|  |  |
| --- | --- |
| IRB | International IRB Attestation Form |

|  |  |
| --- | --- |
| Please provide contact information for a representative who can answer any questions that the IRB might have concerning this submission: | |
| Name: |  |
| Position: |  |
| E-mail: |  |
| Phone #: |  |
| Pager #: |  |
| 2nd Contact: | name + e-mail or phone # |
| Group: |  |

|  |
| --- |
| Purpose: This form provides a written commitment from the Principal Investigator to ensure compliance with local IRB requirements and reporting obligations for international research, when in-country IRB/Ethics Committee Approval is needed. |

**Attestation Statement:**

As the Principal Investigator (PI) for the above-named study, I, [PI Name], certify the following:

1. **IRB Approval Requirement**:
   * Since any international research conducted in a specific country may be subject to the approval of an Institutional Review Board (IRB) or Ethics Committee (EC) in that country, I will ensure that all necessary IRB/EC (or other relevant in-country) approvals are obtained as required by local regulations and research guidelines before any study activities begin in that country.
2. **Maintaining IRB/EC Approvals**:
   * I will maintain compliance with all required in-country IRB/EC approvals throughout the duration of the research study (examples include but are not limited to continuing review, etc.)
3. **Reporting Obligations**:
   * I will fulfill all required reporting obligations as stipulated by the in-country IRB/EC. This includes but not limited to submitting progress reports, amendments, adverse events, and study closure reports to the appropriate in-country authorities within the required timelines.
4. **Ongoing Compliance**:
   * I will ensure that any changes in the study protocol, informed consent process, or other critical aspects of the study are communicated to and approved by the relevant IRB/EC in a timely manner.
5. **Documentation**:
   * I will retain documentation of all required IRB/EC approvals, amendments, and communications, and will make them available for review by the relevant parties (e.g., sponsors, regulatory agencies) upon request.

**Certification:**

By signing below, I certify that the above information is accurate, and I agree to fulfill the obligations described in this attestation.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Principal Investigator Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Princip Investigator Signature