PRENSIP JENERAL SOU KONSANTMAN ENFÒME

Nap swiv prensip moral respè (otonomi) pou moun gras a pwosesis konsantman enfòme a lè se moun ki sijè nan rechèch la, epi se yon pwosesis nesesè kap ede nou asire rechèch la ap fèt yon mannyè ki dakò ak règ moral yo.

KONSÈY:

Objektif model sa se pou asiste moun kap fè rechèch yo ki ap travay sou ki nenpòt kalite rechèch – depi sou tèste remèd pou rive nan etid ki gen ti risk. Itilizasyon modèl sa ap ede asire konsantman enfòme a gen tout eleman l dwe genyen pou IRB a ka apwouve l. Itilizasyon modèl sa ap rann tou pi fasil pwosesis revizyon IRB a. Gras a modèl sa li bay la, IRB swete ede moun kap fè rechèch yo redwi reta pou apwouve rechèch yo ak redwi keksyon oubyen revizyon k obligatwa yo; sak ka ogmante fado pou IRB a apwouve rechèch la. Men, si moun kap fè rechèch la santi pou l fè pwojè pal la li pa ka swiv modèl sa, moun kap fè rechèch la ka chwazi pou l prepare konsantman enfòme pa l. Lè lap prepare konsantman enfòme a, moun kap fè rechèch la dwe asire l li gen tout eleman obligatwa yo ladan l (gade sak anba a). Souvan, li rekòmande pou yo gen tradiksyon konsantman enfòme a tou depan de moun yo kap sijè nan rechèch la. Tanpri pran nòt ; CHA ofwi tradiksyon modèl sa an pan-yòl, pòtigè ak kreyòl ayisyen.

ELEMAN LWA PEYI A EKZIJE POU GEN NAN YON KONSATMAN ENFÒME

Sa w pral jwenn anba a se Regleman ak prensip jeneral ki dwe genyen nan konsantman enfòme (45 CFR46.116) tout moun kap fè rechèch nan CHA oblije swiv lè yap prepare bouyon konsantman enfòme pa yo:

- Yon dekarasyon kap fè konnen etid la se yon rechèch li ye, yon eksplikasyon sou objektif rechèch la ak kantite tan yo panse patisipasyon sijè a ap dire, yon deskripsyon pwosedi yap swiv yo, ak idantifikasyon tout pwosedi ki se eksperyans yap fè.;
- Yon deskripsyon tout risk ak malèz ki posib yo prevwa sijè ka genyen,
- Yon deskripsyon tout avantaj posib yo espere sijè yo oubyen lòt moun ka jwenn nan rechèch sa ;

INFORMED CONSENT GUIDELINES

The ethical principle of respect for persons (autonomy) is maintained by the process of informed consent from human subjects involved in research, and is a necessary process to help ensure that research is conducted in an ethical manner.

GUIDANCE:

The purpose of this template is to assist investigators working on all kinds of research – from drug trials to minimal risk studies. Use of the template helps insure that the informed consent contains all the required elements for approval by the IRB. Using this template also facilitates the IRB review process. By providing a template, the IRB hopes to help researchers reduce delays in approval and reduce questions or required revisions that increase the burden of gaining IRB approval. However, should an investigator find that to conduct their project they must deviate from the template, the investigator may opt to design his/her own informed consent. Often it is recommended to have translated versions of an informed consent, depending on the subject population. Please note, that CHA offers translated versions of this template in Spanish, Portuguese and Haitian Creole.

FEDERALLY MANDATED ELEMENTS OF INFORMED CONSENT:

The following are the Common Rule guidelines regarding informed consent (45 CFR 46.116) which all CHA researchers are required to follow when drafting their own consent forms:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others, which may reasonably be expected from the research;

- Se pou yo fè sijè a konnen tout lòt pwosedi oubyen plan trètman apwopriye ki ka bon pou li
- Yon deklarasyon kap dekri nan ki mezi, si l posib, yap kenbe konfidansyalite dosye yo ki ka idantifye sijè a.
- Yon deklarasyon kap di ki responsablite rechèch la si yon bagay mal ta rive sijè a nan rechèch la ;
- Yon eksplikasyon pou di ki moun pou yo kontakte pou yo jwenn repons pou keksyon enpòtan sou rechèch la ak dwa sijè yo nan rechèch la, ak ki moun pou yo kontakte si yon bagay mal ta rive sijè a nan rechèch la ;
- Yon deklarasyon kap di patisipasyon se yon bagay volontè. Si yon moun refize patisipe pap gen pinisyon pou sa ak sijè a pap pèdi okenn avantaj, epi sijè a ka sispann patisipe ki nenpòt lè san okenn pinisyon, san l pa pèdi okenn avantaj, si se pat sa, li gen dwa pou l jwenn.

- A disclosure of appropriate alternative procedures or courses of any treatment that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- A statement describing any liability for research related injury;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to the subject and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Remak: Anplis tout regleman ki dwe genyen nan tout konsantman enfòme, HIPAA egzije pou gen detay byen patikilye sou kijan yap itilize ak pataje Enfòmasyon Lasante Pwoteje; sa wap jwenn nan modèl konsantman enfòme sa.

Note: In addition to the Common Rule requirements for informed consent, **HIPAA** requires specific details regarding use and disclosure of PHI which is incorporated into this informed consent template.

Sa w pra l jwenn anba a se gwo tit tout eleman ou dwe jwenn nan konsantman enfòme pou yon rechèch. Yo dwe mete tout eleman esansyèl yo (tit segondè yo) ki an wouj nan konsatman enfòme a. Langaj yo konseye pou itilize yo an *italik* epi se sèlman yon gid li ye pou prepare chak seksyon tou depan nati rechèch la. Si yo pa endike lekontrè, yo ka ajiste langaj yo konseye a pou l koresponn a chak pwotokòl endividyèl. Enfòmasyon ki ekri an ble yo se sèlman pou enfòmasyon w yo la; ou pa dwe mete yo nan fòm konsantman final la.

The following is an outline of the required elements of a research consent form. All essential elements (sub-topics) in red font must be incorporated into a consent form. Suggested language is marked in *italics* and is only guidance for preparing each section per the nature of the research. Unless otherwise indicated, suggested language should be tailored for individual protocols. The information in blue font is for your information only and should not be incorporated into the final consent form.

Cambridge Health Alliance
A COMMUNITY OF CARING

KONSANTMAN ENFOME AK OTORIZASYON POU ITILIZE AK REVELE ENFOMASYON PWOTEJE SOU LASANTE POU FÈ RECHECH

Nou eseye fè fòm sa fasil pou w konprann. Men li ka toujou gen ladan l kèk mo ak ide ki pa klè pou ou. Silvouplè santi w alèz pou w mande doktè etid la oubyen moun kap fè etid la pou eksplike kelkeswa sa w pa konprann nan.
Ou kapab al lakay ou ak fòm nan pou w ka diskite ak fanmi w oubyen zanmi w anvan w deside.

Non w (Sijè): _____

Dat Jodi a: _____

Adrès Lakay ou : _____

Eske wap patisipe kounye a nan yon Etid-rechèch kèlkonk

Wi _____ **Non** _____

Tit Etid la: _____

Non Chèchè Prensipal la: _____

Non Chèchè Asitan yo : _____

No Protokol IRB.a: _____

Dat IRB a Apwouve l: _____

Dat IRB a bay pou l Fini: _____

Kote ki Patrone Etid la: _____

INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We try to make this form easy to understand. But it may still have words or ideas that are not clear to you. Please feel free to ask the study doctor or the study staff to explain anything that you do not understand.
You may take this form home to discuss with family or friends before you decide.

Your name (Subject): _____

Today's Date: _____

Home Address: _____

Are you now taking part in any Research Studies? _____

Yes _____ **No** _____

Title of Study: _____

Name of Principal Investigator: _____

Name of Co-Investigator(s): _____

IRB Protocol No: _____

IRB Approval Date: _____

IRB Expiration Date: _____

Study Sponsor(s): _____

1. Envitasyon:

Nòt:
Li apwopriye pou gen yon premye paragraf pou entwodwi etid-rechèch la.

Langaj Sijere :

Ou envite pou w patisipe nan yon etid-rechèch Dr._____ ak/oubyen moun kap travay avèk doktè sa ap fè.

Patisipasyon w volontè. Ou gen chwa pou w patisipe oubyen pou w pa patisipe. Si w patisipe nan etid la ou kapab soti ladan l ki nenpòt lè. Si w pa vle patisipe sa pap chanje okenn pati nan kalite swen lasante wap resevwa. Menm si ou ka soti nan etid la ki nenpòt lè, nap ka itilize kèlkeswa enfòmasyon nou te gen tan pran sou ou pandan w tap patisipe nan rechèch la.

2. Rezon pou Etid la:

Nòt:
Yo dwe di objektif yo ak bi pwotokòl nan yon langaj tout moun ka konprann. Li dwe klè etid la se rechèch li ye epi non sèlman gen yon rezon imedyat men finalman gen yon pi gwo rezon ki fè yap fè rechèch.

Langaj Sijere :

Rezon etid rechèch sa se

3. Rezon ki fè yo chwazi w pou w nan Etid la

Nòt:
Li enpòtan pou enfòme moun ki ka patisipe nan etid la pou kisa yo mande l pou l patisipe. Yo dwe di sijè a pou ki sa yo chwazi l pou etid la (paske yo gen yon maladi patikilye, oubyen yo se volontè ki an bòn sante yap itilize yo pou fè konparezon ak lòt moun, eksetera.)

Langaj Sijere :

Men rezon yo ki fè yo te chwazi w pou w patisipe nan Etid Rechèch sa:

4. Dire Patisipasyon an (konbyen tan wap fè nan etid la) :

1. Invitation:

Note:
An opening paragraph is appropriate to introduce the research study.

Suggested Language:

You are invited to take part in a research study done by Dr._____and/or people who work with this doctor.

Taking part is voluntary. You have the choice to take part or not. If you take part in the study, you may also leave the study at any time. If you don't want to take part, it does not change any part of the standard health care you will receive. Although you can leave the study at any time, we will be able to use any information about you that we got while you were part of the research.

2. Purpose for the Study:

Note:
The objectives and goals of the protocol should be clearly stated in lay terms. It should be clear that the study involves research and that there is not only an immediate purpose, but ultimately, a larger purpose for conducting the research.

Suggested Language:

The purpose of this Research Study is to: .

3. Reasons why you have been selected for the Study:

Note:
It is important to inform the potential participant why they are being asked to participate. The subject should be told why he/she is being selected for the study (because they have a particular condition, or they are a healthy volunteer to be used as a control, etc.)

Suggested Language:

The reasons why you have been selected for this Research Study are

4. Period of Participation (how long you will be involved in the study):

Nòt:
Mete konbyen tan patisipasyon an ap dire ak apeprè konbyen tan randevou yo ap dire. Yo dwe enfòme sijè a sou kantite randevou lap genyen pou etid la, epi yo dwo fè l konnen tou kantite total sijè yo espere ap gen nan etid la. Si ap gen anpil randevou pou etid la, yon tablo oubyen yon kat ki gen detay randevou pou etid la ka byen itil.

Note:
Include how long participation will last and approximately how long visits will last. The subject should be informed of the number of visits required by the study, as well as the total number of subjects expected to enroll. If there are a large number of visits required for the study, a table or outline with study visit details may be helpful.

Langaj Sijere :

Si w chwazi pou w patisipe nan etid la, pwosedi etid la ap dire epi yap kontinye swiv ou pou yon lòt_____. *Yap mande w pou w vin nan randevou kap dire_____èdtan pou yon peryòd _____ .*

Suggested Language:

If you choose to participate in this study, the study procedures will last for _____ _____ and you will be followed for another _____ .
You will be asked to attend visits that will last hours each for a period of _____.

5. Pwosedi yo (kisa n pral fè:

Nòt:
Seksyon sa dwe gen ladan l yon eksplikasyon detaye sou etid la epi li dwe di byen klè tout pwosedi kap gen nan etid la. Li dwe fè yon diferans klè ant swen regilye ak rechèch la. Evite langaj teknik chak fwa sa posib.

5. Procedures (what we will do):

Note:
This section should include a detailed explanation of the study and should clearly state all procedures involved. A clear distinction must be made between standard practice and research. Avoid technical language whenever possible.

Sa nou pral di la yo enpòtan pou yo nan nòt la :

The following are all important to note:

- Eksplikasyon entansyon etid la (Etid pilòt, ankèt, teste yon remèd). Si se yon remèd yap teste, eksplike si yap chwazi echantiyon pa haza, kwaze, si de gwoup yo moun pap konnen ki gwoup yap bay remèd tout bon ak ki gwoup se fo remèd yap ba yo, si yap itilize plasebo (fo remèd), etikèt ouvri, apre konbyen tan remèd la ap soti nan kò moun yo, eksetera.

• Explanation of study design (Pilot Study; Survey, Drug Trial). If drug trial, explain if it is randomized, crossover, double blinding, placebo use, open label, washout periods, etc.

- Dekri kèlkeswa remèd la ak/oubyen aparèy yap itilize. [Non remèd yo pa dwe ekri an abreje epi yo dwe mete non jenerik la ak non komèsyal la regilyèman lè sa apwopriye. Yo **PA** dwe met doz la an abreje. Yo dwe ekri l byen klè (tankou miligram, pa mg). Yo dwe di tou ki kote yap bay moun yo remèd la. Di byen klè si FDA apwouve/pa apwouve remèd la/aparèy la. Si FDA apwouve remèd la/aparèy la men yap itilize pou yon bagay li pa apwouve (mete remak : *remèd/aparey nap itilize nan etid se rechèch nap fè sou li paske FDA pa apwouve pou_____. Men li apwouve pou yo itilize l nan_____)*

• Describe any drugs and/or devices used. [Drug names should be spelled-out in full and include both the generic and trade name consistently, when appropriate. Dosage should **NOT** be abbreviated. It must be written out (i.e., milligrams, not mg). Also the route of administration must be stated. Specify if the drug/device is approved/not approved by the FDA]. If the drug/device is FDA approved but being used off-label (Mention: *The drug/device's use in this study is investigational because it is not approved by the FDA for_____. However, it is approved for use in _____*).

- Egzamen fizik

• Physical exams

- Maladi oumenn ak fanmi genyen

• Medical history

- Keksyonè, ankèt, ekri aktivite moun nan fè chak jou, mezi pou evalyasyon, eksetera

• Questionnaires, Surveys, diaries of activities, rating scales, etc.

- Restriksyon nan zafè manje
- Restriksyon nan remèd (tankou dwòg OTC yo, restriksyon nan remèd fèy/sipleman)
- Tès oksilyè yo avèk tout eksplikasyon (tankou ECG, MRI, CAT scan, egzamen pipi eksetera)
- Tès gwosès, egzijans nan zafè planin [Fòm konsantman an dwe endike eske ap gen nesesite pou fè planin nan etid la. Sa ka aplike ni pou gason ni pou fi (gade anba a pou langaj sijere a). Tou depan de laj timoun ki ka patisipe nan etid la, ya ka dwe ajoute enfòmasyon sa nan fòm konsantman an).
- Gwoup bwase lide [ekri si yap anrejistre oubye filme gwoup yo]
- Randevou, koup fil yo, eksetera

Langaj Sijere

Si w deside pou w patisipe nan etid la, wap gen pou w fè bagay sa yo:

Planin:

Eske w ansent oubyen ou panse w ansent?

☐ *Wí* ☐ *Non*

Eske w kapab ansent?

☐ *Wí* ☐ *Non*

Eske wap fè plan pou w ka ensent?

☐ *Wí* ☐ *Non*

*Kounye a yo PA konnen ki risk pwodwi ki gen nan etid sa gen pou timoun ki pa ko fèt. Poutèt sa fanm yo **PA** dwe patisipe nan etid sa si yo ansent, ap bay bebe tete oubyen ap eseye pou yo ka ansent.*

Si w se yon fanm ki ka ansent, ou dwe fè planin pou tout tan yap fè etid la ak pou_____mwa sa yo apre etid la fini. Ou dwe dakò pou w pran grenn planin oubyen fè ki nenpòt lòt fòm planin. Kèk etid tou ka bezwen pou w itliize de metòd kontwòl. Doktè w la va diskite bagay sa yo avè w.

Si se gason w ye epi w gen yon patnè ki ka vin ansent, kidonk ou dwe itilize kapòt. Epitou wap bezwen asire w patnè w la ap itilze yon metòd planin tou.

- Dietary restrictions
- Medication restrictions (including OTC drugs, herbal/supplement restrictions.)
- Ancillary tests, including explanations (e.g. ECG, MRI, CAT scan, urinalysis, etc.)

Pregnancy Testing / Birth Control requirements [The consent form should indicate whether there is a need for using birth control in the study. This may apply to males as well as females (see below for suggested language). Depending on the age of minors to be enrolled, this information may also be added to an Assent form.]

Focus Groups [specify if any audio or video taping will be done.]

Follow-up visits, phone calls, etc.

Suggested Language:

If you decide to take part in this research study, the following will be done:

Birth Control:

Are you Pregnant or think you are Pregnant?

☐ *Yes* ☐ *No*

Are you able to get Pregnant?

☐ *Yes* ☐ *No*

Are you planning to get pregnant?

☐ *Yes* ☐ *No*

*The risk of the study agent to an unborn baby is NOT known at this time. As a result, women should **NOT** be in this study if they are pregnant, breast-feeding, or trying to become pregnant.*

If you are a woman able to get pregnant, you should use birth control for the entire time of the study and for _____months afterwards. You should agree to be on a birth control pill or any other form of birth control. Also, some studies may need you to use a double control method. Your doctor will discuss these with you.

If you are a male with a partner who could become pregnant, then you should use condoms. You also need to make sure your partner is using some form of birth control as well.

6. Risk, Malèz, Efè Segondè yo ak enkonvenyan yo:

Nòt:
Fè lis tout risk/malèz ki posib yo prevwa k ka rive. Kenbe nan lide n se pa tout moun kap kouri tout risk yo. Kèk nan risk yo ka pran reta oubyen se sèlman yon seri de moun yo ka afekte. Yo dwe eksplike chak bagay ki nan seksyon pwosedi a tankou efè segondè remèd yo, eksetera. Yo dwe eksplike menm bagay ki sanble yo pa ka lakoz okenn danje (tankou yon seri keksyon ki pa fasil pou reponn nan yon ankèt, remèd tretman fèy ka elimine efè yo). Lè se remèd yap teste, si gen risk pou sentòm yo vin pi mal espesyalman nan kantite tan remèd la ap pran pou l soti nan kò moun nan oubyen si se yon bagay ki pa remèd vre yap bay moun nan, yap bezwen pou eksplike sa an detay. Yo dwe eksplike risk ki genyen pou fanm ansent, fanm kab bay timoun tete ak ti bebe k nan vant.

Langaj Sijere:
Pou Etid Sou Konpòtman Moun:

Kèk nan keksyon yo pral poze w yo ka de nati pèsonèl epi yo ka jennen w oubyen met presyon sou ou. Ou ka mande pou w wè keksyon yo anvan w deside si wap patisipe oubyen si w pap patisipe nan etid sa.
Kòm patisipasyon nan etid rechèch sa wap sèlman pèmèt moun kap fè rechèch yo itilize enfòmasyon yap pran nan dosye medikal ou. Tès ak tretman wap resevwa yo ap fè pati swen nòmal pou kondisyon w nan. Ou pap bezwen fè okenn lòt pwosedi oubyen tretman pou etid sa. Konsa pa gen okenn risk wap kouri difèt ou nan etid sa ou pa tap kouri nan tretman regilye w.

Lè Yap Teste Remèd :

Nou pa konnen efè segondè yo:

Tankou pou ki nenpòt_____gen efè segondè nou pa konnen kounye a. Yap kontinye swiv ou pou tout efè segondè ou santi epi ou dwe fè anplwaye etid la konnen si w santi yon bagay ou pat konn genyen.

Efè segondè yon konnen yo:

Pou Tès oksilyè yo:
Radyografi espesyal (scans) sa yo se sèlman pou rechèch la yap fè yo. Yo pap itilize rezilta sa yo pou yo pran desizyon ki an rapò ak dyagnostik oubyen tretman w. Si radyografi espesyal la montre yon bagay ki ka aji sou lasante, yap refere w pou al pran swen apwopriye pou sa.
Si gen kèk metal nan kò w tankou aparèy pou estimile kè w (pacemaker) oubyen vis ak klips yo te mete nan kò w lè tap fè operasyon, oubyen si w tap travay ak metal oubyen zouti ki ka kite ti moso metal nan je w oubyen nan po w, ou ka pa kabab patisipe nan etid MRI la.

6. Possible Risk, Discomforts, Side Effects, and Inconveniences:

Note:
List all risks/discomforts that are reasonably foreseeable. Keep in mind that not all risks will be to the individual. Some risks may be delayed or may impact only certain people. Each item mentioned in the procedure section should be addressed, e.g., medication side effects, etc. Even for things that seem harmless (such as the uneasiness of certain questions in a survey, the potential contraindication of herbal therapies). In a drug trial, if there is risk of symptoms worsening, especially on a washout or placebo, this needs to be detailed. Risks to pregnant/nursing women/fetus must be addressed.

Suggested Language:
For Behavioral Studies:

Some of the questions that you will be asked are of a personal nature and may cause you embarrassment or stress. You may ask to see the questions before deciding whether or not to participate in this study.
Your part in this research study consists only of allowing the researcher to use data from your medical record. The tests and treatments you will receive are part of the standard of care for your condition. This study does not require you to have any additional procedures or treatments. Therefore, being in this study does not involve any risks that you would not face during your routine treatment.

For Drug Trials:

Unknown Side Effects:

As with any_____,there may be side effects that are unknown at this time. You will be monitored for any side effects and should report any unusual events to the study staff.

Known Side Effects:

For Ancillary Tests:
These scans are being performed for research purposes only; the results will not be used to make decisions related to your diagnosis or treatment. If the scan reveals a condition that could affect your health, you will be referred for appropriate follow up care.
If you have any metal in your body such as a pacemaker or surgical pins or clips, or if you work with material or tools that could leave small pieces of metal in your eyes or skin, you may not be in the MRI/study.

Si w santi kè w ap sote oubyen ou pè lè nan yon kote k fèmen, ou ka gen santiman sa yo lè wap fè MRI la. Si w vin santi w pa alèz ditou, se pou w fè moun kap fè rechèch yo konn sa epi yap sispan pwosedi a.

Deklasyon jeneral:
Nap byen kontan pou n pale avè w sou nenpòt keksyon ou genyen sou risk ak/oubyen efè segondè yo.

7. Lòt Chwa nan Plas Patisipasyon:

Nòt:
Fòm konsantman dwe di byen klè sijè a pa oblije patisipe nan etid la pou l resevwa tretman ki te deja disponib. Si, pa egzanp, nan pwotokòl la yap fè konparezon ant 2 remèd ki deja a lavant, yon lòt chwa se ta pran ki nenpòt nan remèd yo san w pa patisipe nan etid la.
Si se yon remèd yap teste, konsa se pou yo fè yon lis detaye nenpòt lòt remèd oubyen tretman sijè a ka chwazi olye l patisipe nan etid la ; se pou yo mete lòt tretman yap fè rechèch sou yo, tretman altènatif, ak tretman ki pa itilize remèd. Yo dwe bay ni non jenerik la ni non komèsyal la nenpòt ki lòt remèd altènatif.
Ou ka chwazi pou w pa patisipe epi w kontinye resevwa swen regilye w.

Langaj Sijere:

Ou ka chwazi pou w pa patisipe epi w kontinye resevwa swen regilye w.

Nouvo Dekouvèt :
Nap fè w konnen ki nenpòt dekouvèt ki ka fè w chanje lide w pou w patisipe nan etid rechèch la.

8. Avantaj: (Ki bon bagay ki ka soti nan rechèch la)

Nòt:
Fè lis tout avantaj ki ka vin disponib gras a rechèch sa. Epitou, fè remake kèk nan avantaj yo ka pa ede chak sijè direkteman. Gade nan lespri nou rekonpans pou patisipasyon nan rechèch la se pa sa nou rele avantaj la.

Langaj Sijere
Rechèch sa ka pa ede w dirèkteman. Men, sa nou aprann nan ka ede lòt moun.

9. Konbyen sa ap koute:

Nòt:
Di byen klè si sijè a oubyen asirans sijè a ap responsab pou peye kèk oubyen yon pati nan pwosedi yo, eksetera, oubyen si se kote kap patrone rechèch la kap peye pou remèd la ak/oubyen pwosedi ki an rapò ak rechèch la. Nou prefere itilize mo “li pap koute w anyen” olye “gratis” paske nou konsidere li mete mwens presyon sou moun nan.

If you feel anxious or scared when in an enclosed space, these feelings could occur while in the MRI. If you become too uncomfortable you should tell the researchers and the procedure will be stopped.

Blanket Statement:
We will be happy to talk with you about any questions you have about these risks and/or side effects.

7. Alternatives to Participation:

Note:
The consent form should clearly state that the subject does not have to participate in the study to receive the treatments that are already available. If, for example, the protocol involves a comparison between two drugs that are commercially available, an alternative would be to receive either one without participating in the study.
If it is a drug trial, then list specifically any medication or treatment options that the subject might choose as an alternative to participation, including other investigational treatments, alternative treatments, and non-pharmaceutical treatments. Both the generic and trade names of any alternative drugs should be given.

Suggested Language:

You may choose not to participate and continue to receive standard care.

New Findings:
We will inform you of any findings that may cause you to change your mind about being in the research study.

8. Benefits: (What good may come from the research)

Note:
List all benefits that will be made available from this research. Also, note that some of these benefits may not help each subject directly. Keep in mind that compensation for participating in the research is not a benefit.

Suggested Language:
This research may not help you directly. However, what we learn may help others.

9. Costs:

Note:
Clearly specify if the subject or the subject’s insurance will be responsible for any or part of the procedures, etc. or if the drug and/or all study related procedures will be paid by the sponsor. Using the term “at no cost” is preferable than saying “free” as it is considered less coercive.

Langaj Sijere

Deklarasyon jeneral:

Ou pa gen anyen w pral peye anplis difèt ou nan etid sa. Ou pa gen anyen wap peye pou tout randevou, pwosedi ak remèd ki an rapò ak etid la. Pou Lajan pou peye ki an rapò ak swen regilye, yap voye bòdwo yo kòm dabitid ba ou oubyen bay asirans ou.

Lè Yap Teste Remèd :

Yap ba w medikaman ki nan etid la san yo pa koute w anyen. Pou tout lòt lajan pou peye ki an rapò ak swen regilye nap voye bòdwo yo kòm dabitid ba ou oubyen bay asirans ou. Kote kap patrone rechèch la dakò pou l peye pou tretman pou tout bagay mal ki an rapò ak rechèch la ki ta rive si w te swiv kòm sa dwa tout prensip jeneral rechèch la

10. Konpansasyon (rekonpans pou patisipasyon w):

Nòt:
Konpansasyon se pa sa nou rele avantaj pou patisipasyon nan etid la, kidonk yo dwe mete l nan yon lis separe.

Langaj Sijere

Yap peye w $_____pou tan ak lajan w peye pou transpò difèt ou nan etid la. Si w pa fin fè tout etid la, yap peye pou kantite randevou w te vini yo. Yap peye nan fen etid la oubyen lè w deside pou w sispan patisipe.

Yap ba w yon kat pou achte kado nan _____.

11. Patisipasyon Volontè:

Nòt:
Li trè enpòtan pou nou mete anpil aksan sou patisipasyon volontè a epi refize patisipe sa pap afekte swen regilye sijè a te konn resevwa

Langaj Sijere:

Patisipasyon w nan etid sa volontè. Yo pap pini w epi w pap pèdi avantaj ou gen dwa pou resevwa si w pa patisipe. Kalite swen medikal la ap toujou rete menn jan an si w patisipe, si w pa patisipe, oubyen si w deside kite etid la.
Ou ka chwazi pou w patisipe nan etid sa. Si w chwazi pou w patisipe, lè sa :

(a) Patisipasyon w volontè epi ou ka soti nan etid la ki nenpòt lè. Pou w soti ou dwe:

Suggested Language:
Blanket Statement:

You will not have any added costs from being in this study. All study related visits, procedures and medications will be given at no cost to you. Costs related to your standard care will be billed as usual to you or your insurance.

For Drug Trials:

The study medication will be provided to you at no cost. All other costs will be billed to you and your insurance company in the usual way, as part of your standard care. The sponsor has also agreed to pay for treatment for any research-related injury, providing all research guidelines are closely followed.

10. Compensation (reward for taking part):

Note:
Compensation is not a benefit for participating in the study and must therefore be listed separately.

Suggested Language:

You will be paid $_____for your time and travel expenses for being in this study. If you do not complete the entire study, you will be paid for the number of visits that you did complete. Payment will be made at the end of the study or when you end your participation.

You will be given a gift certificate to _____.

11. Voluntary Participation:

Note:
It is very important to reemphasize that participation is voluntary and refusing to participate will not affect the standard of care that the subject will otherwise receive.

Suggested Language:

Taking part in this study is voluntary. If you do not take part you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same, whether you take part, refuse to take part, or decide to leave the study.
You may choose to take part in this study. If you choose to take part, then:

(a) Your participation is voluntary and you may leave the study at any time. To leave you must:

1. Voye yon lèt bay ekip kap fè rechèch la. Si w deside pou w soti nan etid la, lè sa wap voye yon lèt siyen ki dwe di ke ou vle kite etid-rechèch la. OUBYEN ou ka ranpli ak siyen yon fòm ''Avi wap Kite''. Men nap kontinye itilize nan etid rechèch la kelkeswa enfòmasyon ou te gen tan ba nou anvan dat wap kite a.

1. Send a letter to the research team. If you decide to leave the study, then you must send a signed letter saying that you want to leave the research study. OR you can fill out and sign a "Notice to Withdraw" form. However, any information collected from you before the date of you leaving will be used in the research study.

2. Si w kite, wap toujou, si se pat sa, kontinye resevwa swen ou te konn jwenn lè w pat nan etid la.

2. If you leave, you will still get the care that you would otherwise get outside of the research study.

Ekip ka fè rechèch ka deside yo pa bezwen patisipasyon w ankò nan rechèch la. Lè sa ekip ka fè rechèch la dwe voye lèt pou fè w konnen. Yo ka fè sa pou plizyè rezon:

The research team may decide that you are no longer needed in the study. Then the research team must notify you in writing. This could be for several reasons:

1. Kò w ka fè yon reyaksyon ak remèd oubyen aparèy yap teste nan etid la.

You have had a reaction to the study drug or device tested.

2. Ou pa respekte tout regleman yo pandan w nan etid la.

2. You did not follow all the rules while in the study.

12. Vi Prive / Konfidansyalite:

Nòt:
Se langaj sa HIPAA rekòmande, poutèt sa nou dwe toujou mete nan preske tout konsantman enfòme yo, espesyalman sa ki gen risk ki pa piti ladan l yo. Kidonk, se pou rezon sa ki fè l pa an italik

Gen lwa (nan eta a ak nan nasyon an) ki la pou pwoteje enfòmasyon sou lasante w, pou yo kenbe yo prive. Nou toujou respekte lwa sa yo.

Nap pwoteje tout enfòmasyon sou lasante tankou Enfòmasyon sou Lasante ki Pwoteje oubyen "**PHI**".(PHI enfòmasyon w ki ka idantifye w tankou non w, adrès ou, nimewo telefòn ou, eksetera.)

Si w patisipe nan etid sa, ou dakò pou w kite ekip kap fè rechèch la itilize enfòmasyon medikal ou. Pa dakò pou w patisipe si w pa vle ekip kap fè rechèch la gen aksè a enfòmasyon sou lasante w. Ekip kap fè rechèch la toujou dakò pou l swiv gid sa yo:

- Ekip ka fè rechèch la ap gade enfòmasyon sou lasante sèlman pandan tan etid la ap fèt la.
- Nou pap mete okenn enfòmasyon ki ka fè yo rekonèt ou nan pyès piblikasyon.
- Nan fen etid la, ekip kap fè rechèch la ap retire tout enfòmasyon ki ka fè yo rekonèt ou (non w, adrès ou; nimewo telefòn ou, eksetera) nan baz done a..

12. Privacy / Confidentiality:

Note:
The language is HIPAA recommended and as such, must remain in almost all informed consents, especially those with more than minimal risk. Hence the reason that it is not italicized.

There are laws (state and national) that protect your health information to keep it private. We always follow those laws.

We will protect all of your health information, including your Protected Health Information or "**PHI**". (Your PHI is information that might identify you, such as your name, address, phone number, etc.)

If you take part in this study, you agree to let the research team use your medical information. Do not agree to take part if you don't want the research team to access your health information. The research team agrees always to follow these guides:

The research team will view your health information only during the life of this study.

We will not include any information that could identify you in any publication.

At the end of the study, the research team will remove all of your identifiable information (name, address, phone number, etc.) from our database.

Komite Revizyon zafè Enstititsyon an (Institutional Review Board(IRB)) nan Cambridge Health Alliance la responsab pou yo sèten chèchè yo respekte lwa federal yo pou pwoteje sijè imen yo. Anplwaye IRB ka mande pou yo gade ki nenpòt dosye ki nenpòt lè pou yo ka sèten anplwaye kap fè rechèch yo swiv lwa yo pou pwoteje w.

The Cambridge Health Alliance's Institutional Review Board (IRB) is responsible for making sure that researchers follow federal laws to protect human subjects. Staff of the IRB may at any time ask to look at any records to make sure the research staff is following the laws to protect you.

Kèkfwa yo mande nou pou n pataje rezilta tès ak pwosedi yo ou te fè nan etid la ak :

Sometimes, we are required to share the results of your study tests and procedures with:

Lòt moun kap fè rechèch nan Etid sa.

Other Researchers on this Study,

Moun ak/oubyen Ajan moun kap patrone Etid la.

Study Sponsor and/or its Agents,

Ajans to ki responsab Akreditasyon.

Accrediting Agencies.

Komite kap Swiv Sekirite Enfòmasyon yo.

Data Safety Monitoring Board,

Anplwaye Klinik yo ki pap patisipe nan etid la men ki ap patisipe nan tretman regilye w.

Clinical Staff not involved in the study, but involved in your regular treatment,

Konpayi Asirans yo.

Insurance Companies,

Ofisye Gouvènman an (si se yon ekzijans)

Government Officers (if required)

Si ki nenpòt nan gwoup sa yo mande pou yo gade enfòmasyon w yo, lè sa nap oblije ba yo l. Epitou, yon fwa nou fin bay enfòmasyon sa yo nou pap garanti ankò konfidansyalite ak kenbe enfòmasyon yo prive. Komite k la pou pwoteje w la rele Komite Revizyon zafè Enstititsyon an (Institutional Review Board(IRB)). IRB ka mande pou yo gade ki nenpòt dosye pou yo ka sèten ekip kap fè rechèch la ap pwoteje w.

If any of these groups ask to look at your information, then we cannot prevent it from been shared. Also, once information is shared, we cannot thereafter guarantee any further confidentiality and privacy. The committee to protect you is called the Institutional Review Board (IRB). The IRB can ask to look at any records to make sure that the research team is protecting you.

Peryod Otorizasyon:

Otorizasyon w nan pwojè rechèch sa ap fini: _____

Period of Authorization:

Your authorization on this research project will expire on: _____

Nòt:
Ou dwe met yon dat oubyen yon evenman apre l fin rive ou pap itilize ankò PHI ou te pran yo dapre otorizasyon yo te ba ou a. Nan objectif rechèch la ou ka di Otorizasyon ap valab jiskaske "etid la fini ak jiskaske tan yo di yap kenbe dosye a fini" oubyen si yo te pran enfòmasyon yo pou yo fè yon baz done pou rechèch oubyen pou yon rezon k sanble ak sa n sot di a (rechèch sou yon period ki long), lè sa ou ka di oubyen pa gen yon dat pou etid la fini oubyen yap sere enfòmasyon yo jiskaske etid la fini sa k vle di yon bonkou tan. Men lòt dat/evenman ki ka make lafen etid la : yo fèmen etid la, yo pap rekeyi done ankò, yap detwi baz done a nan "____" zan apre etid la te fin fèt, otorizasyon FDA pou yo etidye yon remèd, oubyen yon dat byen detèmine. Lè nap chwazi dat yon evenman ap fini, li toujou enpòtan pou nou sèten dat la oubyen evenman ou chwazi a gen ladan l tan pou nou kenbe PHI pou kantite tan nou te di nou tap kenbe dosye yo.

Note:
You must include a date or event after which the PHI collected pursuant to the Authorization will no longer be used. For research purposes, you may state that the Authorization remains in effect until the "end of the study and any applicable records retention period," or, if the data is being collected to compile a research database or for a similar purpose (longitudinal research), then you may state that there is either no expiration date or data will be stored until the end of the study which entails an extensive period of time. Other possible expiration dates/events are: closure of the study; end of data collection; destruction of database; "____" years after closure of study; FDA approval of study drug; or a specific date. In choosing an end event, it is always important to make sure that the date or event you choose allows for retention of PHI for any applicable records-retention periods.

13. Jwenn Ed (Kontak yo):

Nòt:
Yo dwe mete nan Fòm Konsantman an non ak nimewo telefòn moun kle pou yo kontakte yo.

Langaj Sijere:
Sou pwojè rechèch la: Si w gen keksyon sou etid sa, enben ou gen dwa mande èd. Men kèk nan enkyetid moun yo konn genyen:

- Ki benefis oubyen ki risk rechèch la genyen?
- Ki lòt chwa tretman ki diponib?
- Ki dwa m yo kòm yon sijè nan rechèch la?
- Ki sa m dwe fè si m santi m yap banm presyon pou m patisipe kont volonte m
- Kijan yap itilize enfòmasyon sou lasante yo nan etid la ?
- Kijan ya pwoteje enfòmasyon sou lasante m yo ?

Langaj Obligatwa:
Si w gen jan de enkyetid sa yo ak kèlkeswa lòt enkyetid, tanpri kontakte yon manm IRB a oubyen Depatman Relasyon ak Pasyan yo. Biwo yo ouvè lendi jiska vandredi (jou fèt pa ladan) depi 8:30 dimaten jiska 5:00 diswa)

13. Getting Help (Contacts):

Note:
The key contact names and telephone numbers must be included in the Consent Form.

Suggested Language:
About the research project: *If you have questions about this study, then you have the right to ask for help. Some of the concerns that people have are:*

- *What are the benefits or risks of the research?*
- *What are the other treatment choices available?*
- *What are my rights as a research subject?*
- *What should I do if I feel pressured to take part against my will?*
- *How is health information used in a study?*
- *How will health information be protected?*

Mandated Language:
If you have these or any other concerns, please contact either a member of the IRB or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30 in the morning until 5:00 in the evening.

Prezidan IRB a: Dr. Steve Pinals
Telefòn: 617-665-3191

Adrès: 1493 Cambridge Street, Cambridge, MA 02139

Manadjè Relasyon ak Pasyan yo: Lorraine Vendetti
Telefòn: 617-665-1398

Adrès: 1493 Cambridge Street, Cambridge, MA 02139

Sètifikasyon Moun nan ki pran Konsantman an:
Sijè a te enfòme sou:

(i) Pwosedi, objektif, ak risk yo ki gen nan etid la jan yo ekri anwo a,

(ii) Kijan yo ka itilize, pataje, ak rapòte Enfòmasyon sou Lasante l; ak,

(iii) Dwa l yo nan zafè lavi prive l.

Nou bay sijè a yon kopi siyen de Fòm sa.

Siyati Moun ki te Jwenn Konsantman an

Dat

Siyati Sijè a

Dat

Reprezantan Legal Pasyan an (si l aplikab)

Dat

Wòl Entèprèt

❒ Anplwaye CHA

Entèprèt (si w te itilize l)

Ekri Non an

❒ **Lòt**

IRB Chair Person:
Telephone:

Address:

Patient Relations Manager:
Telephone:

Address:

Certification from Person Obtaining Consent:
The subject has been informed of:

(i) The procedure, purpose and risks of the study as described above,

(ii) How his/her Health Information may be used, shared and reported, and

(iii) His/her privacy rights.

The subject has been provided with a signed copy of this Form.

Signature of Person Obtaining Consent

Date

Subject's Signature

Date

Patient's Legal Representative (if applicable)

Date

Interpreter Role

❒ CHA employee

Interpreter (if used)

Print Name

❒ Other

Fòm sa valab sèlman si li gen so ki montre Komite IRB apwouve l.

Atachman

Otorizasyon IRB a

Paj sa se konfimasyon IRB apwouve etid sa.

Tit Etid la:_____

Non Chèchè Prensipal la:_____

No Protokòl IRB.a:_____

Dat IRB a Apwouve l:_____

Dat IRB a Bay pou l Fini:_____

MET SO A LA

_

This form is valid only if it has the IRB Committee's stamp of approval.

Attachment

IRB Authorization

This page confirms that this study has been approved by the IRB.

Title of Study: ____

Name of Principal Investigator: ____

IRB Protocol No.:_____

IRB Approval Date:_____

IRB Expiration Date:_____

STAMP HERE