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| **Biomedical Closure** | **For Internal Use Only** |
| **UnivRS Internal ID:**  **Date Received:** Click here to enter a date. |

**Questions marked with an** \* **are mandatory.**

**Key Information**

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| --- | --- | --- |
| UnivRS Internal Project ID# or old Ethics ID # (Bio xx-xxx):\*  PI Name: \*  Protocol Number (if applicable):  Project Title: \*  Current Expiry Date :\*  Indicate the nature of the project: \* Choose an item.  Close-out visit date (if applicable): Click here to enter a date.   |  |  | | --- | --- | | Sponsor has conducted a close-out visit: | Yes  No  N/A |   Reason for closure:\* Choose an item.  Provide additional details as applicable: |

**Participants: Prospective, Biobank, and Data Registry**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Number of participants enrolled: |  | | Number of participants who completed all project related activities: |  | | Number of participants who were lost to follow-up: |  | | Number of participants who withdrew consent: |  | | Number of participants who were withdrawn: |  | | Number of non-research related deaths (i.e. unrelated adverse event): |  | | Provide additional details as applicable: | | |

**Secondary Use of Health Data and Biological Materials**

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| |  |  | | --- | --- | | Specify the number of charts or biological materials used: |  |   Provide additional details as applicable: |

**Post-Approval Reporting**

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| --- | --- | --- | --- | --- |
| **Reportable Unanticipated Problems include any incident, experience or outcome (including an adverse event or breach of confidentiality) that meets ALL of the following criteria:**   1. Unexpected in terms of nature, severity or frequency; 2. Related or possibly related to participation in research; 3. Suggests that research places research participants or others at a greater risk of harm than was previously known or recognized.  |  |  | | --- | --- | | Were there unreported, unanticipated problems that fit the reporting criteria? \* | Yes  No | | Were there unreported participants' concerns or complaints? \* | Yes  No |   Provide additional details as applicable: |

**Data Security and Storage**

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| --- |
| Describe the final disposition of the data, including arrangements for security, storage, and/or destruction: \*  Data retention period: \*Choose an item.  If ‘Other’ was selected, please specify: |

**Dissemination of Results**

|  |  |  |
| --- | --- | --- |
| Provide a summary of project results and/or outcomes: \*   |  |  | | --- | --- | | Have the results have been submitted for publication, published or presented: \*  If no or N/A, explain: | Yes  No  N/A | |

**Declaration by Principal Investigator:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **The Principal Investigator assumes full responsibility for the information presented in this closure report and confirms that:**   1. **All of the information is accurate and complete as presented;** 2. **There is no further participant involvement at the site, all new data collection is complete and the sponsor closeout activities, if applicable, have been completed;** 3. **For research involving secondary use of existing health data or biological materials, the acquisition of data is complete and/or no additional biological materials are being acquired.** 4. **The data will be retained according to applicable guidelines and regulations.**  |  |  | | --- | --- | | Date the form was completed: Click here to enter a date. | | | Name of Person who completed the form: |  |   If form submitted on behalf of the PI:   |  |  | | --- | --- | | is authorized to prepare and submit this form on behalf of the Principal Investigator | | | Authorized person contact information: | | | Email: | Phone: | |

**Document(s)**

Please provide a list of documents that are being submitted along with this closure: