

PROCEDURE FOR SUBMISSION OF DATA TO THE RESOURCE FACILITY FOR POPULATION KINETICS

The Resource Facility for Population Kinetics (RFPK) is a NIH-funded research resource at the Department of Bioengineering at the University of Washington. RFPK’s mission is to improve the quality of research in the biomedical community by: developing new mathematical and statistical theories and algorithms related to population modeling; developing, promoting and distributing innovative population modeling software products incorporating these theories and algorithms; educating the biomedical research community in population modeling; and disseminating population modeling methodologies in the biomedical and other disciplines.

One of the ways RFPK accomplished its mission is through collaborative projects. This document was developed at RFPK and the University of Washington for the purpose of insuring compliance by the biomedical investigators collaborating with RFPK (the “Collaborators”) with established Institutional Review Board (IRB) practices and rules regarding the collection, analysis and dissemination of human and animal data for the purpose of biomedical research. At the same time, this document allows to establish a mechanism for the controlled exchange of specific biomedical data (hereafter the “Data”) between the Collaborators and the RFPK.

Upon receipt of the Data, RFPK will subject them to mathematical modeling analyses of various kinds for the purpose of furthering the body of knowledge about various health and disease states. Results may be included in the RFPK Annual Progress Report to NIH.

Data should be sent to RFPK only if all the following six conditions are met:

- 1) The Collaborator willingly gives permission for release and exchange of the Data to RFPK for the purpose of biomedical research, and he/she thus states that he/she has the authority to do so.
- 2) The Data must have been properly anonymized, and no patient ID, study code, date or identifying information whatsoever is included that may help identifying the individual subjects or linking the data back to the individual subjects.
- 3) The Data must be sent to the RFPK project not only without identifiers, but also in a manner always consistent with the human subjects’ protocols used in the original studies.
- 4) The Data must have been obtained in compliance with the Collaborator’s institution’s IRB approval process for human or animal subjects, including management of adverse events, and proof of this will be furnished to UW or RFPK agents upon request.
- 5) The Collaborator must be aware that whatever may be discovered during RFPK’s analysis of the Data is not intended for clinical use and may not be used in patient care without FDA approval.
- 6) The Collaborator must be aware that no funds are due to either him/herself or his/her institution in exchange for the Data, and no benefits are anticipated to individual study subjects.

Please fill all fields in the form below and fax this document to +1-206-543-3081 or return to: Mary Smith, RFPK Program Manager, Department of Bioengineering, AERL 241, Box 352255, University of Washington, Seattle, WA 98195-2255, United States. You may also send an electronic mail message with the same information to mchsmith@u.washington.edu. Only one such document is necessary per collaborative project.

TO: THE PRINCIPAL INVESTIGATOR OF THE RESOURCE FACILITY FOR POPULATION KINETICS

FROM: (Name; First, Last)
(Institution or Company)
(Address)
(City)
(State or Province)
(ZIP code)
(Country)
(Phone with country and area code)
(E-mail)

- I plan to share with RFPK personnel human animal data (please check one or both).
- The Data can can not be published on the RFPK website, <http://www.rfpk.washington.edu>.
- The funding source under which the Data were gathered was federal industry other (please check one).
- If NIH funded: the Data were collected under the sponsorship of Grant(s) # _____
- Brief description of the data: _____

The undersigned has read and understood the conditions under which biomedical data can be sent to RFPK.

DATED at _____ on _____. _____ Signature _____ Printed name	RECEIVED at RFPK on _____. _____ Signature _____ Printed name
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