

Daim ntawv kho dua tshiab hnuv tim: 01/20/21

DAIM NTAWV FOOS POM ZOO MUS KOOM QHOV KEV TSHAWB NRHIAV
Txhawm rau kom cov kev tshawb nrhiav ua mus raws li Txoj Cai Tsw Kav uas raug kho dua tshiab

TUS NAB NPAWB NQIS TES UA:

FEEM PAB TXHAWB:

TUS KWS TSHAWB FAWB:

24 TEEV. XOY TOOJ #:

Kev siv “koj” thooob plaws rau hauv cov ntaub ntawv no yog hais txog qhov ncauj lus kev tshawb fawb. Nws kuj hais txog tus neeg uas raug tso cai los muab kev pom zoo cia tus neeg mus koom hauv qhov kev tshawb nrhiav no.

Kev Pom Zoo cia Mus Koom hauv Qhov Kev Tshawb Nrhiav

Koj raug hais kom mus koom rau hauv ib qho kev tshawb nrhiav. Thov siv koj lub sij hawm los txiav txim siab thiab sib tham nws nrog koj tsev neeg thiab cov phooj ywg.

Ua ntej koj pom zoo mus koom, tus kws tshuaj tshawb fawb yuav tsum qhia koj txog:

- 1) Cov ntaub ntawv tseem ceeb no hais txog qhov kev tshawb nrhiav, uas yuav tsum muab nthuav qhia xub thawj, ua ntej yuav muab lwm cov ntaub ntawv qhia;
- 2) Cov hom phiaj, cov txheej txheem, thiab lub sij hawm ntawm qhov kev tshawb fawb;
- 3) Txhua txheej txheem uas yuav tau sim kho mob;
- 4) Txhua feem muaj pheej hmoo tshwm sim tsis zoo uas tej zaum yuav muaj tau, kev xeeb txob, thiab tej txiaj ntsig ntawm qhov kev tshawb fawb;
- 5) Txhua feem muaj txiaj ntsig ntawm cov txheej txheem los sis cov kev kho mob;
- 6) Yuav ceev kom tsis pub neeg paub tau li cas thiab koj tej ntaub ntawv kev noj qab haus huv yuav raug tiv thaiv li cas; thiab
- 7) Txawm tias koj tej ntaub ntawv ntiag tug (tshem tawm ntawm tej ntaub ntawv uas yuav ua rau txheeb xyuas tau koj) los sis tej qauv kuaj ntsuas (piv txwv li, zis, ntshav, npluag nqaij) uas raug muab los siv rau qhov kev tshawb nrhiav no yuav tsum raug siv rau kev tshawb nrhiav tom ntej yog tsis tas muab kev pom zoo ntxiv.

Yog ua tau, tus kws tshawb fawb kuj yuav tsum qhia rau koj txog:

- 1) Txhua yam kev them nqi los sis kev kho mob yog muaj kev raug mob tshwm sim;
- 2) Feem muaj pheej hmoo tsis zoo uas tej zaum yuav tshwm sim tau;
- 3) Tej kis xwm txheej thaum tus kws tshawb fawb yuav tau tso tseg koj qhov mus koom;
- 4) Txhua yam nqi uas yuav tau mus rau koj ntxiv;
- 5) Yog koj txiav txim siab tso tseg qhov mus koom yuav tshwm sim dab tsi;
- 6) Thaum tau hais rau koj txog tej yam tshawb nrhiav tau tshiab uas tej zaum yuav cuam tshuam txog koj qhov txaus siab mus koom;
- 7) Yuav muaj puas tsawg leej neeg los koog rau qhov kev tshawb nrhiav no;

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- 8) Txawm tias koj tej qauv kuaj (yog ntiag tug li uas yuav txheeb tau) tej zaum yuav raug siv koj mus ua lag luam thiab txawm tias koj yuav raug faib nyiaj paj los ntawm qhov muab ua lag luam no;
- 9) Txawm tias yuav muab tej yam ua tau los ntawm qhov kev tshawb nrhiav rau koj, suav txog tus kheej qhov ua tau los, thiab yog li, raws hauv qhov teeb meem tshwm sim;
- 10) Txawm tias qhov kev tshawb nrhiav yuav (yog paub) los sis tej zaum yuav muab tag nrho tej genome; thiab
- 11) Rau kev sim kho mob: Kev piav qhia ntawm qhov kev sim kho mob yuav muaj nyob rau ntawm www.ClinicalTrials.gov, yuav tsum muaj raws li Mes Kas Txoj Cai. Lub Web site (Vas sab) no yuav tsis muaj cov ntaub ntawv uas yuav txheeb xyuas tau tias yog koj tso rau hauv. Qhov ntau tshaj ces, lub Web site (Vas sab) tsuas tso cov ntaub ntawv tseem ceeb hais txog qhov tshawb nrhiav tau los xwb. Koj tuaj yeem mus tshawb nrhiav lub Web site (Vas sab) no tau txhua lub sij hawm.

Yog koj pom zoo mus koom, yuav muab ib daim ntawv theej uas tau kos npe thiab hnuv tim rau ntawm daim ntawv no rau koj thiab muab daim ntawv theej sau ua Lus As Kiv ntawm daim ntawv foos pom zoo mus koom qhov kev tshawb nrhiav no rau koj.

Koj tuaj yeem hu rau tus neeg tshawb xyuas fawb tus xov tooj teev rau thawj nplooj ntawm daim foos no thaum twg los tau yog tias koj muaj lus nug txog qhov kev kawm tshawb nrhiav los sis ntsig txog kev raug mob los ntawm qhov kev tshawb nrhiav no.

Tej zaum koj kuj yuav hu rau Advarra qhov IRB. Ib pawg kws tshuaj xyuas (institutional review board, IRB) uas yog ib pawg kws ua haujlwm tsis zwm rau leej twg yuav los pab tiv thaiv cov cai ntawm cov koom rau qhov kev kawm tshawb nrhiav. Yog koj muaj lus nug txog koj cov cai raws li yog ib tug neeg koom rau qhov kev kawm tshawb nrhiav, thiab/los sis muaj kev txhawj xeeb los sis muaj lust sis txaus siab ntsig txog qhov kev kawm tshawb nrhiav kho mob no, tiv tauj rau:

- Xa Ntawv:
Study Subject Adviser
Advarra
6100 Merriweather Drive, Suite 600
Columbia, MD 21044
- los sis hu rau **tus xov tooj hu dawb**: 877-992-4724
- los sis xa **email**: adviser@advarra.com

Koj qhov mus koom hauv qhov kev tshawb nrhiav no yog yeem siab dawb xwb, thiab koj yuav tsis raug nplua dab tsi los sis poob tej txiaj ntsig yog koj tsis kam lees mus koom los sis txiaiv txim siab tso tseg.

Kev kos npe thiab kev sau hnuv tim rau daim ntawv foos no txhais tau tias qhov kev tshawb nrhiav, suav nrog tej ntaub ntawv saum toj saud yeej raug muab piav qhia rau koj lawm, thiab tias koj yeej yeem siab mus koom:

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Tej Ntaub Ntawv ntawm Kev Pom Zoo:

Tus neeg uas tab tom ua qhov kev tshawb nrhiav no tau piav qhia txog yam uas yuav tshwm sim rau kuv lawm yog kuv mus koom rau hauv qhov kev tshawb nrhiav no. Kuv qhov kos npe hauv qab no txhais tau tias kuv xav mus koom rau hauv qhov kev tshawb nrhiav no. Kuv txiav txim siab tsis mus koom hauv qhov kev tshawb nrhiav no yo kuv tias xav mus koom thiab yuav tsis muaj dab tsi tshwm sim rau kuv yog kuv txiav txim siab tsis mus koom.

Sau Lub Npe Ntawm Qhov Ncauj Lus Kawm Tshawb Fawb

Tus Neeg Koom Qhov Kev Tshawb Fawb Kos Npe
(yog tias tus neeg koom nrog muaj hnuv nyoog siab dua li hais)

Hnuv Tim

Tej Ntaub Ntawv Ntawm Kev Txaus Siab (yog tias muaj - yog tias tus neeg koom ntawd muaj hnuv nyoog qis dua feem ntau):

Kos Npe ntawm Tus Neeg Koom Nrog

Hnuv Kos Npe

Tus Neeg Sawv Cev Raug Li Txoj Cai (raws li muaj):

Sau Lub Npe Ntawm Tus Neeg Sawv Cev Raug Cai

Kos Npe Ntawm Tus Neeg Sawv Cev Raug Cai

Hnuv Tim

Txoj Cai Ntawm Tus Neeg Sawv Cev Raug Cai Los Ua Ib Tug Koom Nyob Hauv Qhov Kev Tshawb Fawb

Yuav Tsum:

Kos Npe ntawm Tus Kws Txhais Lus/Tus Ua Tim Khawv

Hnuv Tim

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LWM YAM NTSIG TXOG RAU TEJ KEV TSHAWB NRHIAV (YOG SIV TAU)

Koj raug hais kom mus koom rau qee qhov kev tshawb nrhiav. Yog koj txiav txim siab tsis mus koom rau hauv qee qhov kev tshawb nrhiav, koj tseem tuaj yeem mus koom tag nrho qhov kev tshawb nrhiav no tau. Thov siv koj lub sij hawm los txiav txim siab thiab sib tham nws nrog koj tsev neeg thiab cov phooj ywg.

Koj qhov mus koom hauv cov kev tshawb nrhiav xaiv tau no yog yeem siab dawb xwb, thiab koj yuav tsis raug nplua dab tsi los sis poob tej txiaj ntsig yog koj tsis kam lees mus koom los sis txiav txim siab tso tseg.

Thov qhia tias koj puas xav mus koom los sis tsis xav mus koom qee qhov kev tshawb nrhiav.

Hom Kev Xaiv Tshawb Nrhiav #1: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #2: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #3: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #4: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #5: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

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Hom Kev Xaiv Tshawb Nrhiav #6: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #7: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #8: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #9: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____

Hom Kev Xaiv Tshawb Nrhiav #10: _____

- Tsis tsim nyog
- Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____
- Tsis Xav Mus Koom Sau Tus Niam Ntawv Npe Rau _____ Hnuv Tim _____