**CONTINUING ETHICAL REVIEW APPLICATION FORM**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:**

***Ethical clearance or approval is typically granted for a period of one year (12 months), after which a continuing review is required to assess the study protocol's ongoing risk. The frequency of this review is outlined in the Study Protocol Approval Letter. As the expiry date approaches, and if renewal or extension is necessary, it is advisable to submit the required form at least 60 days in advance. Please ensure you obtain an electronic copy of the renewal form and input all necessary information in the provided spaces. Once completed, print email the form to erc@altamash.pk or submit the application on A4 size paper and submit to secretary RDRC-AIDM. Date and sign the form before submission.***

*Please write NA if the requested information is not applicable to your study*

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| --- |
| **Ethical Review Committee’s CODE:AIDM/ERC/Month/Year/No. allotted by RDRC of AIDM** |
| **Study protocol title:**  |
| **Initial approval date:** | **Expiry date of last approval:** |
| **Principal Investigator:** |
| **Email:** | **Telephone:** | **Mobile:** |
| **Study site:** |
| **Study site address:** |
| **Sponsor if any:** |
| **Sponsor contact person:** |
| **Email:** | **Telephone:** | **Mobile:** |
| **Application submission date:**  |
| 1. **Start date:**
	1. Date of research site initialization: <dd/mm/yyyy>:
	2. Explanation, if not yet initialized as of date of this application: <reason/s>
 |
|  Action requested:* 1.  Renewal: New participant accrual to continue
	2.  Renewal: Enrolled participant follow up only
	3.  Early Termination: Study protocol discontinued ahead of study indicated duration
	4.  Other (specify):
 |
| 1. **Has there been any amendment since the last review/approval?**
	1.  No
	2.  Yes (Describe briefly and / or attach amendment approval letter):
 |
| 1. **Has there been any change in the participant population, recruitment or selection criteria since the last review/approval?**
	1.  No
	2.  Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s):
 |
| 1. **Has there been any change in the informed consent process or documentation since the last review/ approval? Attach latest version of participant information sheet and informed consent form/document**
	1.  No
	2.  Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s):
 |
| 1. **Has any information appeared in the literature, or evolved from this or similar research that might affect the committee’s evaluation of the risk/benefit assessment of human participants involved in this study protocol?**
	1.  No
	2.  Yes (Describe briefly and provide copy of literature cited, including the Investigator’s

 Brochure if applicable): |
| 1. **Has any unexpected discomfort, complication, or side effect been noted since last review/ approval?**
	1.  No
	2.  Yes Add details ……………………………………………………………………………………………………………………………………………………………
 |
| 1. **Has there been any new intervention or method in the conduct of study that is/are not in the approved protocol**
	1.  No
	2.  Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-compliance/Violation Report Submission/s):
 |
| 1. **Has any investigator been added or deleted since last review/ approval?**
	1.  No
	2.  Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment submission/s. Append CV if not yet submitted to the RDRC- Altamash Institute of Dental Medicine):
 |
| 1. **Has any new collaborating site (institution) been added or deleted since the last review/ approval?**
	1.  No
	2.  Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s):
 |
| 1. **Has any investigator developed equity or consultative relationship with a party related to this study protocol which might be considered a conflict of interest since the last review/approval?**
	1.  No
	2.  Yes (Append a statement of disclosure):
 |
| 1. **Have there been changes in study personnel since the last review/ approval?**
	1.  None:
	2.  Deleted (Enumerate and indicate date/s of Study Protocol Amendment Submission/s )
	3.  Added (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)

**Label the point in bracket and Answer here, e.g, (12.1) Answer.** |
| 1. **Have there been any updates on coverage of insurance certificate (if any) since the last review/approval? Attach an updated insurance certificate.**
	1.  No
	2.  Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
 |
| 1. **Have there been other changes not mentioned above since the last Review/approval? Attach protocol synopsis.**
	1.  No
	2.  Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s):
 |
| 1. **Progress Status (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete)**
	1. <Component 1><Provide description as needed>
	2. <Add components as necessary>
 |
| **Signature of Principal Investigator:** |
| **Date Signed:** |