Appendix G: Research Collaboration Agreement

FOR THE ESTABLISHMENT OF PATIENT & PUBLIC INVOLVEMENT AND ENGAGEMENT GROUP

This Research Collaboration Agreement for the 'Establishment of a Patient & Public Involvement and Engagement Group' project is entered into on the 00th day of XXXX 20XX ("Agreement") by and between:

[Insert Institution A name and address] (Hereinafter referred to as "[Insert institution abbreviation, *Institution A*]").

(e.g. Ziauddin University, 4/B, Shahrah-e-Ghalib, Block 6, Clifton, Karachi, Pakistan 75000, through its Office of Research, Innovation & Commercialization (Hereinafter stated as "ZU").

And

[Insert Institution B name and address] (Hereinafter referred to as "[Insert institution abbreviation, *e.g. Institution B*]").

The foregoing entities are referred to each, individually as "Party" and collectively as "Parties".

Background

A. Patient and public involvement and engagement (PPIE) is an approach to research carried out 'with' or 'by' members of the public rather than 'to', 'about', or 'for' them. This methodology involves an active and meaningful partnership between patients, the public, clinicians, and researchers to identify research priorities, design studies, carry out research, and disseminate findings. This Research Collaboration Agreement (RCA) outlines the framework for collaboration between [*Institution A*] and [*Institution B*] to advance PPIE in clinical research.

B. The establishment of Patient and Public Involvement and Engagement (PPIE) groups across Pakistan is being led by [*Lead Research Group/Department Name*] at [*Institution A*] (Principal Investigator: [*Insert PI Name*]). [*Insert PI Name*] serves as [Insert Role/Position] of the [Insert Network or Organisation Name] and is working towards facilitating PPIE activities in the region.

Description of the Project

This Agreement establishes the framework for supporting [*Institution B*] in setting up its Patient & Public Involvement and Engagement Group and facilitating its effective implementation. This is a project-based initiative, rather than a formal study, with the potential to contribute to research studies in the future if deemed necessary. As part of this

collaboration, [*Institution B*] will contribute to community engagement work, such as reviewing consent materials for planned studies when relevant. Collaborative activities will be mutually agreed upon by the Parties.

1.1 **[*Institution A*] *responsibilities***

- [*Institution A*] *will serve as the national coordinating hub for the establishment, oversight and integration of the PPIE group into the national PPIE network as more groups develop.*
- [*Institution A*] *will a) provide training and mentorship to site teams, b) support the development of a site-specific project plan and operational documents by sharing guidance documents and templates and; c) enhance capacity building by meeting regularly to provide input on recruitment, governance, monitoring, long-term engagement strategies and offer opportunities to get certification in PPIE.*
- [*Institution A*] *will coordinate reimbursement of up to 10 PPIE group members (subject to prior approval and availability of funds): ensuring financial support for time and travel related to the group's activities, training, and public engagement initiatives.*
  - *Up to xx in-person meetings per year (maximum insert duration, e.g. two hours each)*
  - *Up to xx online meetings per year (maximum insert duration, e.g. two hour each)*
- [*Institution A*] *will comply with its research guidelines and hospital policies applicable to this project, which are based on ethical principles that have their origin in the Declaration of Helsinki, and are consistent with Good Clinical Practice (GCP) guidelines as well as applicable regulatory requirements.*

1.2 **[*Institution B*] responsibilities:**

- [*Institution B*] will establish and maintain a Patient & Public Involvement and Engagement Group in collaboration with [*Institution A*] as the national coordinating hub.
- [*Institution B*] will a) appoint a site lead and engagement coordinator to oversee local activities, b) participate in training and mentorship sessions organised by [*Institution A*] and; c) develop a site-specific project plan and operational documents, which address locally identified priorities and contribute to one or more of the following objectives:

  [*Institutions may select one or more of the objectives below to focus on in their site-specific plan*]
  - Review and improve the clinical characterisation protocol (CCP) study processes
  - Evaluate community engagement approaches and strategies
  - Sharing research outputs with patients and the public
  - Co-develop a patient outcome improvement plan for priority infectious diseases (e.g., acute brain infections, dengue, or acute respiratory illnesses)
  - Contribute to the design, conduct & dissemination of observational and interventional clinical studies
  - Co-develop and pilot a tool to measure stigma associated with emerging epidemic diseases

- [*Institution B*] will implement recruitment, governance, and monitoring strategies to ensure meaningful and sustained patient and public involvement and engagement.
- [*Institution B*] will facilitate active engagement of PPIE group members in study design, consent processes, and research dissemination.
- [*Institution B*] will collaborate with the national PPIE network, benefiting from peer support and resource sharing.
- [*Institution B*] will ensure timely documentation and reporting of PPIE activities, including tracking participation, engagement outcomes, participation in evaluation of PPIE efforts and key learnings.
- [*Institution B*] will coordinate with [*Institution A*] for reimbursement of advisory group members' time and travel, in line with the established compensation policy.

  [*Institutions may also add additional responsibilities or objectives if deemed appropriate to their context and priorities.*]

Project Leads

The scientist directing [*Institution A*] activities on the project shall be [*Insert PI Name*] ("Principal Investigator"). The [*Insert PI Name*] Investigator shall coordinate [*Institution B*] activities with *[Insert PI name]* ("Principal Investigator – [*Institution B*]"). If a designated Principal Investigator is unable to continue to serve and a successor is not found, this Agreement may be subject to termination.

Article 1. Project Monitoring

Both [*Institution A*] *and* [*Institution B*] *shall ensure that all systems used to collect, process, store, and manage PPIE-related data, including member profiles, engagement records, study contributions, and public involvement activities, are maintained and upgraded as required to protect the integrity and security of the data. This shall be done in accordance with accepted research standards, ethical guidelines, and applicable laws on confidentiality, privacy, and governance of patient and public data.*

Article 2. Financial Agreement

2.1 Prior agreed reimbursement payments to the PPIE Group members will be managed by [*Institution A*] *on behalf of [insert name of funders, if applicable] and the Principal Investigator.*
2.2 All Parties shall be responsible for their respective tax payments (if any) related to financial disbursements.
2.3 All payments shall be made to the "[name of institution A]", which will disburse funds to participating PPIE Group members.
2.4 All claims shall be sent to: name of institution A]

Article 3. Additional Collaboration Opportunities

3.1 [*Institution B*] *will be invited to [collaborative activities, e.g. workshops, public events] organised by* [*Institution A*]*, where coordinators and members can share best practices, challenges, and lessons learned.*
3.2 These activities will also provide professional development opportunities, including training sessions, peer learning and and talks from PPIE experts.
3.3 Travel, accommodation, and attendance costs for [*Institution B*]*'s coordinators and members will be covered as per prior agreed terms.*

Effective Date and Term

The Agreement shall be effective from [XX/XX/20XX] and will be valid for a term of [*insert duration e.g. duration of grant*].

Article 4. Modification and Termination

4.1 The project may be terminated immediately if required by a governmental regulatory authority or if a party determines that discontinuation is necessary for health, safety or ethical reasons.
4.2 Any Party may terminate this Agreement with thirty (30) days' written notice.
4.3 If a Principal Investigator ceases participation, reasonable efforts shall be made to find a replacement. If no suitable candidate is found, the Agreement will terminate.
4.4 A Party may terminate this Agreement immediately if the other party a) commits criminal misconduct, gross negligence, or unethical behavior, b) willfully violates confidentiality, intellectual property, or contractual obligations.

Article 5. Data Protection and Confidentiality

5.1 As used in this Agreement, the term ***"PHI Data"*** *means all personal information (including without limitation medical data, information and other personal identifiable health information), Data means all information including de-identified medical information gathered, generated, processed for the purposes of the project shall be kept confidential and used solely for the purposes outlined in this Agreement. Under no circumstances such information shall*

be disclosed, shared, or used for any purpose outside the scope of the project without the prior written consent of the other party and in accordance with all applicable data protection laws.
5.2 Data handling must comply with ethical approvals, regulatory conditions, and informed consent protocols.

Article 6. Intellectual Property.
6.1 All rights, title, methodologies and interest in and to any and all study-related materials arising out of the initiative shall be the sole and exclusive property of [*Institution B*] *and* [*Institution A*].
6.2 Any intellectual property (IP) or inventions developed under this Agreement shall be promptly disclosed to the relevant Parties and shall be subject to a royalty-free, non-exclusive license for internal and academic research purposes and not for commercial purposes.

Article 7. Use of a Party's Name.
7.1 Notwithstanding anything in this Agreement to the contrary and without further notice, the Parties hereto acknowledge and agree that each of the Parties may disclose the existence of this Agreement, the title of the project, identify the Parties to this Agreement, and disclose the amount of funding actually received from [*Institution A*] *pursuant to this Agreement, including but not limited to acknowledgment in any publication or presentation relating to the results of the study as provided herein; and that Investigator may disclose the same information in a curriculum vitae. However, no Party shall use the name of the other in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses services, organisations or products, without the prior written approval of the other Party.*

Terms of Agreement.
Nothing herein is intended to conflict with current directives and policies of each Party. If any of the terms of this Agreement is inconsistent with existing directives of the Parties hereto, those portions of this Agreement that are determined to be inconsistent shall be invalid; and the remaining terms and conditions shall remain in full force and effect.

IN WITNESS WHEREOF the Parties hereto have set their hands on the day and year first above written.

Signatures

Date _____	Date _____
[Name]	[Name]
[Designation]	[Designation]
[Institution A]	[Institution B]