Umutwe w'ubushakashatsi:

Ukkuriye ubushakashatsi:

IRB ID:

N'iki gikubiye muri iyi nyandiko?

Iyi ni Ifishi yo gutangiraho uburenganzira bushingiye ku itegeko rya HIPAA. Isobanura uburyo amakuru y'ubuzima bwawe azakoreshwa muri ubu bushakashatsi ndetse n'uzayakoresha. Gushyira umukono kuri iyi fishi bigaragaza ko wifuza kwemera ko amakuru y'ubuzima yawe azakoreshwa muri ubu bushakashatsi.

N'iki nakurikizaho?

1. Soma iyi fishi cyangwa uyisomerwe.

2. Kora ku buryo umuganga ukora mu by'ubushakashatsi cyangwa umukozi ukora mu by'ubushakashatsi agusobanurira ibikubiye mu ifishi.

3. Baza ibibazo (nk'igihe ugomba kwigomwa, amagambo udasanzwe uzi n'ibindi)

4. Fata igihe cyo kubizirikana kandi ubiganireho n'umuryango wawe n'inshuti zawe.

Ni nde uzabona amakuru yo mu bushakashatsi anyerekeyeho?

Kaminuza ya Colorado Denver | Ishami ry'ubuvuzi rya Anschutz na sisitemu z'ubuvuzi bakorana zifite amategeko arinda amakuru yawe akwerekeyeho. Amategeko y'igihugu na leta harimo Itegeko rigenga ubwishingizi bw'ubuzima n'icungamari (HIPAA) na byo birinda ubuzima bwite bwawe. Iyi fishi itangirwaho uburenganzira ikubwira amakuru akwerekeyeho ashobora gukusanywa muri ubu bushakashatsi n'ushobora kuyabona cyangwa kuyakoresha.

Ibigo biri muri ubu bushakashatsi birimo:

[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

Amakuru abitse atuma umenyekana n'ifishi yo gutanga uruhushya n'iyi fishi y'uburenganzira bishyirwaho umukono na we bishobora kurebwa n'abandi bavuzwe ahakurikira bafite uburenganzira bugenwa n'amategeko bwo kureba ayo makuru:

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

* Ibiro byo ku rwego rw'igihugu nk'Ibiro bishinzwe kurengeraabakorerwaho ubushakashatsi n'Ikigo kigenzura ibiribwa n'imiti (FDA) birengera abakorerwaho ubushakashatsi nkawe.
* Abantu bakorera Kaminuza ya Colorado Denver | Ishami ry'ubuvuzi rya Anschutz bafite aho bahuriye n'ubushakashatsi.
* Abantu bakorera Ikigo gishinzwe gusuzuma ubushakashatsi (IRB) gishinzwe gusuzuma ubu bushakashatsi.
* Umuganga ukora mu bushakashatsi n'itsinda ry'abakora ubushakashatsi.
* [Insert sponsor name], ni nde uzishyura ubu bushakashatsi.
* Abakozi bakorera ibigo aho ubushakashatsi buri gukorerwa n'abakozi bari mu bindi bigo bifite aho bihuriye n'ubu bushakashatsi bashinzwe gukora ku buryo dukurikiza amabwiriza yose agenga ubushakashatsi.
* [Add any other groups or entities that have legal authority to audit identifiable study records.]

Amakuru yawe ashobora gukoreshwa no gutangazwa kugira ngo hakorwe ubushakashatsi, hasuzumwe ibyavuye mu bushakashatsi no kureba neza ko ubushakashatsi bwakozwe uko bikwiye.

Dushobora kuvuga ibyerekeye ubu bushakashatsi mu nama. Tunashobora gucapa ibyavuye muri ubu bushakashatsi mu binyamakuru bya ngombwa. Ariko tunakomeza kugira ibanga amazina y'abakorerwaho ubushakashatsi nkawe.

Ufite uburenganzira bwo gusaba kugera ku makuru y'ubuzima arinzwe akwerekeyeho afitwe n'ukora ubushakashatsi.

Ntidushobora gukora ubu bushakashatsi udaduhaye uruhushya rwo kureba, gukoresha no gutanga amakuru akwerekeyeho. Si ngombwa ko uduha uru ruhushya. Nutaduha uruhushya, ubwo ushobora kutajya muri ubu bushakashatsi.

Tuzareba, dukoreshe kandi tunatangaze amakuru akwerekeyeho gusa nk'uko byasobanuwe mu ifishi yo gutanga uruhushya igenewe ubu bushakashatsi n'ifishi yo gutanga uburenganzira ndetse n'Amabwiriza agenga ubuzima bwite; icyakora, abantu badakorera Kaminuza ya Colorado Denver | Ishami ry'ubuvuzi rya Anschutz n'abafatanyabikorwa bayo ntibarebwa n'aya masezerano kandi amakuru akwerekeyeho ashobora gutangazwa nta ruhushya ubitangiye.

Tuzanakora buri kimwe dushoboye kugira ngo tugire ibanga amakuru abitse akwerekeyeho, icyakora, ibi ntitwabikwizeza.

Ikoreshwa n'itangazwa ry'amakuru yawe nta gihe ntibigira igihe ntarengwa. Ushobora guhagarika uruhushya watanze rwo gukoresha no gutangaza amakuru akwerekeyeho igihe cyose wandikiye Umuyobozi Mukuru ushinzwe iby'ubushakashatsi ku mazina n'aderesi byavuzwe ahakurikira. Nuhagarika uruhushya rwawe rwo gukoresha no gutangaza amakuru akwerekeyeho, uruhare rwawe muri ubu bushakashatsi ruzarangira kandi nta yandi makuru akwerekeyeho azakusanywa. Ihagarika rikozwe na we ntabwo rizagira icyo rihindura ku makuru yamaze gukusanywa muri ubu bushakashatsi.

 [Add PI Name and Mailing Address]

Niwemera kuba muri ubu bushakashatsi, uzahabwa kopi yashyizweho umukono n'itariki by'iyi fishi itanga uburenganzira bwerekeye amakuru abitse yawe.

[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]

**Ukora ubushakashatsi (cyangwa umukozi ukora mu izina ry'ukora ubushakashatsi) bazatuma amakuru** yose cyangwa amwe n'amwe **yerekeye ubuzima akwerekeyeho akurikira aboneka kuri:**

* [Organization]

[Delete the following paragraph if not applicable.]

Zimwe mu nzira zikoreshwa mu bushakashatsi harimo gupima akoko cyangwa gukoresha amakuru y'akoko akwerekeyeho. Amakuru y'akoko akwerekeyeho azakoreshwa mu bushakashatsi kandi ntabwo azatangarizwa abandi hamwe n'andi makuru yatuma umenyekana. [Add if applicable.] Amakuru y'akoko yatuma umenyekana azatangarizwa:

**Amakuru akwerekeyeho azabonwa, azakusanywa, azakoreshwa kandi agatangazwa muri ubu bushakashatsi:**

[Delete all that do not apply]

* Izina n'amakuru ku myirondoro y’umuntu (imyaka, igitsina, ubwoko, aderesi, nomero ya telefone n'ibindi)
* Nomero y'ubwiteganyirize yawe
* Ibice by'amakuru y'ubuvuzi ya kera n'agezweho afitiye umumaro ubu bushakashatsi, harimo ariko atagarukira gusa ku Ndwara wasuzumwe, Ubushakashatsi bwakozwe n'Ubuvuzi bwo ku mubiri wahawe, ibizamini byo muri laburatwari n'ibyakorewe tisi, ubushakashatsi burimo kunyuzwa mu cyuma, ibyavuye mu bushakashatsi
* Gusura mu rwego rw'ubushakashatsi n'amakuru y'ibizamini byakozwe mu bushakashatsi
* Ibizamini by'ubwonko
* Ubusinzi, Kunywa ibisindisha cyangwa ibiyobyabwenge
* Gupima cyangwa kwandura indwara zishobora gutangwaho raporo mu Ishami rishinzwe ubuzima rusange, harimo ariko zitagarukiye gusa ku: Virusi y'agakoko gatera SIDA (HIV), hepatite (amoko yose), igituntu cynagwa izindi ndwara zandurira mu mibonano mpuzabitsina.
* Ikizamini cy'indwara ifata ingirangingo z'amaraso
* Tisi n'andi makuru yerekeye ibizamini byafashwe.
* Amakuru yo gutanga fagitire cyangwa ay'imari
* Ikindi (sobanura): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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

**Uburenganzira bushingiye ku itegeko HIPAA buhabwa ibikorwa by'inyongera bitari itegeko byerekeye ubushakashatsi**

Mu ncamake y'ubushakashatsi, uhabwa amahitamoI yo kwemera ibindi bikorwa by'inyongera, bitari itegeko byerekeye ubushakashatsi. Unagomba kuduha uruhushya rwawe, hakurikijwe amategeko ya HIPAA, rwo gukoresha no gutangaza amakuru yakusanyijwe avuye muri ibyo bikorwa bitari itegeko nk'uko byasobanuwe haruguru.

[If applicable] Bimwe na bimwe muri ibyo bikorwa bitari itegeko bishobora kuba birimo gupima akoko cyangwa gukoresha amakuru y'akoko akwerekeyeho. Amakuru y'akoko akwerekeyeho azakoreshwa mu bushakashatsi kandi ntabwo azatangarizwa abandi hamwe n'andi makuru yatuma umenyekana. [If applicable] Amakuru y'akoko yatuma umenyekana azatangarizwa:

Iyo wanzekuduha uruhushya rwo gukoresha no gutangaza amakuru akwerekeyeho, ntushobora kwitabira ibyo bikorwa bitari itegeko, ariko ushobora n'ubundi kwitabira ubushakashatsi bw'ibanze. Shyira inyuguti zibanza z'amazina yawe ku cyo wahisemo:

\_\_\_\_\_ ntanze uruhushya rw'uko amakuru anyerekeyeho, avuye mu bikorwa bitari itegeko nemeye haruguru, yakoreshwa akanatangazwa nk'uko byasobanuwe muri iki gice.

\_\_\_\_\_ **sintanze** uruhushya rw'uko amakuru anyerekeyeho yo mu bikorwa bitari itegeko ibyo ari byo byose yakoreshwa akanatangazwa; nsobanukiwe ko ntazitabira mu bikorwa bitari itegeko ibyo ari byo byose.

***BYUZUZWA N'UWITABIRIYE UBUSHAKASHATSI GUSA***

**Andika** izina ryawe, **shyiraho umukono** n'**itariki** ahakurikira niba wemera gutanga uburenganzira bwo gukoresha no gutangaza amakuru y'ubuzima arinzwe akwerekeyeho nk'uko byasobanuwe haruguru muri ubu bushakashatsi ndetse n'ubundi bushakashatsi butari itegeko ubwo ari bwo bwose wemeye kwitabira hifashishijwe ifishi yo gutanga uruhushya. Mu gushyira umukono kuri iyi fishi yo gutanga uburenganzira, ntabwo wamburwa ubundi burenganzira bugenwa n'amategeko ubwo ari bwo bwose. Turaguha kopi y'ifishi yashyizweho umukono kugira ngo uyibike.

**Izina ry'ukorerwaho ubushakashatsi**

**Umukono w'ukorerwaho ubushakashatsi (afite imyaka 18 cyangwa ayirengeje kandi abasha gutanga uruhushya) Itariki**

**Umukono w'Umuhagarariye wabiherewe uburenganzira mu rwego rw'amategek wabiherewe ububasha Itariki**

**ibyemezo byerekeye ubushakashatsi (niba bikurikizwa)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Ububasha bw'Umuhagarariye wabiherewe uburenganzira mu rwego rw'amategeko cyangwa Isano afitanye n'Ukorerwaho ubushakashatsi (niba bikurikizwa)**