

Instructions for subscribing to the DIDB Platform - EDUCATION/GOVERNMENT SUBSCRIPTION AGREEMENT

The DIDB Platform which includes the Metabolism and Transport Drug Interaction Database™ (DIDB®) and the Pharmacogenetics Database (e-PKGene®) is made available as part of the University of Washington Express Licensing program. You will find the license fee structure for DIDB Database identified in Schedule B of the attached license agreement. To license the DIDB Platform, please do the following:

1. To complete the license, please:
 - a. Print the attached license agreement form and any required schedules.
 - b. Complete the contact information on page 1 of the Agreement and Organization Information Table in Schedule B, and description of proposed use in Schedule D.
 - c. Have the license signed by an authorized representative prior to the expiration date stated in the license agreement.
 - d. Return the completed agreement to license@uw.edu or fax to (206) 616-3322. You may also send a Purchase Order (if desired) at this time. For purchasing questions, please contact Express Licensing Program at (206) 543-3970 or license@uw.edu.
2. UW will review the license, and if everything is in order, you will receive a copy of the executed agreement and an invoice. The invoice will include a license agreement number.
3. Make check payable to: University of Washington.

Please indicate the license number and invoice number on your check. Wire transfer is also available, subject to a \$30 fee. You must follow the instructions on the invoice in order to pay with a wire transfer.

4. Please mail the license fee to:

ATTN: Express Licensing Program
Agreement Reference # 2564
UW CoMotion
University of Washington
4545 Roosevelt Way NE, Suite 400
Seattle, WA 98105

5. Access to DIDB will begin after UW executes and sends the Agreement to you. The date that UW provides access to the Database to you will be the first date of your year of access to the Database.

You may contact our office if you have any questions about this process.

Express Licensing Program
UW CoMotion Innovation Development
Phone: 206.543.3970 Fax: 206.616.3322
Email: license@uw.edu

**Drug Interaction Database Subscription Agreement:
Education/Government Subscription Agreement**

The University of Washington, a public institution of higher education having administrative offices at 4545 Roosevelt Way NE, Suite 400 Seattle, Washington 98105 (“UW”) and _____, with its administrative offices at _____ (“Subscriber”) agree as follows, effective as of the latest date upon which this Metabolism and Transport Drug Interaction Database: Education/Government Subscription Agreement (“Agreement”) is fully executed (“Effective Date”):

Background

UW desires to make available a drug interaction database (“Work”), developed by Professor René Levy and others in UW’s Department of Pharmaceutics, Metabolism and Transport Drug Interaction Database Project Team, School of Pharmacy (“DIDB Platform Team”).

Subscriber is an organization involved in graduate education, teaching and research on the development of pharmaceutical drugs, or a government department or agency, and desires access to Work for Authorized Users under the direction of _____ (“Faculty/Researcher”) and the concurrence of the Chair/Director of the Subscriber Department _____ (“Chair/Director”) to support its program of activities as described in Schedule D.

Definitions

“Agreement” means this Subscription Agreement, with attached Schedules.

“Authorized User” means current employees or graduate students of the Subscriber, who meet the following qualifications: they are working under the supervision of the Faculty/Researcher for the non-commercial activity as described below; they are permitted to access the DIDB Platform from within Subscriber’s premises or from such other places where Users occasionally perform their work or research for the Subscriber; they are conducting work for the Subscriber’s non-commercial benefit; they have been notified of the disclaimers in the Agreement; and, they have been given a password by Subscriber.

“Contact” means individual authorized by Subscriber to receive notices from UW of an administrative nature. Technical Contacts shall be those listed on Schedule B. The administrative Contact for Site shall be:

Name: _____ Phone: _____

Email: _____ FAX: _____

“Delivery Date” means the date that UW provides access to Work to Subscriber. The Delivery Date shall occur within five (5) business days of Effective Date.

“Education” institution means a single department of a not-for-profit higher education institution whose Authorized Users are employees or students enrolled in a graduate program in Pharmaceutical Science or related fields, and who access Work solely for non-commercial educational purposes and activities as described in Schedule D.

“Government” means a single governmental agency studying or involved in pharmaceutical research or governance, which accesses the Work for non-commercial purposes as described in Schedule D.

“License Fee” shall mean the amount due for the permissions herein from Subscriber under this Agreement as set forth on Schedule B.

“Site” means a single street address, building, single campus, or other single geographic location of the organization at which Authorized Users who have access to Work are usually located. Sites authorized to access Work are listed on Schedule B.

“Work” means the Metabolism and Transport Drug Interaction Database™ (DIDB) and Pharmacogenetics Database (e-PKGene®) as specified in Schedule A “Work”.

Permission

Commencing on Effective Date, UW hereby grants to Subscriber, and Subscriber accepts, a limited, non-transferable, non-exclusive license to display, query and view results from Work at the access level designated in Schedule B for internal purposes and provided Subscriber complies with the terms of this Agreement, including Schedule C, "Information for Users."

Authorized Users may print output from the Work, provided such printouts are primarily for use by individuals as part of their internal practice and provided that the printouts are not a substantial portion of the Work. **Subscriber’s Authorized Users shall not download substantial portions of the Work for any purpose, including local storage or use.**

Notwithstanding the foregoing Subscriber shall be entitled to use the DIDB Platform within the scope and under the supervision of the Subscriber Faculty/Researcher for the program/activities in Schedule D.

Conditions

Subscriber acquires no proprietary interest in Work.

Subscriber shall not remove or obscure rights management markings, such as copyright notices and patent numbers, from Work or printouts from Work.

Subscriber shall not sublicense, sell, display, lend, rent, lease or otherwise transfer all or any of Work.

Subscriber provides UW with a short description of the non-commercial, internal activities related to the Subscriber’s intended use of the Work to be included in this Agreement at Schedule D.

Only Authorized Users may access Work, and access to Work is not granted for any third party purpose.

Subscriber agrees not to access or download any portion of the Work using automated polling systems and Subscriber agrees not to download, retain, or reproduce substantial portions of the Work, whether by automated polling systems, manual execution of sequential queries, or any other means.

Subscriber acknowledges and agrees to UW review of the access logs and queries of Subscriber's Authorized Users. UW review of the access and queries shall be at the sole discretion of UW.

Subscriber shall notify in writing each Authorized User of the disclaimers provided in Agreement regarding information contained in Work and restrictions for purpose of access to Work by providing Schedule C, "Information for Users," to all Authorized Users.

Subscriber agrees to acknowledge that the Work is the intellectual property of the University of Washington and Copyright in the Work shall be cited in all output from the Work and/or in any reference to the output from the Work as follows: "Copyright University of Washington, UW Metabolism and Transport Drug Interaction Database, accessed: [Fill in appropriate date information]"

Subscriber agrees that UW may publically acknowledge the license relationship between the Subscriber and UW, provided that UW Party does not use the logo, trade/service marks of the Subscriber without the Subscriber's prior written approval.

Subscriber acknowledges that the Work is provided AS IS for information and educational purposes only and that any analyses, reports and other information contained in or produced as a result of the Work and searches of the Work are intended as a supplement to, and not a substitute for, the knowledge, expertise, skill and judgment of Authorized Users.

Subscriber acknowledges that the Work is limited to information sources and data related solely to metabolism and transport. All other mechanisms of drug interaction are expressly not included and SUBSCRIBER'S RELIANCE UPON WORK IS SOLELY AT SUBSCRIBER'S OWN RISK.

Subscriber shall promptly notify UW of Subscriber's involvement in any merger, acquisition, or change in the organizational reporting, educational or government status of the Subscriber that would have an effect on the qualification of the Subscriber for this Agreement and the Licensee Fee.

Subscriber shall not access Work or provide information from Work for any patient treatment.

Feedback and Training

Subscriber may request and implement a new password to Work as necessary, such as termination of an Authorized User.

UW may contact Subscriber's Authorized Users to request feedback on use of Work to assist in development of Work at mutually convenient times, up to a limit of five (5) hours annually, unless Subscriber authorizes additional time.

Subscriber may wish to arrange with the DIDB Platform Team for training and additional information and examples of searches of the Work. The training shall be at mutually convenient times and venue. Contact the DIDB Platform Team for training and feedback related to the Work at the following address: didbase@uw.edu

Subscription For one (1) year from Delivery Date, UW shall endeavor to correct program defects as identified by UW relating to Work's operation, to provide periodic updates to the content of Work as these are prepared by the DIDB Platform Team, and to provide to Subscriber instructions in response to inquiries made in the form of electronic mail to UW at the following address: didbase@uw.edu

Delivery UW shall provide Subscriber access to Work by means of password and Internet address for Work. Delivery is authorized by Subscriber to be made to the Technical Contact, who shall serve as Subscriber's Technical Contact for UW with respect to Work. UW shall contact Technical Contact within five (5) business days of receipt of payment to arrange for initial training Work orientation phone call.

Payment Subscriber shall pay to UW License Fee as set forth on Schedule B, due upon execution of this Agreement. Should payment not be received from Subscriber by UW within ninety (90) days of Effective Date, UW, at its sole discretion, may terminate this Agreement without notice.

Term This Agreement shall expire one (1) year from the Effective Date ("Term") and may be renewed annually, provided UW sends Subscriber an invoice for one (1) year of service, and Subscriber's timely payment of the License Fee is received by UW.

Termination Provided Subscriber has paid License Fee; Subscriber may terminate this Agreement at any time upon thirty (30) days written notice to UW. UW shall not refund to Subscriber any portion of License Fee received by UW for early termination.

UW may terminate this Agreement upon notice if Subscriber is in breach of this Agreement and fails within thirty (30) days of a written demand for performance to cure such breach. After notice period elapses, access to Work will be immediately terminated.

The provisions under which this Agreement may be terminated shall be in addition to any and all other legal remedies which either party may have for the enforcement of any and all terms hereof, and do not in any way limit any other legal remedy such party may have.

Termination of this Agreement shall terminate all rights and permissions granted to Subscriber relating to Work. The obligation to pay any required License Fee survives termination of this Agreement.

Disclaimers The Work has been developed as part of research conducted at the University of Washington. The Work is experimental in nature and is made available "AS IS," without obligation by UW to provide accompanying services or support except as specified in this Agreement. The entire risk as to the quality and performance of the Work is with Subscriber.

Subscriber acknowledges that the intended audience for the Work is researchers knowledgeable in drug interactions, and that no clinical use of the Work is intended or allowed by this Agreement.

Subscriber acknowledges that the Work is solely a selected compilation of publicly available literature, and UW makes no warranty on the accuracy, validity, completeness

or availability of information cited in the Work. The information contained in the Work is intended as a supplement to, and not a substitute for, the knowledge, expertise, skill and judgment of Authorized Users. The absence of a warning for a given drug or drug combination should not be construed to indicate that the drug or drug combination is safe, appropriate or effective in any given patient.

Subscriber acknowledges that UW is an agency of the state of Washington and has obligations to maintain public records under RCW 42.56 et seq. If UW receives a public disclosure request for Subscriber's database access records related to Work or any part thereof, UW shall notify Subscriber of the request. UW, at its sole discretion, can respond to the request. If UW releases any Subscriber database access records through an operation of law, the release shall not be deemed a breach of this Agreement.

UW EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, PERTAINING TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF WORK OR ANY SUBJECT MATTER OTHERWISE PROVIDED TO SUBSCRIBER UNDER THIS AGREEMENT.

Indemnification To the extent allowed by law, Subscriber shall indemnify and hold harmless UW, and its regents, Work developers, employees, students, and agents, harmless from all suits, actions, claims, losses, damages, costs, fees, and expenses resulting from Subscriber's possession and/or use of Work, including but not limited to any damages, losses, or liabilities whatsoever with respect to death or injury to any person and damage to any property. This indemnification clause shall survive the termination of this Agreement.

General This Agreement shall be construed in accordance with, and its performance shall be governed by, the laws of the State of Washington, United States. Any suit, action, or proceeding arising out of or relating to this Agreement shall be decided in King County, Washington, U.S.A. Subscriber accepts the venue and jurisdiction of the Federal District Court of Western Washington, Seattle, or the King County Superior Courts. The application of the United Nations Convention for contracts for the International Sales of Goods is hereby expressly excluded.

Notices hereunder shall be delivered by hand, air courier express, or certified mail with return receipt requested to the address of the Subscriber identified as the Contact, and shall be deemed delivered three (3) days after mailing.

No omission or delay of either party hereto in requiring due and punctual fulfillment of the obligations of any other party hereto shall be deemed to constitute a waiver by such party of its rights to require such due and punctual fulfillment, or of any other of its remedies hereunder. Amendments to this Agreement must be in writing, reference this Agreement, and must be signed by duly authorized representatives of UW and Subscriber. Headings are provided for convenience only.

If any provision of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not be in any way affected or impaired thereby.

This Agreement and the rights and benefits conferred upon Subscriber hereunder may not be assigned or otherwise transferred by Subscriber without the prior written consent of UW. This Agreement may be assigned by UW.

Failure of UW to perform or delay in the performance of UW's obligations under this Agreement due to any cause or event not reasonably within UW's control, including but not limited to casualty, labor disputes, failure of equipment, compliance with government authority or Act of God, shall not constitute a breach of this Agreement, and UW's performance shall be excused during such delay.

This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations, or understandings, either oral or written, between the parties relating to the subject matter hereof.

UW and Subscriber have executed this Agreement by their respective duly authorized representatives on the dates given below.

Subscriber:

By: _____
Name: _____
Title: _____
Date: _____

University of Washington:

By: _____
Name: _____
Title: _____
Date: _____

Subscriber's Faculty/Researcher Concurrence:

By: _____
Name: _____
Title: _____
Date: _____

Subscriber's Chair/Director Concurrence:

By: _____
Name: _____
Title: _____
Date: _____

UW Metabolism and Transport Drug Interaction Database Subscription Agreement

Schedule A

Work

The Metabolism and Transport Drug Interaction Database™ (DIDB®) and the Pharmacogenetics Database (e-PKGene®) are part of the knowledge base (“DIDB Platform”) designed for scientists and clinicians working in the field of drug metabolism and drug interactions. The DIDB Platform was developed at the University of Washington's Department of Pharmaceutics, School of Pharmacy with input from pre- clinical and clinical researchers in industry. It has been licensed since 2002 and is currently used by pharmaceutical companies, regulatory agencies, contract research organizations and academic institutions worldwide.

The DIDB Platform has the largest manually curated collection of data related to drug interactions in humans. The platform includes specific data and results from peer-reviewed journal articles referenced in Medline, reference textbooks, guideline documents, FDA Prescribing Information, and NDA Reviews. Both *in vitro* and *in vivo* drug interaction studies are included in the database, making it useful to pre- clinical and clinical scientists. PK Profiles of drugs, QT Prolongation data, including results of TQT studies from recent NDAs, as well as Regulatory Guidances and Editorial Summaries/Syntheses can also be found.

Information from new articles and NDAs is selected, analyzed, and added to the Database every day by research scientists with PhD, PharmD, or MD degrees. Users can search the Database using a large number of queries and approach the data from many different perspectives. In addition, database scientists are available for online assistance (complex searches, summaries on topics of interest).

With the recent addition of organ impairment data and e-PKGene as of 2013, the DIDB Platform contains several datasets that are critical for evaluating the exposure of drugs and metabolites in various important clinical situations:

- Drug-Drug (but also herbals, food products) Interaction data in humans (includes *in vitro* and *in vivo* data);
- Disease-Dug Interaction data: difference in drug exposure in renally- and hepatically- impaired subjects versus those with normal renal or hepatic function;
- Pharmacogenetic-Drug Interaction data: impact of genetic variants of enzymes and transporters on the pharmacokinetic responses to drugs and metabolites.

**UW DIDB Platform
Subscription Agreement**

**Schedule B
License Fee and Contact Information**

Education	<i>Key Restrictions:</i> For a single department’s graduate students and faculty to use for internal educational purposes only at a single Site; no commercial, clinical or third party use or access
Government	<i>Key Restrictions:</i> For a single agency for non-commercial purposes
Annual Subscription Fee: \$2,894	

License Fee and Contact Information

Payment Information

With each payment, Subscriber shall indicate the number of Sites for which Work is licensed and the appropriate royalty calculation.

Payment shall be made in U.S. dollars by check or money order to University of Washington:

ATTN: Express Licensing Program
 UW CoMotion
 University of Washington
 4545 Roosevelt Way NE, Suite 400
 Seattle, WA 98105
 Phone: (206) 543-3970 Fax: 206-616-3322

Remember to indicate the license number and invoice number on your check. Wire transfer is also available subject for an additional \$30 fee to be added to the payment.

Subscriber shall be responsible for any charges, taxes and/or customs duties associated with payments made under this Agreement.

Organization Information Table	
Education & Government	Technical Contact
Subscriber: _____	Name: _____
Government Department: _____	Title: _____
	Phone: _____
	Fax: _____
	Email: _____

**DIDB Platform
Education/Government Subscription Agreement
Schedule C
Information for Users**

Your Educational Institution/Government Department is a Subscriber to University of Washington's, DIDB Platform which includes the Drug Interaction Database™ (DIDB®) and the Pharmacogenetic Database (e-PKGene®). Subscribers are required to notify Authorized Users of the disclaimers and restrictions related to the DIDB Platform.

You have been provided this information sheet because you are an Authorized User under the terms and conditions of the DIDB Platform Education/Government Subscription Agreement. The information outlines conditions on use of the DIDB Platform.

Authorized User(s):

- Only an Authorized User(s) may access and use the DIDB Platform and no access can be granted for any third party purpose.
- Authorized Users are defined as current employees or graduate students of the Subscriber, who meet the following qualifications: they are working under the supervision of the Faculty/Researcher for the non-commercial activity as described below; they are permitted to access the DIDB Platform from within Subscriber's premises or from such other places where Users occasionally perform their work or research for the Subscriber; they are conducting work for the Subscriber's non-commercial benefit; they have been notified of the disclaimers in the Agreement; and, they have been given a password by Subscriber ("User(s)/Authorized User(s) You").

Use:

- **Subscriber desires to provide access to the Work to support Subscriber programs and activities as described below:**

- Users may display, query, and view results from the DIDB Platform.
- Users may not sublicense, sell, publicly display, lend, rent, lease or otherwise transfer all or any of the DIDB Platform.
- **Users may not allow any patient or non-Authorized User access to the DIDB Platform. The DIDB Platform has not been designed or created for the purpose of patient use. The intended use of the DIDB Platform is research by professionals in pharmaceutical research who are knowledgeable in drug interactions.**
- **Users acknowledge that the DIDB Platform is provided AS IS for information and educational purposes only and that any analyses, reports and other information contained in or produced as a result of the DIDB Platform and searches of the DIDB Platform are intended as a supplement to, and not a substitute for, the knowledge, expertise, skill and judgment of health care professionals.**

Downloading:

- Users may download portions of the DIDB Platform.
- Users may save individual articles displayed in the DIDB Platform format on their desktop for temporary use. Users shall remove such portions of the DIDB Platform and/or articles displayed in the DIDB Platform format as soon as practicable.
- Users shall NOT access or download any portion of the DIDB Platform using automated polling systems. Users shall NOT download, retain, or reproduce substantial portions of the DIDB Platform, whether by automated polling systems, manual execution of sequential queries, or any other means.
- Users shall not share the DIDB Platform with anyone other than other Authorized Users. Users may not send downloaded or printed portions of the DIDB Platform to external contacts, clients or other persons who are not Users.
- Users may not download the entire DIDB Platform or substantial portions of the DIDB Platform for any purpose, including local storage or use.
- Users may print output from the DIDB Platform provided the printouts are for internal use and do not constitute a substantial portion of the DIDB Platform.

Printing

- Users may print output from the DIDB Platform provided the printouts are for internal use or are for Subscriber communication and do not constitute a substantial portion of the DIDB Platform.

Intellectual Property and Copyright:

- The DIDB Platform including the Drug Interaction Database and Pharmacogenetic Database is the intellectual property of the University of Washington.
- Copyright in the Work shall be cited in all output from the Work and/or in any reference to the output from the Work as follows: a) for DIDB: "Copyright University of Washington. UW Metabolism and Transport Drug Interaction Database, accessed: [Fill in appropriate date information] ..."; and for ePKGene: "Copyright University of Washington. UW Pharmacogenetic Database (e-PKGene®) accessed: [Fill in appropriate date information] ..."
- Any use of the Work by the Subscriber's Authorized Users in publications shall include a citation to the DIDB as a footnote and/or in the reference or acknowledgment section as follows: "This information is based on or an extract from the UW Metabolism and Transport Drug Interaction Database (DIDB), Copyright University of Washington. DIDB Accessed: [Fill in appropriate date information]; and "This information is based on, or an extract from, the UW

Pharmacogenetic Database (e-PKGene®), Copyright © University of Washington. Accessed: {Fill in appropriate date information}.

- In licensing the DIDB, Subscriber does not acquire any proprietary interest in the DIDB.
- Users may not remove or obscure rights management markings, such as copyright notices and patent numbers, from the DIDB Platform or from any printout from the DIDB Platform.

Disclaimers:

- The DIDB Platform has been developed as part of research conducted at the University of Washington.
- The DIDB Platform is experimental in nature and is made available “AS IS,” without obligation by UW to provide accompanying services or support except as specified in this Agreement. The entire risk as to the quality and performance of the DIDB Platform is with Subscriber.
- **The intended audience for the DIDB Platform is researchers knowledgeable in drug interaction, and Subscriber agrees not to allow any Patient or non-Authorized User access to the DIDB Platform.**
- The DIDB Platform is solely a selected compilation of publicly available literature, and UW makes no warranty on the accuracy, validity, completeness or availability of information cited in the DIDB Platform.
- The information contained in the DIDB Platform is intended as a supplement to, and not a substitute for, the knowledge, expertise, skill and judgment of Users.
- The absence of a warning for a given drug or drug combination should not be construed to indicate that the drug or drug combination is safe, appropriate or effective in any given patient.

Contact for Questions and Information on the Subscription Agreement:

The Drug Interaction Database Platform (DIDB Platform) is made available through a Subscription Agreement between your organization and the University of Washington and use of the DIDB is defined by the terms and conditions of the Subscription Agreement. For additional information on the Subscription Agreement, please contact:

Contact name: _____
Title: _____
Email: _____
Phone: _____

For Technical Information on the DIDB Platform: Contact didbase@uw.edu

**DIDB Platform
Education/Government Subscription Agreement
Schedule D:**

Subscriber Activities/Program Description

Subscriber desires to provide access to the Work to support Subscriber programs and activities as described below or on a separate description (Please initial any attached description):