

Polycystic Kidney Disease Research Resource Consortium  
**EXTERNAL MATERIAL AND DATA SHARING AGREEMENT**

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This External Material and Data Sharing Agreement (this “AGREEMENT”) is entered into as of March 16, 2022 (the “EFFECTIVE DATE”) by and among the institutions participating in the Polycystic Kidney Disease Research Resource Consortium Master Material/Data Transfer Agreement (“CONSORTIUM AGREEMENT”) entered into as of July 16, 2021 (each a “PARTY” and collectively the “PARTIES”) to make certain materials and/or data available to external academic researchers.

## **I. BACKGROUND**

The PARTIES have entered the Polycystic Kidney Disease Research Resource Consortium Master Material/Data Transfer Agreement to support, accelerate, and expand basic and translational research activities amongst the PARTIES. The PARTIES will focus on the development of resources (cell lines and animal models) to analyze cilio-cystic disease protein function, localization, and interactions and how defects in these functions contribute to the pathogenic mechanisms involved in cyst initiation and progression.

The PARTIES agreed to cooperate under the direction of the U24 Central Coordinating Site (“U24-CCS”) and National Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”), to eliminate obstacles in cystic kidney disease related research that are hindering progress toward the development of improved and innovative treatment strategies for cystic kidney disorders.

The PARTIES desire to offer to the wider scientific and public health communities controlled access to materials and/or data so that investigators can perform hypothesis-driven research, confirmatory investigations, and follow-up studies.

## **II. DEFINITIONS**

- A. “CONSORTIUM” means the institutions participating in in the Polycystic Kidney Disease Research Resource Consortium Master Material/Data Transfer Agreement.
- B. “EXTERNAL RECIPIENT” means an academic researcher or investigator from a center or institution which is not a PARTY.
- C. “LETTER OF TRANSFER” or “LOT” means an implementing letter signed by the EXTERNAL RECIPIENT acknowledging the transfer of the MATERIAL and/or DATA and any restrictions thereto. A copy of the LOT is attached hereto as Appendix A.
- D. “HUMAN MATERIAL LETTER OF TRANSFER” or “HUMAN MATERIAL LOT” means an implementing letter signed by the EXTERNAL RECIPIENT acknowledging the transfer of human MATERIAL and any restrictions thereto. A copy of the HUMAN MATERIAL LOT is attached hereto as Appendix B.
- E. “SAMPLE(S)” means the existing and newly collected human biological samples obtained from the studies identified and conducted in accordance with the CONSTORTIUM AGREEMENT.
- F. “ORIGINAL MATERIAL” means the SAMPLE(S) as well as any other biological material(s) that will be used during the conduct of the protocols implemented under the Consortium.
- G. “MATERIAL” means the ORIGINAL MATERIAL PROGENY and UNMODIFIED DERIVATIVES. MATERIALS shall not include MODIFICATIONS OR OTHER

SUBSTANCES CREATED BY THE EXTERNAL RECIPIENT THROUGH THE USE OF THE MATERIAL WHICH ARE NOT MODIFICATIONS, PROGENY, OR UNMODIFIED DERIVATIVES.

- H. "MODIFICATIONS" means substances created by EXTERNAL RECIPIENT which contain/incorporate a portion of the MATERIAL(S).
- I. "PROGENY": mean unmodified descendants from the Original Material, such as virus from virus, cell from cell, or organism from organism.
- J. "CONSORTIUM MEMBER" means a PARTY.
- K. "DATA" means the relevant data from a specific project that is made available to an EXTERNAL RECIPIENT and is described in the applicable LOT.
- L. "PROVIDER" means CONSORTIUM MEMBER(S) who is directed by the U24-CCS to provide MATERIAL and/or DATA to an EXTERNAL RECIPIENT identified in a LOT or HUMAN MATERIAL LOT.
- M. "U24 CENTRAL COORDINATING SITE" ("U24-CCS") shall mean the scientific and management group participating identified in the CONSORTIUM AGREEMENT that provides logistical and scientific support to the NIDDK and other members of the Consortium and is responsible for the implementation of the LOT or HUMAN MATERIAL LOT.

### **III. MATERIAL TRANSFER AGREEMENT**

#### **1. Organizational Structure and Approach**

- A. The LOT and Human Material LOT are attached to this Agreement as Appendix A and Appendix B respectively and are the means by which Material and/or Data shall be made available to External Investigators. The Parties agree the LOT and Human Material LOT shall be negotiated by the U24-CCS and signed by the External Recipient. The U24-CCS shall consult with PROVIDER (to the extent applicable) in the review and approval of the Human Material LOT.
- B. The U24-CCS shall be responsible for systematically evaluating requests for sharing of Materials. The U24-CCS will determine whether the request is approved in full, approved contingent upon modification, or disapproved. Following approval by the U24-CCS, the applicable CONSORTIUM MEMBER shall be notified by the U24-CCS and shall use reasonable efforts to provide the Material and/or Data to the External Recipient in accordance with the applicable LOT or Human Material LOT. The addresses for notices are listed in Appendix C. The U24-CCS shall be solely responsible for ensuring compliance with U.S. laws, rules and regulations related to export control and shall conduct all compliance reviews of the External Recipient institution, of the External Recipient's scientist and those under the control of the External Recipient's scientist who will use the Material and/or Data, and of the proposed research with the Material and/or Data.
- C. The U24-CCS shall store and maintain the accepted LOT or Human Material LOT.
- D. The U24-CCS has responsibility for preparing, codifying, and overseeing implementation of the policies regarding release of Materials to External Recipients.
- E. The guidelines described herein refer specifically to Materials and/or Data stored by CONSORTIUM MEMBER(S).

#### **2. How to Apply**

- A. Applications for Materials by External Recipients will be processed via [www.pkd-rrc.org](http://www.pkd-rrc.org).

- B. When requesting Materials and/or Data:
- i. External Recipient shall provide a rationale for access and provide assurance that they have sufficient resources, expertise, and funding to complete the research proposed; acceptable to the U24-CCS.
  - ii. External Recipient shall ask for the minimum amount (both type and number) needed to perform scientifically meaningful experiments. It may be desirable or necessary to modify study designs or utilize different materials to address the question where availability is limited.
- C. In order to access Materials and/or Data from the CONSORTIUM MEMBER, External Recipient must complete and submit the following documents electronically:
- *Prior to review by the U24-CCS:*
    - **Material Transfer Registration Request:** available via [www.pkd-rrc.org](http://www.pkd-rrc.org), which shall provide the U24-CCS and CONSORTIUM MEMBER (as applicable) with the External Investigator's identifying information (name, address, position, institutional affiliation, email address, and a brief description of the purpose of the request and the type of Material and/or Data requested)
  - *Following review and approval by the U24-CCS:*
    - **LOT** (see Appendix A); or
    - **Human Material LOT** (see Appendix B)
- External Recipient must sign the LOT or Human Material LOT to receive Materials and/or Data. By signing this agreement, they agree to the terms and conditions therein regarding the use of the Materials and/or Data.

#### **IV. Dispute Resolution**

If a dispute between the PARTIES related to this AGREEMENT arises, either PARTY, by notice to the other PARTY(IES), may have the dispute referred to the PARTIES' respective officers for attempted resolution by good faith negotiations within thirty (30) days after the notice is received. Nothing in this Paragraph will prevent any PARTY from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies. Pending the resolution of any dispute or claim pursuant to this Article IV the PARTIES agree that performance of all obligations will be pursued diligently.

#### **V. Warranties**

Any MATERIAL and/or DATA delivered pursuant to this AGREEMENT are understood to be experimental in nature and may have hazardous properties. NO PARTY MAKES REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KINDS, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER PROPRIETARY RIGHTS.

#### **VI. Indemnification; Limitation of Liability**

No indemnification for any loss, claim, damage, or liability is intended or provided by any PARTY under this AGREEMENT. Each PARTY shall be, to the extent allowed by applicable laws and appropriations made for such purpose, liable for any loss, claim, damage, or liability that said

PARTY incurs, but only in proportion and to the extent such claims arise from said PARTY's activities under this AGREEMENT. No indemnification for third party claims is intended or implied.

SIGNATURES BEGIN ON NEXT PAGE

SIGNATURE PAGE

The PARTIES have executed this AGREEMENT by their respective duly authorized representatives on the day and year hereinafter written.

ACCEPTED AND AGREED

FOR UNIVERSITY OF MARYLAND, BALTIMORE:

DocuSigned by:  
*Michael Rollor*  
438D9406E07A454...

Signature \_\_\_\_\_ Date 3/16/2022

Typed Name: Michael A. Rollor, Ph.D.  
Title: Associate Vice President, ORD-CCT

FOR UNIVERSITY OF KANSAS MEDICAL CENTER:

DocuSigned by:  
*Lisa Hoebelheinrich*  
65D0257F82FF496...

Signature \_\_\_\_\_ Date 3/21/2022

Typed Name: Lisa Hoebelheinrich, J.D.  
Title: Associate Vice Chancellor for Research Administration

FOR THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA FOR UNIVERSITY OF ALABAMA AT BIRMINGHAM:

DocuSigned by:  
*Melinda T. Cotten*  
7220092A62674E2...

Signature \_\_\_\_\_ Date 3/24/2022

Typed Name: Melinda T. Cotten  
Title: Associate Vice President, Research Business Operations

FOR JOHNS HOPKINS UNIVERSITY:

DocuSigned by:  
*Stephen Fisher*  
CFB4FFDBFBFE34A1...

Signature \_\_\_\_\_ Date 3/24/2022

Typed Name: Stephen B. Fisher  
Title: Associate Director, Office of Research Administration

FOR CHILDREN'S NATIONAL HOSPITAL:

DocuSigned by:  
*Conrad Hohenlohe*  
2896687D5E54482...

3/24/2022

Signature

Date

Typed Name: Conrad Hohenlohe

Title: Director, Grants and Contracts

Pre-Award Manager, Grants and Contracts

## Appendix A

### Polycystic Kidney Disease Research Resource Consortium LETTER OF TRANSFER

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This Letter of Transfer is made effective as of \_\_\_\_\_, 2022 (“Effective Date”) in response to the request by [INSERT NAME OF EXTERNAL INVESTIGATOR] (“Recipient”) for the Material and/or Data to be provided by the Polycystic Kidney Disease Research Resource Consortium (“Provider”). The Recipient agrees to the following before the Recipient receives the Materials and/or Data.

#### BACKGROUND

WHEREAS, Recipient has submitted a request to use the Materials and/or Data for conducting the research described in the “**Material Transfer Registration Request**” via the secure Polycystic Kidney Disease Research Resource Consortium website, and such request has been approved by the U24-CCS.

Now, therefore, RECIPIENT agrees to the following terms:

#### **DEFINITIONS:**

“**Materials**” means the Original Material, Progeny and Unmodified Derivatives. “Materials” shall not include Modifications or other substances created by the Recipient through the use of the Materials which are not Modifications, Progeny, or Unmodified Derivatives.

“**Original Material**” means the material made available by the Provider, described as: [DESCRIPTION OF THE MATERIAL].

“**Progeny**”: mean unmodified descendants from the Original Material, such as virus from virus, cell from cell, or organism from organism.

“**Unmodified Derivatives**”: mean substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material. Examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Original Material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

“**Data**” means the relevant data from a specific project that is made available to Recipient and is described as: [DESCRIPTION OF DATA].

“**Commercial Purposes**” means the use of Materials and/or Data by or on behalf of or for research sponsored by (or transfer of Materials and/or Data to) a for-profit company.

“**Modifications**” means any substance created by Recipient which contains or incorporates any of the Materials.

“**Research**” means the research described in the Material Transfer Registration Request submitted via www.pkd-rrc.org, which was approved by the U24-CCS and attached as Exhibit 1.

## **TERMS AND CONDITIONS OF THIS AGREEMENT:**

1. Recipient agrees that the Materials and/or Data are to be used solely for teaching or non-for-profit research detailed in the Research and for the duration described in the Material Transfer Registration Request.

2. Recipient shall use the Materials and/or Data in accordance with safe laboratory practices and the highest standards of skill and care. Recipient shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials. In the event Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly inform Provider and follow Provider's reasonable instructions, which include return or destruction of the identifiable information. Recipient agrees to use the Data in compliance with all applicable statutes and regulations, including the Health Insurance Portability and Accountability Act of 1996.

3. Materials and/or Data are to be used only in the Recipient's laboratories, and only by those personnel working directly under Recipient's supervision.

4. Materials and/or Data will not be given or made available to any third party. The Recipient agrees to refer to the Provider any request for the Material and/or Data from anyone other than those persons working under the Recipient's direct supervision.

5. Provider retains ownership of the Materials and/or Data, and any Modifications. Except as specifically set forth in this Agreement, no express or implied license or other rights are provided to Recipient under any proprietary rights of Provider.

6. Recipient agrees and acknowledges that:

(a) Materials and/or Data will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless such use is expressly approved by Provider in writing and Recipient's use shall be in accordance with the relevant clinical protocol, informed consent and subject to any required Institutional Review Board and/or ethics review committee approvals and/or other necessary approvals as applicable;

(b) Materials and/or Data will not be used for Commercial Purposes;

(c) Materials and/or Data will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material Transfer Registration Request, to allocate their respective right in any and all inventions (and any patent rights or other rights arising therefrom);

7. It is acknowledged that the results of the research using the Materials and/or Data may be important to Provider in its attempts to attract good researchers and secure research funding for its research. Such recognition may be primarily established by reference to the use of Materials and/or Data by third parties, such as Recipient, in publications. It is further acknowledged that the failure to obtain such recognition may adversely affect Provider's ongoing research activities and funding. Accordingly, Recipient agrees that it will notify Provider and, at least 30 days prior to submission, provide a copy of any Publication concerning the Research to Provider. Recipient shall reasonably consider any comments Provider offers and will make appropriate attributions in all such publications where Provider's Materials were used in Recipient's Research. Recognition for the contribution of Provider should be established by acknowledging use of the Materials and/or Data by Recipient in any such publication using the following statement:



*“Studies utilized resources provided by the NIDDK sponsored Polycystic Kidney Disease Research Resource Consortium”.*

8. Recipient will inform Provider of results of the Research, with a written report of the results within sixty (60) days after conclusion of the Research. [*not required, can be removed if requestor objects*].

9. Any Materials and/or Data transferred pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. Provider MAKES NO REPRESENTATIONS NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD PARTY PROPRIETARY RIGHTS, OR THAT THE MATERIALS WILL NOT POSE A HEALTH OR SAFETY RISK.

10. Recipient shall pay Provider for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to Recipient. Payment shall be in made in the manner indicated on the Material Transfer Registration Request.

11. All Materials will be shipped EXW <sup>1</sup> Provider's place of business for activities carried out pursuant to this Agreement (unless Provider and Recipient mutually agree to a different Incoterm shipping classification).

12. Except to the extent prohibited or, where applicable, to the extent authorized by law, Recipient assumes all liability for claims for damages that may arise from its use, storage, and/or disposal of the Materials and/or Data for activities carried out pursuant to this Agreement. Provider will not be liable to Recipient for any loss, claim, or demand made by Recipient, or made against Recipient by any other party, due to or arising from the use, storage, and/or disposal of the Materials and/or Data by Recipient, except to the extent permitted by applicable law when such loss, claim, or demand is caused by the gross negligence and/or willful misconduct of Provider.

13. Recipient agrees to handle, store, and use the Materials and/or Data in a safe manner and in compliance with all applicable statutes and regulations, including applicable governmental regulations and guidelines as well as the requirements of national drug regulatory authorities and other relevant regulatory agencies.

14. Recipient certifies that it has obtained any Institutional Review Board and/or ethics review committee and/or other approvals that may be required for the use of Materials and/or Data received under this Agreement as outlined in the respective Material Transfer Registration Request.

15. This Agreement will terminate upon completion of the Research by Recipient. At that time, Recipient will discontinue use of the Materials and/or Data and will promptly give written notice to Provider. The Provider may, at its option, direct Recipient to either:

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<sup>1</sup> EXW is an Incoterm abbreviation for “EX Works.” EX Works means that the Provider delivers when he places the goods at the disposal of the Recipient at the Provider's premises or another named place (i.e. works, factory, warehouse, etc.) not cleared for export and not loaded on any collecting vehicle. This term thus represents the minimum obligation for the Provider, and the Recipient has to bear all costs and risks involved in taking the goods from the Provider's premises.

(a) Destroy any remaining Materials, Modifications, and/or Data, and to certify that destruction in writing; or

(b) Return any remaining Materials, Modifications, and/or Data. The cost of shipment will be at Recipient's expense.

16. Provider or Recipient may terminate this Agreement upon thirty (30) days written notice the other party.

17. Expiration or termination of this Agreement does not relieve either party of any obligation which arises before expiration or termination, including without limitation obligations for payment and reporting. Any provision of this Agreement which contemplates performance or observance subsequent to any termination or expiration of this Agreement shall survive any termination or expiration of this Agreement and continue in full force and effect.

*Signature page to follow*

**RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.**

**RECIPIENT INFORMATION and AUTHORIZED SIGNATURE**

Recipient Scientist: \_\_\_\_\_  
Recipient Organization: \_\_\_\_\_  
Address: \_\_\_\_\_  
Name of Authorized Official: \_\_\_\_\_  
Title of Authorized: \_\_\_\_\_  
Official: \_\_\_\_\_  
Signature of Authorized Official: \_\_\_\_\_  
Date: \_\_\_\_\_

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

\_\_\_\_\_  
Recipient Scientist

\_\_\_\_\_  
Date

**EXHIBIT 1  
RESEARCH**

**[PLEASE PROVIDE A DESCRIPTION OF THE PROPOSED RESEARCH]**

## Appendix B

### Polycystic Kidney Disease Research Resource Consortium HUMAN MATERIAL LETTER OF TRANSFER

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This Human Material Letter of Transfer is made effective as of \_\_\_\_\_, 2022 (“Effective Date”) in response to the request by **[INSERT NAME OF EXTERNAL INVESTIGATOR]** (“Recipient”) for the Materials to be provided by the Polycystic Kidney Disease Research Resource Consortium (“Provider”). The Recipient agrees to the following before the Recipient receives the Material.

#### BACKGROUND

WHEREAS, Recipient has submitted a request to use the Materials for conducting the research described in the “**Material Transfer Registration Request**” via [www.pkd-rrc.org](http://www.pkd-rrc.org) and such request has been approved by the U24-CCS.

Now, therefore, RECIPIENT agrees to the following terms:

#### **DEFINITIONS:**

“**Materials**” means the Original Materials, Progeny and Unmodified Derivatives. “Materials” shall not include Modifications or other substances created by the Recipient through the use of the Materials which are not Modifications, Progeny, or Unmodified Derivatives.

“**Original Materials**” means the human material made available by the Provider: **[DESCRIPTION OF HUMAN MATERIAL]**.

“**Progeny**”: mean unmodified descendants from the Original Material, such as virus from virus, cell from cell, or organism from organism.

“**Unmodified Derivatives**”: mean substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Materials. Examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Original Material proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

“**Commercial Purposes**” means the use of Materials by or on behalf of or for research sponsored by (or transfer of Materials to) a for-profit company.

“**Modifications**” means any substance created by Recipient which contains or incorporates any of the Materials.

“**Research**” means the research described in the Human Material Transfer Registration Request submitted via [www.pkd-rrc.org](http://www.pkd-rrc.org), which was approved by the U24-CCS and attached as Exhibit 1.

#### **TERMS AND CONDITIONS OF THIS AGREEMENT:**

1. Recipient agrees that the Materials are to be used solely for teaching or non-for-profit research detailed in the Research and for the duration described in the Material Transfer Registration Request.

2. Recipient shall use the Materials in accordance with safe laboratory practices and the highest standards of skill and care. Recipient shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials, which may include:

- i. The Privacy Act of 1974, as amended, at 5 U.S.C. §552a (“Privacy Act”), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) or other equivalent privacy regulations; and
- ii. 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and
- iii. A certificate of confidentiality issued by NIH in accordance with 42 U.S.C 241(d) of the Public Health Service Act

3. Materials are to be used only in the Recipient’s laboratories, and only by those personnel working directly under Recipient’s supervision.

4. Materials will not be given or made available to any third party. The Recipient agrees to refer to the Provider any request for the Material from anyone other than those persons working under the Recipient’s direct supervision.

5. Provider retains ownership of the Materials and any Modifications. Except as specifically set forth in this Agreement, no express or implied license or other rights are provided to Recipient under any proprietary rights of Provider.

6. Recipient agrees and acknowledges that:

(a) Materials will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless such use is expressly approved by Provider in writing and Recipient’s use shall be in accordance with the relevant clinical protocol, informed consent and subject to any required Institutional Review Board and/or ethics review committee approvals and/or other necessary approvals as applicable;

(b) Materials will not be used for Commercial Purposes;

(c) Materials will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material Transfer Registration Request, to allocate their respective right in any and all inventions (and any patent rights or other rights arising therefrom); and

(f) If the Materials provided to Recipient have been collected from human subjects (“Subjects”), such Materials will be de-identified and all Protected Health Information (“PHI”), as defined by HIPAA, will have been removed and Recipient will not be provided with any information that could be used to identify the Subjects from whom the Materials were derived, although the Provider may retain a confidential link to the Subjects identity. Recipient shall not make any attempts to determine the identity of those Subjects, or to contact the Subjects. Should a Subject from whom Materials were collected object to the use set forth herein, then Recipient agrees to promptly comply with the Provider’s request to return or destroy any such Materials.

7. It is acknowledged that the results of the research using the Materials may be important to Provider in its attempts to attract good researchers and secure research funding for its research. Such recognition may be primarily established by reference to the use of Materials by

third parties, such as Recipient, in publications. It is further acknowledged that the failure to obtain such recognition may adversely affect Provider's ongoing research activities and funding. Accordingly, Recipient agrees that it will notify Provider and, at least 30 days prior to submission, provide a copy of any Publication concerning the Research to Provider. Recipient shall reasonably consider any comments Provider offers and will make appropriate attributions in all such publications where Provider's Materials were used in Recipient's Research. Recognition for the contribution of Provider should be established by acknowledging use of the Materials by Recipient in any such publication using the following statement.

*"Studies utilized resources provided by the NIDDK sponsored Polycystic Kidney Disease Research Resource Consortium".*

8. Recipient will inform Provider of results of the Research, with a written report of the results within sixty (60) days after conclusion of the Research.

9. Any Materials transferred pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. Provider MAKES NO REPRESENTATIONS NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD PARTY PROPRIETARY RIGHTS, OR THAT THE MATERIALS WILL NOT POSE A HEALTH OR SAFETY RISK.

10. Recipient shall pay Provider for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to Recipient. Payment shall be in made in the manner indicated on the Material Transfer Registration Request.

11. All Materials will be shipped EXW<sup>1</sup> Provider's place of business for activities carried out pursuant to this Agreement (unless Provider and Recipient mutually agree to a different Incoterm shipping classification).

12. Except to the extent prohibited or, where applicable, to the extent authorized by law, Recipient assumes all liability for claims for damages that may arise from its use, storage, and/or disposal of the Materials for activities carried out pursuant to this Agreement. Provider will not be liable to Recipient for any loss, claim, or demand made by Recipient, or made against Recipient by any other party, due to or arising from the use, storage, and/or disposal of the Materials by Recipient, except to the extent permitted by applicable law when such loss, claim, or demand is caused by the gross negligence and/or willful misconduct of Provider.

13. Recipient agrees to handle, store, and use the Materials in a safe manner and in compliance with all applicable statutes and regulations, including applicable governmental regulations and guidelines as well as the requirements of national drug regulatory authorities and other relevant regulatory agencies.

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<sup>1</sup> EXW is an Incoterm abbreviation for "EX Works." EX Works means that the Provider delivers when he places the goods at the disposal of the Recipient at the Provider's premises or another named place (i.e. works, factory, warehouse, etc.) not cleared for export and not loaded on any collecting vehicle. This term thus represents the minimum obligation for the Provider, and the Recipient has to bear all costs and risks involved in taking the goods from the Provider's premises.

14. Recipient certifies that it has obtained any Institutional Review Board and/or ethics review committee and/or other approvals that may be required for the use of Materials received under this Agreement as outlined in the respective Material Transfer Registration Request. Recipient shall provide such approvals to Provider. The transfer of the Materials will be contingent upon Provider's IRB approving the release of the Materials to Recipient for these purposes, providing an opinion that such approval is not required or granting a waiver of consent.

15. This Agreement will terminate upon completion of the Research by Recipient. At that time, Recipient will discontinue use of the Materials and will promptly give written notice to Provider. The Provider may, at its option, direct Recipient to either:

(a) Destroy any remaining Materials and Modifications, and to certify that destruction in writing; or

(b) Return any remaining Materials and Modifications. The cost of shipment will be at Recipient's expense.

16. Provider or Recipient may terminate this Agreement upon thirty (30) days written notice the other party.

17. Expiration or termination of this Agreement does not relieve either party of any obligation which arises before expiration or termination, including without limitation obligations for payment and reporting. Any provision of this Agreement which contemplates performance or observance subsequent to any termination or expiration of this Agreement shall survive any termination or expiration of this Agreement and continue in full force and effect.

*Signature page to follow*



**RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.**

**RECIPIENT INFORMATION and AUTHORIZED SIGNATURE**

Recipient Scientist: \_\_\_\_\_  
Recipient Organization: \_\_\_\_\_  
Address: \_\_\_\_\_  
Name of Authorized Official: \_\_\_\_\_  
Title of Authorized: \_\_\_\_\_  
Official: \_\_\_\_\_  
Signature of Authorized Official: \_\_\_\_\_  
Date: \_\_\_\_\_

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

\_\_\_\_\_  
Recipient Scientist

\_\_\_\_\_  
Date

**EXHIBIT 1  
RESEARCH**

**[PLEASE PROVIDE A DESCRIPTION OF THE PROPOSED RESEARCH]**

**Appendix C**  
**PARTICIPATING INSTITUTION CONTACTS FOR CONSORTIUM**  
**INFORMATION AND NOTICES**

**UNIVERSITY OF MARYLAND, BALTIMORE**

**For technical and scientific notices:**

Terry Watnick, M.D.  
Professor of Medicine  
Division of Nephrology  
University of Maryland School of Medicine  
22 S. Greene Street, Rm N3W143  
Baltimore, MD 21201  
T: 410-706-5803  
E: [twatnick@som.umaryland.edu](mailto:twatnick@som.umaryland.edu)

**For delivery of materials:**

Terry Watnick, M.D.  
Professor of Medicine  
Division of Nephrology  
University of Maryland School of Medicine  
22 S. Greene Street, Rm N3W143  
Baltimore, MD 21201  
T: 410-706-5803  
E: [twatnick@som.umaryland.edu](mailto:twatnick@som.umaryland.edu)

**For legal notices:**

Associate Vice President, CCT  
University of Maryland, Baltimore  
Office of Research and Development  
620 West Lexington Street, 4<sup>th</sup> Floor  
Baltimore, MD 21201

Copy to:  
University Counsel  
University of Maryland, Baltimore  
220 Arch Street, Rm. 03-111  
Baltimore, MD 21201

**THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA FOR**  
**UNIVERSITY OF ALABAMA AT BIRMINGHAM**

**For technical and scientific notices:**

Bradley K. Yoder, Ph.D.  
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