**Protocol Amendment Form**

□ Version.................................... Date ............/............/............

1. Protocol Title…………………………………………………………………………………………………………….………………….

2. Principal Investigator’s name……………………………………………………………………………………………….…………….

3. Research Site………………………………………………………………………………………………………….……………………...

4. Protocol Number …………………………………………………...……………………….……………………

5. Please fill in the table below and modified the related documents (submission form, protocol, etc.), highlight the revised part.

Please send the amended documents along with this form.

|  |  |  |  |
| --- | --- | --- | --- |
| **Page, Item, Content to be amended** | **Reason for Amendment** | **Previous Content** | **New Content** |
|  |  |  |  |

6. The amendment effect well-being or may harm to research participants

❒ Yes ❒ No

7. The amendment may need any change in participant information sheet/informed consent form

❒ No

❒ Yes ❒ Consent form Addendum for previously consented subjects, version date........................

❒ New Consent form version date ......................

For ❒ New subject

❒ Reconsent for previously consented subjects

Signature .............................................................., date……………………

(.............................................................)

Principal Investigator