**Instructions:** See Appendix A-10 of HRP-103 Investigator Manual for information about using this form. Edit/Remove all highlighted text from the document before using with subjects.

**EUCHEAN TICHCHIKIN POROUS**

**Ei taropwe epwe mak non foosun fonuwom**

TAROPWEN OM FINATA KOPWE FIFFITI EWE KATONEOCHUN POROUS—MWOCHOMWOCHEN TAROPWE

**ITENAPEN EWE KAEON ANGANGEN KATONEOCHUN POROUS: insert title**

|  |  |
| --- | --- |
| **ITEN CHON ANGANGEN KATONEOCHUN POROUS** | **EKKEWE NAMPAN TENGWA** |
|  |  |

Non fansoun emerechensi ngeni om fiffiti ei angangen katoneochun porous, kose mochen kokkori 911.

***EI TAROPWE EPWE MAK NON FOOSUN FONUWOM***

**MWOCHOMWOCHEN TAROPWEN OM FINATA**

**TAROPWEN OM FINATA KOPWE FIFFITI KATONEOCHUN POROUS—MWOCHOMWOCHEN TAROPWE**

**Nepoputan**

Non Seatle Children’s mei wor chommong kaeon katoneochun porous mi fis. Popunapen ei katoneochun porous, non ennetin, faniten ach sipwe sinei minafon mettoch An semirit fiti ei angangen katoneochun porous epwe anisir ne kaeo minafon mettoch pwan anisi ar keo ngeni tumwuneochun inisin semirit.

Sia tingoreok kopwe fiti ika kopwe mwut ngeni noum semirit epwe fiti ei kaeon angangen katoneochun porous. Om fiti ei katoneochun porous aa pusin **om finata.** Sia peseok kopwe awora fansoun ach sipwe porous won ei kaeon angangen katoneochun porous fengen me om family me chiechiom. Me mwen kopwe no ngeni sopwosopwonon ei taropwe, ekkewe researchers repwe awora ngonuk menapen keyen tichchikin porousen ei kaeo, kapachenong:

* Met kopwe sinei fanitei ei kaeon katoneochun porous.
* Met ekkewe tufichin ewe kaeon angangen katoneochun porous.
* Ifan tamen kopwe nom non ewe kaeo me ew taropwen met mi namot ngonuk
* Met ekkewe efeiengau me aweiresin ei kaeon katoneochun porous.
* Met ekkewe tufichin om fiffiti ewe kaeon angangen katoneochun porous.
* Ekkewe och sokkun ika kose mochen fiffiti.

Before going through the rest of this form, the investigator should provide the subject with the information from the key information section of the study consent form. NOTE: This information is required to be provided before the rest of the form.

Wetinimwo en ika noum na semirit ousapw fiti, en ika noum na oupwe sopwosopwono me angang aninnis seni ewe Pioingen Semirit. Om finata esapw osukosuka ewe aninnisin tumwun ngonuk me noum semirit.

Me mwen kopwe finata ika en mi mochen fiti ach ewe kaon katoneochun porous, ekkewe chon angangen katoneochun porous ina repwe ngonuk tichchikin porous. Ewe tichchikin porous epwe anisuk me finata ika en mi mochen fiti ika mwut ngeni noum semirit epwe fiti.

**Met epwe namot ngonuk kopwe sinei me mwen kopwe finata ika kopwe fiti ei angangen kuten porous?**

### **PWATA ewe kaeon angangen kuten porous aa fis.**

Me mwen kopwe finata ekkewe chon angangen katoneochun porous repwe uronuk popun ewe angangen katoneochun porpus aa fis. Repwe awewei met ekkewe chon angangen katoneochun porous ra aneanei repwe sinei seni ei kaeo.

### **MET epwe fis non ewe angangen katoneochun porous.**

Ekkewe chon angangen katoneochun porous repwe uronuk:

* + Ifan taman ewe kaeo epwe fis fanitom me noum semirit.
  + Met epwe fis nupwen en ika noum semirit oua fiti.
  + Ika ew me nein ekkewe angangen ika safean ika test pekin sossot.
  + Ifan esin ewe kaeon katoneochun porous aa sakkofesen seni ewe aninnisin tumwun en ika noum ewe semirit oua angei.
  + Fitemon aramas sia eureura repwe fiffiti.

### **Met ekkewe om TETTENIN FINATA.**

Ekkoch kaeon angangen katoneochun porous, nge esapw meinisin, ra awora tumwun me safeian. Ekkewe chon angangen katoneochun porous repwe aporousa meinisin om ika an noum ewe tettenin finata faniten safei me tumwun. Aa namot kopwe sinei me om ika an noum ewe finata faniten tumwun me mwen kopwe epwungano kopwe fiti ewe kaeon angangen katoneochun porous.

### **Met ekkewe EFEINGAUEN ewe kaeon katoneochun porous.**

Ekkewe chon angangen katoneochun porous repwe uronuk:

* + Met ekkewe efeiengau ngonuk ika ngeni noum ewe ika ou fiti.
  + Ifan esin ewe angangen katoneochun porous aa nonno ngeni keukun efeiengau ngeni ach tumwun.
  + Wetinimwo epwe wor efeiengauan ese mwo ftat non ei fansoun.
  + Met epwe fis ika ee wor ew feiengauen ewe angangen katoneochun porous me ion epwe wiisen meoni safeian ewe feiengau.
  + Met epwe fis ika ka keuno seni ewe kaeo me emwmwenin kopwe ifa ne eukano ewe kaeo.
  + Met epwe fisi ngeni ekkewe rekoot ika ka eukano.
  + Nupwen minafon tichchikin porous epwe tour ngonuk.

### **Met ekkewe TUFICHIN ewe kaeon angangen katoneochun porous.**

Ekkewe chon angangen katoneochun porous repwe awora tufichum me noum ewe semirit. Repwe uronuk ika ewe angangen katoneochun porous epwe awora tufich ngeni chon niuing ika mwiicheich nesor me penon.

### **Mi namot kopwe sinei porousen MWONOMWONONON**

Ika ka fiti ewe kaeo, mi nom non annuk sipwe tumwunu tichchikin porousom epwe mwonomwonono.

Ekkewe chon angangen katoneochun porous repwe urenuk ion repwe angei ewe tichchikin porous fanitom me chon fiti. Ei tichchikin porous itan research data.

Ika mei wor om annukun mwonomwononon pworousom, iwe sia chok tongeni angang rekoot nupwen ka mwutata. Ei och awewen ewe sokkun tichchikin porous ewe kaeo epwe forata, aea, ika ngeni, ion epwe tongeni angei ika ngeni, me popunapen repwe tongeni aea ika ngeni.

Ei tichchikin porous epwe tongeni appachanong mettoch esin:

* Rekootun safei nanew ika nesor me penon.
* Rekootun Angangen katoneochun porous, awewe ren taropwen chosa, kapas eis, chosa, ika repootun porousen uruon om safei
* Pekin Safei ika rekootun lab faniten ewe kaeo, me
* Tichchikin porousom esin itom, neeniom, ika raanin upwutiwom

Ei tichchikin porous mei tongeni no ngeni:

* Researchers (awewe ren doctors me chon angang) re fiffiti ei kaeo ikei me non ekkoch center,
* Research sponsors-ei aa apachanong ese nifinifin aramas ika kompeni mi angang ngeni, fiti, ika an ewe sponsor,
* Review boards (awewe ren Seattle Children’s Institutional Review Board), rekootun me Board minen pekin tumwun, me ekkoch wiisen katonen ewe angangen research (awewe ren monitors),
* Kinikinin kafomen esin an Merika we Mwuun Mwenge me Safei (FDA) me ewe Kinikinin Pekin Safei me Aninnisin Aramas (DHHS), kapachenong kinikin esin non ekkoch fonu, me
* Neuwisin Pekin Safei minne sia pwunguno seni annuk ach sipwe repootei tichchikin porous faniten eppetin ika nemeneman semwen chou, feiengau, kawet, ika tter.
* ***Ika ewe sponsor ee meoni niwinin om safei, sia pwunguno ach sipwe ngeni itom, raanin upwutiwom, me nampan noum kaaton pekin safei, ika nampan noum sooson.***

Ei tichchikin porous mei tongeni no ngeni:

* Awesin me atawen ewe resultun ewe kaeo mi awewetiw non ei taropwe,
* Kaeon resultun ei research,
* Chekiin ika ei study mi pwung fofforun, me
* Ekkewe non-research obligations (ika sia ekieki en ika emon mi tongeni feiengau).

Ka tongeni katon ika copyni ewe tichchikin porous mi tongeni aea ika pwarata. Inaamwo, ren ekkoch sokkun kaeon research, fitu tichchikin research esapw tongeni epwe kawor ngonuk otun ei kaeo. Ei ese osukosuka om pwungun kopwe katon met mi nom non om rekootun (pioing) pekin safei.

Ese wor keukun fansoun om kopwe aea ika atoura tichchikin porousom. Researchers repwe sopwei ne nennengeni rekoot ren fitu ier, iwe esapw iteiten epwe tufich kopwe sinei inet repwe wes. Ika tichchikin porousom epwe ochu ngeni ei kaeo, mi tongeni repwe aea nesor me penon faniten ekkoch research. Sisapw eisinuk om kopwe mwutata me mwen ei research nesor me penon.

Om mwutata aean ika touren tichchikin porousom esapw expire, nge en mi tongeni ekkeunoi inet chok. Ka tongeni feeri ei ne esinesin ngeni ewe kumin kaeo non mak. Ika kopwe ekkeunoi om mwutata, ese wor minafon tichchikin porousom epwe angang, nge tichichin porous aa fen angang sa tongeni aea me ngeni ekkoch.

Sipwe pwan wanong tichchikin porous seni ei kaeo non om rekootun pekin safei, kapachenong ei taropwe, pun ei kaeo mei apachanong tumwunum. Rekootun pekin safei mei sakkopat annuk seni rekootun resesarch. Iir mei nomweno me ekkoch iir pachenong on tumwunum ra tongeni katon, awewe ren doctors, chon meeni om pekin safei, me ekkoch mi nom non annuk.

Ewe aean ika touren porousom epwe fiti annukun mwonomwonono, nge ekkei annuk ee chok eoch ngeni doctors, pioing, me ekkoch chon pekin safei. Ekkoch pekin safei re angei tichchikin porousom ren pekin ei kaeo ra tongeni ngeni ekkoch ika mwo kese mwutata ika pun mi pwunguno seni annuk repwe epwenueta.

Ika ekkewe resultun ewe kaeo aa tawe, sisapw aea tichchikin porous mei affata nge en.

Om mwutata mi ffatetiw nupwen ka sainnei ei taropwe. Ika ka finata nge sise tongeni aea ika ngeni tichchikin porousom, kese tongeni fiffiti ei kaeo.

Ekkewe researchers repwe awora tichchikin porousen [www.ClinicalTrials.gov](http://www.clinicaltrials.gov/).

Note: Only use the following language if the study (1) relies on medical records (or a patient’s health care provider) as a source of information about the treatment and/or diagnosis of one or more of the specially protected categories below; or (2) involves treatment and/or diagnosis of one or more of the specially protected categories below. For the following section, delete any types of information that do not apply to your study. If none apply, delete the whole section.

**Mwumwutan Aean ika Touren Tichchikin Porous**

Forutan, aean, ika touren tichchikin ekkoch porous mi namot ngeni fitemon ra awora pwen ew mwumwutan. Ion ra nom non ewek kinikinin ier fan repwe awesi ei kinikin. Faniten semirit kukkun seni ewe ier mi ffatetiw, ewe Sam me Iin/Chon Pwunguno repwe Tupwunuk repwe awesi ei kinikin. Makkei nepoputan itom fan ren om mwutata ika en mi tipeew ngeni forutan, aeaean, ika touren ekkei tichchikin porous:

|  |  |
| --- | --- |
|  | Semwen chou ka angei seni nisou aa apachanong AIDS/HIV (ier 14 iwe feita) |
| Nepoputan itom |
|  | Pekin om safei mi apachanong osukosuken pekin pochokkunen inisum ne neuneu, me met epwe pekin test results (ier 14 iwe feita) |
| Nepoputan itom |
|  | Tterin mwekutukut me tterin ekiek (ier 13 iwe feita) |
| Nepoputan itom |
|  | Safeingau ika Sakaungau (ier 13 iwe feita) |
| Nepoputan itom |

### **Mi namot kopwe sinei NIWININ**

Ina repwe urenuk ika epwe wor kapachetan niwinin ngonuk om fiti ewe angangen katoneochun porous.

# **Epwe ifa ika kose mochen fiti? Epwe ifa ika ka mochen keuno?**

**Om fiti ei katoneochun porous aa pusin om finata.** Mi WEWEOCH ika ke ura APW. Ika ka poputa, en ika noum ewe ami mi tongeni keuno me fiti inet chok. Ese wor pakkingin ika peutunon tufich ika ke ura APW ika ren om mwittir keuno.

Pwan ew, ekkewe chon angangen katoneochun porous ra tongeni emwekutuk me noum ewe semirit seni ewe kaeo. Repwe feeri ika pun epwe koon otufichuk me noum ewe semirit. Ika re ekkeunoi ewe kaeo, repwe awewei ngonuk popun pwata.

# **Epwe ifa ika ka mochen fiti?**

Ika ke mochen sinei porousen ewe kaeon angangen katonoechun porous kopwe churi emon chon angangen katoneochun porous. Ewe chon angangen katoneochun porous, fengen me emon chon chiaku, repwe uronuk porousen ewe kaeo. Sia peseok kopwe kapas seis! Ika kopwe fiti, ina repwe eisinuk kopwe sainnei ei taropwe. Ewe taropwe ka sainnei kopwe annomwu. Kopwe pwan angang copyin ewe taropwen mwumwuta non foosun Merika mi awewei ewe kaeo. Ewe chong angangen katoneochun porous epwe sainnei ewe taropwe non foosun Merika.

**Euchean Nampan Tengwa:**

|  |
| --- |
| Faniten kapas eis ren ewe kaeon angangen katoneochun porous, kokkori ewe chon angangen katoneochun porous won ewe nampan tengwa won ewe ewin peichin ei taropwe. Wattiw itom me nampan noum tengwa iwe ewe chon angangen ewe katoneochun porous epwe kokkoruk fengen me emon chon chiaku.  **Ika en/ika noum ewe semirit epwe wor ew emerechensi faniten om fiti ewe kaeon angangen katon eochun porous, kokkori 911.**  Aramas re fiffiti ei angangen katoneochun porous mei wor ar pwung. (Saingonon peichin ei taropwe epwe uronuk porousen an ekkewe chon fiffiti ei angangen katoneochun porous pwung). Ika mei wor om kapa eis faniten ekkei pwung, ka tongeni kokkori ewe IRB won (206) 987-7804. Ewe IRB iir ewe mwiicheich ra nengeneochu me epwungu ewe angangen katoneochun porous faniten semirit. Ewe IRB aa wiisen tumwunu ekkewe pwuung an semirit me family re fiffiti ewe angangen katoneochun porous. Wattiw itom me nampan noum tengwa iwe ewe chon angangen ewe katoneochun porous epwe kokkoruk fengen me emon chon chiaku. En mi pwan tongeni kokkori ewe IRB ika mei wor om kapas eis, osukosuk ika complaint faniten ewe kaeo ika ke pwan mochen foos ngeni emon me nukun ewe kumin kaeo. |

**KOSE MOCHEN CHECHEMENI: Ika ka finata kopwe fiffiti ewe kaeon angangen katoneochun porous, ewe chon angangen katoneochun porous epwe chiakuni ewe Taropwen om finata non foosun Merika ngeni foosun fonuwom. Ewe taropwen om finata aa chiaku epwe affatatiw tichchikin ewe kaeon angangen katoneochun porous. Ewe taropwe repwe ngonuk ika ra chiakuni. Ei mi kan tori ukukun 1-2 week.**

## *Mefien Chon fiffiti/Sam me Iin/Chon Tumwunuk*

**Ua angei ew afanafanen ewe kaeon katoneochun porous. Ewe chon chiaku mi sinekape foosun fonuwei mi nom otun ewe afanafan. Mei wor fansoun ai upwe kapa seis Ngang mi weweiti pun ekkewe aramas mi nom non ewe tetten won ewin peichin ei taropwe epwe ponuweni ai kapa seis nesor me penon faniten ewe kaeo ika ren an ekkewe chon fiffiti ewe angangen katoneochun porous pwung. Ngang mi sinei ewe nampan tengewa upwe kokkori ika epwe wor emerechensi.** **Ua tipeew ngeni non ai finata upwe fiti ika mwutata nei ei semirit epwe fiti ei kaeon angangen katoneochun porous.**

### **KOSE MOCHEN CHECHEMENI: Ika ewe chon fiffiti ei kaeon angangen katoneochun porous emon semirit mi mwumwu ika emon mi nom fan tumwunun ewe state kose mochen affata ngeni ewe chon angangen katoneochun porous ika chon angang mi angei mwumwutan.**

**Iten ewe Chon Fiffiti ewe Angangen Katoneochun Porous**

**An ewe Chon Fiffiti ewe Angangen Katoneochun Porous Signature (mi namot ngeni >13 ier)**

|  |  |  |
| --- | --- | --- |
| **Raanin Ikenai** |  | **Kunok** |

**Iten Sam me Iin ika Chon Pwunguno repwe Tupwunuk**

**An Sam me Iin ika Chon** **Pwunguno repwe Tupwunuk Signature**

|  |  |  |
| --- | --- | --- |
| **Raanin Ikenai** |  | **Kunok** |

**Iten Sam me Iin ika Chon Pwunguno repwe Tupwunuk**

**An Sam me Iin ika Chon Pwunguno repwe Tupwunuk Signature**

|  |  |  |
| --- | --- | --- |
| **Raanin Ikenai** |  | **Kunok** |

|  |  |
| --- | --- |
| **An chok ewe kumin kaeo aea:** | |
| Ika sise angei an eruwemonun Sam me Iin signature, affata pwata: (fini ew) | |
| * Ewe IRB epwe epwungu ika mwumwuta seni emon Sam me Iin mi naf. * Eruwemonun Sam me Iin aa sopono, ese ffat, tufuchingau, ika ese tufichin nom. | * Emon chok Sam ika Iin mei wor wiisan ngeni tumwunun ewe semirit. |

|  |  |
| --- | --- |
| **An chok ewe kumin kaeo aea:** | |
| Etipeew | * Angei |
| * Ese angei faniten tufichin emon ewe mi keuk iwe sise tongeni anisi. |

***Porousen Chon Chiaku***

KOSE MOCHEN CHECHEMENI: Iten Chon Chiaku epwe rekoot ika om finata mi makketiw won echo mwochen chiakun taropwen om finata me/ika Chiakun taropwen om finata.

|  |  |
| --- | --- |
| **Iten Chon Chiaku**  ***(Ika chon chiaku mi aninnis otun ewin afanafanen ewe kaeo)*** | **Raanin Ikenai** |

## *Porousen Chon Pwarata*

KOSE MOCHEN CHECHEMENI: Iten me an emon chon pwarata signature mi namot numpwe kopwe aea ewe mwochomwochen taropwen finata om kopwe makketiw om finata/mwumwuta seni sam me iin mwirin ewe ewin afanafanen ewe kaeo ika ew annuk seni ewe IRB.

***Porousen Chon Pwarata***

**Ngang mi nom otun ewe afanafanen ei kaeon katoneochun porous.**

**Iten ewe Chon Pwarata**

**An Chon Pwarata Signature**

|  |  |  |
| --- | --- | --- |
| **Raanin Ikenai** |  | **Kunok** |

Copyin ngeni: Chon Fiffiti Research ika Sam me Iin/**Chon Pwunguno repwe Tupwunuk**

Rekootun Pekin Safei **(*ika mi weweoch*)**

# **An Chon Fiffiti ewe Angangen Katoneochun Porous Pwung\***

**Emon me emon ion mi tingor repwe fiti ewe kaeon angangen katoneochun porous mi wor ar pwung.** Faniten en ika noum ewe chon fiffiti ewe angangen katoneochun porous, mei wor ami ekkei pwung:

1. Repwe urenuk met ewe kae ee mochen sinei.
2. Repwe urenuk met epwe fisi ngonuk ika noum ewe otun ewe kaeo. Repwe urenuk wetinimwo ekkewe angangen kaeo, safei, ika mwesin mi sakkofesen seni met repwe aea ngeni met mi piin sossot.
3. Repwe uronuk porousen ekkewe mi fiffis me euchean efeiengauan, mwirimwirin, ika met esapw kinamwe ngonuk me noum ewe semirit otun ewe kaeon angangen porous.
4. Repwe urenok ika emon me neimi me noum ewe semirit mi tongeni nennengeni kopwe angang tufich seni om fiffiti, me, ika ina, met sokkun tufich kopwe angang.
5. Repwe urenuk ekkewe sakopaten aninnis en ika noum ewe am mi tongeni angang me ifan esin eochun ika ngawan ngeni om fiti ewe kaeo.
6. Repwe mwutata om kapa eis faniten ewe kaeo me mwan om tipeew ngeni kopwe fiffiti me otun ewe angangen ewe kaeo.
7. Repwe urenuk met sokkun pekin safei epwe kawor ika epwe wor osukousk.
8. Om kose mochen fiffiti ika siwini om ekiekin om fiffiti ika an noum semirit fiffiti mwirin an aa poputa ewe kaeo, ei pwungun finata esapw osukosuka om ika an noum ewe semirit pwung ami angang aninnisin tumwun ika ouse fiti ewe kaeo.
9. Om kopwe angang ew copyn ewe taropwen om finata mi sign me mak raanin.
10. Om kosapw osukosuk nupwen ekiekin ika en mi mochen tipeew ngeni kopwe fiti ewe kaeo ika tipeew faniten noum ewe semirit an epwe fiti ewe kaeo.

\*Siwini ngeni An California State ewe Chon fiti ewe sossot pwung