



Requirements to Issue an Ethical Clearance or National Endorsement of Health Research in Sudan

Required Documents:

المستندات المطلوبة :

- 1- Written request to issue the ethical clearance addressed to the Research Directorate.
- 2- The project proposal in print-out (9 copies), each in a separate file.
- 3- Each copy should include the Principal Investigator's (PI) resume, including the recently published articles in relation to the project.
- 4- For higher education (e.g. MD Thesis), the following should be included:
 - ☐ acceptance from the supervisor
 - ☐ The supervisor's resume.

C.V. should include:

- **Title** of the supervisor.
 - **Degree** of the supervisor.
 - Current **position**.
 - Most recent **(5) publications** on the proposed subject.
- 5- The names of the collaborating investigators, their qualifications and their roles in the study.
 - 6- A formal letter from the institute to which the investigators belong mentioning their acceptance to perform the study.

- 7- A formal acceptance letter from the hospital (or other study site) to have the study conducted in their premises.
- 8- Any ethical clearances obtained by the PI from other research ethics committee (if present).
- 9- A copy of the Informed Consent.
- 10- An electronic copy of the proposal should be sent to fmohresearch@yahoo.com



Important Notice to Researchers

Conditions to issue ethical clearance or national endorsement in Sudan

- The copies of the study proposal and all supporting documents should be handed in the **first week** of the month.
- The eligible proposals are first submitted to the nearest monthly meeting of the Technical Committee.
- After technical approval, the proposal will be shifted to the next Ethics Committee Meeting.
- The average time for having the ethical clearance is **6-8 weeks** from submission.
- In case of proposed amendments, or refusal from the Technical Committee, the PI will receive the written comments of the committee **after one week** from the meeting.
- The PI should reply to the comments of the Technical Committee thoroughly, and then **resubmit the modified proposal** before two weeks from the next meeting, i.e. in the first week of the month.
- The modifications done by the PI should be described in a separate sheet with the summary of amendments, and how the PI worked on each (including the page numbers in the modified proposal).

- The modified proposal is treated as **a new proposal**, including the above mentioned requirements.
- The renewal of the ethical clearance is needed for any study more than one year, and should be renewed annually.
- The renewal of the ethical clearance is also considered as a new process, though the old ethical clearance and the technical/progress report should be accompanied to the forms.