

DATA USE AGREEMENT

1. This agreement is between the Telemetric and Holter ECG Warehouse managed by the University of Rochester (THEW), and _____, hereinafter termed "User". Both parties mutually agree to enter into this agreement to comply with the following specific paragraphs.

2. This Agreement addresses the conditions under which THEW will disclose and the User 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 the User does not obtain any right, title, or interest in any of the data furnished by THEW. The User recognizes that there may be errors in the Data. User 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 will be designated as "point-of-contact" for the Agreement on behalf of _____.

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

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

5. The User represents and warrants that such data file(s) will be used solely for the following purpose(s):

The User represents and warrants further that the User shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. The User agrees that, within the User's research group, access to the data covered by this Agreement shall be limited to individuals on a need-to-know basis only.

The THEW data file(s) covered under this Agreement are from the DEFINITE trial.
Files: E-HOL-0401-013

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

7. All Data contained in the THEW 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 (2) 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. Any scientific projects which utilize the THEW data files from item 5 will require approval from the ad hoc committee consisting of individuals from the THEW and Northwestern University representative.

9. Any publication, presentation, or abstract that incorporates or relies on the Coded Data Set ("Publication") shall be submitted by the Recipient(s) to the ad hoc committee described in item 8 for review and comment prior to publication.

10. With respect to all Recipients each such Recipient shall acknowledge in writing that (a) the user does not obtain any title (data ownership) in any of the data furnished by THEW, and (b) there may be errors in the Coded Data Set. Further, as a condition of receiving any or all of the Coded Data Set, each Recipient shall agree in writing that such data is provided "as is" with no warranties or guarantees of any kind offered by Northwestern University and the THEW, and shall waive any and all claims of any kind against Northwestern University and the THEW arising out of such Recipient's use of the Coded Data Set.

11. Parties to this Data Use Agreement will agree to use and/or disseminate data in compliance with applicable consenting documents, the Privacy Rule enacted pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and all other applicable privacy laws and regulations, safeguarding subjects' privacy and confidentiality. No Recipients will be allowed to disseminate the Coded Data Set to individuals or entities not directly affiliated with and under the control of the Recipient contracting with University of Rochester on behalf of THEW for purposes of obtaining some or all of the Coded Data Set, and no uses of the Coded Data Set, other than those approved by the ad hoc committee will be allowed.

12. 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.

13. User will indemnify, defend and hold harmless THEW and the University of Rochester from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorneys fees) arising out of or in connection with the use of all or any portion of the THEW data by the User or any of its subcontractors, agents, employees or other assigns.

14. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in section 5.

15. On behalf of the User the undersigned individual hereby 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 Individual - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone and Fax No., and 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)

Data Release Form to be signed by each user of the DEFINITE dataset through the THEW.

I, _____, understand that by signing this agreement that:

- 1) I do not obtain any title (data ownership) in any of the data furnished by THEW, and
- 2) there may be errors in the Coded Data Set.

Furthermore I acknowledge by signing this document that the data (E-HOL-0401-013) is provided “as is” with no warranties or guarantees of any kind offered by Northwestern University and the THEW, and I shall waive any and all claims of any kind against Northwestern University and the THEW arising out of such Recipient’s use of the Coded Data Set.

(Name and Title of Individual - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone and Fax No., and E-Mail Address)

(Signature)

(Date)
