INCWADANA YEENKCUKACHA YALOWO UTHABATHA INXAXHEBA NEFOMU YOKUNIKA IMVUME

*Please see Section 8 of our Health Research Ethics Committee (HREC) Standard Operating Procedures (SOPs) for more detailed information about requirements for Informed Consent (IC). You will find the SOPs here:* [*http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx*](http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx)*.*

*(Please delete this paragraph before submitting your Informed Consent Form (ICF) to the HREC)*

|  |  |
| --- | --- |
| **ISIHLOKO SEPROJEKTHI YOPHANDO:** | |
|  | |
| **IINKCUKACHA ZOMPHANDI OYINTLOKO (PI):** | |
| **Isihlonipho, igama lokuqala, ifani:** | **Inombolo yesingqinisiso kwiNdlela yokuziphatha:** |
| **Idilesi epheleleyo yeposi:** | **Inombolo epheleleyo yoMphandi oyiNtloko:** |

Singathanda ukukumema ukuba uthathe inxaxheba kwiprojekithi yophando. Nceda uthathe ixesha ufunda iinkcukacha ezibhalwe apha, eziza kucacisa ngeenkcukacha zale projekthi. Nceda ubuze abasebenzi okanye ugqirha wophando malunga nayiphi imibuzo onayo malunga nayiphi na indawo ongayiqondi kakuhle kule projekthi. Kubaluleke kakhulu ukuba waneliseke ngokupheleleyo ukuba ukuqonda ngokucacileyo okuqulathwe kolu phando nendlela onokubandakanyeka ngayo. Kwakhona, ukuthabatha kwakho inxaxheba **ukwenza ngokuzithandela ngokupheleleyo** kwaye uvumelekile ukuba ungarhoxa ekuthatheni inxaxheba.Ngamanye amazwi, ungakhetha ukuthatha inxaxheba, okanye ungakhetha ukungathathi nxaxheba. Akukho nto imbi eza kwenzeka ukuba ukuba uthi hayi: oko akuzi kukuchaphazela kakubi nangayiphi na indlela. Ukwala ukuthatha inxaxheba akuzi kubandakanya sohlwayo okanye ukulahlekelwa kokuzuzwayo okanye ukuncitshiswa koncedo olufumanayo nofanele ukulufumana.Ukhululekile ukuba ungarhoxa kolu phando nanini na, nokuba uqale ngokuvuma ukuthabatha inxaxheba.

Olu phando luvunyiwe yiKomiti yeeNdlela zokuziPhatha ngokuseSikweni kuPhando lwezeMpilo yeYunivesithi yaseStellenbosch. Uphando luza kwenziwa ngokwezikhokelo neenqobo zeSaziso saMazwe ngamazwe seHelsinki , iziKhokelo zaseMzantsi Afrika zokuQhutywa kakuhle kwezoNyango (2006), iziKhokelo zeBhunga loPhando lwezoNyango ezimalunga neNdlela yokuziPhatha ngokuseSikweni kuPhando (iMRC) (2002), neSebe lokuziPhatha kwezeMpilo kuPhando lwezeMpilo: Imithetho-siseko, iiNkqubo noPhando (2015).

## Lumalunga nantoni olu phando?

* *Where will the study be conducted? Are there other sites? State the total number of participants to be recruited at your site, and the number of participants altogether.*
* *Explain in participant-friendly language what your project aims to do and why you are doing it. Imagine having a conversation with one of your participants. Write in plain English and use the active form; avoid passives as far as possible. This applies to all text that you add to this form.*
* *Explain all procedures.*
* *Explain any randomisation process that may occur.*
* *Explain the use of any medication, if applicable.*

## Kutheni uceliwe ukuba uthathe inxaxheba?

* *Explain this question clearly.*

## 

## Luya kuba yintoni uxanduva lwakho?

* *Explain this question clearly.*

## Ingaba uya kuzuza ngokuthatha kwakho inxaxheba kolu phando?

* Explain all benefits objectively. If there are no personal benefits then indicate who would be likely to benefit from this research, e.g. future patients.

## Ingaba kukho imingcipheko ebandakanyekayo ekuthatheni kwakho inxaxheba kolu phando?

* Identify any risks objectively.

## Ukuba akuvumi ukuthatha inxaxheba, zeziphi ezinye iindlela onazo ezinokulandelwa?

* *Clearly indicate in broad terms what alternative treatment is available and where it can be accessed, if applicable.*

## Ngubani oza kukwazi ukufikelela kwiingxelo zakho zezonyango?

* *Explain that the information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Clearly indicate who will have access to the information.*

## Noxa kungaqhelanga kwenzeka, kuza kwenzeka ntoni xa unokwenzakala nangayiphi indlela kuba uthatha inxaxheba kolu phando?

*Background information:*

* *The sponsor of a trial must ensure that the participants in health research are covered by comprehensive insurance in the event of physical (bodily) harm or injury, including death. This means that the insurance company will compensate a participant for medical expenses which may have resulted directly from their participation in research without the participant having to prove that the sponsor was at fault.*
* *Stellenbosch University has insurance to cover participants in all non-industry sponsored research studies that are registered with the HREC.*
* *It is important to explain to each participant that:*
* *By agreeing to participate in this study, he/she agrees that there is a risk that the study medicine(s) or procedure(s) may cause him/her harm. If it does, the sponsor will reimburse him/her for his/her medical expenses without the participant having to prove that the sponsor was at fault.*
* *The participant may, however, still claim for emotional pain and suffering if he/she so chooses. In this event, he/she will have to prove that the sponsor was negligent and did not take all reasonable and foreseeable steps to prevent the injury or emotional trauma. This will be a separate legal matter.*

*For more information, please see Section 9 of HREC SOPs on Participant Insurance.*

*(Please delete this text before submitting your ICF to the HREC).*

*Recommended wording - please use one of the following text excerpts in this section:*

*(Please delete the irrelevant section before submitting your ICF to the HREC).*

*For non-sponsored health research or research sponsored by Stellenbosch University where the*

*principal investigator is a staff member or student of Stellenbosch University; or for NIH/US*

*government funded research:*

Iyunivesithi yaseStellenbosch iza kukubonelela nge-inshorensi ebanzi engenangxaki kwaye iza kuhlawulela naziphi na iindleko zezonyango eziye zabakho ngenxa yokuthatha inxaxheba kuphando (isenokuba kungenxa yokuba lowo uthatha inxaxheba usebenzise amayeza kolu phando, okanye uthathe inxaxheba ngenye indlela). Othatha inxaxheba akuzi kudingeka ukuba aqinisekise ukuba umxhasi ngemali nguye onetyala.

*For industry-sponsored health research:*

Umxhasi ngemali uza kukubonelela nge-inshorensi ebanzi engenangxaki kwaye uza kuhlawulela naziphi na iindleko zezonyango eziye zabakho ngenxa yokuthatha inxaxheba kuphando (isenokuba kungenxa yokuba lowo uthatha inxaxheba usebenzise amayeza kolu phando, okanye uthathe inxaxheba ngenye indlela). Othatha inxaxheba akuzi kudingeka ukuba aqinisekise ukuba umxhasi ngemali nguye onetyala.

Ingaba uza kuhlawulwa ngokuthatha inxaxheba kolu phando kwaye ingaba kukho iindleko ezibandakanyekayo?

* Uza kuhlawulwa ngokuthatha inxaxheba kolu phando kwaye iindleko zakho ziza kubuyiswa ngotyelelo ngalunye usiza kolu phando.

Akuzi kudingeka ukuba uhlawulele nantoni na, ukuba uthatha inxaxheba.

* *The amount and method of payment to research participants should reflect the following three components:*
  + *Compensation for time;*
  + *Compensation for inconvenience; and*
  + *Reimbursement of expenses.*

*Please see Section 9 of HREC SOPs on Participant Insurance, Appendices IX and X on Compensation for Injury.*

Ingaba ikhona enye into ekufuneka ukuba uyazi okanye uyenze?

* Kufuneka wazise ugqirha wakho wosapho okanye wesiqhelo ukuba uthatha inxaxheba kuphando. (Yifake ukuba iyangena)
* Kufuneka wazise nenkampani ye-inshorensi yonyango yakho ukuba uthatha inxaxheba kuphando. (Yifake ukuba iyangena)
* Ungatsalela umnxeba uGqr [insert PI’s name here] ku-[insert PI’s tel number here] ukuba uneminye imibuzo okanye ufumana naziphi na iingxaki.
* Ungatsalela umnxeba iKomiti yokuziPhatha kuPhando lwezeMpilo ku-021 938 9677/9819 ukuba kusekho into angakakucaciseli yona ugqirha wakho okolu phando, okanye ukuba unesikhalazo.
* Uza kufumana ikopi yezi nkcukacha nefomu yokunika imvume ukwenzela ukuba uzigcinele.

### Isifungo somthathi-nxaxheba

Ngokutyikitya apha ngezantsi, mna …………………………………..…………. ndiyavuma ukuthatha inxaxheba kuphando olunesihloko esithi (insert title of study here).

Ndibhngeza ukuba:

* Ndizifundile ezi nkcukacha nefomu yokunika imvume, okanye ndiyifundelwe, ibhalwe ngolwimi endilwaziyo nendiziva ndikhululekile kulo;
* Ndiye ndalifumana ithuba lokubuza imibuzo kwaye yonke imibuzo yam iphendulwe ngokwanelisayo.
* Ndiyaqonda ukuba ukuthatha kwam inxaxheba kolu phando **ndikwenza ngokuzithandela** kwaye khange ndinyanzeliswe ukuba ndithathe inxaxheba.
* Ndingakhetha ukuyeka kuphando nanini na kwaye akukho nto imbi eza kwenzeka ngoko - andisayi kohlwaywa okanye ndicalulwe nangayiphi na indlela.
* Ndisenokucelwa ukuba ndilushiye olu phando lungekapheli, ukuba ugqirha wophando okanye umphandi ucinga ukuba oko kundifanele ngcono, okanye ukuba isicwangciso sophando andisilandeli ngale ndlela kuvunyelwene ngayo.

Kutyikityelwe *(indawo)* e......................…........………. ngomhla (*umhla*) we- …………....……….. ngo-2016.

Utyikityo lomthathi-nxaxheba Utyikityo lwengqina

### Isibhengezo somphandi

Mna *(igama)* ……………………………………………..……… ndibhengeza ukuba:

* Ndizicacisile iinkcukacha ezikolu xwebhu ngendlela elula necacileyo ku…………………………………..
* Ndimkhuthazile ukuba abuze imibuzo ndaza ndathatha ixesha elaneleyo ukuyiphendula.
* Ndanelisekile kukuba uyiqonda ngokwaneleyo yonke imiba yolu phando, njengoko icacisiwe apha ngentla.
* Ndiyisebenzisile/andiyisebenzisanga itoliki. *(Ukuba kusetyenziswe itoliki, loo toliki mayityikitye esi sifungo singezantsi).*

Kutyikityelwe *(indawo)* e......................…........…………….. ngomhla (*umhla*) we- …………....……….. ngo-2016.

Utyikityo lomphandi Utyikityo lwengqina