

**ITHIMBA LENKAMBO ENHLE EMITHINI YOKUGOMELA IGCIWANE
LESANDULELA NGCULAZI/INGCULAZI**

UMBIKO OYISIPHAKAMISO

UKWAKHIWA KWENKUNDLA YEZIMPIKISWANO KANYE NOKUVUMELANA

**UKUSHAYWA KOMTHETHO WENKAMBO ENHLE NENOMTHETHO OCWANINGENI
ENINGIZIMU AFRIKA:**

**OKWENZEKAYO OKUQONDENE NEZINCWANINGO ZOMUTHI WOKUGOMELA
IGCIWANE LESANDULELA NGCULAZI**

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1. IMININGWANE YESENDLALELA

Uhlaka lwenkambo enhle nolusemthethweni eNingizimu Afrika lusesikhathini soguquko ngezinguquko eziningi ezintsha ukuguqula izimiso kanye nezinqubo ezinkulu ocwaningeni lwezempilo eNingizimu Afrika. Lesisimo esiguqukayo siveza impicabadala enkulu kubaphenyi, kuma RECs, Izinhlango Ezingekho ngaphansi kukahulumeni (ama NGO) kanye nasemiphakathini. Ezinye zezinto ezinkulu eziguqukayo zibandakanya kokubili ukuguqulwa komthetho kanye nokubuyekeza iziqondiso zenkambo enhle.

(1) Ukuguqulwa komthetho:

Umthetho sivivinyo Kazwelonke Wezempilo - iNational Health Bill (iNHB) usanda kuphapheni yiPhalamende kodwa awuqalile ukusebenza. Uzothatha indawo yomthetho osasebenza wezesayensi yezokucwaninga bese wengezwa ngemithetho yokuphatha ezenkambo enhle kanye nenqubo mgomo.

(2) Umumo wokumiswa kwendawo:

Umthetho sivivinyo Kazwelonke Wezempilo – iNHB uhlinzeka ukusungula kokumiswa kwemikhandlu emibili - iNational Health Research Ethics Committee (NHREC) kanye ne Essential National Health Research Committee (ENHRC). Izindima ezizodlalwa yimikhandlu kanye nokusebenzisana ngokudlelana iyasombuluka.

(3) Iziqondiso ezintsha zenkambo enhle

- Iziqondiso zabe Medical Research Council's (zango 2004) enkambweni enhle ocwaningeni lokwelapha: Izincwaningo zomuthi ovimbela IGCIWANE LESANDULELA NGCULAZI lingakaveli zizoshicilelwa maduze nje.
- Izimiso, izakhiwo kanye nezinqubo zenkambo enhle yocwaningo ngempilo zabe NHREC (zango 2004) zizoshicilelwa maduze nje.

(4) Iziqondiso zenkambo enhle ziyabuyekizwa:

- Iziqondiso zabe Medical Research Council's (zango 2002) enkambweni enhle yocwaningo lokwelapha: Izimiso Ezijwayelekile zizobuyekizwa maduze nje.
- Iziqondiso zoMnyango Wezempilo (zango 2000) zokusebenza kahle ekuqhubeni izincwaningo zokwelapha ziyabuyekizwa.

2. IZINJONGO ZENKUNDLA YOKUBONISANA

Ezigxilise esendlalelweni esichazwe ngasenhla, inkundla yokubonisana ihlose:

1. Ukuveza nokuthola impicabadala ebangelwa wuhlaka olukhona lwenkambo enhle nesemthethweni kanye nokwenzeka ngenxa yezincwaningo zomuthi wokugomela IGCIWANE LESANDULELA NGCULAZI, kubhekwe ekutheni lungenelwe ngabantwana
2. Ukusebenzela ukuthola ukuvumelana ekutheni konje lungakhuliswa kanjani uhlaka olukhona ukuze lulekelele ngocwaningo oluqinile kanye nokuvikela abangenele ucwaningo

3. ABANGENELE INKUNDLA YOKUBONISANA

Abangenele bavela kwi Research Ethics Committees (iRECs kanye ne NHREC); Isigungu Esishaya Imithetho (iMCC); Imikhandlu Eyeluleka Umphakathi - ama Community Advisory Boards (ama CABs) ezikhungweni okungenelwa kuzo; izikhulu zoMnyango Wezempilo; abezimiso zomthetho wenkambo enhle, Izinhlangotho Ezingekho ngaphansi kukaHululemi kanye nezinhlangano ezilwela amalungelo oluntu, kanye nabaphenyi eNingizimu Afrika. Isamba esingama 50 abangenele bahambela inkundla yokubonisana. Bheka Isengezo 1 ngohlu lwabangenele.

4 IMIBUZO ESEMOKA

Imibuzo ebucayi eyaxoxwa kusosonke isikhathi senkundla yokubonisana yayibandakanya:

1. Yimaphi amandla kanye nemikhawulo esohlakeni olusemthethweni lwenkambo enhle, futhi yiziphi izinto ezenzekayo ngohlaka kwababambe iqhaza (ama RECs, abaphenyi kanye nemiphakathi engenele) ezibandakanye nokuhlela kanye nokubuyezwa kwezincwaningo zomuthi wokugomela IGCIWANE LESANDULELA NGCULAZI?
2. Ngabe uhlaka luyokwenziwa kanjani ukuze lube ngcono?

5 IQOQO LEZINDIKIMBA EZISEMQOKA, KUBANDAKANYA NEZIPHAKAMISO

1. **Yimaphi amandla kanye nemikhawulo esohlakeni olusemthethweni lwenkambo enhle kanye nezinto ezenzekayo ngohlaka kwababambe iqhaza?**
 - a. Kwezinye izehlakalo uhlaka olusemthethweni lwenkambo nhle alucacile kahle futhi aluhlangene, luveza inselelo kwababambe iqhaza ekuhleleni kanye nasekubuyezweni izincwaningo zomuthi wokugomela IGCIWANE LESANDULELA NGCULAZI

- i. Izixabhelelo zabe NHB ngezincwaningo zomuthi wokugoma iGCIWANE LESANDULELA NCGULAZI sekuqaliwe ukuthi kukhulunywe ngazo kodwa kusenokungavumelani ngalokho ngempela okuyizixabhelelo.

Izixabhelelo ezingaba khona:

Kumthetho Sivivinyo Kazwelonke i National Health Bill, umahluko wokucwaninga phakathi kwe “elaphayo” (i “therapeutic” –TR) kanye noku “ngelaphi “ i non-therapeutic” -NTR) usagciniwe, kodwa awukachazwa. Akucacile ukuthi izigaba zocwaningo lomuthi wokugoma iGCIWANE LESANDULELA NCGULAZI zingahlelwa kanjani ngononina.

I NHB iqinisekisa ukuthi ngocwaningo (akukhathaleki ukuthi kuhlelwe njengo “kwelaphayo iTR noma nokungelaphi iNTR) izinqubo zokuvuma kumele zibandakanye abazali/abaphathi kanye nezingane, uma benokuqonda okwenziwayo. Lokhu kusho ukuthi abaphenyi kumele babhekane nezinkinga zokuqhuba umsebenzi wokubheka abazali noma wokushiya ngaphandle izingane abazali bazo noma abaphathi abasemthetweni bengatholakali.

I NHB idinga ukuthi amandla okuqonda kwengane ngocwaningo kumele kuqinisekise. Lokhu kungenziwa kanjani? Umsebenzi ozokwenziwa udinga kuthuthukiswe izindlela ezifanele zokuhlola ulwazi lwengane ngokwethembeka.

Uma izincwaningo zomuthi wokugomela iGCIWANE LESANDULELA NCGULAZI zichazwa njenge NTR (izincwaningo zokungaba ukuphepha kwasekuqaleni/indlela amasosha omzimba aphenula ngayo kunoma isiphi isimo esivelayo), izinga lengozi ye “ngozi engenkulu” kumele kuhlangebanwe nalo. Kungenzeka izincwaningo zomuthi wokugomela iGCIWANE LESANDULELA NCGULAZI zihlangabezane nalelizinga? Abanye bayaphika bathi izingozi zokungenelela kocwaningo ziyokwedlula lelizinga. Abanye bayaphika ukuthi lokhu akunjalo.

Uma izincwaningo zomuthi wokugomela iGCIWANE LESANDULELA NCGULAZI zihlelwa njenge NTR, “kumele kutholwe isigunyazo esivela kuNgqongqoshe. Konke lesisihlinzeko singaqaliswa kanjani ukuthi sisebenze kahle? Abanye bayaphika bathi lomsebenzi uyonikezwa abanamandla abafanele abafana ne NHREC okanye ama RECs. Phezu kwalokho uNgqongqoshe Wezempilo angagunyaza kuphela amandla okucwaninga agxilise ezilinganisweni ezithize okubandakanya ukuthi ucwaningo aluphambene no “mgomo womphakathi”. Lokhu kungaqondwa kanjani futhi kusetshenziswe? Kumele kwenziwe omunye umsebenzi ngaloludaba.

Uma ucwaningo luhlelwa njenge TR, alubanga “ngolulungele kahle” ingane. Konje “okulungele kahle” ingane kungaqondwa kanjani/kusetshenziswe kanjani? Kudingeka omunye umsebenzi ngamaphuzu okumele athathwe acatshangwe ukunquma okulungele kahle, kanye nokuthuthukisa “ukuhlololwa” lokhu.

- ii. Izimiselo zomthetho ezizoshaywa maqondana noMthetho sivivinyo zisahlolwa. Zona zizocacisa izindlela zokwenza kanye nokuqikelelwa kokuvikelwa kwabangenele ucwaningo, okubandakanya abangenele ucwaningo lomuthi wokugomela iGCIWANE LESANDULELA NCGULAZI. Lezizimiselo zomthetho akulula ukuthi zishicilelelwe ezinyangeni eziyisithupha (okusho uJanuwari ka 2005).

Iziphakamiso ezifakwa ezimiseleni zomthetho yithuba elihle lokuchaza kahle izinhlamvu zamazwi, ukwenaba emiqondweni yokuthize okunohlonze, kanye nokwandisa ukuvumelana ngezimiso kanye nezinqubo ezikhona ezisemthethweni.

- iii. Kukhona iziqondiso ezine zenkambo enhle ezihambisana nocwaningo lomuthi wokugomela iGCIWANE LESANDULELA NGCULAZI.

Iziqondiso ezithize azikakhululwa ngokusemthethweni (iziqondiso ze MRC zika 2004 enkambweni enhle yocwaningo lokwelapha: Ucwangingo lomuthi ovimbela IGCIWANE LESANDULELA NGCULAZI lingakaveli: kanye nenkambo enhle yabe NHREC yango 2004 ocwaningeni lokwelapha: Izimiso, izakhiwo kanye nezinqubo) kanye nezinye kuyabuyekizwa (Iziqondiso zabe DOH zango 2000 *ekusebenzeni kahle uma kuqhutshwa izincwaningo zokwelapha*) kanye nezinye zizobuyekizwa maduze nje (Iziqondiso zabe MRC zango 2002 zenkambo enhle ocwaningweni lokwelapha: *Izimiso Ezivamile*).

Ezindabeni ezithize ezixakile, ezifana nokungenela kwabantwana, ukuqondiswa kuyangqubuzana. Iziqondiso ngokungenela kwabantwana akuklasile kahle ngalamaphuzu alandelayo:

- Indlela ethathwa maqondana nokucutshungulwa kwezingozi
 - Igama elinikezwa amazinga engozi avunyelwe ucwaningo lwengane, kanye nengqikithi yezinga lengozi evunyelwe ucwaningo lwengane
 - Ngubani ovumela ukuthi ingane ingenele
 - Yibaphi abazali abavumeleke ukuthi bavume ukuthi, ngokuya kwezinhlobo zokuhlelwa kocwaningo
 - Yibaphi abazali abavumeleke ukuvumela ukuthi, ngokuya kwezingozi lapho KUNGEKHO khona umhlomulo oqondile
 - Yibaphi abazali abavumeleke ukuvuma ukuthi, ngokuya kwezingozi lapho KUKHONA umhlomulo oqondile
- b. Ngenxa yendida, ukuguqulwa kohlaka lwenkambo enhle esemthethweni, ukuqonda kanye nokwazisisa kudinga kuthuthukiswe
- i. Ababambe iqhaza badinga amathuba okuthuthukisa ukuqonda kwakho imithetho kanye neziqondiso ezihambisa ucwaningo ngomthetho, okubandakanya udaba oluyindida lokungenela komntwana.
- c. Amasu namacebo okufaka igalelo ohlakeni lwenkambo enhle esemthethweni kumele kuthuthukiswe futhi kube namandla amakhulu.
- i. Ababambe iqhaza, kubandakanya abamele imiphakathi engenele, badinga amasu namacebo okuxhumana kanye nokufaka iziphakamiso ohlakeni ukuze kwenziwe ngcono ukuvikelwa kwabangenele kanye nokulimazeka kwemiphakathi.
- d. Kwezinye izindaba, kunokuntuleka kwemininingwane yolwazi efanelekile.
- i. Ngabe abamele umphakathi bakubona kanjani ukungenela kwabantwana izincwaningo zomuthi wokugomela iGCIWANE LESANDULELA NGCULAZI?

ii. Konje kungaqinisekiswa kanjani ukuqonda kahle kwengane?

2. Uhlaka lungenziwa njani lube ngcono (isibonelo, ngokuguqulwa komthetho, ukwenziwa kweziqondiso eziklasile, ukulwela kanye nokuba nomthamo omkhulu wentuthuko)?

1. Igalelo ohlakeni lwenkambo enhle esemthethweni

Kwenziwa lezizincomo ezilandelayo:

- a. Ukufakwa kwemibono ezimiselweni zomthetho Emthethweni sivivinyo Wezempilo Kazwelonke: Ukwakha ithimba lokwenza umsebenzi elingabhala iziphakamiso ngezimiselo zomthetho ukuze kunciphe ukungavumelani nemithetho ekhona/iziqondiso zenkambo enhle, ukuchaza izigaba ezingacacile kanye nokwenza ngcono okuphakanyisiwe
- b. Ukulwela ukuguqulwa komthetho ukuze kunikwe amandla uhlaka lwenkambo enhle esemthethweni okuhambelana nokungenela kwengane ucwaningo. Ukuxhaswa kwesiphakamiso sokuguqulwa komthetho mayelana nokwelulwa kwesigaba 76 soMthetho sivivinyo wabantwana ukubandakanya izimiso ezihambelana nocwaningo. Xhumana ne: strodea@ukzn.ac.za
- c. Ifuzela eziqondisweni zenkambo enhle ocwaningeni lwezempilo
 - i. Lwela ukuthi abe MRC bashicilele futhi babuyekeze Incwadi 5: Iziqondiso zabe MRC ngenkambo enhle yocwaningo lokwelapha: *Izincwaningo Zokuvikela iGCIWANE LESANDULELA NGCULAZI* lingakangeni. Xhumana nabe: adri.labuschagne@mrc.ac.za
 - ii. Lwela ukuba khona kweziqondiso zenkambo enhle eziklasile ezindabeni ezibucayi, ezifana nokungenela kwengane.
 - iii. Ukulwela ukubuyekwezwa kweNcwadi 1 yabe MRC (yango 2002): Iziqondiso enkambweni enhle yocwaningo lokwelapha: Izimiso Ezivamile. Xhumana nabe adri.labuschagne@mrc.ac.za
 - iv. Faka imibono eziqondisweni zoMnyango Wezempilo (zango 2000) ekusebenzeni okuhle uma kuqhutshwa izincwaningo zokwelapha. Xhumana noDokotela L Makubalo kule web site makubl@health.gov.za
 - v. Thumela izincomo ngeziquondiso zabe MCC esigabeni I kanye no II ngezincwaningo zomuthi wokugomela iGCIWANE LESANDULELA NGCULAZI. Xhumana no S Munbodh kule web site munbods@health.gov.za

2. Thuthukisa umthemo kanye namasu wababambe iqhaza ukuze baqonde kangcono amandla, ubuthakathaka kanye nefuzela lohlaka kanjalo negalelo elikulona.

- a. Imiphakathi engenele:

- i. Thuthukisa ukuqonda okuyikho ngokubona komphakathi izinto ngokuma kwazo kanye nezinkathalo ngokuthi kube nocwaningo oluzwakalayo.
- ii. Thuthukisa izindlela zokuxhumana nemiphakathi ngezindaba ezimayelana nokungenela kwabantwana, isibonelo, nxusa amazwi okusekelwa kanye nokubona kwentsha izinto ngokuma kwazo kanye nabazali ngodaba lokungenela kwabantwana ezincwaningeni zomuthi wokugomela iGCIWANE LESANDULELA NGCULAZI
- iii. Ukwakha umthamo wabamele umphakathi ukuthi baqonde imithetho kanye neziqondiso, isibonelo, ukuba khona komhlangano wokufundisana ngoMthetho sivivinyo Wezempilo Kazwelonke
- iv. Ukuthuthukiswa kwamasu lapho abamele umphakathi ngamunye bengakwazi ukuhamba becoshela ngodaba lokungenela kwabantwana ucwaningo lomuthi wokugomela iGCIWANE LESANDULELA NGCULAZI kanye nokulekela ngokwenza ngcono uhlaka lokusebenza

b. Ama RECs:

- i. Ukwakhiwa komthamo wama RECs ukuze baqonde ngefuzela lomthetho kanye neziqondiso zokubuyezwa kwezinqubo mgomo, isibonelo, ukusungulwa kokuzosetshenzelwa kukho nangakho bese kuba nembizo yokuhlenganisa imiqondo
- ii. Ukuthuthukiswa kwamasu lapho ama RECs engaxhumana ekuchazweni kwemithetho/kweziqondiso ukuze kubuyezwe inqubo mgomo ukuze kuphokophelwe ekuvezweni kwendlela enokuvumelana, isibonelo, ukuhlale kuxhunyanwa, incwajana ekhipha imibiko ngezikhathi ezithize, ukuba khona komhlangano obanjwa ngonyaka

3. Ukuqhutshwa kocwaningo kanye nokuthuthukiswa kwezinto zokusebenza:

- a. Ukuthuthukiswa kwezinto zokuhlola ukuqonda kwabantwana ngokungenela ucwaningo
- b. Ukuthuthukisa kokuhlolwa kwesidingo somthetho sivivinyo Wezempilo Kazwelonke ukuthi ucwaningo “lokungelaphi” (“non-therapeutic”) akuphambene nomgomo womphakathi
- c. Ukuthuthukisa kokuhlolwa kwesidingo somthetho sivivinyo Wezempilo Kazwelonke ukuthi ucwaningo “lokwelapha” (“therapeutic”) kumele lube ngolulungene ingane