# IPHETSHANA LOMTHATHI-NXAXHEBA NEFOMU YOKUNIKA IMVUME

*Nceda ujonge iCandelo 8 leeNkqubo zokuSebenza ezinguMmiselo (Standard Operating Procedures - SOPs) zeKomiti yokuZiphatha kuPhando lwezeMpilo (Health Research Ethics Committee - HREC) ukuze ufumane ingcaciso eneenkcukacha ezithe vetshe malunga neemfuno zeMvume eSekelwe kuLwazi (Informed Consent - IC). Uya kuzifumana apha ezo SOP: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx.*
*(Nceda uwususe lo mhlathi ngaphambi kokuba ungenise iFomu yakho yeMvume eSekelwe kuLwazi (Informed Consent Form - ICF) kwi-HREC).*
***QAPHELA: Nceda uqaphele ukuba eli liphepha elilungiselelwe ukuba libe sisikhokelo, ngoko ke abaphandi kufuneka bakuhlele oku likuqulathileyo ukuze kubonakalise iinkcukacha zolo phononongo lungqalileyo neendlela zokuziphatha kulo.***

| **ISIHLOKO SEPROJEKHTI YOPHANDO:** | |
|---|---|
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| **IINKCUKACHA ZOMPHANDI OYINTLOKO (PI):** | |
| **Isibizo igama, ifani:** | **Inombolo yesalathiso sokuziphatha:** |
| **Idilesi yeposi ngokupheleleyo:** | **Inombolo yoqhagamshelwano yomphandi oyintloko:** |

Singathanda ukukumema ukuba uthathe inxaxheba kwiprojekthi yophando. Nceda uthathe ixesha ufunda ingcaciso ebhalwe apha, neza kucacisa ngeenkcukacha zale projekthi. Nceda ubuze kubasebenzi okanye kugqirha wolu phononongo malunga nayo nayiphi na imibuzo emalunga nayo nayiphi na indawo ongayiqondi kakuhle kule projakthi. Kubaluleke kakhulu ukuba mawube waneliseke ngokupheleleyo kukuba ukuqonda ngokucacileyo oko kuqulathwe lolu phando nendlela onokubandakanyeka ngayo kulo. Kananjalo, intatho-nxaxheba yakho **ingokuzithandela ngokupheleleyo** kwaye uvumelekile ukuba ungala ukuthatha inxaxheba. Ngamanye amagama, usenokukhetha ukuthatha inxaxheba, okanye ungakhetha ukungathathi nxaxheba. Akukho nto imbi iza kwenzeka ukuba uthi hayi: oku akuyi kukuchaphazela kakubi nangayiphi na indlela. Ukwala ukuthatha inxaxheba akuyi kubandakanya sohlwayo okanye ilahleko yeenzuzo okanye ukuncitshiswa komgangatho wokhathalelo oluselungelweni lakho. Uvumelekile kananjalo ukuba ungarhoxa kolu phononongo nanini na, nkqu nokuba ubuqale ngokuvuma ukuthatha inxaxheba.

IKomiti yeeNdlela zokuZiphatha kuPhando lwezeMpilo kwiYunivesithi yaseStellenbosch iye yalugunyazisa olu phononongo**.** Olu phononongo luza kwenziwa ngokuvumelana nemiqathango engqongqo nemigaqo yeSibhengezo samazwe ngamazwe saseHelsinki, iMigaqo yoKwenziwa koMsebenzi wezoNyango ngokuFanelekileyo eMzantsi Afrika (2006), iBhunga loPhando lwezeMpilo (MRC) iMigaqo yokuZiphatha kuPhando (2002), neSebe lokuZiphatha ngokwezeMpilo kuPhando lwezeMpilo: IMigaqo, iiNkqubo neZenzo zoPhononongo (2015).

**Ingaba lumalunga nantoni olu phononongo lophando?**

- *Ingaba luya kwenziwa phi olu phononongo? Ingaba zikhona ezinye iisayithi? Chaza inani labathathi-nxaxheba abaya kugaywa kwisayithi yakho lilonke, nenani labathathi-nxaxheba xa bebonke.*

- *Kucacise ngolwimi olulungele abathathi-nxaxheba oko kujongwe ukwenziwa yiprojekthi yakho kwa nokuba kutheni uyenza. Yiba nomfanekiso-ngqondweni wakho uncokola nomnye wabathathi-nxaxheba bakho. Bhala ngesiNgesi esilula uze usebenzise uhlobo lokuthetha apho isivakalisi siqala ngentloko; kuphephe kangangoko unako ukusebenzisa uhlobo lokuthetha apho intloko isekugqibeleni kwisivakalisi. Oku kusebenza kuyo yonke itekisi oyifakayo kule fomu.*
- *Cacisa zonke iinkqubo.*
- *Cacisa nayiphi na inkqubo yohlengahlengiso olungacwangciswanga enokwenzeka.*
- *Cacisa usetyenziso lwamayeza ukuba oko kuyangena.*
- *Yahlula ngokucacileyo phakathi koko kulukhathalelo/kungumsebenzi ongummiselo, noko kungokungqale/kusisongezelelo solu phononongo lophando.*

**Kutheni umenyiwe nje ukuba uthathe inxaxheba?**

- *Wucacise ngokucacileyo lo mbuzo.*

**Ziya kuba yintoni iimbopheleleko zakho?**

***Wucacise ngokucacileyo lo mbuzo, wenze indima yomthathi-nxaxheba kwiinkqubo zolu phononongo ibe lula kangangoko ukuze nawuphi na umntu akuqonde oko kulindelekileyo nexesha ekuqikeleleka ukuba le misebenzi ingalithatha.***

**Ingaba uya kuzuza ngokuthatha inxaxheba kolu phando?**

- *Zicacise zonke iinzuzo ezithe ngqo ngokunyanisekileyo. Ukuba akukho zinzuzo kumntu buqu chaza ukuba ngubani osenokuba nokuzuza kolu phando, umz. izigulane zexesha elizayo.*

**Ingaba kukho nayiphi na imingcipheko ebandakanyekayo ekuthatheni kwakho inxaxheba kolu phando?**

- *Chonga nayiphi na imingcipheko ngokunyanisekileyo.*

**Ukuba awuvumi ukuthatha inxaxheba, ndlela ziphi ezinye onazo?**

- *Ligcine eli candelo kuphela ukuba liyasebenza.*
- *Kuchaze ngokucacileyo ngamagama ambaxa ukuba loluphi unyango olulolunye olufumanekayo kwa nokuba lungafunyanwa phi, ukuba oko kuyasebenza.*

**Ngubani oza kukwazi ukufikelela kwiirekhodi zakho zonyango?**

- ***Ligcine eli candelo kuphela ukuba liyasebenza.***
- *Cacisa ukuba ingcaciso eqokelelweyo iya kugcinwa iyimfihlo yaye ikhuselekile. Nceda uluthathele ingqalelo uthotyelo lwe-POPIA. Ukuba ithe yasetyenziswa kupapasho okanye kwithesisi, amagama achonga abathabathi-nxaxheba aya kuhlala engaziwa. Chaza ngokucacileyo ukuba ngubani oya kuba nakho ukufikelela kule ngcaciso.*

**Nangona kungenakufane kwenzeke, yintoni eya kwenzeka ukuba uyenzakala ngendlel' ethile ngenxa yokuba uthathe inxaxheba kolu phononongo lophando?**

- *Ligcine eli candelo kuphela ukuba liyasebenza uze ukususe ukubhekisa 'kumxhasi-ngezimali' ukuba akukho mxhasi-ngezimali ubandakanyekayo kolo phononongo.*

*Ingcaciso ngemvelaphi:*

- *Umxhasi-ngezimali welinge lophando kufuneka aqinisekise ukuba abathathi-nxaxheba abakuphando lwezempilo bafakiwe kwi-inshorensi epheleleyo xa kunokwenzeka ukuba kubekho ubungozi (basemzimbeni) okanye umenzakalo, kuquka nokusweleka. Oku kuthetha ukuba inkampani ye-inshorensi iya kumbuyekeza umthathi-nxaxheba ngeendleko zezonyango ezinokube ziziziphumo ngqo zentatho-nxaxheba yakhe kuphando ngaphandle kokuba kude kufuneke ukuba umthathi-nxaxheba abonakalise ubungqina bokuba ityala ibilelomxhasi-ngezimali.*

- *IYunivesithi yaseStellenbosch ine-inshorensi yokukhavarisha abathathi-nxaxheba kuzo zonke izenzo zophononongo lophando ezingaxhaswa ngamashishini ngemali nezibhalisiweyo kwi-HREC/UREC.*
- *Kubalulekile ukumcacisela umthathi-nxaxheba ngamnye ukuba:*
    - *Ngokuvuma ukuthatha inxaxheba kolu phononongo, uyavuma ukuba kukho umngcipheko wokuba i(ama)yeza okanye i(ii)nkqubo y(z)olu phononongo i(zi)ngamenzakalisa. Ukuba oko kwenzekile, umxhasi-ngezimali uya kumbuyekeza ngeendleko zonyango ngaphandle kokuba kude kufuneke ukuba umthathi-nxaxheba abonakalise ubungqina bokuba impazamo ibiyeyomxhasi-ngemali.*
    - *Umthathi-nxaxheba usenako ukuba angathi, noko kunjalo, afake ibango leentlungu nokuhlupheka ngokwasemphefumlweni ukuba ukhetha ukwenza njalo. Xa kuthe kwenzeka oko, kuya kufuneka ukuba abonakalise ubungqina bokuba umxhasi-ngezimali/umphandi uye waba nokungakhathali kwaye khange awathathe onke amanyathelo asengqiqweni nabonakala kwangaphambili okuthintela umenzakalo lowo okanye umothuko wangokwasemphefumlweni. Lowo iya kuba ngumba wezomthetho owodwa.*

*Ukuze ufumane ingcaciso ethe vetshe, jonga iCandelo 9 lee-SOP ze-HREC ngokuphathelene ne-Inshorensi yoMthathi-nxaxheba.*

*(Nceda uyisuse le tekisi ngaphambi kokuba ungenise i-ICF yakho kwi-HREC).*

*Usetyenziso lwamagama olucetyiswayo - nceda usebenzise esinye sezi zicatshulwa zetekisi ezilandelayo kweli candelo:*

*(Nceda ulisuse icandelo elingangeniyo ngaphambi kokuba ungenise i-ICF yakho kwi-HREC).*

*Ukulungiselela uphando lwezempilo olungaxhaswa ngamali okanye uphando oluxhaswa ngemali yiYunivesithi yaseStellenbosch nalapho umphandi oyintloko ililungu labasebenzi okanye umfundi wakwiYunivesithi yaseStellenbosch; okanye ukulungiselela i-NIH/i-US uphando oluxhaswa ngemali ngurhulumente:*

- IYunivesithi yaseStellenbosch iya kubonelela nge-inshorensi epheleleyo engabeki tyala mntwini kwaye iya kuhlawulela naziphi na iindleko eziye zabakho ngenxa yokuba abathathi-nxaxheba bethathe inxaxheba kolu phando (nokuba kungenxa yokuba umthathi-nxaxheba ebesebenzisa amayeza kolu phononongo, okanye uthathe inxaxheba ngenye indlela). Akuyi kufuneka ukuba umthathi-nxaxheba abonakalise ubungqina bokuba impazamo ibiyeyomxhasi-ngezimali.

*Ukulungiselela uphando lwezempilo oluxhaswa ngezimali lushishino:*

- Umxhasi-ngezimali uya kubonelela nge-inshorensi epheleleyo engabeki tyala mntwini kwaye uya kuhlawulela naziphi na iindleko eziye zabakho ngenxa yokuba abathathi-nxaxheba bethathe inxaxheba kolu phando (nokuba kungenxa yokuba umthathi-nxaxheba ebesebenzisa amayeza kolu phononongo, okanye uthathe inxaxheba ngenye indlela). Akuyi kufuneka ukuba umthathi-nxaxheba abonakalise ubungqina bokuba impazamo ibiyeyomxhasi-ngezimali.

**Ingaba zikhona naziphi na iindleko ezibandakanyekayo ukuba ndigqiba ekubeni ndithathe inxaxheba?**

- Ngabaphandi abanoxanduva ngazo zonke iindleko ezingokuphathelene ngqo nophononongo.
- Ukuba olu phononongo luthe lwasebenzisa ingcaciso ngokusekelwe kwiiNkqubo zokuSebenza ezinguMmiselo okanye kwimisebenzi yezonyango lwezempilo engummiselo, yahlula ngokucacileyo ukuba ngubani onoxanduva ngeendleko zonyango (sisigulane okanye liqela lophononongo).
- Uya kubuyekezwa ngokuthatha inxaxheba kolu phononongo kwaye iindleko zakho ziya kubuyekezwa ngotyelelo ngalunye. Akuyi kufuneka uhlawulele nayiphi na into engokuphathelene nolu phando ukuba uyayithatha inxaxheba.
- *Isixa nendlela yokuhlawulwa kwabathathi-nxaxheba kufuneka ibonakalise ezi zibakala zithathu zilandelayo:*

- *Ukubuyekezwa ngexesha;*
- *Ukubuyekezwa ngenkxamleko; kunye*
- *Nokubuyekezwa ngeendleko.*

*Nceda ujonge iCandelo 14 lee-SOP ze-HREC ngokuphathelene nokuBuyekezwa kwaBathathi-nxaxheba kuPhando. Nceda ubhekisele KWIZIKHOKELO ZESAHPRA (2022) NGOKUPHATHELENE NOMZEKELO WESIKHOKELO SEMBUYEKEZO NGEXESHA, INKXAMLEKO NEENDLEKO (TIE) ZABATHATHI-NXAXHEBA KWILINGE LOPHANDO LWEZONYANGO njengesalathiso sokumisela i-TIE efanelekileyo kubathathi-nxaxheba. Nceda ungene kwiwebhusayithi ye-HREC ngokuthi ucofe apha*

**Ingaba ikho enye into ofanele ukuba uyazi okanye uyenze?**

- *Yiquke ukuba iyangena:* Kufuneka wazise ugqirha wakho wosapho okanye wesiqhelo ukuba uthatha inxaxheba kuphononongo lophando.
- *Yiquke ukuba iyangena:* Kufuneka kananjalo wazise nenkampani ye-inshorensi yonyango yakho ukuba uthatha inxaxheba kuphononongo lophando.
- Ungafowunela [faka igama lomphandi oyintloko apha] ku-[faka inombolo yomnxeba yomphandi oyintloko apha] ukuba unayo nayiphi na imibuzo eyeminye okanye ukhawulelana nazo naziphi na iingxaki.
- Ungafowunela iKomiti yokuZiphatha kuPhando lwezeMpilo ku-021 938 9677/9819 ukuba kusekho into umphandi angakucaciselanga yona kakuhle, okanye ukuba unesikhalazo.
- Uza kufumana ikopi yale ngcaciso nefomu yemvume oza kuzigcinela yona ngokukhuselekileyo.

**Isibhengezo somthathi-nxaxheba**

Ngokutyikitya apha ngezantsi, mna …………………………………..…………. ndiyavuma ukuthatha inxaxheba kuphando olunesihloko esithi (faka isihloko sophando apha).

Ndibhengeza ukuba:

- Ndiyifundile le ngcaciso nefomu yemvume, okanye ndiyifundelwe, yaye ibhalwe ngolwimi endilwazi kakuhle nendikhululekileyo kulo.
- Ndiye ndaba nethuba lokubuza imibuzo kwaye ndanelisekile kukuba yonke imibuzo yam iphendulwe.
- Ndiyaqonda ukuba ukuthatha kwam inxaxheba kolu phononongo **kungokuzithandela,** kwaye andikhange ndinyanzelwe ukuba ndithathe inxaxheba.
- Ndiyaqonda ukuba uphando lwahlukile kukhathalelo lwam lwezonyango okanye kunyango lwam kwa nokuba ukwala ukuthatha inxaxheba kuphando akuthethi ukuba andisayi kulufumana ukhathalelo lwezonyango. *[Nceda ukususe oku ukuba akusebenzi kuphononongo lwakho]*
- Ndingakhetha ukulushiya olu phononongo nanini na kwaye andiyi kwehlelwa yinto embi ngokwenza njalo – andiyi kudliwa mali okanye ndicalulwe nangayiphi na indlela.
- Ndisenokucelwa ukuba ndilushiye olu phononongo ngaphambi kokuba luphele, ukuba ugqirha wophononongo okanye umphandi ubona ukuba oko kokona kundilungeleyo okanye ukuba andisilandeli isicwangciso sophononongo ebesivumelene ngaso. *[Xa oku kungangeni, nceda ukususe]*

Sityikityelwe (*indawo*) e.....................….......…………….. ngomhla (*umhla*) we- …………...……….. 2022.

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**Utyikityo lomthathi-nxaxheba** **Utyikityo lwengqina**

**Isibhengezo somphandi**

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

- Ndimcacisele u………………………………….. ingcaciso ekolu xwebhu ngendlela elula nangokucacileyo
- Ndiye ndamkhuthaza ukuba abuze imibuzo, ndaza ndathatha ixesha elaneleyo ukuyiphendula.
- Ndanelisekile ukuba uziqonda ngokupheleleyo zonke iinkalo zolu phando, njengoko kuchaziwe ngasentla.
- Ndiyisebenzisile/andiyisebenzisanga itoliki. (*Ukuba kusetyenziswe itoliki, loo toliki mayityikitye esi sibhengezo singezantsi).*

Sityikityelwe (*indawo*) e.....................….......…………….. ngomhla (*umhla*) we- …………...……….. 2022.

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**Utyikityo lomphandi**

**Utyikityo lwengqina**

**Imvume yokuba yonke idatha engachazi gama kwabelwane ngayo kunye nababhali beejenali:**

*Nceda ufundisise ezi ntetho zingezantsi (okanye uzifundelwe) uze ucinge malunga noko uza kukukhetha. Nokuba ugqibe entwenini, oko akuyi kukuchaphazela ukuba ungaba kolu phononongo lophando kusini na, okanye ukhathalelo lwempilo yakho lwesiqhelo.*

Xa olu phononongo lugqityiwe, singathanda ukupapasha iziphumo zolu phononongo kwiijenali. Iijenali ezininzi zifuna ukuba sabelane nazo ngedatha yakho engachazi gama ngaphambi kokuba zipapashe iziphumo. Ngoko ke, singathanda ukufumana imvume yakho yokuba kwabelwane ngedatha yakho engachazi gama kunye nababhali beejenali.

**Imvume yokuba kwabelwane ngeesampuli kunye/okanye nengcaciso kunye nabanye abaphandi:**

*Nceda ufundisise ezi ntetho zingezantsi (okanye uzifundelwe) uze ucinge malunga noko uza kukukhetha. Nokuba ugqibe entwenini, oko akusayi kukuchaphazela ukuba ungaba kolu phononongo lophando kusini na, okanye ukhathalelo lwempilo yakho lwesiqhelo.*

Ukuze kwenziwe olu phando sele sixoxe ngalo, kufuneka siqokelele size sigcine [chaza iisampuli eziza kuqokelelwa umz. Igazi/inwebu/umchamo njl. njl. nomthamo wegazi/inwebu/umchamo njl. njl.] nengcaciso yezonyango esuka kubantu abafana nawe abanesifo [*isifo X*]. Ezinye zeemvavanyo siza kuzenza ngoko nangoko. Ezinye iimvavanyo zingenziwa kwilixa elizayo. Xa sele silwenzile uphando esiceba ukulwenza kule projekthi yophando, singathanda ukugcina iisampuli kunye/okanye nengcaciso yakho. Abanye abaphandi abakwihlabathi jikelele bangacela ukusebenzisa ezi sampuli kwilixa elizayo [*nceda uchaze ukuba ezi sampuli ziza kuthuthwa zisuswe eMzantsi Afrika, apho ziza kugcinwa khona ezi sampuli kwa nokuba ngubani oza kuba nokufikelela kwezi sampuli]*. Ukukhusela ubomi bakho babucala, siza kusebenzisa inombolo yophononongo efana yodwa endaweni yegama lakho. Siza kuyisebenzisa le khowudi kuphela kwiisampuli zakho nakwingcaciso yakho. Siza kwenza konke okusemandleni ethu ukugcina le khowudi isekhusini. Kodwa noko kunjalo kuhlala kunokwenzeka ukuba kubekho umntu onokufumanisa malunga negama lakho kodwa oko akunakufane kwenzeke. Ngoko ke, singathanda ukucela imvume yakho yokuba sabelane ngeesampuli zakho nengcaciso yakho kunye nabanye abaphandi.

**Korekisha into oyikhethayo ngokujoliswe ekubeni kwabelwane ngedatha yakho engachazi gama kunye nababhali beejenali:**

Ndiyavuma ukuba kwabelwane ngedatha yam engachazi gama kunye nababhali beejenali ngelixa lopapasho lweziphumo zolu phononongo

☐ Utyikito____________

OKANYE

Andivumi ukuba kwabelwane ngedatha yam engachazi gama kunye nababhali beejenali ngelixa lopapasho lweziphumo zolu phononongo

☐ Utyikito____________

**Korekisha into oyikhethayo ngokujoliswe ekubeni kwabelwane ngeesampuli kunye/okanye nengcaciso yakho kunye nabanye abaphandi:**

Andifuni ukuba iisampuli zam kunye/okanye nngcaciso yam kwabelwane ngayo kunye nabanye abaphandi

☐ Utyikito____________

OKANYE

Iisampuli kunye/okanye nengcaciso yam kungabelwana ngayo kunye nabanye abaphandi ukuze zihlalutywe kabanzi nokulungiselela uphando lwakwilixa elizayo olunxulumene … [*chaza umxholo wophononongo lwakho, umz. uphando lwesifo seswekile*]

☐ Utyikito____________