Umutwe w’icigwa:

Umushakashatsi mukuru:

Ibiranga IRB:

Ibi vyandiko ni iki?

Ibi ni urupapuro rw’uruhusha HIPAA. Rudondora uburyo amakuru y’amagara yawe azokoreshwa muri iki cigwa n’abazoyakoresha. Gushira igikumu kuri uru rupapuro vyerekana ko wemera gutanga uruhusha ko amakuru y’amagara yawe akoreshwa kuri iki cigwa.

Ni igiki gikurikira nokora?

1. Soma uru rupapuro, canke barugusomere.

2. Witwararike ko umuganga akora icigwa canke umurwi w’icigwa agusigurira ivyanditswe kuri uru rupapuro.

3. Baza ibibazo(nk’umwanya wiyemeza, amajambo utamenyereye, n’ibindi.)

4. Fata umwanya wo kwiyumvira kuri ibi, kandi ubiganire n’umuryango wawe n’abagenzi bawe.

Ninde azobona amakuru yanje muri ubu bushakashatsi?

University of Colorado Denver | Anschutz Medical Campus n’ibindi bigo vy’ubuvuzi bakorana barafise amategeko yo gukingira amakuru akwerekeye. Amategeko ya Reta arimwo Health Insurance Portability and Accountability Act (HIPAA) (Itegeko ryisungwa ku gutororokanya no gukingira ibijanye no gutegekaniriza amagara muri kazoza) navyo birakingira ivyo udashaka ko bija ahabona. Uru ruhusha rukubwira amakuru akwerekeye ashobora gutororokanywa kuri iki icigwa n’abashobora kuyabona canke kuyakoresha.

Ibigo biri muri iki cigwa birimwo:

[Delete those affiliate institutions that are not involved with this study. Do not use this form for VA research.]

* University of Colorado Denver | Anschutz Medical Campus
* University of Colorado Health
* Children’s Hospital Colorado
* Denver Health and Hospital Authority

Ivyatororokanijwe vyerekana umwidondoro wawe, n’urupapuro rwemeranijwe hamwe n’uru rupapuro rw’uruhusha washizeko umukono rurashobora kurabwa n’abandi badondanguwe hepfo bafise uruhusha bahabwa n’amategeko rwo kuraba iyo nkuru:

[Delete any institutions that are not involved with this study. Add any others that are involved.]

* Ibiro vy’amareta nka Office of Human Research Protection na Food and Drug Administration (FDA) Uburyo bwo gukoresha imfungurwa n’imiti bikingira abantu bakorwako ubushakashatsi nkawe.
* Abantu bo kuri University of Colorado Denver | Anschutz Medical Campus bari mu bushakashatsi.
* Abantu bari mu murwi (Institutional Review Board) IRB (umurwi w’isuzuma z’inzego) bajejwe gusuzuma iki cigwa.
* Umuganga ajejwe icigwa n’umurwi w’abashakashatsi bakorana
* [Insert sponsor name], ninde azoriha ico cigwa c’ubushakashatsi.
* Abarongozi ku bigo ubushakashatsi bukorwako n’abarongozi ku bindi bigo biri muri iki cigwa bijejwe kwitwararika ko dukurikiza amategeko yose kuri ubwo bushakashatsi.
* [Add any other groups or entities that have legal authority to audit identifiable study records.]

Inkuru zawe zirashobora gukoreshwa no gushirwa ahabona, mu gukora ubushakashatsi, mu kwiga ivyatowe, no kwitwararika ko ubushakashatsi bwakozwe neza.

Turashobora kuvuga kuri iki cigwa c’ubushakashatsi mu makoraniro. Turashobora no gushira ivyavuye muri ubu bushakashatsi mu binyamakuru bizwi. Ariko tuzonyegeza amazina y’abantu nkawe igihe cose bakozweko ubu bushakashatsi.

Urafise uburenganzira bwo gusaba uruhusha umushakashatsi bwo gushikira amakuru y’amagara yawe akingiwe. [If applicable include: To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.]

Ntidushobora gukora iki cigwa tudafise uruhusha rwawe rwo kubona, gukoresha no gutanga inkuru zawe. Ntutegetswe kuduha uru ruhusha. Igihe utaruduhaye, urashobora kutaja muri iki cigwa.

Tuzobona, tuzokoresha, dutange amakuru yawe gusa nk’uko biri mu rupapuro kuri iki cigwa no ku rupapuro rw’uruhusha no ku nyandiko zijanye nuko duhisha amakuru; ariko abantu bari hanze ya University of Colorado Denver | Anschutz Medical Campus nabo bakorana bashobora kutazoba muri iri sezerano gutyo amakuru yawe akaja ahabona utatanze uruhusha.

Tuzokora ibishoboka vyose ngo amakuru yawe ntaje ahabona, ariko ivyo ntitubigusezeraniye.

Ugukoresha no gushira ahabona amakuru yawe ntibigira umwanya ntarengwa. Urashobora guhagarika uruhusha rwo gukoresha no gushira ahabona amakuru yawe igihe cose ubicishije mu nyandiko ku mushakashatsi mukuru w’icigwa, kw’izina n’ikibanza vyavuzwe hepfo. Mu gihe uhagaritse uruhusha rwo gukoresha no gushira ahabona amakuru yawe, igice cawe muri iki cigwa kizoba giheze kandi ntayandi makuru akwerekeye azotororokanywa. Uguhagarika uruhusha kwawe ntibizogira ico bikora ku makuru yamaze kwegeranywa muri iki cigwa.

 [Add PI Name and Mailing Address]

Mu gihe wemeye kuba muri iki cigwa, uzoronka ikopi y’uru ruhusha iriko umukono n’igenekerezo y’ivyatororokanijwe.

U[The following section is for outside disclosures of research information that you will make. Include the name of any specific study-related person or group, external to the University, such as the Sponsor, outside laboratory or Contract Research Organization (CRO). Include recipients of information for optional research procedures. If there will be no outside disclosures of data, delete this section]

**Umushakashatsi(canke abo bakorana bakora mu kibanza ciwe) bamenyekanisha amakuru y’amagara yawe akurikira yose canke amwe muri yo ku:**

* [Ishirahamwe]

[Delete the following paragraph if not applicable.]

Zimwe mu ntambuko z’ubushakashatsi zirimwo ibipimo vy’ibigize umubiri wawe canke gukoresha makuru y’ibigize umubiri wawe. Amakuru y’ibikugize azokoreshwa ku bushakashatsi kandi ntazohabwa abandi bafise amakuru akuranga. [Add if applicable.] Amakuru y’ibigize umubiri wawe amenyekana azotangwa ku:

**Amakuru yawe azobonwa, azokwegeranywa, azokoreshwa kandi ashirwe ahabona muri iki cigwa:**

[Delete all that do not apply]

* Izina n’amakuru y’ibikuranga (imyaka, igitsina, ubwoko, aho uba, nomero ya terefone, n’ibindi.)
* Nomero yawe yo gutegekaniriza kazoza
* Ibice y’ivyegeranijwe muri kahise canke ubu ku magara yawe bifise akamaro muri iki cigwa, harimwo ariko bitagarukira ku bipimo, Kahise, n’ivyigwa vy’ibigize umubiri vya laboratware, ivyigwa vy’iradiyo, n’intambuko y’inyishu
* Urugendo rw’ubushakashatsi n’ivyegeranyo vy’ibipimo vy’ubushakashatsi
* Ibipimo vy’inyifato
* Kunywa inzoga nyinshi, inzoga canke gukoresha ibiyayuramutwe
* Gupima ubwandu n’indwara zitegerezwa kubwirwa igisata c’amagara y’abantu harimwo ariko zitagarujira ku: mugera wa Sida, epatite (ubwoko bwose)igituntu, canke izindi ndwara zandurira mu bihimba vy’irondoka.
* Gupima indwara y’amaraso ushobora kwandura uyihawe n’abavyeyi yitwa derepanositoze
* Ibipimo vy’ibice vy’umubiri n’inyishu.
* Impapuro z’amafaranga yarishwe canke amakuru y’ubutunzi
* Ikindi (Ni ukivuge): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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[Delete this section if there are no optional study procedures.]

 **HIPAA Uruhusha kuzindi ntambuko z’icigwa zidategerezwa**

Mu ncamake y’icigwa, wari wahawe akaryo ko kwemeza izindi ntambuko z’ubushakashatsi. Utegerezwa kandi kuduha uruhusha, ufatiye ku mategeko ya HIPAA yo gukoresha no gushira ahabona izi zindi ntambuko zishobora kwongerwako, nkuko zavuzwe haruguru.

[If applicable] Zimwe muri izo ntambuko zishobora kuba ibigize umubiri wawe canke gukoresha amakuru y’ibigize umubiri wawe. Amakuru y’ibigize umubiri wawe azokoreshwa kandi ntazotangwa ku bandi bafise ayandi makuru ajanye nawe. [If applicable] Amakuru y’ibigize umubiri wawe azotangwa kuri:

Mu gihe wanse kuduha uruhusha rwo gukoresha no gushira hanze amakuru yawe, ntushobora kuba muri izi zindi ntambuko, ariko urashobora kubandanya uri mu cigwa nyamukuru: Rero ni ahawe ho guhitamwo ibikurukira:

\_\_\_\_\_ Ndatanze uruhusha ku makuru yanje, kuva ku ntambuko zongewemwo nemeye ibiri hejuru, ngo bikoreshwe kandi bishirwe hanze nkuko vyavuzwe muri iki gice.

\_\_\_\_\_ **Sintanze uruhusha** ku makuru yanje ku ntambuko nimwe yongewemwo ngo ikoreshwe canke ishirwe hanze; ndatahura ko ntazoja muyindi ntambuko yindi iyo ariyo yose.

***VYUZUZWA N’UMUNTU AKORWAKO UBUSHAKASHATSI GUSA***

**Andika** izina ryawe, **ushireko** **umukono** **n’igenekerezo** munsi asangwa wemeye gutanga uruhusha rwo gukoresha no gushira ahabona amakuru yawe akingiye y’amagara nkuko vyavuzwe hejuru muri iki cigwa n’ibindi vyigwa wemeye kujamwo biciye ku masezerano yo kwemeza, ntuzoheba uburenganzira bwawe nabumwe uhabwa n’amategeko. Tuzoguha igopi y’urupapuro ruriko umukono ngo urubike.

**Izina ry’umuntu**

**Umukono w’umuntu (imyaka 18 canke ayirenza ashobora kwiyemeza) Igenekerezo**

**Umukono w’uwuserukira uwo muntu imbere y’amategeko urekuriwe gufata ingingo Igenekerezo**

**z’ubushakashatsi (igihe ikwiriye)**

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**Ububasha bw’uwuserukira imbere y’amategeko uwo muntu mu muryango (igihe bikenewe canke ahari)**