers (see footnote) will be accessed? Please note the standard is that only the minimum necessary information to conduct the research should be accessed.
Patient medical records number

B. What health information will be accessed? Please note that the standard is that only the minimum necessary information to conduct the research should be accessed with identifiers (listed under A). Various paramets from electrocardiograms, echocardiograms, and cardiac MRIs

C. With whom will this PHI be disclosed (shared, transferred or otherwise given access to), and why? PHI will only be accessed by the principial investigator and co-investigator.
Make sure to indicate any persons other than the primary investigator who will receive the information, and specify which, if any, of the 18 identifiers[1] will be shared. Only the minimum necessary information, if any, should be shared.

- [1] Names

D. Could this research be practicably conducted without access to and use of this PHI (items listed in A and B combined)? No

If No, Explain Why not? [Please explain your response and be sure to include why de-identified data or a limited data set couldn't be used, instead of asking for a waiver or alteration.]
In order to coorelate stuides collected from different databases, at least one patient identifier will be needed.

E. Could this research be practicably carried out without a waiver/alteration of authorization? No Why not?
Due to the large sample size and retrospective nature, obtained informed consent from all patients woul be impractical.

F. Does the research present **more** than minimal risk to the privacy of the subject?
No Why not? [Appropriate answers to next questions are essential to minimize risk.] Research data will be stored in an encrypted, password protected database that only the invistigators will have access to. In the unlikely event that this data was compromised, only patient MRNs and various cardiac parameters would be available which would pose minimal risk to subjects.

1) What is the plan to protect the identifiers (i.e. the list of 18 listed in A) from improper use or disclosure? If a linking code is being used describe security measures to safeguard the code.
All data will be stored in an encrypted, password proteceted database that only the pricipal investigator and co-investigator will have access to.

2a) When and how do you plan to destroy the identifiers at the earliest opportunity consistent with the research? Examples include at the end of subject participation, after FDA approval, after specimen processing, after data analysis, etc.
N/A

- All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial three digits of the zip code if according to the current publicly available information from the bureau of the census the initial three digits of the zip code for all the geographic units contains more than 20,000 persons.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and for all ages over 89 all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical records numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/License numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL's)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number characteristic, or code, except a special re-identification code that cannot be shared with the investigator

OR

2b) What are the justifications for retaining the identifiers indefinitely? Examples include indefinite longitudinal studies, specific legal or regulatory requirements, etc.
Data will be retained in the encrypted, password protected database for use in future studies relating to electrocardiographic diagnosis of other cardiac pathological states.

I assure that the protected health information will not be disclosed to any other person or entity not listed on this form except where required by law or for the authorized oversight of this research project. If at any time I want to reuse this PHI for other purposes or disclose it to other individuals or entities I will seek approval from the IRB.

Steve Liao
Name of Principal Investigator

Steve Liao - Electronically Signed 9/5/15
Signature Date