



MEMORANDUM

Office of the Dean

Research and Graduate Education

Michael A. Corn, J.D.
Director, Research and Industry
Relations Support
1349 Pacific Street, HSC A-349A
Box 356340
Seattle, Washington 98195-6340
Telephone: (206) 616-8222
FAX: (206) 221-3911
mccorn@u.washington.edu

March 26, 2002

To: Department Chairs and Administrators

From: Michael A. Corn *MAC*
Director for Research and Industry Relations Support

Cc: Paul Ramsey, Albert Berger, Ruth Mahan, Gigi Streidl, Malcolm Parks, Carol
Zuiches, Suzanne Page, Ari Stantander

Re: Delegation of Signing Authority on Preapproved Form –
Preclinical Trial Nondisclosure Agreement

This memorandum is to advise you that consistent with Alvin Kwiram's communication of October 8, 2001, a copy of which is attached, Dean Ramsey has approved the delegation of signing authority to the Chairs of all departments in the School of Medicine with respect to the signing of the above-referenced preapproved form of Preclinical Trial Nondisclosure Agreement. Please note that this delegation is subject to the following terms and conditions:

1. This delegated signing authority may only be exercised consistent with Dr. Kwiram's communication of October 8, 2001.
2. Department Chairs may re-delegate this signing authority to division heads within their departments, provided that any such delegation is in writing and a copy of the written delegation has been forwarded to my office. Division heads are not authorized to re-delegate this signing authority to any other person.
3. Department Chairs are not authorized to re-delegate this signing authority to any persons other than those identified in the foregoing paragraph, including department administrators.
4. There is no authority to alter or vary the form of agreement in any manner, nor to sign any other other type or form of nondisclosure or similar agreement on behalf of the University.

5. Upon signing any agreement pursuant to this delegation, an additional copy of each agreement must be provided to my office and to Ari Santander in the Office of Intellectual Property and Technology Transfer.

By way of background, I should advise you that this form was developed in order to provide an additional tool that our investigators can use while having preliminary discussions of a possible clinical trial with a sponsor. We are aware that there are times when it may be very difficult for our investigators to obtain assistance in responding to a company agreement that has been presented by a sponsor as a pre-condition to further discussions. Rather than have our investigators placed in the position of having to sign an agreement on their own behalf in which they may incur unacceptable personal liabilities, we have developed a pre-approved form in which the University, and not the investigator, is the contracting party.

The use of this form is not mandatory, but it is hoped that it may facilitate the signing of appropriate confidentiality agreements in circumstances where investigators do not have the time to involve the Office of Grants and Contract Services, the Office of Intellectual Property and Technology Transfer, or the Attorney General's Office. I believe that overall this is a fair agreement and that the interests of prospective sponsors, the University and our investigators are all appropriately balanced and protected.

I think that it would be useful for faculty who conduct clinical trials to keep copies of this form with them when they anticipate the possibility of discussions about potential future trials, and I suggest that you encourage your faculty to do so. It should also be pointed out that this agreement can be signed by fax which can make the process go very quickly. As long as the form has not been changed in any way and the appropriate description of the protocol has been inserted on the last page, the process of getting this agreement signed should be relatively easy.

Copies of this agreement and information about its use can also be found at the following UW website:

<http://www.depts.washington.edu/gcs/delegation.html>

Please do not hesitate to contact me if you have any questions. I would also encourage you to provide copies of this communication to affected members of your department.



COPY

UNIVERSITY OF WASHINGTON

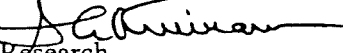
OFFICE OF THE PROVOST

October 8, 2001

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OCT 15 2001

TO: Deans of Health Sciences Schools

FROM: Alvin L. Kwiram 
Vice Provost for Research

Associate Director Management & Finance
School of Medicine
University of Washington

SUBJECT: Delegation of Authority - Confidentiality Agreement Form

Attached you will find a form of confidentiality agreement that has been pre-approved for use before substantive discussions begin with a sponsor about the prospects for conducting a clinical trial at the University. This "Pre-Clinical Trial Nondisclosure Agreement" may be used by any of our health sciences faculty and investigators so that they may receive information in confidence from companies and other sponsors in order to evaluate whether the University is interested in conducting a clinical trial.

I believe the form is self-explanatory, but it should be noted that certain information regarding the protocol (and the scope of the confidentiality obligation) must be completed on the last page of the agreement. After signing, a copy of the agreement must be delivered to the Office of Intellectual Property and Technology Transfer. Currently, Ari Santander is the person responsible for keeping these agreements.

In accordance with authority granted to this office until further notice, the Deans of the Schools of Medicine, Nursing, Pharmacy, Public Health and Community Medicine, and Dentistry and the Chairs of the Departments within those schools are hereby delegated the authority to sign this form of agreement on behalf of the University. Please note that investigators are not authorized to sign this agreement on behalf of the University (although they are required to sign an acknowledgement that they have reviewed the agreement).

In addition, there is no authority to alter or vary from this form of agreement. If either an investigator or a company desires to change this agreement, a normal review and negotiation process will be required.

You may also access this form at the following website address <http://www.depts.washington.edu/gcs/delegation.html>.

- c: Lee L. Huntsman
- Steven G. Olswang
- Michael Corn
- Gigi Streidl
- Ari Santander
- Suzanne Page
- Carol Zuiches

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OCT 09 2001

VICE PRESIDENT FOR MEDICAL AFFAIRS
DEAN SCHOOL OF MEDICINE

OFFICE OF THE ASSOCIATE DEAN
RESEARCH & GRADUATE EDUCATION

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PRE-CLINICAL TRIAL NONDISCLOSURE AGREEMENT

IMPORTANT NOTICE

THIS FORM OF AGREEMENT HAS BEEN APPROVED BY THE UNIVERSITY OF WASHINGTON. IT MAY BE USED ONLY FOR DISCLOSURES OF CONFIDENTIAL INFORMATION MADE IN CONNECTION WITH AN EVALUATION OF THE POSSIBLE CONDUCT OF A CLINICAL TRIAL BY THE UNIVERSITY. THE AGREEMENT MAY BE SIGNED ON BEHALF OF THE UNIVERSITY BY THE CHAIR OF THE INVESTIGATOR'S DEPARTMENT OR THE DEAN OF THE INVESTIGATOR'S SCHOOL. A COPY OF THE SIGNED AGREEMENT MUST BE PROVIDED TO THE UNIVERSITY'S OFFICE OF INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER.

This agreement (the "Agreement") is entered into by the University of Washington ("University"), a public institution of higher education and an agency of the State of Washington, having its principal campus located in Seattle, Washington, and the undersigned company ("Company").

Whereas, Company possesses certain confidential information ("Information") relating to the matters described on the last page of this Agreement (the "Protocol") and is willing to disclose or provide certain portions of the Information to the University's investigator identified on the last page of this Agreement ("Investigator") to facilitate discussions with and an evaluation by the Investigator regarding the possible conduct of a clinical trial relating to the Protocol.

Now, therefore, in consideration of Company's disclosure of the Information to the University and the Investigator, University and Company hereby agree as follows:

1. University shall have no right or license, express or implied, to use the Information, except to facilitate the intended discussions and evaluation and all Information disclosed to Investigator shall remain the property of Company.

2. Except as otherwise expressly provided in this Agreement, University (including Investigator) shall keep the Information confidential and shall not disclose to others either the Information or any results of the discussions or evaluation. Neither University nor Investigator shall use or reproduce, nor allow or assist others to use or reproduce, the Information or results of the discussions or evaluation for any purpose other than the intended discussions and evaluation without the prior written consent of Company. The Information shall not be evaluated by any laboratory, clinical testing or experimentation outside of the University without the express written consent of Company.

3. The Information shall only be disclosed to employees or agents of University who have a direct need to know the Information in the performance of the discussions and evaluation described herein and University shall take reasonable measures to ensure that any person receiving the Information shall: (i) understand the confidential nature thereof, and (ii) not disclose or make unauthorized use thereof.

4. University shall protect the Information using the same degree of care, but no less than a reasonable degree of care, as University uses to protect its own confidential information.

5. Upon written request of Company, University and Investigator shall promptly return to Company all embodiments of the Information in their possession including the results of any discussions or evaluation.

6. This Agreement shall apply only to information that is: (i) marked as confidential at the time of disclosure, or (ii) not marked as confidential at the time of disclosure but thereafter identified as confidential by Company in a writing to Investigator no more than fifteen (15) days after such disclosure.

7. University's obligations herein shall not apply to any information that: (i) is unrelated to the Protocol; (ii) is independently developed by University without the use of any Information; (iii) is received without an obligation of nondisclosure by University from a third-party who has a lawful right to so disclose; (iv) is furnished to a third party by Company without a similar restriction on the third party's rights; (v) is currently in the public domain; (vi) hereafter comes into the public domain through no action or fault on the part of University or Investigator; (vii) is approved for release by written authorization of the Company; and (viii) is disclosed pursuant to the requirement of a governmental agency or by reason of law (including disclosures of public records pursuant to RCW 42.17.250 et seq. and any administrative rules adopted pursuant thereto).

8. Unless earlier terminated in writing by either party, this Agreement shall terminate sixty (60) days after the date of execution of this Agreement by University; providing, however, that University's obligations hereunder shall survive for a period ending five (5) years after such execution.

9. This Agreement embodies the entire agreement between the parties and supersedes and cancels all prior agreements and understandings relating to its subject matter. Any amendment to this Agreement or waiver of any of its terms shall be in writing and shall be executed by duly-authorized representatives of the parties. The failure of either party to enforce strict performance by the other party of any provision of this Agreement or to exercise any right or remedy under this Agreement shall not be construed as a waiver or relinquishment of such party's

rights under this Agreement. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and assigns.

The University of Washington

Company Name:

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Investigator – Read and Reviewed:

Signature: _____

Title: _____

Name: _____

Date: _____

PROTOCOL

Drug or Medical Device

Drug (Description: _____)

Medical Device (Description: _____)

Other (Description: _____)

General Description of Protocol

