THE REPUBLIC OF SUDAN

NATIONAL MINISTRY OF HEALTH

HEALTH RESEARCH COUNCIL

NATIONAL APPLICATION FORM FOR ETHICAL

APPROVAL OF A RESEARCH PROJECT

The application technical and ethical guidelines format are to be read before completing this form to ensure that the questions are answered appropriately.

You may find it helpful to read both national technical and ethical guidelines and then fill the format. You can add **extra pages.**

Before requesting an individual's consent to participate in research, the investigator must read chapter three in the **Guidelines for Ethical Conduct of Research Involving Human Subjects.**

The Arabic version of the **informed consent** is the form to be used to take the consent from the **Sudanese** research **participants**, so you should fill it in details and in a language or another form of communication that the individual can understand the research subject.

Ministry of Health

Health Research Council

2012

Do not include this page with your application

research.dep.fmoh@gmail.com

بسم الله الرحمن الرحيم

NATIONAL MINISTRY OF HEALTH

NATIONAL HEALTH RESEARCH COUNCIL

NATIONAL HEALTH RESEARCH ETHICS COMMITTEE

NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

The first page of the National Application Form

1-Status: Tick the right choice

☐ submission.Second s☐ssion.Date of the first submission

☐ Third submission. Date of the first submission…….

☐n submission. Date of the first submission…….

2-Title:.....

3-Principal investigator

4-Institute of affiliation: .....

5- Amount of budget and the Funding agent/s:

6-Purpose of study: Tick the right choice ✓

☐cademic degree ☐ogram activity ☐research grantsOthers☐

7-Mention the supporting collaborators (agents) if there are any :(Technical,/logistic/financial support).....

8-Type of the research: Tick the right choice ✓

☐edical research. ☐cal ☐emiological ☐l research

☐ Health system research (health services, Health financing).

9- Does the project Involve collection or use of human tissue or blood?

☐ N☐

10-Does the project Involve uses of stored human tissue or blood?

☐ ☐

11-Will lab tests be done outside The Sudan?

☐ ☐ ☐plicable

12-Will there be any invasive procedures to the human body?

☐ ☐

research.dep.fmoh@gmail.com

13-Will any substance or drug be introduced into or applied to participants' human bodies?

☐ Yes No ☐

14-Will there any use of data from patients' records?

☐ Yes ☐ No

15- Is there any similar study done in Sudan before?

☐ Yes ☐ No ☐ I don't know

16-If yes mention the:A- Name of the: Title of the previous study/ies:

C-Date of the previous study/ies: .....

For office use only

Proposal No.:
Date Received:

research.dep.fmoh@gmail.com

Please read the technical and ethical guidelines thoroughly before filling the form

Part 1: Technical proposal form

SUMMARY SHEET

1		Principal investigator Prof/Dr/Mr. Mrs./Miss
	1.1	Title of post, position or appointment presently held by principal investigator
	1.2	Complete Postal address / e-mail Office Tel. Mobile Tel.
2		Institution responsible for the research programme Name and address
3	3.1	Co- investigator(**1**) Prof/Dr/Mr. Mrs/Miss
	3.2	Title of post, position or appointment presently held by co- investigator**(1)**

		Complete Postal address / e-mail Office Tel. Mobile Tel.
		Co- investigator(**2**) Prof/Dr/Mr. Mrs/Miss
		Title of post, position or appointment presently held by co- investigator**(2)** Complete Postal address / e-mail Office Tel. Mobile Tel.
		Co- investigator(**3**) Prof/Dr/Mr. Mrs/Miss
		Is the research proposed in this application submitted to elsewhere for : Support? If so, to which institute or organization, and what kind of support expected?
4		Is the research proposed in this application reviewed by your Institutional

		ethical committee? Institutional ethical clearance letter enclosed Yes No
5		Applicant's signature Date: signature:
6		Institutional endorsement Head of institution Title:_____ Name_____ Date:_____ Signature

☒ **For more co- investigators use separate paper**

research.dep.fmoh@gmail.com

SHEET FOR RESEARCH PROJECT DESCRIPTION

Title of research:

1. Introduction/ Background(Including statement of the problem, relevance of the problem to the national health or local health objectives (biomedical, behavioral and health systems development).

2. Review of literature and existing information(showing the relevance of the proposed research problem to the national health or local health objectives (biomedical, behavioral and health systems development).

research.dep.fmoh@gmail.com

3. Statement of Objectives

General objective:
Specific objectives:

4. Variables

5. Statement of research hypothesis (if any)

6. Methodology

Research design:
Selection of research area (description of place where the study will be conducted, population, health facilities, health personnel,….etc)
Study population:(demographic profile, recruitment inclusion and exclusion criteria)

Sampling: (sample selection method, method of calculating the sample size ,how sampling error or bias will be minimized)
Study instruments: (including questionnaire ,details of laboratory tests, detailed sample taking procedures, drug dosage, clinical case sheet, check list……etc.)
Data collection plan: (description of how data will be collected, by whom, and their training,….etc)

7. Data analysis plan

Data processing: (sorting, coding, manual, computer processing…etc)

Data analysis: (describe what type of statistical analysis will be used (SPSS, odd ratio, logistic regression….etc), dummy tables….etc.

8. Work plan:

• Place (include institutional technical facilities available)
•Time (include when study to commence, duration, if in stages the time schedule for each part)

9. Budget :(Personnel/ consumable items/ transportation/ field expenses…..etc.)

research.dep.fmoh@gmail.com

Part Two: Ethical Considerations

1. What is an estimate of total time involved for participants in the study?

2. Who will carry out the research procedures?
3. What other research studies is the principal investigator currently involved with?
4. Where will the research procedures take place?
5. Does the project Involve collection or use of human tissue?
6. If yes: will this material be used in further studies?
7. Does the researcher, the host department, the host institution, have any financial interest in the outcome of this research? If “yes”, please give details.

1) Minimization of Harm

8. How do the research procedures differ from standard treatment procedures?
9. What are the benefits to research participants taking part?

research.dep.fmoh@gmail.com

10. What are the physical or psychological risks, or side effects to participants or third parties? Describe what action will be taken to minimize any such risks or side effects.
11. What facilities/procedures and personnel are there for dealing with emergencies?
12. What arrangements will be made for monitoring and detecting adverse outcomes?
13. Is the trial being reviewed by a data safety monitoring board (DSMB)?
14. If yes, who will fund of the DSMB?
15. What are the criteria for terminating the study?
16. Will any potential toxins, mutagens or teratogens be used?
17. If **yes**, specify and outline the justification for their use

18. Will any radiation or radioactive substances be used?
19. Has the National Committee for atomic energy completed risk assessment?
20. If **yes**, please enclose a copy of the risk assessment, and the contact name and phone number
21. If **no**, please explain why
22. Will any drugs be administered for the purposes of this study?
23. If yes:
a. is approval of the concerned authorities required?
b. trade name of drug
c. Chemical name of drug
d. Pharmacological class:
e. Pharmacological class, e.g., long half life, receptor selectivity.
f. Recommended dose range
g. Form of administration in the study

h. Known or possible interactions with non-trial drugs the participants may be taking
i. Side effects and adverse reactions
24. Does the study involve the use of healthcare resources?
25. If **yes**, please specify:
26. What effect will this use of resources have on waiting list times for patients ie. for diagnostic tests or for standard treatments?

2) Privacy and Confidentiality

27. How will participants be recruited? (e.g. advertisements, notices)
28. Where will potential participants be approached? (e.g. outpatient clinic) If propriate describe by type (eg students)
29. Who will make the initial approach to potential participants?
30. How will data including audio and video tapes be handled and stored to safeguard confidentiality (both during and after completion of the research project)?
31. What will be done with the raw data when the study is finished?
32. How long will the data from the study be kept and who will be responsible for its safe keeping?
33. Who will have access to the raw data and/or clinical records during, or after, the study?
34. Describe any arrangements to make results available to participants, including whether they will be offered their audio tapes or videos.

3) Informed Consent

- Consent should be obtained in writing, unless there are good reasons to the contrary. If consent is not to be obtained in writing, the justification should be given and the circumstances under which consent is obtained should be recorded.
- Attach a copy of the information sheet and consent form.

35. By whom, and how, will the project be explained to potential participants?
36. When and where will the explanation be given?
37. Will a competent interpreter be available, if required?
38. How much time will be allowed for the potential participant to decide about taking part?
39. In what form (written or oral) will consent be obtained? If oral consent only, state reasons
40. Are all participants able to consent themselves?
41. If no, explain why, and who will consent for them?
42. Is there any special relationship between the participants and the researchers? E.g. doctor/patient, student/teacher
43. Will there be any financial cost to the participant, e.g. travel costs? If so, will such cost be reimbursed?
44. Will any payments be made to participants or will they gain materially in other ways from participating in this project?
45. If **yes**, please supply details

4) Declarations

1.Declaration by Principal Investigator

The information supplied in this application is, to the best of my knowledge and belief, accurate. I have considered the ethical issues involved in this research and believe that I have adequately addressed them in this application. I understand that if the protocol for this research changes in any way I must inform the ethics committee.

NAME OF PRINCIPAL INVESTIGATOR:

.....

SIGNATURE OF PRINCIPAL INVESTIGATOR:

.....

DATE.....

2. Declaration by Head of Department in which the Principal Investigator is located or appropriate Dean or other Senior Manager

I have read the application and it is appropriate for this research to be conducted in this department I give my consent for the application to be forwarded to the concerned ethics committee.

NAME AND DESIGNATION: .....

SIGNATURE: .....

INSTITUTION: .....

DATE: .....

موجهات إقرار موافقة الشخص الخاضع للبحث أو من ينوب عنه

research.dep.fmoh@gmail.com

أنا الباحث(تعرفه باسمك كاملاً ثم أذكر الجهة أو المؤسسة التى تتبع لها والتي تقوم بالبحث), نقوم ببحث أو دراسة عن(ثم تقوم بشرح عنوان البحث وأغراضه بالتفصيل).

لقد تم إختيارك لتشارك في هذا البحث أنت(أو طفلك) ومعك عدد آخر من المشاركين(ثم تشرح له بالتفصيل لماذا أختير هو ومن معه من المشاركين).

نتوقع بمشاركتك أنت والمشاركين الآخرين أن نتحصل على نتائج تفيد(أشرح له الفوائد المتوقعة من البحث على كل من(المشارك نفسه أم المجتمع أم مقدمي الخدمات .....إلخ).

خلال هذه الدراسة سأقوم(أشرح له بالتفصيل الإجراء الذي تنوي القيام به تجاه المشارك: أخذ معلومات, أخذ عينة من سوائل الجسم مثل(دم أو بول .....إلخ أو نسيج(مثال :عظم, أو إعطاء عقار أو لقاح أو إجراء تدخلي مثل إجراء عمليات جراحية أو تجربة جهاز طبي أو فحص معملي حديث.....إلخ).

الإجراء الذي سأقوم به تجاهك به بعض من المخاطرأو الأعراض الجانبية (ثم تقوم بشرحها له إن وجدت أو يتوقع حدوثها) . أو تؤكد له خلو البحث من أية مخاطر على المشارك أو من ينوب عنه.

في حال ظهور أي من المضاعفات أو أعراض جانبية سوف نقوم بتقديم الرعاية الصحية لك في(تشرح له الجهة التي سيتلقى فيها الخدمة) بالعلاج المناسب.

ونحن إذ نأمل فى مشاركتك معنا فى هذا البحث , نؤكد لك على سرية المعلومات و الوثائق الخاصة بك , و أنه لن يطلع عليها إلا الباحث المعنى و لجنة أخلاقيات البحوث الصحية القومية.

(يمكن صياغتها بطرق أخرى مثلاً : سنملأ إستمارة توضح معلومات شخصية عنك , و هذه المعلومات ستحفظ بطريقة مشفرة وسرية - أو سنستخدم رقم ولن يظهر إسمك فى أى إستمارة – و سوف نخبرك بنتيجة الفحوصات (فى حالة عمل فحوصات معملية)عن طريق طبيبك المعالج , لن نجمع منك أى عينات أخرى , أما العينات التى يتم جمعها سوف تستعمل لغرض هذه الدراسة فقط). و نود أن نشير كذلك إلى أن المشاركة فى البحث طوعية وأن رفضك للمشاركة فى البحث لا تفقدك الحق فى أى فوائد من البحث (يمكنك ذكر هذه الفوائد – مثلاً تشخيص وعلاج المرض , تحصين , و غيرها) , مع التأكيد على أنه لن يتم منحك أى قيمة نقدية مقابل المشاركة فى هذا البحث (إلا أنه قد يتم تعويضك عن نفقات السفر – على سبيل المثال) و أنه بمشاركتك ستكون أحد المتطوعين والذين يشملهم البحث و عددهم حوالى .....مشارك متطوع .

كما نؤكد لك إمكانية الإنسحاب من البحث فى أى وقت تشاء , و دون إبداء توضيح لأسباب الإنسحاب , ويتم ذلك بالتوقيع على طلب الإنسحاب , و لن يؤثر ذلك أيضاً على حقك فى الإستفادة من البحث .

سنقدم لك الرعاية الصحية فى حالة حدوث مضاعفات من إجراء هذا البحث.

إذا كان لديك أى سؤال أو إستفسار يخص البحث , المشاركين معك فى البحث , أو حقوقك كمشارك أثناء تنفيذ البحث يمكنك الإتصال على(ثم تمده باسم وعنوان الشخص أو الجهة التي سيتصل عليها المشارك) :

research.dep.fmoh@gmail.com

و فى حالة حدوث أى مضاعفات من أثناء تنفيذ البحث يمكنك الإتصال على(ثم تمده باسم وعنوان الشخص أو الجهة التي سيتلقى فيها المشارك الرعاية الصحية)، اضافة اسم ورقم تلفون من اجل اي استفسارات.

إقرار موافقة الشخص الخاضع للبحث

لقد إطلعت على المعلومات الحالية والتي تم شرحها لي وأتيح لى طرح الأسئلة عنها كيفما شئت , و قد تلقيت الإجابات الوافية عن كل الأسئلة , و أنا أقر بالموافقة (أو أقر عن إبنى) على المشاركة **طواعية** فى هذه الدراسة و أعلم بحقى فى التوقف عن المشاركة فى أى وقت دون أن يؤثر ذلك على حقوقى فى (مثلاً : تلقى العناية الطبية اللازمة فى أى وقت لاحقاً) .

رمز

المشارك.....

إسم المشارك:

.....

.....

توقيع المشارك

.....

.....

رمز من ينوب عن المشارك(في حال الطفل أو المعاق ذهنياَ ....إلخ)

.....

.توقيع من ينوب عن المشاركشرعاَ.....

عنوان من ينوب عن المشارك:.....

.في حال عدم قدرة المشارك على قراءة الإقرار ويحتاج إلى من يشرح أو يترجم له:

إسم الشارح(االمترجم)

.....

research.dep.fmoh@gmail.com

عنوان الشارح أو(المترجم):

.....

توقيع الشارح أو(المترجم):

.....

توقيع الباحث:

.....

research.dep.fmoh@gmail.com