

DATA USE AGREEMENT

1. This agreement is between the Telemetric and Holter ECG Warehouse managed by the University of Rochester (THEW), and [Name] _____, [Office] _____, [Center] _____ of the U.S. Food and Drug Administration (FDA) (each a Party or collectively the Parties). The Parties mutually agree to enter into this agreement and to comply with the following specific paragraphs.

2. This agreement addresses the conditions under which THEW will disclose and the FDA will obtain and use the data file(s) specified in section 5. The Parties agree further that any additional instructions or interpretations concerning this agreement or the data specified herein but not specified in this agreement shall not be valid unless issued in writing by the THEW signatory to this agreement shown in section 14.

3. The Parties mutually agree that FDA does not obtain any right, title, or interest in any of the data furnished by THEW (Data). FDA recognizes that there may be errors in the Data and will not hold THEW or the University of Rochester liable for any such errors.

4. The Parties mutually agree that the following named individual/s (User(s)) will be designated as the "point-of-contact" for this agreement on behalf of FDA:

[Name/s] _____
[Title/s] _____
[Address] _____

[Tel.] _____
[E-mail address] _____

5. The User represents that the Data will be used solely for the following purpose(s):

The User represents that he or she will not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data covered by this agreement to another party. The User agrees that the Data covered by this agreement shall be limited to individuals on a need-to-know basis.

The following THEW data file(s) is/are covered under this agreement:
Files:

6. The User agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use or access to the Data.

7. All Data is intended to be de-identified for the purposes of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the regulations promulgated thereunder. In the event of an inadvertent disclosure of “protected health information” as defined in 45 CFR Section 164.501, User agrees to: (a) fully comply with HIPAA and the regulations promulgated thereunder with respect to the use of such protected health information; and (b) report in writing to the name and address specified in Section 5 of this agreement any protected health information that is contained in the THEW data files accessed by User.

8. In an effort to avoid simultaneous submission of similar articles to scientific journals, the User *agrees to notify THEW upon the submission of any and all manuscripts submitted for publication based on findings from analysis of the THEW data.* Notification shall include the title of each manuscript, an abstract for each manuscript, and the name(s) of the journal(s) to which the manuscript(s) will be submitted. Notification shall be directed to the THEW point-of-contact specified in the THEW signatory to this agreement shown in section 14. The User agrees to send a reprint of the manuscript that uses the Data to the THEW signatory to this agreement shown in section 14, whenever the manuscripts are published.

9. The User agrees that the following credit line and disclaimer will be used on all reports, publications and other materials resulting from use of the Data:

Data used for this research was provided by the Telemetric and Holter ECG Warehouse of the University of Rochester (THEW), NY.

10. The User agrees that in the event THEW determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid file(s) that is not authorized by this Agreement, or has used the aforesaid files for commercial purposes, THEW in its sole discretion may require the User to: (a) promptly investigate and report to THEW the User's determinations regarding any alleged or actual unauthorized disclosure and/or uses, (b) promptly resolve any problems identified by the investigation; (c) if requested, submit a formal response to an allegation of unauthorized disclosure and/or use; (d) if requested, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures and/or uses; and (e) if requested return data files to THEW. The User understands that as a result of THEW's determination or reasonable belief that unauthorized disclosures and/or uses have taken place, THEW may refuse to release further data to the User for a period of time to be determined by THEW.

11. No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this agreement, except that the FDA, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

12. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the Data specified in section 5.

13. The User attests that he or she is authorized to enter into this agreement and agrees to all the terms specified herein. There are no intended third party beneficiaries to this agreement.

(Name and Title of User(s) - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No.)

(Fax No.)

(E-Mail Address)

(Signature)

(Date)

14. On behalf of THEW, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Jean-Philippe COUDERC, PhD, MBA
Center for Quantitative Electrocardiography and Cardiac Safety
University of Rochester Medical Center, Rochester, NY
heartjpc@heart.rochester.edu

(Typed or Printed Name and Title of THEW Representative)

(Signature)

(Date)