**THE KIDNEY PRECISION MEDICINE PROJECT (“KPMP”)**

**RESEARCH COLLABORATION AGREEMENT TEMPLATE**

This Research Collaboration Agreement (this “**Agreement**”), is effective as of the date of last signature (the “**Effective Date**”), by and between:

1. [Company name], a company incorporated in [address] whose registered office is at [address] (“**Company**”).

and

1. The University of Washington, an institution of higher education and an agency of the State of Washington having its principal campus located in Seattle, Washington (“**Institution**”).

**Recitals**

(A) Whereas, the Parties wish to engage in scientific research related to the [*abbreviated description of the research*] and described in Appendix A “Ancillary Study Application”;

(B) Whereas, the Parties wish to engage in a research collaboration activities as described in Schedule 1 “Approved Ancillary Study” or “Project Plan”;

(C) Whereas, the Parties recognize, because of the contributions made to KPMP by the National Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”), which is a component of the National Institutes of Health (“NIH”), an agency of the U.S. Department of Health and Human Services, NIDDK has an interest in the activities of the work under this Agreement;

(D) Whereas, KPMP is fully funded by NIH/NIDDK, a federal agency, therefore federal rules, regulations, NIH grant policy and other NIH applicable policies apply to all Parties to this Agreement. Further, Institution, as an NIDDK grantee, agrees to comply with all applicable terms and conditions of the grant award, all legal obligations therein that include data sharing policies, and other applicable federal regulations;

(E) Whereas, KPMP is fully funded by NIH/NIDDK, a federal agency, therefore the United States Government may retain some rights in intellectual property.  NIH/NIDDK, as a Federal Agency, shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States **any subject invention** throughout the world. 35 U.S.C. § 202 (c)(4); “**Subject Invention"** means **any invention** of a recipient/consortium participant conceived or first actually reduced to practice **in the performance of work under a funding agreement**; <https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.2.4_inventions_and_patents.htm>

(F) Whereas, Company acknowledges that a Memo of Understanding (MoU) must be signed between Company and NIH/NIDDK within 120 days of the Effective Date of this Agreement. The MoU will reflect the scope and terms of the signed Final Research Collaboration Agreement (RCA);

(G) Whereas**,** the research collaboration contemplated by this Agreement is of mutual interest and benefit to the Company and the Institution, and will further the instructional and research objectives of the Institution in a manner consistent with its status as a public, state educational and research institution.

**Agreement**

 The Parties, intending to be legally bound, agree as follows:

1. **Definitions**

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

 **“KPMP Affiliate Institution”** means any entity contributing resources to KPMP. These resources include data, samples, software, or other. A list of currently engaged entities can be found in Appendix B.

**“Company”** means the primary private-sector entity and its affiliates, directly engaged via this Research Collaboration Agreement.

## “**Applicable Laws**” means applicable laws, rules, and regulations, including any rules, regulations or other requirements of regulatory authorities that may be in effect from time to time. For clarity, Applicable Laws include good laboratory practices and good clinical practices.

## “**Background Intellectual Property**” has the meaning set forth in Section 4.1.

## “**Commercial Purposes**” means Direct Exploitation, as used in Section 4.8 (a), including the direct sale or licensing of KPMP Resources and Data and direct commercialization of actual Results. Company is understood by both parties to be a Data User, as defined in the [KPMP Data Use Policy](https://drive.google.com/file/d/1EZU64XpvMSyNNHIwm6pOHrUWFL9DIxBu/view), and will abide by all policies stipulated in the KPMP Data Use Policy.

## “**Confidential Information**” means all information or material that on or after the Effective Date is provided or communicated to a Party by or on behalf of the other Party pursuant to this Agreement or any discussions or negotiations with respect thereto, including any data, ideas, concepts or techniques contained therein, that is marked or designated in writing as confidential within 30 days unless otherwise agreed. Confidential Information may be disclosed orally, visually, in writing, by delivery of biosamples or data containing Confidential Information or in any other form now known or hereafter invented.

## “**Control**” means: (a) to possess, directly or indirectly, the power to direct the management or policies of a Party, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Party.

## “**Data Protection Laws**” means all Applicable Laws in relation to (a) data protection; (b) privacy; (c) interception and monitoring of communications; (d) restrictions on or requirements relating to the Processing (as defined in Schedule 4) of Patient Data of any kind including laws addressing identity theft or security breaches.

## “**De-identified Participant Data**” means Participant Data which has been stripped of all subject information that could make the person identifiable and where the Party that shares the data has no reasonable knowledge that the remaining information could be used to identify the individual on its own or in combination with other information that could be reasonably obtained. This includes but is not limited to the removal, masking or generalization of all 18 U.S. Health Insurance Portability and Accountability Act (HIPAA) identifiers. This means that there can be no data points left that could be reasonably used to link the data set to a particular individual, such as age older than 89 years old; geographic location smaller than a State (or equivalent); exact elements of dates directly related to an individual (i.e.: date of birth, date of death, dates of hospital visits, etc.); any unique identifying number, characteristic or code directly linked to an individual (i.e.: national ID number, social security number, bank account number); contact details of any type; biometric identifiers (e.g.: finger and voice prints); photos and comparable images; etc. and supplier has no knowledge that the remaining information could be used to identify the individual.

“**Derived Data**” is data generated, derived, or exists otherwise as output from activities pursuant to the Research Plan. Derived Data includes but is not limited to sequencing data.

## “**Document Retention Period**” has the meaning set forth in Section 2.6.

## “**Final Report**” has the meaning set forth in Section 2.9.

## “**HCO**” has the meaning set forth in Section 3.5I.

## “**HCP**” has the meaning set forth in Section 3.5(c).

## “**Independent Interpretation**” means the results arising from the independent analysis of the Project Results and/or Project Interpretation outside of Project Plan by Institution(s) and/or **KPMP Affiliate Institution**(s).

## “**Informed Consent**” means the individual patient-level permission, in full knowledge of the possible risks and benefits, to use Samples and associated Patient Data for a particular purpose, obtained in accordance with all Applicable Laws.

##  “**Institution and KPMP Affiliate Institution Research Documentation**” means all documents, records, accounts, notes, reports (including the Final Report prepared pursuant to Section 2.9) and other data relating to the Research Activities, whether in written, electronic, video or other tangible form created by or on behalf of Institution.

## “**Institution Researchers**” has the meaning set forth in Section 2.4.

## **“Institution Principal Investigator**” means Dr. Jonathan Himmelfarb, an employee/agent of the Institution to supervise the Research Activities at the Institution identified in the Research Plan.

## **“IRB”** refers to the Institutional Review Board that reviewed and approved the research and provided a waiver of authorization, to the extent required under applicable laws and Institution policy.

## “**Limited Data Set**” is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: Names; Postal address information, other than town or city, State, and zip code; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and Full face photographic images and any comparable images.

## “**Losses**” means any and all liabilities, claims, demands, causes of action, damages, loss and expenses, including interest, penalties and reasonable lawyers’ fees and disbursement.

## “**Parties**” means Institution and Company, and “**Party**” means either Institution or Company.

## “**Participant Data**” means any information relating to an identified or identifiable natural person who can be identified directly or indirectly and in particular includes but is not limited to the following information about a living individual: first and last name, age, date of birth, gender, address, contact information, government-issued identifiers (such as passport and social security numbers), or any specific physical, health related, physiological, genetic, mental, economic, cultural or social information about that natural person.

##  “**Payment or Transfer of Value**” has the meaning set forth in Section 10.1(d).

## “**Project Interpretation**” means the results created in the Project Plan activities as determined by Institution.

## “**Project Results**” means any tangible or intangible output of the Project Plan activities whatever its form or nature which may include, but is not limited to, derived knowledge, derived information, derived data or material derived from Biosamples.

## “**Research Activities**” means all tests, studies and other activities described and carried out in accordance with the Research Plan or required to obtain the information set out in Research Plan.

## “**Research Budget**” has the meaning set forth in Section 3.1.

## “**Research Plan**” means a description and activities of the research to be undertaken by Affiliate Institution and as set forth in Schedule 1, and as amended from time to time by the Parties in writing.

## “**Research Use**” means the use of Results (or Background Knowledge necessary to use Results) for all purposes other than for Direct Exploitation and includes, but is not limited to, the application of Results as a tool for research, including clinical research and trials.

## “**Resources/KPMP Resources**” means all assets under the control and responsibility of KPMP including but not limited to participants’ information, data, biosamples, KPMP-derived data or materials, technology developed within KPMP with the support of federal funding, and training or publicity materials created within KPMP with the support of federal funding.

## “**Samples**” means those Samples set forth in the Research Plan and: (a) any substance or structure that is a derivative, analog, modification, replication, complex, or subunit of such Samples, and (b) any other compositions made using such Samples.

## “**Sequence Data**” means data generated from whole exome, whole genome, genotype, panel, or any other type of sequencing activity performed on the Samples that represents the contents of a partial or full DNA region.

## “**Term**” has the meaning set forth in Section 8.1.

## **Research**

## Research Activities and Research Plan . The Parties shall conduct the Research Activities in accordance with this Agreement and the Research Plan. Terms for the establishment and ownership of existing intellectual property or intellectual property derived during the KPMP collaborative project will be governed by federal law and regulation, as well as policies of the participating academic or private entities, if appropriate.

## Conduct of Research Activities . The Parties shall: (a) perform or cause to be performed the Research Activities in good scientific manner in accordance with generally accepted professional standards of workmanship and effort at a quality comparable to research performed at major public and private research universities within the United States and in compliance with Applicable Laws; (b)  pursue the objectives of the Research Plan efficiently and expeditiously by allocating sufficient time, effort, equipment and skilled personnel to complete such activities diligently and promptly; (c) adhere to the foundational principles of team science upon which KPMP is built; (d) include in intellectual property claims, all investigators who contribute to said intellectual property by using KPMP resource; (e) adhere to the same policies and guidelines as all KPMP members; (f) adhere to all NIH and KPMP rules and guidelines governing access to data and resources, transparency, and data sharing to the public domain and; (g) share results from their studies for inclusion in the KPMP knowledge network and to work with KMAP to establish resources such that incoming data is accessible and understandable.

## Use of KPMP Resources (including Biosamples and associated De-identified Participant Data . Institution acknowledges that it has adequate facilities and relevant permissions and ethical approvals for the collection of clinical samples. Institution further confirms that (a) the use of data, biosamples or any other KPMP resources for the Research Activities and Research Plan and (b) sharing and ownership of the Data and associated De-identified Patient Data (and other Project Results and Project Interpretation as specified in Section 4 by/with a commercial entity Company is in accordance with Applicable Laws and the relevant Informed Consents.

## Use of the KPMP Resources is limited to the Company Investigator and researchers under the direct supervision of the Company Investigator and are held to the provisions and restrictions of this Agreement. No further distribution of KPMP Resources to third parties will be allowed without the prior written approval of Institution who is bound by all established NIH/NIDDK data sharing policies.

## Company shall not use or disclose KPMP Resources in any manner that is not specifically authorized by this Agreement or would constitute a violation of federal law, specifically HIPAA or any other applicable privacy law. Company must obtain specific authorization in the form of an Amendment to this Agreement to use or disclose KPMP Resources for any other purpose other than specifically set out and authorized herein.

## Company agrees that it will NOT (a) attempt to identify KPMP participants; (b) contact any participants who are the subject of KPMP Resources if Resources are de-identified, unless the approved Project Plan includes direct contact with participants as in accordance with IRB approvals and applicable law or; (c) disclose individual participant results, including results of analysis at an individual participant level, upon presentation or publication of KPMP data or information.

## Company will report in writing any unauthorized use or disclosure of KPMP Resources not provided for in this Agreement within 5 working days of becoming aware of the unauthorized use of disclosure and will take immediate steps to stop the unauthorized disclosure and cure the breach of confidentiality.

## Company agrees to maintain appropriate safeguards to prevent the use or disclosure of KPMP data, biosamples, or resources and will securely manage them in accordance with HIPAA and applicable industry standards.

## If at any time during the Term or thereafter, Institution or any KPMP Affiliate Institution receives an Informed Consent withdrawal request from a patient included in the Research Plan, Institution shall promptly inform Company of this.

## Institution Principal Investigator . The Institution Principal Investigator shall be responsible for all activities undertaken by Institution pursuant to this Agreement and shall supervise the work of all those employees or agents of Institution who are engaged in carrying out the Research Activities (“**Institution Researchers**”). The Institution Principal Investigator shall serve as the primary contact on all matters related to the Research Activities and the Research Plan. If the Institution Principal Investigator ceases to be associated with Institution, becomes incapacitated or is otherwise unable or unwilling to perform under this Agreement, Institution shall provide prompt written notice thereof and shall use diligent efforts to secure a substitute Institution Principal Investigator.

## Updates on the Research Plan . During the Term, the Institution Principal Investigator and representatives of Company shall meet at regular intervals (in person, by teleconference or by videoconference) as agreed by the Parties to discuss the progress of the Research Activities and the Project Results and Project Interpretation.

## Recordkeeping . Institution shall prepare and maintain complete, current, accurate, organized and legible records of all research documentation in compliance with Applicable Laws and applicable Institution policies (the “**Institution Research Documentation**”). Such records shall not include or be combined with records outside the scope of this Agreement. Institution shall retain all Institution Research Documentation during the Term and thereafter until (a) the 3rd anniversary of the date that this Agreement expires or terminates; or (b) such later date as may be required by Applicable Laws or Institution document retention policies (the “**Document Retention Period**”). Upon the expiration of the Document Retention Period, or as otherwise agreed by the Parties, Institution shall transfer the Institution Research Documentation to Company at Company’s request and expense; provided, however, Institution shall be permitted to retain a copy of Institution Research Documentation, or any such records as required by law or that consist of archives or backups made in the normal course of business.

## Regulatory Inspections. Institution shall promptly inform Company and NIH/NIDDK if any governmental or regulatory authority (a) conducts, or gives notice of intent to conduct, an audit of the Institution Research Documentation or an inspection of Institution’s facilities where the Research Activities are performed or (b) takes, or gives notice of its intent to take, legal or regulatory action alleging improper or inadequate practices in the performance of the Research Activities or potentially impacting performance of the Research Activities. Institution shall have the right to be present at and provide assistance for any such inspection or regulatory action with respect to the Research Activities. Institution shall promptly provide Company and NIH/NIDDK with copies of any such notices and related correspondence following receipt thereof. Institution shall further inform Company of the findings of any such action or such inspection that may have an impact on the performance of Research Activities and any related quality systems.

## Supply of Samples and Patient Data . Institution is solely responsible for accessing KPMP Resources and conducting Research Activities at Institution’s facilities as specified in the Research Plan.

## Final Report. Institution shall submit a final written report to within thirty (30) days after the earlier of (a) the completion of the Research Activities or (b) the expiration or earlier termination of this Agreement for any reason. Such final report shall include a comprehensive summary of the Research Activities undertaken and the Project Results and Project Interpretation generated in connection with the Research Plan (the “**Final Report**”).

## **Research Funding**

## Research Budget . Company will reimburse Institution for all costs and expenses incurred by Institution in performing the Research Activities calculated in accordance with the Institution’s usual and customary practices and in accordance with the research budget set forth in Schedule 2 (the “**Research Budget**”). Institution agrees that the aggregate amount specified in the Research Budget is the maximum amount payable under this Agreement and represents full and complete obligation to reimburse Institution for all Research Activities to be performed, and expenses incurred, by Institution under this Agreement. The Parties acknowledge that the amounts to be paid under this Agreement are reasonable cost recovery for the work performed by Institution and that it has not received any other compensation or inducement in connection with this Agreement or its participation in the Research Activities.

## Invoices and Payments. Institution shall invoice for the costs incurred by Institution to undertake the Research Activities up to the maximum amount of the Research Budget. Institution shall invoice for the compensation set forth in the Research Budget according to the payment schedule in Schedule 2. Each invoice shall be payable to Institution within thirty (30) days after receipt. All amounts payable by under this Agreement may be subject to indirect costs (overhead) at the rate the Institution may be obliged to charge. All invoices shall include the applicable Purchase Order number, a reference to the Research Plan, categorisation of the costs being claimed by category as detailed in the Research Budget, and the information set forth in Schedule 3, which may be updated from time to time upon written notice by Institution.

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| --- |
| **All invoices and invoice-supporting documentation shall be submitted electronically (in .pdf, .docx, .xls or .ppt format) as follows:** |
| (To be completed prior to signature execution) |

## Monitoring. Institution shall maintain complete and accurate books, records and accounts that, in reasonable detail, fairly reflect the use of the financial support provided by hereunder. Company or its authorized representatives shall have the right and at Company’s sole cost and expense, during mutually agreeable times and with reasonable notice and in compliance with all applicable laws and generally applicable policies and procedures validly adopted thereto by Institution, to: (a) monitor the conduct of the Research Activities and inspect Institution’s premises where the Research Activities are or are to be carried out, (b) review and audit during the Document Retention Period all non-financial Institution Research Documentation and any other non-financial books, records, accounts and data relating to the Research Activities, and (c) interview the Institution’s Principal Investigator and the Institution Researchers. Institution shall cause the Institution Principal Investigator, the Institution Researchers, and other Institution personnel to reasonably cooperate with any such activities at Company’s sole cost.

Direction of Payments. Payments will be made payable by check to ***The University of Washington*** (Taxpayer Identification No. 91-6001537) and delivered to:

Grant and Contract Accounting

Attention: UW OSP #A\_\_\_\_\_\_

University of Washington

12455 Collections Drive

Chicago, IL 60693

USA

## Transparency Requirements. Institution and Company will perform activities in accordance with the Project Plan disclosed in this Agreement, in full transparency and compliance with the conditions set forth in the federal grant funded by NIH/NIDDK known as the “Kidney Precision Medicine Project”.

## **Ownership of Project Results, Interpretation and Samples**.

## Background Intellectual Property . For the avoidance of doubt, all intellectual property and know-how existing as of the Effective Date or developed or acquired outside of the scope of this Agreement that is used in connection with the Research Activities and that is specifically and explicitly identified in the Research Plan (“**Background Intellectual Property**”), shall remain the property of the Party introducing the same. Nothing in this Agreement shall transfer any rights in such Background Intellectual Property to the other Party. In the event Company identifies that a license to certain Background Intellectual Property owned by Institution is necessary for Company to develop or exploit commercially any Project Results and/or Project Interpretation, and if Institution is able to grant Company rights in such Background Intellectual Property, and such license would not interfere with other licensing plans, Institution shall use reasonable efforts via a separate agreement to grant to Company a non-exclusive license, on commercially reasonable terms and to the extent legally available, to the applicable intellectual property rights in such Background Intellectual Property.

## Ownership of KPMP Resources . As between the Parties, KPMP as represented by the Institution shall solely own all KPMP Resources.

## Use of Participant Data. With the exception of KPMP data that is publicly available via kpmp.org, Institution may grant to Company a worldwide, irrevocable, perpetual, non-exclusive, non-transferable, fully paid-up, royalty-free license to Derived Data, Protected Health Information (PHI), a Limited Data Set (LDS), or De-identified PHI solely for use in and in accordance with the Research Study as described in this Agreement. Such license shall be in accordance with the KPMP Data Use Policy.

## Company agrees to use KPMP Participant Data for internal research purposes only and will not sell, license, or use for direct commercial exploitation any KPMP Participant Data.

## Company agrees that KPMP Participant Data may not be used for direct clinical diagnostic, prognostic, or treatment purposes.

## The De-identified Participant Data shall be treated in accordance with the Participant Data Management Terms in Schedule 4.

## Ownership of Derived Data. Institution and Company shall be free to use such Derived Data for any purpose (subject to Section 4.4.1 and 4.4.2 with regards to Institution) without the obligation to consult or seek approval.

4.4.1 Institution shall not make Derived Data available to any individual participants to whom the Derived Data relates unless deemed appropriately shareable by KPMP and to the extent possible, subject to applicable policy and/or law.

4.4.2 Institution shall not use the Derived Data to inform any clinical decision regarding individual participants to which the Derived Data relates.

## Ownership of Project Interpretation. The Parties agree that Project Interpretation may be freely used for any purpose; provided, however, the foregoing shall not operate to convey any Intellectual Property Rights of a Party to the other Party.

## Ownership of Independent Interpretation. Each Party is empowered under this Agreement to conduct its own Independent Interpretation. The Party conducting the Independent Interpretation shall solely own any Intellectual Property Rights derived from this Independent Interpretation. The owning Party of Intellectual Property Rights derived from Independent Interpretation shall be solely responsible for the prosecution of any Patents. For the avoidance of doubt, the Party owning the Intellectual Property Rights derived from that Independent Interpretation shall be free to use such Independent Interpretation and Intellectual Property Rights therein without the obligation to consult or seek approval from the other Party.

## Inventions conceived and first reduced to practice jointly by Company and Institution in performance of a Research Plan shall be owned jointly by the Company and Institution. These jointly owned elements shall be referred to as “**Joint Inventions**”. Institution may grant Company an option to negotiate an exclusive, royalty-bearing, worldwide license to Institution’s interest in each Joint Invention on commercially reasonable and Institution’s standard terms. Company’s option may be exercised at any time during a period of sixty (60) days after the written submission to the Company by the Institution of a disclosure describing the joint invention. If Company exercises the option, the Parties shall have an additional sixty (60) days to negotiate in good faith a mutually acceptable licensing agreement for the joint invention. If Company does not exercise its option in the given timeframe or if the Parties fail to reach an agreement during this period, Institution shall be free to dispose of its interest in such joint invention with no further obligation to the Company.

## **Confidentiality****.**

## <reserved>

## Confidentiality Obligations . During the Term and for three (3) years from the date of Disclosure, the receiving Party undertakes and shall cause, its officers, directors and other employees and agents (including the Institution Principal Investigator and the Institution Researchers if Institution is the receiving Party) to, (a) use reasonable efforts, but no less than the efforts used to protect its own confidential information, (b) use the same degree it uses to protect its own information of a similar nature, to keep secret and maintain the Confidential Information confidential, other than the receiving Party’s rights to share such Confidential Information solely according to provisions of the Research Plan, and (c) to exercise all reasonable precautions to prevent unauthorized access to the Confidential Information received by the receiving Party. Each receiving Party may disclose Confidential Information to its employees, agents, consultants, advisors, affiliated investigators or other representatives, including but not limited to legal counsel and accountants, provided that such individuals (i) have reasonable need to know the information for the advancement of the Research Plan, and (ii) are advised of and are, by written agreement and/or by virtue of their employment status or affiliation with the receiving Party under obligation, and/or understand the terms of the Agreement and agree to maintain the non-disclosure and use restrictions set forth in this Agreement (each, a “Representative”). Each receiving Party shall be responsible for the compliance of their Representatives with the terms of this Agreement and any breach thereof.

## Each receiving Party agrees to use or copy the Confidential Information it has received solely for the Research Plan as set forth in this Agreement and not to use the Confidential Information for any other purpose.

## Each receiving Party shall, to the extent reasonably practicable and legally permissible, (1) promptly notify the disclosing Party upon becoming aware of any court order or other legal requirement that purports to compel disclosure of any Confidential Information of the disclosing Party and (2) shall not prevent the disclosing Party, at disclosing Party’s request and expense, from seeking to protect the confidentiality of the Confidential Information before any tribunal or governmental agency. It is acknowledged that Confidential Information may be required to be disclosed under the Washington State Public Records Act, RCW 42.56 et seq.  The receiving Party shall use reasonable efforts to furnish no more than the minimal portion legally required to be disclosed and disclosure under this provision shall not otherwise affect the confidential status of the disclosing Party’s Information pursuant to this Agreement.

## Exceptions . The provisions of Section 5.2 shall not apply to any Confidential Information which the receiving Party can demonstrate to the reasonable satisfaction of the disclosing Party:

## was already in the possession of the receiving Party and at the receiving Party’s free use and disposal, or in the public domain prior to its disclosure by the disclosing Party hereunder;

## was prior to disclosure, pursuant to this Agreement, legally acquired by the receiving Party from a third party having good title thereto and the right to disclose the same;

## comes into the public domain, otherwise than through the fault of or breach of this Agreement by the receiving Party or any of its Affiliates; or

## is independently generated by the receiving Party or any of its Affiliates without any recourse or reference to the Confidential Information disclosed by the disclosing Party.

## The Parties understand and agree that:

## The Parties will comply with the **NIH/NIDDK Data Sharing** guidelines and policies, as also outlined in the Data Sharing Plan attached hereto and incorporated herein as Schedule 4.

* + 1. Resource sharing plans for the data and samples generated under the KPMP will follow the policy and objectives stated by NIDDK in the original KPMP NOAs. Specifically, consistent with achieving the objectives of the KPMP, all study data (including, but not limited to, raw data, metadata, digital pathology images, and computational data sets), protocols (including analytical methods), technologies, biological samples (including but not limited to biopsies, nephrectomy tissue, tissue blocks, all slides in any form, blood, urine and stool) and other research resources are to be shared immediately across the Consortium, and made publicly available to the larger community as soon as quality control procedures have been completed, and, in accordance with *KPMP Steering Committee (SC) Policies*, subject to approval by NIDDK. Data derived from KPMP resources must be released to the KPMP Central Hub immediately after quality control assessments are complete. Quality control assessments are defined in the [KPMP Manuals of Procedures](https://kpmp.org/researcher-resources/). For data from technologies in ongoing development and without quality control assessments that are described in the KPMP Manual of Procedures, data should be disclosed to KPMP immediately after reproducibility is demonstrated.
		2. Should data derived by Company from KPMP Resources have intellectual property value that will delay data sharing to the KPMP beyond the time frame just described, a formal disclosure by the Company to the Institution (labeled as Confidential) should be provided within 24 hours after QC assessments are complete. The disclosure must be reviewed by the Institution prior to patent filing. This written disclosure should include a high-level description of the invention to enable determination if all contributing KPMP investigators are included in the invention. The Institution will review within 7 business days. Investigators have 30 days for intellectual property filing after disclosure to the Institution. Immediately following the intellectual property filing deadline, the data supporting the invention must be made available to the Institution, consistent with consortium sharing policy. If data release is expected to take longer than 30 days, the Institution must be notified and will consider a limited time extension. A new [duality of interest disclosure](https://drive.google.com/file/d/1VfTWMXus2c51R5c9L2sBZ-5mu67mUEXy/view) must be submitted following patent filing.
		3. Data derived from participant clinical records linked to biological data will only be made publicly available once risk of explicit or inferred identification has been mitigated in consultation with the Institution and the KPMP Data and Safety Monitoring Board (DSMB). Limited exceptions to the requirement for community dissemination may be identified by the Institution and are subject to approval by the NIDDK. The NIDDK, in consultation with the Institution, will make all final decisions concerning data and sample deposition and data access policies, and all policies are subject to change by the NIDDK as deemed necessary to sustain program principles and priorities, or to ensure the highest standards for responsible research conduct within the project.

## Press Releases and Use of Name . Except as expressly permitted by this Agreement, neither Party shall use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates or employees in any publication, press release, promotional material, or other form of publicity without the prior written approval of the other Party. The restrictions imposed by this Section 5.7 shall not prohibit either Party from making any disclosure that is required by Applicable Laws.

## **Publication of Project Results, Project Interpretation, and Independent Interpretation.**

## Company acknowledges that the Institution will review any and all publications that result from use of the KPMP Resources prior to any manuscript submission, in accordance with the KPMP Publications & Presentations (P&P) Charter. Company agrees to include participating KPMP Investigators as co-authors in any and all publications, consistent with ICMJE standards and KPMP manuscript review and approval which is outlined in the [KPMP Publications & Presentations (P&P) Charter](https://drive.google.com/file/d/1c5kr3twRjxtGojsEx4GJQOirT9Z3sKpE/view).

## The Parties may jointly submit publications regarding the Project Interpretation and Results; provided, however, the Parties understand and agree there shall be no independent publications of any Independent Interpretation until such time as the results generated hereunder are released via the KPMP. Notwithstanding the forgoing or anything to the contrary in this Agreement, Institution shall have the right to independently publish the results of its research, including any Independent Interpretation wholly authored by Institution employees/agents.

## The Parties agree to comply with the International Committee of Medical Journal Editors criteria regarding authorship (available at: [*http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html*](http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)*)* and recommendations regarding disclosure of potential conflicts of interest, including any financial or personal relationships, that might be perceived to bias their work (available at: [*http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html*](http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html)*)*. In so doing, the Parties agree to disclose in any manuscript, journal submission or elsewhere, as appropriate or required, any financial or personal relationship with Company, all individuals who have provided medical writing or editorial support for the publication, and all funding sources for the publication and any related study. The Parties further agree to provide any additional disclosure required by any medical or scientific institution, medical committee or other medical or scientific organization with which they are affiliated.

## The Parties agree to include the following acknowledgement of funding in all abstracts, presentations, and publications: “***Research reported in this publication was completed by investigators at the KPMP. This KPMP project is supported by the NIH National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Project #: 2U24DK114886. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health****.”*

## The Parties recognize NIH/NIDDK’s right to publish the Derived Data pursuant to Section 5.5.

## **Privacy Notice**.

## Privacy laws require Company to notify Institution that personal information about Institution employees (such as name and contact information) obtained in connection with this Agreement may be used for general administrative purposes related to the Research Activities and to contact Institution and its employees about opportunities for further collaboration with Company. Company may share such information with Company affiliates and third-party service providers for these purposes. Institution has the right to ask for a copy of this information, correct inaccuracies, and to opt out of its use for these purposes at any time.

## **Term and Termination.**

## Term. This Agreement shall commence upon the Effective Date and shall continue for [*specified term as per Research Plan*] unless this Agreement is earlier terminated in accordance with this Section 8 (the “**Term**”).

## Termination for Material Breach by Either Party . If a Party is in material breach of this Agreement, and such breach remains uncured for 30 days after notice of breach, then the other Party shall have the right to immediately terminate this Agreement by giving written notice of termination to the breaching Party.

## Termination. Company has the right in its sole discretion to terminate this Agreement for any reason or no reason upon 30 days written notice to Institution. Institution/KPMP also has the right in its sole discretion to terminate the Agreement for any or no reason upon 30 days’ notice to Company.

## Consequences of Termination . Upon expiration or earlier termination of this Agreement:

## each Party shall, subject to Section 5, return to the other Party all Confidential Information of the other Party (except one copy of such Confidential Information may be retained for archival purposes, and any such copies that are required to be retained by law, including records subject to RCW 40.14, or records to the extent contained in an archive or backup made in the normal course of business);

## Institution shall deliver to Company the Final Report;

## in cases of termination of this Agreement by Institution pursuant to Section 8.2 or by Company pursuant to Section 8.3, Company shall reimburse Institution for all non-cancellable obligations committed before receipt of the notice of termination, provided that in no event shall such expense exceed the aggregate amount budgeted in the Research Budget.

## Limitation of Liability . In no event shall either party be liable to the other party for any claims by the other party for indirect, incidental, consequential, special, punitive, or exemplary damages, including lost profits, arising or alleged to arise from this Agreement, its breach, or the transactions contemplated herein, however caused, under any theory of liability.

## Survival . Termination of this Agreement shall not affect any rights and obligations of the Parties that accrued prior to termination. All provisions of this Agreement which, in accordance with their terms, are intended to have effect after termination or expiration of this Agreement shall survive indefinitely the termination or expiration of this Agreement.

## **Indemnification and Insurance.**

* 1. Mutual Indemnification. To the extent permitted by applicable law, including in the case of Institution, RCW 28B20.250 et seq., and subject to the limitations set forth in this Agreement, each party (the “Indemnifying Party”) will defend, indemnify, and hold harmless the other party, including its regents, directors, officers, employees, faculty, students and agents (collectively, the “Indemnified Parties”), from and against any and all losses, claims, liabilities, damages, and costs of whatever kind and nature, including attorney fees and legal costs, for death or injury of any person and for loss or damage to any property, occurring or claimed to occur as a result of the negligence of the Indemnifying Party or the failure of the Indemnifying Party to perform its obligations under this Agreement; providing, however, the Indemnifying Party shall not be obligated to defend, indemnify, and hold harmless any Indemnified Party to the extent any such losses, claims, liabilities, damages, and costs are the result of the negligence of an Indemnified Party or the failure of an Indemnified Party to perform any obligation under this Agreement.

## Insurance. Each Party will maintain adequate and appropriate insurance or self-insurance with respect to its activities in connection with the conduct of research activities hereunder. Each Party may request copies of documentation evidencing the existence of such insurance. Such insurance or self-insurance will be in such amounts and subject to such deductions as are required under Applicable Laws and industry practices customary for well-insured entities engaging in similar activities in the State of Washington.

## Institution Self-Insurance. Institution hereby notifies Company that as an agency of the State of Washington and in accordance with Washington law, Institution maintains a self-insurance program pursuant to RCW §§28B.20.250, 28B.20.253, and 28B.20.255. Upon Company’s request, Institution will provide Company proof of insurance or loss coverage.

* 1. Company Insurance and Proof of Coverage. Company agrees to maintain during the term of this Agreement comprehensive general liability and professional insurance coverage with limits of not less than $1 million per occurrence and $3 million annual aggregate (or an equivalent program of self-insurance satisfactory to Institution). Upon Institution’s request, Company will provide Institution proof of insurance or loss coverage required under the terms of this Agreement. In addition, Company agrees to notify Institution in writing, within 15 days, in the event of a material modification or change in such coverage.

## **Representations, Warranties and Covenants.**

## Institution represents and covenants to Company as follows:

## Institution has the full power and authority, and has taken all necessary actions, to execute and perform its obligations under this Agreement, and entering into this Agreement, performing its obligations hereunder and granting rights to Company as set forth herein do not conflict with any other agreement to which it is a party;

## None of Institution, the Institution Principal Investigator or Institution Researchers have, or at any time during the Term will have: (i) any undeclared financial or other conflict of interest in the outcome of the Research Activities, or (ii) entered into any contract that conflicts with the performance of the Research Activities, or creates a conflict of interest; Institution Principal Investigator or Institution Researchers must have a signed KPMP Investigator Agreement on file with Institution;

## Entering into this Agreement and performing the Research Activities hereunder does not, and shall not, cause Institution, the Institution Principal Investigator, or any Researcher to be in noncompliance with any policy or procedure of any institution or entity with which Institution or such personnel are affiliated (KPMP Affiliate Institution). Institution further represents that the terms and conditions hereof are consistent with the Institution Principal Investigator’s obligations to Institution;

## Institution and Institution Principal Investigator acknowledge that they have been selected to conduct the Research Activities because of their experience, expertise and resources and agree that any costs reimbursed for services provided herein: (i) was determined by means of good faith, transparent communication between the Parties, and (ii) constitutes fair assessment and calculation of the cost for the service rendered in light of Institution’s and Institution Principal Investigator’s expertise and experience. Institution and Institution Principal Investigator acknowledge that they will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and will not make or cause another to make any offer or payment to any individual or entity for the purposes of influencing a decision for the benefit of Company;

## Institution agrees on behalf of the Institution Principal Investigator that s/he will fully comply with all applicable disclosure obligations relating to Institution Principal Investigator’s relationship with Company that may be externally imposed on Institution Principal Investigator based on the requirements of any institution, medical committee or other medical or scientific organization with which Institution Principal Investigator is affiliated; All participants shall disclose any known conflicts of interest no later than 5 business days following execution of this Agreement and as per the KPMP Confidential Disclosure Agreement. All participants in the project shall declare any new conflicts of interest within 2 days of the date of establishment of the relationship.

## Institution has not used, and shall not use in the Research Activities any Person who: (i) is excluded, debarred, suspended or otherwise ineligible to participate in U.S. federal health care, procurement, or non-procurement programs, (ii) has been convicted of a criminal offense that requires exclusion from a U.S. federal health care program, or (iii) is otherwise disqualified or suspended from performing scientific or clinical investigations or subject to any restrictions or sanctions by the U.S. Food and Drug Administration or any other governmental or regulatory authority or professional body with respect to the performance of the Research Activities;

## Institution shall obtain from the Institution Principal Investigator, the Institution Researchers and each of its other employees and agents who are performing the Research Activities, or who otherwise have access to any Confidential Information of Company, rights to all information and inventions generated in the conduct of the Research Activities consistent with applicable Institution policies and procedures, such that Company and its Affiliates shall receive from Institution, without payments beyond those required by Section 3, the assignments, licenses and other rights granted hereunder to Company, Company-Affiliates and their designees; and

## Neither Institution nor Institution Principal Investigator shall use any funding provided by any governmental authority in addition to the federal grant awarded to Institution for the performance of activities of KPMP to conduct any of the Research Activities **if** such funding would impair the ability of Institution or the Institution Principal Investigator to perform any of the Research Activities or own, assign and license any intellectual property consistent with the terms of this Agreement.

## **Miscellaneous.**

## Assignment . This Agreement may not be assigned by either Party in whole or in part without the prior written consent of the other Party, except that Company without such consent may assign this Agreement and its rights and obligations hereunder to any of its Affiliates or any successor in interest to all or substantially all of the business to which this Agreement relates. Company shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Company-Affiliates.

## Subcontractors . Institution shall not engage or make use of subcontractors for the purpose of performing the Research Activities or any other obligations under this Agreement except as expressly authorized by Company in writing and described in the approved Ancillary Study or Research Plan. Any such permitted subcontract shall be subject to the applicable terms and conditions of this Agreement, prior to disclosing to such subcontractor any Company Confidential Information; provided, however, that no such subcontract shall release Institution from any of its obligations under this Agreement except to the extent such obligations are satisfactorily performed by such subcontractor in accordance with this Agreement.

## Governing Law and Dispute Resolution . The interpretation and construction of this Agreement shall be governed by the laws of the state of Washington, USA, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

## Jurisdiction. Subject to Section 11.8, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the USA for any action, suit or proceeding arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding related thereto except in such courts.

## Notices . Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified below or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 11.5. Such notice shall be deemed to have been given as of the date delivered by hand or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service.

Address for Notice

|  |  |  |
| --- | --- | --- |
| **Institution** | To: University of WashingtonOffice of Sponsored ProgramsAttention: Director of Sponsored Programs4333 Brooklyn Ave NEBox 359472Seattle, WA 98195-9472(206) 543-4043 (Voice)(206) 685-1732 (Facsimile)osp@u.washington.edu (Electronic Mail) | With a copy to:In the case of a legal notice relating to a dispute, claim or controversy arising out of or relating to this Agreement, a copy of such notice shall also be provided to:Washington State Attorney General’s OfficeUniversity of Washington DivisionAttention: Senior Assistant Attorney General4333 Brooklyn Ave NEBox 359475Seattle, WA 98195-9475(206) 543-4150 (Voice)(206) 543-0779 (Facsimile)agouw@u.washington.edu (Electronic Mail) |
| **Company** | To: | With a copy to: |
|  |  |  |

## Relationship of the Parties . Nothing contained in this Agreement shall be construed as creating a partnership, joint venture or agency relationship between the Parties or, except as otherwise expressly provided in this Agreement, as granting either Party the authority to bind or contract any obligation in the name of or on the account of the other Party or to make any statements, representations, warranties or commitments on behalf of the other Party. All persons employed by a Party shall be employees of such Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

## Construction. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular and the word “or” has the inclusive meaning represented by the phrase “and/or.” The headings of this Agreement are for convenience of reference only and do not define, describe, extend, or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. The term “including” or “includes” as used in this Agreement means including, without limiting the generality of any description preceding such term. No rule of strict construction shall be applied against any Party.

## Equitable Relief . The Parties recognize that any threatened breach or breach of Sections 4, 5 or 6 may cause irreparable harm that is inadequately compensable in damages and that, in addition to other remedies that may be available at law or equity, the non-breaching Party is entitled to seek injunctive relief for such threatened or actual breach in any court of competent jurisdiction.

## Amendment, Modification and Waiver . No amendment, modification, or waiver of any of the terms of this Agreement shall be deemed valid unless made in writing and duly executed by authorized representatives of both Parties. Each Party shall have the right to enforce the Agreement in strict accordance with its terms. The failure of either Party to enforce its rights strictly in accordance with terms shall not be construed as having in any way modified or waived same.

## Severability .If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, then to the fullest extent permitted by Applicable Laws and if the rights and obligations of any Party will not be materially and adversely affected: (a) such provision will be given no effect by the Parties and shall not form part of this Agreement; (b) all other provisions of this Agreement shall remain in full force and effect; and (c) the Parties shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Laws and achieves, as nearly as possible, the original intention of the Parties. To the fullest extent permitted by Applicable Laws, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

## Entire Agreement . This Agreement and all attachments constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersede all prior oral and written agreements, understandings, promises and representations with respect thereto. In the event of any inconsistency between any such Schedules and this Agreement, the terms of this Agreement shall govern. This Agreement shall be deemed by Institution and NIH/NIDDK as exhibiting equivalent language to what is mandated in the KPMP General Collaborations Policy, the KPMP Master CDA/MTA Agreement, the KPMP Data Use Agreement, the KPMP Ancillary Studies Policy, and the KPMP Publications and Presentations Charter.

## Counterparts . This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one agreement. The Parties agree that execution of this Agreement by industry standard electronic signature software or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defence or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

## [*Remainder of page intentionally left blank. Signatures follow.*]

**Execution**

THIS AGREEMENT IS EXECUTED by the authorised representatives of the Parties as of the Effective Date.

|  |  |  |
| --- | --- | --- |
| **SIGNED for and on behalf of** |  | **SIGNED for and on behalf of** |
|  |  |  |
| Signature |  | Signature |
| Name: |  |  | Name: |  |
| Title: |  |  | Title: |  |
| Date: |  |  | Date: |  |

Although not a party to this Agreement, the Institution Principal Investigator acknowledges that he/she has read this Agreement and understands the obligations Institution has undertaken on his/her behalf.

**Acknowledged and Understood:**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:

Title:

Schedule 1 – Approved Project Plan

[Insert approved Project Plan here]

Schedule 2 – Research Budget, Costs to be Reimbursed, or Transfers of Value

 **Company Deliverables** [Insert text]

 **Institution Deliverables** [Insert Text]

Schedule 3 - Invoice Requirements

 [Insert U. Washington Invoice Policies and Processes requirements here]

**Schedule 4 – Patient Data Management Agreement (“PDMA”)**

1. Company represents (a) that Company’s Investigator Representatives have obtained appropriate ethics training and IRB authorization to the extent such IRB review and approval are required by federal regulations or Company’s policies to conduct the Research Study identified in Schedule 1 of this Agreement and, as required by applicable law, to access the KPMP Data (b) that the KPMP Data contains the minimum necessary information to accomplish the identified Research Study.
2. Company shall not use or disclose the KPMP Data in any manner that (a) is not specifically authorized by this Agreement or (b) would constitute a violation of federal law, specifically HIPAA and regulations enacted pursuant thereto (“HIPAA Standards”) or any other applicable privacy law. Company must obtain specific authorization in the form of an Amendment to the Agreement or another signed agreement to use or disclose the KPMP Data for any purpose other than that specifically authorized herein.

Company will allow the use of KPMP Data only by Company’s Investigator and Company’s Investigator’s research team (“Company’s Representatives”) who are under the direct supervision of Company’s Investigator and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any further distribution of KPMP Data beyond Company’s Representatives requires the advance written approval of Institution.

1. Company agrees that it will not (a) attempt to identify the participant(s) contained in the KPMP Data, (b) contact any participant(s) who are the subject of the KPMP Data if the KPMP Data is a LDS or a De-Identified Dataset; and (c) contact any participant(s) who are the subject of any PHI KPMP Data, unless otherwise authorized to do so in accordance with the applicable IRB approval and applicable law; or (d) disclose individual participant results, including results of analysis at an individual participant level, when the KPMP Data are presented or published.

Company agrees that it will maintain appropriate safeguards to prevent the use or disclosure of the KPMP Data and securely manage the KPMP Data in accordance with HIPAA and applicable industry standards. This includes, use of appropriate technical perimeter hardening and monitoring its system and perimeter configurations and network traffic for vulnerabilities, indicators of activities by threat actors, and/or the presence of malicious code. In addition, Company will use access, authorization, and authentication technology appropriate for protecting KPMP Data from unauthorized access or modification, and capable of accounting for access to KPMP Data. The overall access control model of the Company’s systems shall follow the principle of least privileges and ensure limited administrative access, removal of system and device default passwords and removal of access for terminated users. Company will implement encryption controls to protect KPMP Data both stored and in transit from unauthorized access. The Company shall discontinue use of encryption methods and communication protocols which become obsolete or have become compromised. The Company shall have a process for backup and restoration of data.

1. Company agrees that it shall report in writing any unauthorized use or disclosure of the KPMP Data not provided for in this Agreement within 5 working days of becoming aware of an unauthorized use or disclosure. Company shall take immediate steps to stop the unauthorized disclosure and cure the breach of confidentiality.

Company acknowledges that the Institution will review any and all publications that result from use of the KPMP Data prior to any manuscript submission, in accordance with the KPMP Publications & Presentations (P&P) Charter and this Agreement. Company agrees to include participating KPMP Investigators as co-authors in any and all publications, consistent with ICMJE standards and KPMP manuscript review and approval which is outlined in the [KPMP Publications & Presentations (P&P) Charter](https://drive.google.com/file/d/1c5kr3twRjxtGojsEx4GJQOirT9Z3sKpE/view) (Appendix D).

Within 30 days of when the Research Study is completed, or this Agreement expires per timeline specified in the Research Plan, or is terminated (whichever occurs first), any KPMP Data described in the Research Plan will both be destroyed in compliance with all applicable statutes and regulations and certified in writing upon request to Institution as being destroyed, unless Recipient obtains written authorization from the Institution to retain the KPMP Data for an alternative defined period of time.

**Schedule 5 - Results Sharing Plan**

Reflect and Reference all relevant Articles within the Agreement.

Description of Derived Results are agreed to be shared back to the KPMP according to mutually agreed-upon Terms and Timing.

**APPENDIX A: APPROVED ANCILLARY STUDY APPLICATION**

**APPENDIX B: KPMP AFFILIATE INSTITUTION LIST <reserved>**