**Annual Report Form**

**Please complete the form within 30 days after receiving the form or before the expiring date of guarantee and send back to at the Ethical Review Committee for Human Research, Faculty of Public Health, Mahidol University, in order to follow discipline of the Ethical Review Committee**

**❒ Annual research’s result report and the requirement for the extension of the Certificate**

 **of Approval**

**❒ Summarize the result of annual research project and declare closing of the Project**

**1. Protocol Title** (English)………………..…….…………………………...…...………………….

**2. Principal Investigator** ………………………………………..……..………...…………………

**3.** **Affiliation** …………………………....………………………...…………………………………

**4. Protocol No.** ……………………………

**5. Certificate of Approval** (COA. No.) ……………… Date of Approval: ………………………

 Date of Expiration: ……………..………

**6.** **Funding Source** ❒ have fund ❒ within the university

❒ out of the university/indicate ………………………

 ❒ No

**7. Can you collect the participants of research project?** ❒ all ❒ not all, according to the plan

**8. Problems and obstacles in continuing research**  **❒**no **❒** yes, please indicate the details

………………………………………………….………………………………….…………………

……………………………………………………………………..…………………………………

**9. Details about the participants** ❒no ❒ yes, please indicate the details following:

The number of the participants from the project’s start until now …………………… :divided to

-the number of the participants in continuing research …………………………….people

-the number of the participants who loss follow up (drop out) ……………………..people

-the number of the participants with completely collected data……………………people

### -the number of the participants still in follow up process after completion on collected data

### 10. Details about event or adverse event that occur with the participants

###  ❒ No ❒ Yes: (please indicate in 1.2)

1. The number of adverse event found……..times.

Please clarify the adverse event ………………………………………………………..

1. The number of serious adverse event………………………………………..times

 The participants who had the event and the serious adverse event above occurred

❒ Had been admitted to the hospital…people/times, involving to the research…times

❒ Die……………………..people, involving to the research……….times

❒ Others indicate…………………………………………………………

**11. In continuing the research, do you have protocol amendment?**

❒ No ❒ Yes …..… times ❒ Notify MUPH-IRB at (data)……...………….

 ❒ Not Notify

**12. In continuing research. Do you have protocol deviation?**

❒ No ❒ Yes …..… times ❒ Notify MUPH-IRB at (data)……...…………. ❒ Not Notify

**13. Do you have the information searched and added in risk / Benefit involving the research?**

❒ No ❒ Yes /Please indicate …………………………………...………………

………………………………………………….………………………………….…………………

**14. How do you have plans to present the research result?**

* To publish in journal within the country; indicate……………………...……..……
* To publish in international journal; indicate ……………………………………….
* Oral presentation ……………………………….…………..………………………
* Poster presentation ………………………………....………………………………
* Others…………....……………………………
* No plan to present

**15. The process of preparing the result of the study**

* Preparing the manuscript
* Have already sent the article to the editor of the journal
* Accepted ❒ Not accepted
* Others indicate…………………………………………………..

**16. Any contribution that you need from Ethics Committee for Human Research**

………………………………………………….………………………………….…………………

……………………………………………………………………..…………………………………

**17. Indicate data for:**

❒ In case of the project not end, expect to close the project, (d/m/y) …………....……

and to renewal certificate of approval ❒ 1 year ❒ ........ (month)

❒ Closing of the project, (d/m/y) ………....……

Signature …………..…………….…….…….…

(………….……………………………)

Principal Investigator

Date………………………

Remarks: If you have more information, you can add contents and enclosing with this form