FORMULIR REVIEW LANJUTAN

Continuing Review Submission Form

KOMITE ETIK PENELITIAN KEDOKTERAN DAN KESEHATAN

Medical and Health Research Ethical Comittee

FAKULTAS KEDOKTERAN UNIVERSITAS ISLAM INDONESIA

Faculty of Medicine, UII

Protocol No. :

Protocol title :

Principle investigator :

1. Action requested:
   a. Renew - New participant accrual to continue
   b. Renew - Enrolled participant follow up only
   c. Terminate - Protocol discontinued

2. Have there been any amendments since the last review
   a. No
   b. Yes (describe briefly in attached narrative)

3. Summary of protocol participants:

   _____ accrual ceiling set by iec/irb

   _____ new participants accrued since last review

   _____ total participants accrued since protocol began

4. Accrual exclusions

   - ❑ None
   - ❑ Male
   - ❑ Female
   - ❑ Other (specify: _____)

5. Impaired participants

   - ❑ None
   - ❑ Physically

- ❑ Cognitively
- ❑ Both

6. Have there been any changes in the participant population, recruitment or selection criteria since the last review?

   - ❑ No
   - ❑ Yes (explain changes in attached narrative)

7. Have there been any changes in the informed consent process or documentation since the last review?

   - ❑ No
   - ❑ Yes (explain changes in attached narrative)

8. Have any unexpected complications or side effects been noted since last review?
   - ❑ No
   - ❑ Yes (discuss in the attached narrative)

9. Have any participants withdrawn from this study since the last iec/irb approval?

   - ❑ No
   - ❑ Yes (discuss in the attached narrative)

10. Investigational new drug/device

    ☐ none ☐ ind ☐ ide

    fda no. ……..

    name: ……

    sponsor: ……

    holder: ……

    Ionizing radiation use (x-rays, radioisotopes, etc)

    - ❑ None
    - ❑ Medically indicated only

11. Have any participating investigators been added or deleted since last review?

    ❑ No
    ❑ Yes (identify all changes in the attached narrative)

12. Have any new collaborating sites (institutions) been added or deleted since the last review?

    ❑ No
    ❑ Yes (identify all changes and provide an explanation of changes in the attached narrative)

13. Change in medical advisor/investigator?
    a. None
    b. Delete :
    c. Add :

14. Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?
    a. NO
    b. YES (Append a statement of disclosure)

Signatures:

Date: …….

Principal Investigator
