APPLICATION FORM FOR PROPOSED RESEARCH PROJECT AT THE SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Sefako Makgatho University Research Ethics Committee (SMUREC)
Prof GA Ogunbanjo: SMUREC Chairperson
PO BOX 163, MEDUNSA, 0204

Molotlegi Street, Ga-Rankuwa, 0208
Telephone: 012 521 5617 / 3698| Fax: 012 521 3749
Email: lorato.phiri@smu.ac.za

A. PARTICULARS OF APPLICANT/CHIEF RESEARCHER

Surname: First names:

Title: Sex: Race

Staff /Student No: School: Department:

Tel: . Cell No.: Internal Box No:

E-mail address (Researcher)

E-mail address (Supervisor, if applicable)

B. DETAILS OF RESEARCH PROJECT

(Tick appropriate block(s) with a 'x'

1.a New project ☐ or : Continuation of project ☐

1.b Independent research : ☐ or : Contract research: ☐

Post-graduate research: ☐ or : Undergraduate research : ☐

Degree (specify): _____

At which university is the degree registered? _____

2.a Title of project: _____

_____

_____

b. Co-workers (Not for post-graduate research. See Guidelines)

Name	Department/Institution	Signature

c. Research Coordinator (In the case of independent or contract research)

Name	Department/Institution	Signature

d. Supervisor (In the case of post-graduate or undergraduate research)

Name	Qualification	Department/ Institution	Signature

e. Co-supervisor (In the case of post-graduate or undergraduate research)

Name	Qualification	Department/Institution	Signature

f. Hospital Superintendent/Health Care Manager

Name	Department/Institution	Signature

g. Other involved departmental heads

Name	Department/Institution	Signature

C. SPECIAL REQUIREMENTS

Will the research involve the following:

	Yes	No		Yes	No
Experimental animals			Approval from Animal ethics Committee attached (separate application form required)		
Special apparatus			Is it available at Sefako Makgatho		
Special drugs (medicaments)			Explanation of who will supply the drugs attached		
Radio isotopes			Completed radio Isotopes form attached (Appendix 4)		
Special laboratory facilities			Is it available at Sefako Makgatho? If no, attach a statement of requirements		
Electron microscopy			Completed Electron microscope form attached (Appendix 3)		
Health care services			Signature of health care manager attached		
Statistical analysis			Has a statistician been consulted? If yes, attach form. (Appendix 2) If no explain.		
Recording of participants using photographic images and illustration that include digital (video and still), film and radiographs. If yes see Appendix 5			If yes clearly indicate in your protocol the informed consent, privacy and confidentiality measures		

D. ETHICAL ISSUES

1. *Indemnity*

   If a hospital (human, dental or veterinary) will be involved, please attach the written approval of the Superintendent. Should the use of the service laboratories be required, attached a letter of consent of the hospital management that this is in order.

2. *Consent*

   Will patients/human volunteers form part of the experiment/trial/survey? If so, kindly modify the attached form, specifically for your project. (Appendix 1)

E. BUDGET

Who will finance this project? (Tick appropriate block with a "x")

Sefako Makgatho Health Sciences University		Health Department		Self		Other (specify)	

Please indicate the institutions where application has been made for financial support or where it is intended to apply for financial support.

MRC		NRF		CSD		Other (specify)	

NB: Approval of the research project does **NOT** imply that the requested funds will be made available to the applicant.

F. DECLARATION BY RESEARCHER(S)

Should this project be approved, I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research. I/we guarantee to ensure compliance with these approved conditions. Furthermore, I/we undertake **not to change the procedure as detailed in the protocol but will submit a further application to the Research Committee if changes become necessary**

TITLE, INITIALS & SURNAME: _____
CHIEF RESEARCHER:

SIGNATURE: _____ **DATE:** _____

TITLE, INITIALS & SURNAME: _____
HEAD OF DEPARTMENT

SIGNATURE:_____ **DATE:**_____

TITLE, INITIALS & SURNAME: _____
CHAIRPERSON: SCHOOL RESEARCH COMMITTEE

SIGNATURE:_____ **DATE:**_____

TITLE, INITIALS & SURNAME: _____
DEAN OF SCHOOL

SIGNATURE: _____ **DATE:**_____

APPENDIX 1

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY ENGLISH CONSENT FORM

Statement concerning participation in a Clinical Trial/Research Project*.

Name of Project / Study / Trial*

.....

.....

.....

I have read the information on */heard the aims and objectives of* the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I know that photographs / electronic images / sound recordings* will be taken of me. I am aware that this material may be used in scientific publications which will be electronically available throughout the world. I consent to this provided that my name / and hospital number* is / are* not revealed. Regarding images of the face, I understand that it may not be possible to disguise my identity, and I consent to the use of these images*.

I understand that participation in this Clinical Trial / Study / Project* is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Trial / Study / Project* has been approved by the Sefako Makgatho University Research Ethics Committee (SMUREC), Sefako Makgatho Health Sciences University / Dr George Mukhari Hospital. I am fully aware that the results of this results of this Trial / Study / Project* will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Trial / Study / Project*.

....
Name of patient/volunteer Signature of patient or guardian.

....
Place. Date. Witness

Statement by the Researcher

I provided verbal and/or written* information regarding this Trial / Study / Project*
I agree to answer any future questions concerning the Trial / Study / Project* as best as I am able.
I will adhere to the approved protocol.

....
Name of Researcher Signature Date Place

*Delete whatever is not applicable.

AANHANGSEL 1

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY AFRIKAANS CONSENT FORM

Verklaring ten opsigte van deelname aan 'n Kliniese Eksperiment/Navorsingsprojek*

Naam van Projek/Studie/Eksperiment*

..... ……

.....

.....

Ek het die inligting in verband met die beoogde studie gelees*/het die doelwitte en oogmerke van die beoogde studie aangehoor* en is die geleentheid gegun om vrae te stel asook voldoende tyd toegelaat om oor die aangeleentheid te besin. Die doelwit en oogmerke van die studie is duidelik genoeg vir my. Ek is geensins onder enige druk geplaas om deel te neem nie.

Ek verstaan dat deelname aan hierdie Kliniese Eksperiment/Studie/Projek* geheel en al vrywillig is en dat ek te eniger tyd daarvan kan onttrek sonder om enige redes aan te voer. Dit sal geen invloed hê op die gereelde behandeling van my toestand nie, en sal ook nie die behandeling wat ek van my eie dokter ontvang, beïnvloed nie.

Ek is bewus daarvan dat hierdie Eksperiment/Studie/Projek* goedgekeur is deur die 'Sefako Makgatho University Research Ethics Committee (SMUREC)', Sefako Makgatho Health Sciences University / Dr George Mukhari Hospitaal. Ek is ten volle bewus daarvan dat die uitslae van hierdie Eksperiment/Studie/Projek* aangewend sal word vir wetenskaplike doeleindes, en gepubliseer mag word. Ek stem daartoe in, met dien verstande dat my privaatheid gewaarborg is.

Hiermee verleen ek toestemming om deel te neem aan hierdie Eksperiment/Studie/Projek*.

.....	.....
Naam van pasiënt/vrywilliger	Handtekening van pasiënt of voog

.....	.....	.....
Plek	Datum	Getuie

Verklaring deur Navorser

Ek het mondelingse en/of skriftelike* inligting ten opsigte van hierdie Eksperiment/Studie/Projek* voorsien. Ek verklaar myself bereid om enige toekomstige vrae ten opsigte van die Eksperiment/Studie/Projek* na die beste van my vermoë te beantwoord.
Ek sal myself onderwerp aan die goedgekeurde protokol.

.....	.....	.....……	……..
Naam van Navorser	Handtekening	Datum	Plek

*Skrap waar nie van toepassing nie.

APPENDIX 1

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY SETSWANA CONSENT FORM

Seteitemente se se ka ga go tsaya karolo mo Tekopatlisisong / Porojeke ya Patlisiso*.

Leina la Porojeke / Patlisiso / Tekelelo*

..... ……

.....

.....

Ke buisitse tshedimosetso mo */ke utlwile maitlhomo le maikemisetso a* patlisiso e e tshitshintsweng mme ke filwe tšhono ya go botsa dipotso le go fiwa nako e e lekaneng ya go akanya gape ka ntlha e. Maitlhomo le maikemisetso a patlisiso e a tlhaloganyega sentle. Ga ke a patelediwa ke ope ka tsela epe go tsaya karolo.

Ke tlhaloganya gore go tsaya karolo mo Tekopatlisisong e / Patlisiso / Porojeke* ke boithaopo le gore nka ikgogela morago mo go yona ka nako nngwe le nngwe kwa ntle ga go neela mabaka. Se ga se kitla se nna le seabe sepe mo kalafong ya me ya go le gale ya bolwetsi jo ke nang le jona e bile ga se kitla se nna le tlhotlheletso epe mo tlhokomelong e ke e amogelang mo ngakeng ya me ya go le gale.

Ke a itse gore Tekopatlisiso / Patlisiso / Porojeke* e e rebotswe ke Patlisiso le Molao wa Maitsholo tsa Khampase ya Sefako Makgatho University Research Ethics Committee (SMUREC), Yunibesithi ya Sefako Makgatho Health Sciences / Bookelo jwa Ngaka George Mukhari. Ke itse ka botlalo gore dipholo tsa Tekelelo / Patlisiso / Porojeke* di tla dirisetswa mabaka a saentifiki e bile di ka nna tsa phasaladiwa. Ke dumelana le seno, fa fela go netefadiwa gore se e tla nna khupamarama.

Fano ke neela tumelelo ya go tsaya karolo mo Tekelelong / Patlisiso / Porojeke* e.

....
Leina ka molwetse/moithaopi Tshaeno ya molwetse kgotsa motlamedi.

....
Lefelo. Letlha. Paki

_____

Seteitemente ka Mmatlisisi

Ke tlametse tshedimosetso ka molomo le/kgotsa e e kwadilweng malebana le Tekelelo / Patlisiso / Porojeke* e.
Ke dumela go araba dipotso dingwe le dingwe mo nakong e e tlang tse di amanang le Tekelelo / Patlisiso / Porojeke* ka moo nka kgonang ka teng.
Ke tla tshegetsa porotokolo e e rebotsweng.

....……
Leina la Mmatlisisi Tshaeno Letlha Lefelo

*Phimola sengwe le sengwe se se seng maleba.

TLALELETŠO 1

Sefako Makgatho Health Sciences University SEPEDI CONSENT FORM

Setatamente mabapi le go tšea karolo ka go Protšeke ya Dinyakišišo tša Teko ya Klinikhale *.

Leina la Protšeke / Dinyakišišo / Teko*

..... …….

.....

.....

Ke badile/ke kwele ka ga tshedimošo mabapi le *maikemišetšo le morero wa* dinyakišišo tšeo di šišintšwego gomme ke ile ka fiwa monyetla wa go botšiša dipotšišo gomme ka fiwa nako yeo e lekanego gore ke naganišiše ka ga taba ye. Ke tloga ke kwešiša maikemišetšo le morero wa dinyakišišo tše gabotse. Ga se ka gapeletšwa go kgatha tema ka tsela efe goba efe.

Ke a kwešiša gore go kgatha tema Protšekeng/Dinyakišišong tše tša Teko ya Klinikhale* ke ga boithaopo gomme nka tlogela go kgatha tema nakong efe goba efe ntle le gore ke fe mabaka. Se se ka se be le khuetšo efe goba efe go kalafo yaka ya ka mehla ya maemo a ka gape e ka se huetše le ge e ka ba tlhokomelo yeo ke e humanago go ngaka yaka ya ka mehla.

Ke a tseba gore Teko/Protšeke/Dinyakišišo tše* di dumeletšwe ke Sefako Makgatho University Research Ethics Committee (SMUREC), Yunibesithi ya Limpopo (Khamphase ya Medunsa) / Dr George Mukhari Hospital.Ke tseba gabotse gore dipoelo tša Teko/Dinyakišišo/ Protšeke tše * di tla dirišetšwa merero ya saense gomme di ka phatlalatšwa. Ke dumelelana le se, ge fela bosephiri bja ka bo ka tiišetšwa.

Mo ke fa tumelelo ya go kgatha tema Tekong/Dinyakišišong/ Protšekeng *.

.....
Leina la molwetši/ moithaopi Mosaeno wa molwetši goba mohlokomedi.

....
Lefelo. Letšatšikgwedi.
Tlhatse

Setatamente ka Monyakišiši

Ke fana ka tshedimošo ka molomo le/goba yeo e ngwadilwego * mabapi le Teko/Dinyakišišo/ Protšeke ye .*
Ke dumela go araba dipotšišo dife goba dife tša ka moso mabapi le Teko/Dinyakišišo/ / Protšeke ka bokgoni ka moo nka kgonago ka gona.
Ke tla latela melao yeo e dumeletšwego.

.... ……..
Leina la Monyakišiši Mosaeno Letšatšikgwedi Lefelo

*Phumola tšeo di sego maleba.

ISITHASISELO 1

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY ISIZULU CONSENT FORM

Isitatimende esimaqondana nokuhlanganyela oHlolweni Lokwelashwa/kuPhrojekthi Yocwaningo*

Igama lePhrojekthi/loCwaningo/loHlolo*

..... ……

.....

.....

Ngilufundile ulwazi*/ngizizwile izinhloso nezinjongo* zocwaningo oluhlongoziwe futhi nganikezwa nethuba lokubuza imibuzo nganikezwa nesikhathi esanele sokuphinde ngicabange ngodaba. Inhloso nenjongo yocwaningo kucace ngokwanele kimi. Azange ngicindezelwe ukuthi ngihlanganyele nganoma iyiphi indlela.

Ngiyaqonda ukuthi ukuhlanganyela kulolu Hlolo/Cwaningo/ kule Projekthi* yoHlolo ngokokuzithandela ngokuphelele nokuthi ngingahoxa kulo noma nini ngaphandle kokunikeza izizathu. Lokhu angeke kube nomthelela ekwelashweni okuvamile kwesimo sami futhi angeke kube nomthelela ekunakekelweni engikuthola kudokotela wami ovamile.

Ngiyazi ukuthi lolu Hlolo/Cwaningo/le Projekthi* igunyazwe yi-Sefako Makgatho University Research Ethics Committee (SMUREC), Sefako Makgatho Health Sciences University / Dr George Mukhari Hospital. Nginolwazi olugcwele lokuthi imiphumela yalolu Hlolo/Cwaningo/yale Projekthi* izosetshenziselwa izinhloso zesayensi futhi ingashicilelwa. Ngiyakuvuma lokhu, uma nje ingasese lami liqinisekisiwe

Lapha nginikeza imvume yokuhlanganyela kulolu *.

....
Igama lesiguli/levolontiya Isignesha yesiguli noma yomgadi.

....
Indawo. Usuku. Ufakazi

Isitatimende somCwaningi

Nginikezele ngolwazi ngomlomo kanye/noma olubhaliwe* maqondana nalolu Hlolo/Cwaningo/nale Phrojekthi*. Ngiyavuma ukuphendula nanoma yimiphi imibuzo yesikhathi esizayo maqondana noHlolo/Cwaningo/ne Phrojekthi* kahle kakhulu kangangoba ngikwazi. Ngizobambelela kusivumelwano senqubo esigunyaziwe

....……
Igama loMcwaningi Isignesha Usuku Indawo

* Cisha noma yini engasebenzi.

APPENDIX 2

STATISTICAL ANALYSES

The Chairperson,
Sefako Makgatho University Research Ethics Committee (SMUREC),
Box 163
SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Dear Sir/Madam

STATISTICAL ANALYSES

I have studied the research protocol of

_____

titled: _____

_____

_____

_____

and I agree/do not agree * to assist with the statistical analyses.

Yours sincerely,

_____
Signature: Statistician

_____
Name in block letters

_____
Date

* Please delete which is not applicable. If you do not agree to assist with the statistical analyses, please provide reasons on a separate sheet.

APPENDIX 3

ELECTRON MICROSCOPE UNIT

A. Outline requirements

_____
_____
_____
_____
_____
_____
_____
_____
_____

B. Give estimation of cost (this should be discussed with the Director of the Electron Microscope Unit)

_____
_____
_____
_____
_____
_____
_____
_____
_____

SIGNATURE: _____ **DATE:** _____

DIRECTOR: ELECTRON MICROSCOPE UNIT

APPENDIX 4

RADIO ISOTOPES

a) Will isotopes be used during the course of the experiment: _____

b) If affirmative, state the isotopes to be used

_____

_____

c) State the quantity of radioactive materials to be stored:

_____

_____

For what period? _____

Used at any given moment? _____

d) State the name of the registered laboratory where the work will be conducted

_____

e) Do you have previous experience in the handling of radioactive material? If affirmative, please qualify

_____

_____

f) Do the laboratory personnel have any experience in the handling of the radioactive material: Please qualify

_____

g) State the method of disposal after use

_____

_____

SIGNATURE: _____ **DATE:** _____

RADIATION PROTECTION OFFICER

(Approval of above-mentioned information must be obtained before submission to SMUREC)

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Department of Medical Illustration and Audio-Visual Services

PATIENT PHOTOGRAPHY REQUEST FORM

DIAGNOSIS:

.....

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DETAILS OF PHOTOGRAPH(S):

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.....

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.....

.....

TICK AS REQUIRED:

- ☐ PRINTS (Black & White)
- ☐ PRINTS (Colour)
- ☐ COLOUR SLIDE
- ☐ DIGITAL IMAGES
- ☐ VIDEO*

PURPOSE:

- ☐ RESEARCH
- ☐ PUBLICATION
- ☐ RECORD
- ☐ TEACHING

Extra Copies Required For:

Signature: ..... Date: .....

* PLEASE NOTE THAT PRIOR NOTICE FOR THIS PROCEDURE IS REQUIRED.

PARTICULARS OF PATIENT:

SURNAME & INNITIALS: .....

HOSPITAL/FILE NUMBER: .....

AGE: ..... **ID NO:** .....

WARD/DEPARTMENT/CLINIC: .....

CONSULTANT/DOCTOR.: .....

HAS THE PATIENT BEEN PHOTOGRAPHED BEFORE: ☐

FOR DEPARTMENTAL USE ONLY:

SCALE: .....

VIEWS: .....

TOTAL NUMBER OF VIEWS: .....

INSTRUCTIONS: .....

.....

.....

.....

.....

.....

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.....

PHOTOGRAPHER: .....

DATE: .....

CONSENT BY PATIENT:

I hereby consent to being photographed/video taped, and I agree that the photographs/video may be used for the purpose explained to me by Prof./Dr./Mr./Ms._____ *(Doctor/Consultant's Name - Please print your name)*

Patient signature:_____ *(Patient signature)* **Date:** _____

CHECK LIST FOR PROPOSED RESEARCH PROJECT
AT THE SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Chief Researcher: _____

Department: _____

School: _____

Type of project: _____

Degree: _____

Title of project: _____

_____

Documents submitted	Yes	No
1. Completed Research protocol		
2. Completed research application form		
2.1 Signature of Chief Researcher		
2.2 Signature of Head of Department		
2.3 Signature of Chairperson: School Research Committee		
2.4 Signature of School Dean		
2.5 Appendix 1: Completed Consent form (English version)		
2.6 Appendix 1: Completed Consent form (Translated local language version)		
2.7 Appendix 2: Completed statistical analyses form with statistician's signature		
3. Data collection tool (including questionnaire)		

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Suggested format for research protocols

The research protocol should be typed in double spacing. The title or research question should be clearly stated, including the details of the chief researcher, supervisor and co-supervisor, where applicable. The following headings are suggested, although some studies may require a slightly different format:

1. The **study problem** (or, rationale of the study). In a paragraph or two, explain what the problem is.

2. **Literature Review** (or background to the study): In half to three pages, explain what is known from the literature.

3. **Aim & objectives of study:** State the aim of study and 1 to 4 objectives. These must be short, succinct and exact behavioral statements. (e.g. To determine the length of hospital stay of pediatric patients with HIV infections)

.

4. **Methods:**

4.1 Give a brief account of the methods you intend to employ, including the study design.
4.2 **The sample:** How are potential subjects identified, and how is the sample drawn?
4.3 **Materials, Apparatus and Instruments** (give a concise and systematic list).
4.4 **Data collection:** How will data be collated? Which tests will be done and which research instruments (psychosocial) will be used?
4.5 **Data analysis:** How will data be collated and analyzed, including statistical analysis, if appropriate?
4.6 **Reliability and validity of study:** How will these be accomplished in the study?
4.7 **Bias:** What types of bias will be encountered? How will they be minimized?
4.8 **Ethical considerations:** *Informed* consent must be included and indicate all authorities to be contacted for permission to conduct the study. There is a consent form available*, which must be attached to the protocol.
4.9 **References:** A recognized system is preferred e.g. Vancouver or Harvard. Please be precise in its use. Six to ten references are usually appropriate - this is **not** a thesis
4.10 **Appendices:** All Data collection forms and questionnaires: should be attached, where relevant. If designed for this study, questionnaires should be attached. If questionnaires are extremely well known, they need not be attached. If in doubt, it should be attached.

- **Length of protocol:** It is unlikely that a protocol shorter than three pages (including references, but excluding data collection forms and questionnaires) will contain enough information for Research Committee to assess the merits of a research project. A long protocol does not necessarily convince the Committee either. Protocols longer than **ten pages** (including references, excluding data collection forms and questionnaires) will not be considered. If your department requires a long protocol, it will have to be shortened for Research Committees. The ideal length is **3-5** pages. For higher degree candidates, a longer protocol is acceptable