

Terms and Conditions Agreement for Use of Data in the Friedreich's Ataxia Integrated Clinical Database

For accessing and using data within the Friedreich's Ataxia Integrated Clinical Database:

Terms and Conditions

I request access to data contained within the Friedreich's Ataxia Integrated Clinical database ("FA-ICD"), administered by Critical Path Institute ("C-Path") and sponsored by the Friedreich's Ataxia Research Alliance ("FARA"), and agree to the following terms and conditions for using the data:

1. I will not attempt to establish the identity of, nor make contact with, any of the study subjects.
2. I will not disclose these data beyond the use(s) specifically outlined in my Data Access Request.
3. I will require anyone with whom I share these data to comply with the terms and conditions detailed in this agreement
4. I have accurately provided all information in the Data Access Request regarding persons who will use these data and the analyses that are planned using these data.
5. I will comply with any rules and regulations imposed by my institution and its institutional review board in requesting and using these data provided that they do not conflict with the terms and conditions detailed in this agreement.
6. I will comply with any applicable regulations that govern in the location where the data are held by the recipient.
7. I will not sell, rent, transfer, redistribute or otherwise disclose to unauthorized persons any of the data comprising FA-ICD.
8. I will not attempt in any way to patent know-how, knowledge, algorithms or other intellectual property generated by the use of these data.
9. I will ensure that any authorized individuals with whom I share the FA-ICD data will use appropriate administrative, physical and technical safeguards to prevent the unauthorized use or disclosure of the data other than as provided for by this Agreement.
10. In the case of unauthorized access and/or use or disclosure of the data not provided for by this Agreement, I will notify C-Path as soon as practicable but not later than five (5) days of becoming aware of such use or disclosure.
11. I acknowledge that neither FARA nor C-Path make any representation or warranty, express, implied, statutory, or otherwise with respect to the FA-ICD or the data contained therein.
12. I acknowledge that neither FARA nor C-Path, nor any of their respective directors, officers, employees, agents, or affiliates shall have any liability to me as a result of my use of the FA-ICD or any of the data contained therein (whether as a result of direct, indirect, incidental, special, exemplary, punitive, consequential or other damages) however caused and on any theory of liability. This limitation will apply even if I have been advised of the possibility of such damage.

13. By accessing FA-ICD, I agree to indemnify, defend and hold harmless FARA and C-Path and each of their respective directors, officers, employees, agents and affiliates (each an “indemnified party” and collectively, the “indemnified parties”), from and against any and all liabilities, losses, damages, costs and expenses (and all legal costs including reasonable attorneys’ fees, court costs, expenses and settlements resulting from any action or claim) incurred by, or asserted against any indemnified party arising from or relating to any claim or action brought by a third party that arises from or results from my use of FA-ICD and/or my possession and use of any data obtained from FA-ICD, whether by download or otherwise. If any such claim or proceeding arises, the applicable indemnified party shall give written notice of the claim to me promptly after the indemnified party receives notice of its existence. I shall have the right, at my expense, to employ counsel to defend against the claim, and to compromise, settle or otherwise dispose of the claim, all at my expense, provided that no compromise or settlement of any claim admitting liability of or imposing duties or performance upon any indemnified party may be effected without the prior written consent of such indemnified party. If I do not initiate efforts to defend against or resist the claim within thirty (30) calendar days after receiving notice from any indemnified party, the indemnified party shall be free to investigate, defend, compromise, settle or otherwise dispose of the claim and incur other costs in connection therewith, for the account and at my expense, in such manner as the indemnified party deems in its best interest.

14. Abstract publications:

14.1 If I publish abstracts using data from FA-ICD, I will cite the Friedreich’s Ataxia Integrated Clinical Database as the source of the data.

14.2 If I publish abstracts using data from FA-ICD, I will acknowledge use of data from the Friedreich’s Ataxia Clinical Outcome Measure Study conducted by the investigators of the Collaborative Clinical Research Network in Friedreich’s Ataxia.

14.3 Group authorship of the Friedreich’s Ataxia Integrated Clinical Database is not required to be cited in the authorship line of the abstract.

15. Publication of manuscripts:

15.1 If I publish manuscripts using data from FA-ICD, I will include the phrase “for the Friedreich’s Ataxia Integrated Clinical Database*” on the author line of the manuscript, after the named authors, with the asterisk referring to the following statement:

“*Data used in the preparation of this article were obtained from the Friedreich’s Ataxia Integrated Clinical Database administered by the Critical Path Institute and funded by the Friedreich’s Ataxia Research Alliance. The Friedreich’s Ataxia Research Alliance and the Critical Path Institute contributed to the design and implementation of the database, but did not participate in the analysis of the data or the writing of this report. We acknowledge use of data from the Friedreich’s Ataxia Clinical Outcome Measure Study conducted by the investigators of the Collaborative Clinical Research Network in Friedreich’s Ataxia, as well as data from placebo arms from clinical trials.”

15.2 If I publish manuscripts using data from FA-ICD, I will include language similar to the following in the methods section of my manuscripts to accurately acknowledge data gathered by FARA:

“Data used in the preparation of this article were obtained from the Friedreich’s Ataxia Integrated Clinical Database administered by Critical Path Institute. The Friedreich’s Ataxia Research Alliance, a non-profit organization dedicated to advancing research and treatments for Friedreich’s ataxia, sponsored this database.”

15.3 I will submit all manuscripts to the FA-ICD steering committee prior to submitting them to a journal. This review will be for both scientific content and to ensure that the acknowledgements required in items #15.1 and 15.2 above are correctly implemented. FARA will maintain confidentiality of the manuscript until the publication date and will complete its review within two weeks of receipt.

15.4 I agree that, after review by the FA-ICD steering committee of the material presented, I will not make any changes to content relating to FARA, C-Path or FA- ICD without securing approval from the steering committee. I also agree to submit the material to a peer reviewed publication within six months of said review.

15.5 I agree to inform FARA of the publication reference within three months of the material being published.

16. I agree to allow my institution/organization name and a brief description of proposed research or study to be made publicly available.

IMPORTANT NOTE: It is the policy of C-Path to add additional data as it becomes available. I understand that any processed data that I download may be preliminary and my results may change as new data are added.

17. If I download data from FA-ICD for the purposes of analysis and future publication in the form of abstracts and/or publications, I will note the date of the download, and I will check the database to determine if updated data have been provided prior to submission of any material for publication.

By accepting this agreement, I confirm my understanding that failure to abide by these terms and conditions will result in termination of my access to FA-ICD data.