

Project leader: _____ Date: _____
Last name, first

Project title: _____

**NICER DATA USE AGREEMENT (DUA)
FOR PROJECT LEADER**

An approved final copy of your NICER-related research request must be submitted with this DUA.

Introduction

The Foundation National Institute for Cancer Epidemiology and Registration is hereafter referred to as NICER. The project leader, responsible for completing DUA if third party (i.e. non-NICER personnel), is defined as any one of the following: responsible investigator/requestor, first and/or senior/last authors as defined in the attached approved NICER-related research request. Please note in the case of students and fellows, the department chair or advisor from the student's academic institution must also sign the DUA. Projects designed to be ongoing with specific individual agreements (i.e. those with uniquely created study documents) documenting principles of collaboration between NICER and a third party are not required to complete a separate NICER DUA. Otherwise a completed DUA is required from all third party projects approved by NICER for data use.

This DUA relates exclusively to data use as specified in the attached approved NICER-related research request. NICER data may involve two distinct categories of data: NICER only data and NICER plus data. NICER only data refers to use of any pooled portion of the NICER database held by the coordinating centre (NCC) under NICER-registry contract agreement. Whereas NICER plus data refers to requests proposing use of any portion of the pooled NICER database plus any additional data outside these (i.e. any data not contained in the NICER database; e.g. date-of-birth for linkage study, treatment variables for pattern of care study).

Information regarding persons with cancer is sensitive. Therefore, specific data handling precautions and laws have been enacted to insure the confidentiality of individuals included in cancer registry data in Switzerland. In utilizing NICER data on such individuals for research purposes, it is absolutely necessary to ensure that uses of data will be limited to only NICER approved research activities. Uses for any other reason, particularly those resulting in personal disclosures are strictly forbidden. In addition, collection, use and/or release of any information about providers (i.e. the physicians and hospitals that provide care for cancer patients) may compromise the willingness of these providers to cooperate with the activities of the cantonal cancer registries. Therefore, considerations regarding the privacy of providers are equally important.

In order for the NCC to provide your requested NICER data, it is necessary that you agree to the following provisions:

1. You agree that the statements and methods made in your attached approved NICER-related research request are complete and accurate.
2. You have applied for and received the necessary ethics committee approval to conduct your research and provided written documentation of approval to NCC.
3. You agree to conduct all research utilizing NICER data in accordance with the “NICER Guidelines for Scientific Collaboration, Publication, and Authorship”.
4. You will not use NICER data for any purposes other than those described in your attached approved NICER-related research request.
5. You will not permit others to use the requested NICER data except for collaborators involved with the research as described in your attached approved NICER-related research request. Within your institution or organization, access to the NICER data shall be limited to the minimum number of individuals necessary to achieve the purpose stated in your attached approved NICER-related research request.
6. You will establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the NICER data and to prevent unauthorized use or access to it. You will provide NCC with written documentation of safeguards employed. You agree to allow NCC, at their discretion, to conduct onsite inspections to ensure compliance with the data storage/confidentiality/security policies.
7. You agree not to place the NICER data on personal computers, portable devices, and removable media unless these media are password protected AND encrypted. Portable devices include any non-fixed equipment that contains an operating system which may be used to create, access, or store NICER data. This includes but is not limited to laptops, personal digital assistants (PDAs), and smart phones. Removable media include, but are not limited to CDs, DVDs, MP3 players, removable memory, and USB drives (thumb or flash drives). You may use an institutionally provided VPN to link to a time sharing system for data access. The home based PC may support the VPN. Any NICER data taken off the time sharing system and placed on a home based computer must also be password protected AND encrypted.
8. In the event that NICER data are lost or stolen, you agree to report the loss to NCC within 24-hours/first business day of discovering the loss.
9. All NICER data must reside at your institution under your purview. If you plan to move to a different institution, you must contact NCC in writing prior to moving for instructions on how to handle the NICER data. You may not duplicate any files containing NICER data prior to moving nor can you take NICER data with you without written permission from NCC. If you chose not to take the NICER data with you, you must destroy the files or designate a new project leader at your institution. Prior to moving you must notify NCC in writing confirming the data were destroyed and/or by having the new project leader submit a DUA.

10. You will not attempt to link nor permit others to link the NICER data with individually identified records in another database without approval (as described in NICER-related research request) from NCC and the applicable cantonal registries.
11. No one having access to the NICER data will attempt to learn the identity of any persons with cancer in these data and/or their physicians or treating hospitals. In the event that you discover or are able to deduce the identity of a specific patient or provider, you agree that you will not attempt to use the individual information or contact these individuals or institutions.
12. No findings or information derived from the NICER data may be released if such findings contain any combination of data elements that might allow the deduction of patient or provider identity. In results tables, cell sizes less than 11 (eleven) must be suppressed. You agree that NCC and applicable cantonal registries shall be the sole judge as to whether any finding derived from the NICER data would, with reasonable effort, permit anyone to identify an individual or provider, or to deduce the identity of an individual or provider with a reasonable degree of certainty.
13. You agree to provide NCC with a copy of all manuscripts to be submitted for publication prior to submission. You further agree not to submit such findings to any third party until receiving NCC approval to do so. NCC agrees to make a determination about approval and to notify the project leader within 20 business days after receipt of any findings. NCC review of the findings is for the sole purpose of assuring that data confidentiality is maintained and that individual patients and/or providers cannot be identified. NCC and/or applicable cantonal registries may withhold approval for publication only if they determine that the format in which data are presented may result in potential identification of individual patients and/or providers.
14. You agree that in the event NCC and/or any applicable registry determines or has a reasonable belief that you have violated any terms of this agreement NCC may request that you return the data and all derivative files to NCC. You understand that the result of determination or reasonable belief that a violation of this agreement has taken place, NCC may refuse to release further NICER data to you.
15. All files received from NCC may be retained for a maximum of five years. At the completion of the project or five years from receipt all files containing NICER data must be destroyed and notification of destruction must be sent to NCC. Investigators who need to retain files beyond that period must contact NCC for approval .

Signature of Project Leader

Your signature indicates that you agree to comply with the above stated provisions. Deliberately making a false statement regarding any matter herein is punishable by applicable law.

Name (printed or typed)

Institution/Organization

Street Address

Post code/City

Phone number

Fax number

Email address

Signature

Date