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| Strata Oncology / Protocol Number STR-001-001 | Istraataa Onkoloojii / Lakkoofsa protokoolii STR-001-001 |
| [1]Page [2] of [3][4] | [1]Fuula [2]irraa [3][4] |
| Daniel Anderson, MD | Daniel Anderson, MD |
| Chesapeake IRB Approved Version 8 May 2017 | Chesapeake IRB Hiikaa Fudhatama qabu 8 Caamsaa 2017 |
| Revised 8 May 2017 | Kan fooyyeffame 8 Caamsaa 2017 |
| CONSENT FORM FOR OBSERVATIONAL RESEARCH STUDY PARTICIPATION | UNKA FIRII QORANNOO WALIIGALTEE KAN HIRMAANNAA QALBIFANNAA QORANNOO |
| and | fi |
| AUTHORIZATION TO DISCLOSE HEALTH INFORMATION | KENNAMA AANGOO ODEEFFANNOO FAYYAA IFA GOCHUUF |
| Sponsor / Study Title: | Ispoonsarii / Mata duree Qorannoo: |
| Strata Oncology / “An Observational Study Profiling Biospecimens from Cancer Patients to Screen for Molecular Alterations” | Istraataa Onkoloojii / "Hordoffii Qorannoo kan Dhukkubsatoota Kaanserii irraa gara iskiriiniitti jijjiirama moliikiyulaariitiif” |
| Protocol Number: | LakkoofsaPirotokoolii |
| STR-001-001 | STR-001-001 |
| Principal Investigator: | Qorataa Olaanaa: |
| (Study Doctor) | (Dokteera Qorannoo) |
| Daniel Anderson, MD | Daniel Anderson, MD |
| Telephone: | Bilbila: |
| 952-993-1517 (24 Hours) | 952-993-1517 (saa’atii 24 ) |
| Address: | Teessoo: |
| Metro MN Community Oncology Research Consortium | Dhaabbiilee Qorannoo yeroodhaaf waliin ta’uun hojjetan kan Meeitroo MN Onkoloojii Hawwaasaa (Metro MN Community Oncology Research Consortium) |
| 3800 Park Nicollet Blvd | 3800 Park Nicollet Blvd |
| St. Louis Park, MN 55416 | St. Louis Park, MN 55416 |
| [1]This is an important form. | [1]Kun unka barbaachisaa dha. |
| Please read it carefully. | Maaaloo of-eeggannoodhaan dubbisi. |
| It tells you what you need to know about this research study. | Waa’eeqorannookanaawaanatibeekuu si barbaachisu sittihima. |
| If you agree to take part in this study, you will need to sign this form. | Yooqorannoo kana keessattihireefudhachuufwalii-galte, unka kana mallatteessuusibarbaachisa. |
| Your signature means that you have been told about the study and its risks and you want to take part in this study. | Mallattoonkeekunis, waa’eenqorannoosanaasittihimamuusaa fiwaantokkobalaairraaoolchuudhaaf, akkasumasqorannoo kana keessattiga’eefudhaachuubarbaaduukeeibsa. |
| Your signature also gives your authorization (permission) to access, use, and disclose your health information. | Akkasumasmallatoonkeeaangoo (hayyama)waantokkobiraga’uuf, fayyadamuuf, dabalataanisodeeffannoofayyaakeeibsuufkanooluudha. |
| [1]This is a clinical trial, a type of research study. | [1] Kun qorannooyaaliiwal’aansaqormaataqabatamaata’eirratti kan hundaa’edha. |
| The study staff will explain the clinical trial to you. | Gumiin qorannichaa, waa’eeyaaliiwal’aansaqormaataqabatamaata’eirrattihundaa’esiifibsa. |
| Clinical trials include only people who choose to take part. | Yaaliinwal’aansaqormaataqabatamaata’eirrattihundaa’e kun, kaninni of keessattihaammatunamootahireefudhachuuffilatanqofa. |
| Please take your time to make your decision about taking part. | Maaloowaa’eehireefudhachuukeetiikanamurteessuufyeroofudhadhu. |
| You may discuss your decision with your friends and family. | Waa’eemurtookeetii kana hiriyootayknmaatiikeewaliinmari’achuudandeessa. |
| You can also discuss it with your health care team. | Akkasumas, GumiiKunuunsaFayyaakeetiiwaliinmari’achuudandeessa. |
| If you have any questions, you can ask the study staff for more explanation. | Yoogaaffiikamiiniyyuuqabaatteef, ibsadabalataatiifGumiiqoranichaagaafachuudandeessa. |
| [1]This study is being sponsored nationally by Strata Oncology and coordinated locally by the Metro-Minnesota Community Oncology Research Consortium (MMCORC). | [1]Qorannoon kun gita sadarkaa biyyaatti deggersi maallaqaa kan taasifamuuf karaa Istraataa Onkoloojii yoo ta’u, gita naannawwatti ammoo karaa “ Metro-Minnesota Community Oncology Research Consortium (MMCORC)” waliin ta’uun kan hojjetu ta’a. |
| The principal investigator for this study is Daniel Anderson, MD. | QorataaolaanaanqorannookanaaDaniel Anderson, MD jedhama. |
| [1]You are being asked to be in this research study because you have cancer and your healthcare provider has leftover material from your tissue biopsy which may be used for additional research. | [1]Qoranno kana keessatti hirmaannaa akka gootaniif ni gaafatamtu, sabaabiin isaas dhibeen Kaanserii qaama keessatti waan argamuu fi kunuunsaan dhimma fayyaa keessan hordofu hambaa tishuun ‘biopsy’ keessanii qorannoo dabalataaf fayyaduuf hafee jira. |
| This study may help identify potential research or treatment opportunities for you. | Qorannoon kun waanta gara fuul-duraatti ta’u danda’u adda baasuuf yookiin carraa yaalii argachuuf sifayyaduu danda’a. |
| Why is this study being done? | Qorannoon kun maaliif geggeefamaa? |
| The purpose of this study is to investigate the genes in your tumor, provide a report back to your study doctor, and collect data about whether this information helps doctors in treating patients with approved medicines or helps study doctors enrolling subjects in a clinical trial. | Kaayyoon qorannoo kanaa jiinota dhullaa keessatti argaman qorachuudhaan gara Dokteera keessaniitti gabaasa dhi’eessu fi dokteeronni qoricha bebbeekamoo ta’aniin dhukkubsatoota akka gargaaruu danda’aniif yookiin yaalii kilinikaaa keessatti dokteerota baratan akka fayyaduuf odeeffaannoo walitti qabuuf gargaara. |
| [1]Some cancer patients have tumors with particular mutations (changes), which may be treated with “targeted therapy” drugs. | [1] Dhukkubsatootni Kaanserii tokko tokko, dhullaakan jijjiirama adda ta’eensalphaatti yaalii Qorichaan wal’aanamuu danda’u. |
| Some of these drugs are available by prescription, and some are only available through clinical trials testing experimental drugs. | Gosa Qoricha kanaa keessaa muraasni kan argaman yoo ta’u tokko tokko ammoo karaa yaalii qorannoo qofaadhaan argamuu danda’u. |
| In order to find out if you might benefit from targeted therapy, your left-over tumor sample needs to have genetic testing. | Wal’aansa xiyyeeffannoon laatameef kanaan fayyadamoo taataniittu yoo ta’eef qorachuuf, fakkisaa (sample) dhullaa hafeetiif qorannoo jiiniitu taasifamuu qaba. |
| Genetic tests can detect changes in the DNA of cancer cells. | Qorannoowwan jiinii, jijjiirama DNA,seeliiKaanserii keessaa hubachuutu danda’ama. |
| Knowing whether your cancer has a particular mutation can help guide the type of treatment you receive. | Gosti wal’aansa isin fudhattanii kun dhibeen Kaanserii isin keessa jiru isa kam akka ta’e hubachiisa. |
| The Strata study will use a genetic test to find out whether you have a mutation that might benefit from targeted therapy opportunities. | Qorannoon Istraatichaa yaalii qorannoo jiinii kan fayyadamu yoo ta’u, kunis qorannoo xiyyeeffannoon laatameef irratti hundaa’uun carraawwan kanaan fayyaadamaa ta’uu fi dhiisuu keessan adda baafachuuf. |
| [1]Strata Oncology has partnered with certain companies who are or have developed new targeted therapy drugs, and for some subjects, the Strata test results will show that there is a potential match to a targeted therapy drug (approved or in clinical trials). | [1]Istraataa Onkoloojiin kaampaanii takko tokkoon walii-galee qorichoota xiyyeeffataman argachaa kan turee fi firiin qorannoo istraataa kanaa kan mul’isus sirriitti kan mijatu ta’uu isaati (fudhatama kan argate ykn yaalii Kilinikaan). |
| If test results match to a Strata company partner’s targeted therapy drug, Strata will also make a report (which doesn’t identify your private information) to that Strata company partner. | Firiin qorannooxiyyeeffannoo wallaansa qorichaa yoo Kaampaanii Istiraataa waliin hojjetanii wajjin kan wal simatu ta’e, akkasumas Istiraataan dhaabbiilee wajjin hojjetuuf utuu odeeffannoo waa’ee dhuunfaa keessanii addaan hin baasin gabaasa dhi’eessa. |
| Your participation in the Strata study does not guarantee that any targeted therapy drugs are right for you, or that you will qualify to participate in any specific clinical trial after the Strata study, it only tells you and your study doctor there might be possible targeted therapy options available. | Qorannoo Istiraataa kanaa keessatti hirmaannaan isin taasiftaniin waa’ee daawwaa isin fayyadamtanii kamiifuu sirriidha jedhee wabii kan hin taane yookiin akka isin qorannoo Kilinikaa kamiyyuu keessatti hirmaannaa taasisuuf ga’oo ta’uu keessan kan mirkaneessu osoo hin taanee, kan inni ibsu haala isinii fi dokteeraqorannoo keessanii gidduu jiru qofa. |
| There may be other trial options available to you as well that are not mentioned on the test report. | Filannoon yaalii kan biroon isiniif argamuu kan danda’an kan gabaasa yaalii qorannoo irratti hin gabaafamin jiraachuu danda’u. |
| [1]In addition to learning from the results of the overall Strata study, Strata expects to benefit by helping to match some study subjects with certain targeted therapies. | [1] Walii-gala qorannoo Istiraataa kanaa irraa barachuutti dabalataan ogeessi qorannichaas mata-duree qorannoo murtaa’oo ta’an waliin wal-bira qabee ilaaluuf ni gargaarama. |
| Strata may be paid for the research and potential matching services it provides. | Istiraataan kun haala qorannoo fi tajaajila addaa namni tokko addumaan gumaacheef kaffalamuu danda’a. |
| [1]Strata will also combine the data from all of the Strata study subjects into a database (which doesn’t identify any specific subjects) that can be analyzed for future research purposes. | [1] Istiraataan kun, odeeffannoo kan mata-duree qorannoo hundumaa gara kompuuteraatti walitti qabuun, gara fuula duraattis odeeffannoon kun kaayyoon isaa qorannoo kan biroofis kan fayyadu ta’a. |
| There is no limit on the length of time we will store your samples and information. | Fakkisaa fi odeeffannoo fayyaa keessani nuti kuufannu dheerina yeroon hin daangeffamu. |
| We may keep using them for research indefinitely unless you decide to withdraw from the project. | Pirojekticha addaan kutuuf hamma hin murteessinitti isaan kana qorannoof yeroo dheeraadhaaf kan itti gargaaramnu ta’a. |
| How many people will take part in the research study? | Namoota hagamiitu qoranicha keessattii qooda fudhata? |
| [1]People across the United States who are 18 years of age or older with cancer will participate for up to three years. | [1] Uummatni ‘United States’ kan umurii waggaa 18 guutan yookaan kan isaan olii kan dhibee Kaanserii qaban hanga waggaa sadiitti kan itti hirmaatan ta’a. |
| The study plans to enroll up to 100,000 subjects. | Qoranichi barnoota hanga 100,000 galmeessuuf karoora qaba. |
| What will happen if I take part in this research study? | Qorannoo kana keessatti yoon qooda fudhe maaltu ta’a? |
| [1]After you sign and date this form, your personal cancer medical history will be recorded in the study database. | [1] Erga unka kana mallatteesitanii galchitanii booda seenaa dhuunfaa keessanii kan yaalii kaaserii kompuutera keessatti galmaa’a. |
| Your demographics, including your gender, birth date, race, and ethnicity (if available) will also be recorded in the study database. | Qorannoon waa’ee eenyummaa keessanii, saala, guyyaa dhalootaa, sanyii fi kan sab-lammii (yoo argame) qorannoo Kompuutera keessatti galmeeffamuu dha. |
| Your study doctor and/or study staff will send Strata a left-over sample of your tumor that they already have. | Dokteeriin qorannoo keetii fi/ykn istaafiin qorannoo hambaa dhangala’aa fakkisaa dhullaa keessanii kan isaan bira jiru gara istiraataatti kan egan ta’a. |
| You do not have to have a new biopsy in order to participate in the Strata study. | Qorannoo Istiraataa keessatti hirmaachuuf ‘biopsy’ (dhangala’aa/tishuu qorannoof muramee ba’e) haaraa qabaachuu isin hin barbaachisu. |
| Strata will process the sample using genetic sequencing testing and create a test report. | Istiraataan adeemsa tartiiba yaalii qorannoo fayyadamuun gabaasa qorannoo uuma. |
| [1]Your test results, with matching clinical trial information and approved medicine options (if relevant), will be sent to your study doctor and/or study staff to discuss with you. | [1] Firiin qorannoo keessanii odeeffannoo qorannoo Kilinikaa fi filannoo qoricha fudhatama qabanii (barbaachisaa yoo ta’u) walitti firoomsuun gara dokteera qorannoo keessaniitii fi /ykn Istaafii qorannootti erguun isin waliin irrattti kan mari’atamu ta’a. |
| If there is a matching clinical trial, you and your study doctor can decide whether to see if you are eligible to participate in that study. | Yoo yaaliin qorannoo Kilinikaa kan isaan wal-fakkaatu jiraate, isinii fi dokteerri qorannoo keessanii akka isin qorannoo kana keessatti ga’aaa ta’uu fi ga’aa ta’uu dhiisuu keessan murteessuuf ni danda’u. |
| Your study doctor and/or study staff will keep the study database updated with treatment decisions going forward. | Dokteera qorannoo keessanii fi / ykn Istaafiin qorannichaa odeeffannoo qorannoo kompiyuutera keessaa hammayyeesuun murtoo wal’aansaa adeemsifamaa jiru kana kan wal simsiisan ta’a. |
| [1]If your test results don’t show a matching targeted therapy, Strata may, in the future, review your results again in case they match to a new Strata company partner’s targeted therapy. | [1] Firiin qorannoo keessanii yaalii xiyyeefatameen wal hin simatu yoo ta’e Istiraataan gara fuula duraatti irra deebi’uun qorannoo fayyaa keessanii Kaampaanii Istiraataa haaraa waliin kan ilaalu ta’a. |
| If they do match, Strata will update your test results and send them to your study doctor again. | Yoo kan wal-simatan ta’e Istiraataan firii qorannoo keessanii ammayeessuun gara dokteera qorannoo keessatti irra deebi’uun erga. |
| [1]W[2]e [3]would like to keep the samples and data we collect as part of this study to be used in future research about people with your condition. | [1] Nu[2] ti [3] qorannoo kana keessatti fakkisaa fi odeeffannoo akka qaama qorannoo kanaatti walitti qabne qorannoo gara fuula duraa keessattis namoota dhibee wal-fakkaataa qaban illee kan gargaaruu dha. |
| There is no limit on the length of time we will store your samples and information. | Fakkisaa fi odeeffannoo keessan, kan nuti walitti qabannu dheerina yerootiin hin daangeeffamu. |
| What are my responsibilities as a research subject? | Akka mata-duree qorannoo kanaatti, itti gaafatamummaa ani qabu maali? |
| [1]There are no required visits or treatments for this study. | [1] Qorannoo kanaaf daawwannaan yookaan wal’aansi barbaachisu hin jiru. |
| At your regularly scheduled visits, your study doctor or study staff will enter relevant health and medical information into the study database. | Yeroo sagantaa daawwannaa keessan isa dhaabbataatti, dokteeriin qorannoo keessanii yookiin Istaafiin qorannoo odeeffannoo fayyaa ykn kan wal’aansaa murteessoo ta’an gara kompuuteraatti kan galchan ta’a. |
| How long will I be in this research study? | Dhimma Qorannoo kanaa keessa yeroo hammamiifan jiraadha? |
| [1]Your involvement in this study will last for 3 years. | [1]Qorannoo kana keessatti hirmaannaan keessan waggoottan sadiif kan turuu dha. |
| While you are in the study, you should tell the study doctor or study staff if you want to stop being in the study at any time. | Turtii yeroo qorannoo kana keessatti taasiftanitti, yeroo kamittiyyuu hirmaannaa qorannoo kana addan kutuu yoo barbaaddaniif dokteera qorannoo yookaan Istaafii qorannoo keessanitti himuu dandeessu. |
| If the study doctor and study staff are unable to contact you after repeated attempts during the study, they may contact a person listed on the disclosure form on file at the study center (your authorized representative) for updated contact information or to learn about changes in your health. | Yoo dokteeriin qorannichaa fi Istaafiin qorannoo yeroo yaalii kanatti deddeebi’anii isin quunnamuuf kan hin dandeenye ta’e, isaan kun namoota sitti dhiyaatan kan maqaan isaanii unka irratti tarreeffaman (nama bakka bu’umsi laatameef) kan odeeffannoo akka ammayoomsuuf ykn waa’ee jijjiirama fayyummaa keetii irra baruuf isaan quunnamuu. |
| Are there any benefits to participating in the study? | Qorannicha keessatti hirmaanna taasisuun faayidaa qabaa? |
| [1]If you participate in this study, we may find gene changes that are important to your cancer treatment. | [1] Qorannoo kana keessatti kan hirmaattan yoo ta’e, dhibee Kaanserii keessaniitiif jijjiirama jiinii argachuu dandeenya ta’a. |
| Your testing results may indicate that you potentially match to a relevant targeted therapy clinical trial or approved medicine, thereby increasing your opportunities for treatment options. | Firiin qormaata keessanii kan agarsiisuyaalii xiyyeeffannoo kan sakatta’iinsa kilinikaa murteessa ta’e yookiin qoricha fudhatama argate waliin kan wal-simate ta’uu isaa agarsiisuu kan danda’u yoo ta’u, kun ammoo carraa filannoo wal’aansaa keessan kan ol kaasu ta’uu danda’a. |
| With or without matching targeted therapy information, you and your study doctor may get useful information to help in your treatment decisions. | Odeeffanno wal’aansa xiyyeefatame kana walitti firoomsuun ykn osoo walitti hin firoomsin iyyuu, isinii fi dokteeriin qorannoo keessanii waa’ee murtoo wal’aansa keessaniif odeeffanno gargaaru argachuun ni danda’ama. |
| You will also be a part of cancer research, which might lead to better treatments for you and others with your disease. | Isin iyyuu dabalataan qaama qorataa dhimmaa dhibee Kaanserii kan taatan yoo ta’u, kun immoo wal’aansa keessanii fi dhibee kan biroof illee carraa wal’aansa wayyuu akka uumamu taasisuu danda’a. |
| We cannot and do not guarantee or promise that you will receive any benefits from this study. | Sababa qorannoo kanaatiin faayidaa addaa adda akka argattan wabii yookiin waadaa isiniif gallu hin qabnu. |
| There is no way to know in advance whether participating in the Strata study might make any difference in your treatment or outcome. | Qorannoo Istiraataa keessatti hirmaannaa taasisuun keessan wal’aansa keessan irratti ykn firii keessan irratti jijjiirama qabaachuu danda’a kan isin jechisiisu karaan tokko illee hin jiru. |
| What are the risks of this study? | Balaan qorannoo kanaa maalfaa dha? |
| Because the Strata study uses a tumor sample that your study doctor and/or study staff already has, and no new biopsy or samples are required, there is no safety or discomfort risk from Strata study participation. | Sababiin isaas qorannooIstiraataa kanaafdokteeriin kee fi/ykn Istaafiin qorannoo fakkisaa dhangala’aa dhullaa kanaa waan qabaniif kan biraan barbaachisaa miti. Hirmaannaa qorannoo Istiraataa tasisuudhaan nagummaa yookiin qananii dhabuubalaan balaan isin irra ga’u hin jiru |
| [1]There is a small risk that someone could find your protected health information and identify you. | [1] Namni tokko odeeffannoo fayyummaa keessanii adda baafachuun balaa xiqoo qabaata. |
| We will do our best to keep this from happening by using a code of letters and numbers to protect your identity and the associated data that is collected. | Hanga dandeenyutti haalli kun akka hin mudanneefga’ee keenya cimsinee baa’uudhaan koodii xalayaa fi eenyummaa kee eeguudhaaf ni fayyadamnna. |
| The coded data may be saved for many years. | Odeeffannoon iccitiidhaan waraabamee kaa’ame waggoota dheeraaf turuu danda’a. |
| Privacy Risks | Balaawwan dhuunfaa kan ta’an |
| If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. | Yoo odeeffannoon qorannoo jiinii keessanii namoota hin hayyamaminifiifiin kan ilaalamu ta’e, odeeffannoo fayyaa kan dhuunfaa keessanii dhabuuf saaxilamuu dandeessu. |
| Compensation for injury language | Nama jecha Afaaniin miidhameef beenyaa baasuun, |
| In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities. | Unka waliigaltee kana Karaa kamiin iyyuu hin mallatteessu, mirgi seeraa keessanis isiniif hin eegamu, akkasumas qoratootni, Ispoonserri ykn dhaabbiileen irratti hirmaatan kan seeraa fi kan itti gaafatamummaa hojii ogummaa keessan irraa kan gad-lakkisiisu ta’a. |
| What are the costs of taking part in this study? | Kaffalttiin qorannoo kana keessatti qooda fudhachuuf kaffaltiin godhamu maalfaa dha? |
| There is no cost to you for participating in this study. | Qorannoo kana keessatti hirmaannaa taasisuuf baasiin tokko illlee isiniif hin jiraatu. |
| Will I be paid for taking part in this study? | Qorannoo kana kdessatti qooda fudhachuu kootiin naaf kffaalamaa? |
| You will not be paid for taking part in the Strata study. | Qorannoo kana keessatti qooda fudhachuuf isiniif hin kaffalamu. |
| What other choices do I have if I do not take part in this research study? | Qorannoo kana keessatti yoo ani hin hirmaadhu ta’e filannoo kan biroon ani qabu maalii? |
| [1]This study does not provide treatment for your advanced cancer. | [1] Qorannoon kun dhibee Kaansarii sadarkaa olaanaa keessaniif wal’aansa hin taasisu. |
| Your alternative is not to be in this study. | Filannoon keessan kan biroon qorannoo kana keessatti argamuu miti. |
| Your study doctor might recommend other kinds of genetic testing, outside of the Strata study. | Dokteeri qorannoo keessanii gosa qorumsa jiinii kan biraa qorannoo istiraataan alatti kan isin ajaju ta’a. |
| What will happen if new information becomes available? | Odeeffannoo haaraan yoo argameef maaltu uumama? |
| Your study doctor or study staff will let you know if new information becomes available that would affect your willingness to continue participating in this study. | Dokteerri qorannoo ykn Istaafiin qorannoo keessanii odeeffannoon akka isin qorannoo kana keessan itti fufiinsaan qooda fudhachuuf murteessitan kan miidhu jiraachuu isaa dursee kan isin beeksisu ta’a. |
| Who can answer my questions about the research study? | Waa’ee sakkatta’iinsa qorannichaa, gaaffii koo eenyutu deebisuu danda’a? |
| [1]You may talk to[2][3]Daniel Anderson, MD at (952) 993-1517 or your local study doctor about any questions or concerns you have about this consent form or the study. | [1] itti haasa’uu dandeessu [2] [3] Daniel Anderson, MD karaa lakoofsa bilbilaa (952) 993-1517ykn qorataa naannoo keetii waa’ee gaaffii kami unka walii galtee ykn qorannichaaf qabdan ilaalchisee. |
| You can ask questions at any time: before you decide to start the study, at any time during the study, or after completion of the study. | Yeroo kamitti iyyuu taanaan: osoo qorannicha eegaluuf hin murteessin, erga eegaltanii fi erga xumurtanii booddees gaaffii gaafachuu ni dandeessu. |
| Getting answers to your questions about your rights as a research subject | Akkuma mata dureee qoranichaa gaaffiilee waa’ee mirgaawwan keessaniif deebii argachuu dandeessu. |
| [1]This study has been reviewed by an Institutional Review Board (IRB). | [1] Qorannoon kun dhaabbiilee olaanoo /Institutional Review Board (IRB)/ tiin gamaaggamameera. |
| This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner. | Koreen kun qorannoo kana keessa deebi’ee ilaaluun isaa, kan inni gargaaruuf nageenyi mirgoota keessanii eegamaa ta’uu isaa fi hammam akka qorannoon kun haala haqa qabeessa ta’een adeemaa jiraachuu isaa mirkaneeffachuuf gamaaggama. |
| For questions about your rights as a research subject, contact: | Akka mata-duree qorannichaatti gaaffiiwwan waa’ee mirgoota keessaniif deebii argachuuf, teessoo itti aanee jiru quunnamaa. |
| By mail: | Xalayaadhaan: |
| Study Subject Adviser | Gorsituu dhimma mata duree qorannoo |
| Chesapeake IRB | Chesapeake IRB |
| 6940 Columbia Gateway Drive, Suite 110 | 6940 Columbia Gateway Drive, Suite 110 |
| Columbia, MD 21046 | Columbia, MD 21046 |
| [1]or call [2]toll free[3]: | [1]yookaan bilbili [2] bilbila tolaa fayyadamuun [3]: |
| 877-992-4724[5] | 877-992-4724[5] |
| [1]or by [2]email[3]:[4]adviser@chesapeakeirb.com[5] | [1] yookaan karaa  [2] imeeyilii [3]: [4] adviser@chesapeakeirb.com [5] |
| Please reference the following number when contacting the Study Subject Adviser: | Yeroo gorsituu mata duree qorannoo haasofsiiftan maaloo lakkoofsa itti aananii jiran fayyadamaa: |
| Pro00019183. | Pro00019183. |
| Where can I get more information? | Odeeffannoo dabalataa eessaan argachuu danda’a? |
| [1]A description of this clinical trial will be available on [2]http://www.ClinicalTrials.gov[3], as required by U.S. Law. | [1] Ibsi yaalii Kilinikaa kun kan inni irratti argamu [2] http://www.ClinicalTrials.gov [3] akka seera U.S tiin ajajametti. |
| This Web site will not include information that can identify you. | Marsariitii (Web site) n kun odeeffannoo isin ilaallatu of keeesssatti hin hammatu. |
| At most, the Web site will include a summary of the results. | Fuulli marsariitiin kun baay’inaanfirii waliigalaa of keessatti hammata. |
| You can search this Web site at any time. | Yeroo kamitti iyyuu fuula marsariitii kanaa argachuu dandeessu. |
| The study identifier is NCT03061305. | Mallaattoon qorannichi adda baafamee ittiin beekamu NCT03061305 dha. |
| Can I stop being in this study? | Qorannoo kana keessatti argamuu irraa of kutuu nan danda’aa? |
| [1]Joining a study is voluntary. | [1] Gara qorannoo kanaatti dhufuun fedha ofiitiin. |
| You can withdraw from the study at any time with no penalty or loss of benefits to you. | Qoranicha keessa yeroo kamitti iyyuu adabbii malee faayidaan tokkoillee osoo isinitti hin hir’atin addaan kutuu ni dandeessu. |
| Your decision will not affect your care in any way, either now or in the future. | Murtoon keessan ammas ta’ee garaa fuula duraatti kunuunsa isiniif taasifamu irratti dhiibbaa hin qabu. |
| [1]If you decide to withdraw from the study, please let your study doctor or the study staff know. | [1] Yoo qorannicha addaan kutuuf murteessitan, maaloo dokteerri qorannoo keessanii ykn Istaafiin qorannichaa akka beekan taasisaa. |
| The information collected up to the time that you withdraw from the study may still be used by the Strata to the extent permitted by applicable law, but no new information will be collected. | Odeeffannoon hanga yeroo isin qorannichaa addaan hin kutiniitti waliti qabame akka seera hojii irra oolmaa Istiraataa tiin hayyamametti kan itti fayyadaman yoo ta’u, garuu odeeffannoo haaraan walitti hin qabamu. |
| If you stop being in the study early, the study doctor may ask you some questions about being in the study. | Yoo dursitanii qoranicha addaan kuttan, ogeessi qoranichaa waa’ee waantota qoranicha keessatti argamanii gaaffii tokko tokko isin gaafachuu ni danda’a. |
| [1]The study doctor or Strata can remove you from the study at any time, even if you want to stay in the study. | [1] Hagam yoo isin qorannicha keessa turuu barbaaddan illee ogeessi qorannichaa ykn Istiraataan qorannicha keessaa ala isin gochuu danda’a. |
| This could happen if: | Kun kan inni ta’uu danda’u yoo: |
| The study doctor believes it is best for you to stop being in the study. | Dokteerri qorannicha, qorannicha keessatti argamuu dhaabuun keessan isiniif gaariidha jedhee kan itti amanu yoo ta’e dha. |
| You do not follow directions you have received about the study. | Qajeelfama waa’ee qorannootiif fudhattanii hin hordoftan. |
| Strata or a governmental entity with appropriate jurisdiction stops the study for any reason. | Istiraataan qaamni hojii raawwachiiftuu mootummaa waliin ta’uun sababa ta’e tokkoon qorannoo kana dhaabsisuu/addaan kutuu danda’u. |
| [1]After you join the study, your study doctor might decide not to participate in the study any longer. | [1] Erga isin qorannoo kana quunnamtanii booda , dokteeriin qorannoo keessanii akka isin itti fuftanii hirmaannaa hin taasifneef tarii murteessuu ni danda’a. |
| Your study doctor will let you know if he/she decides not to participate in the study anymore. | Dokteeriin qorannoo keessanii akka isin beektan ni taasisa yoo inni/isheen akka isin hirmaanna itti hin fufne murteessan. |
| You will be informed of another study doctor you can contact with study-related questions for the rest of your participation if you choose to continue taking part in the study. | Yoo qorannoo kana keessatti itti fuftanii qooda fudhachuun filannookeessan ta’eef, dokteerii kan biroo quunnamuun gaaffiiwwan qorannoo kan wal-fakkaatan keessatti hirmaannaa keessan itti fufuu dandeessu. |
| If your study doctor changes, you will be notified and you may have to sign and date a new consent form. | Yoo dokteeriin qorannoo keessanii isin irraa geeddarameef, isinitti beeksisuudhaan akka isin unka walii-galtee haaraa mallatteessitantu taasifama. |
| Confidentiality | Haala iccitii ta’een |
| [1]The study sponsor may combine the study results with results of other studies to develop a better understanding of advanced cancer and treatment for advanced cancer. | [1] Qaamni deggersa maallaqaa taasisu firii qorannoo kanaa, isa kan biro waliin walitti dabaluudhaan, caalmaatti hubannoo waa’ee Kaanseriitii fi jijjiirama wal’aansa Kaanseriitiif taasisuu danda’a. |
| The information may be given to the FDA or other government health agencies as part of applications or to meet other reporting requirements. | Odeeffannoon ‘FDA’ dhaaf ykn akka qaama beeksisaatti dhaabbata fayyaa kan mootummaa biroof akka waantota gabaasaaf barbaachisan kan biroo ittiin guutuuf kennuu danda’a. |
| In no event will you be identified by name in any published reports about this study or any other scientific publications or presentations. | Mudannoo kamiin iyyuu keessatti maqaadhaan gabaasa maxxansaa irratti, maxxansaa saayinsaawwaa, fi dhi’eessii irrattis qorannoo kanaa keessatti addaan hin baafamtani hin ibsamtani. |
| [1]There is no way to ensure records are kept completely confidential, however steps will be taken to ensure it is as secure as possible. | [1] galmeewwan kun guutummaan guutuutti iccitiidhaan akka eegamaniif ajajuuf karaan hin jiru, Haata’u iyyuu malee hamma danda’amaa ta’etti eegannoodhaan akka qabamuuf tarkaanfiin kan fudhatamu ta’a. |
| Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law. | Odeeffannoon waa’ee fayyaa keetii erga yeroo tokko qaama aboo qabuun akka itti fayyadamuuf hayyamameefiin booda, seera dhuunfaa kan Federaalaatiin itti fufee dhorkamuu hin danda’u. |
| A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. | Seerri Federaalaa kan, “the Genetic Information Nondiscrimination Act (GINA)” jedhamu, dimshaashumatti wabii Kampaanii Fayyaatiif seera qabeessa akka inni hin taane ibsuun, karoorri Gurmuu Fayyaa fi hojjettootni hedduun odeeffannoo jiinii keetii irratti hundaa’uudhaan akka adda baafamtu si gochuu danda’u. |
| This law generally will protect you in the following ways: | Seerri kun akka itti aanee jirutti si fayyaduu/eeguu danda’a: |
| Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research. | Kaampaaniin Inshuuraansii Fayyaa fi karoorri gurmuu fayyaa akka qaamni deggersa baajetaa taasise odeeffannoo jiinii keesaniitti fayyadamuuf hin hayyamu. |
| Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. | Kaampaaniin Inshuuraansii Fayyaa fi karoorri gurmuu fayyaa yeroo maallaqa Inshuuraansiif kaffalamu murteessutti odeeffanno jiiniikeessaniitti gargaaramuu dhiisuu danda’a. |
| Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. | Odeeffannoo jiinii keessanii,hojjechiiftotni hojjetoota 15 fi isaa ol qaban kan qaamni deggersa maallaqaa taasise qorannoo kana irraatti hundaa’uun murtoo taasisu miindessu, guddisu, hojii irraa isin geggeessuuf ykn walii galtee uumuuf irra fayyadamu kana hin garagaaramani. |
| All health insurance companies and group health plans and all employers with 15 or more people must follow this law. | Kaampaaniin Inshuuraansii Fayyaa fi karoorri gurmuu fayyaa fi hojjechiiftotni hojjetoota 15 fi isaa ol qaban hundinuu seera kana hordofuu qabu. |
| Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance. | Beekuu kan qabdani seerri Federaalaa kun dhiibbaa ala baasuu jiinii kan Kampaanota Inshuuraansii kan jireenyaa, kan hir’ina qaamaa ykn kan kunuunsa yeroo dheeraa gurguraniin taasifamu irraa kan dhowu miti. |
| [1]You may take back your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. | [1] Teessoo fuula jalqabaa unka kanaa irratti tarreeffaman gargaaramuudhaan yeroo kamitti iyyuu dokteera qorannoo keessaniif barreessuudhaan hayyama keessan deebiftanii fudhachuun itti fayyadamuu fi odeeffannoo fayyaa keessanii kan boroof hiruufis tarii gargaaramuu dandeessu. |
| If you do this, you will not be able to stay in this study. | Yoo kana gootaniif, qorannoo kana keessa turuu hin dandeessan. |
| No new health data that identifies you will be gathered after your written request is received. | Erga barreeffamni fedhii keessan ibsu fudhatameen booda odeeffannoon fayyaa haaraan waa’ee keessan ibsu kan walitti qabame hin jiru. |
| However, health data about you that has already been gathered may still be used and given to others as described in this form. | Haata’u iyyuu malee, odeeffannoon fayyaa waa’ee keessanii kan walitti qabamee jiru, akkuma unka irratti ibsamee jiru, hanga ammaatti tajaajila kennaa kan jiruu fi gara duraattis warra kan biroof tajaajila kennuu kan danda’uu dha. |
| [1]To ensure the scientific integrity of the study, you agree that you may not be able to review some of your records related to the study until after the study has been completed. | [1] Dhugummaa Saayinsaawaa qorannoo kanaa raggaasisuuf, kan isin walii galtan hanga qorannoon kun walitti qabamee xumuramutti akka galmee qorannoo keessanii keeessa deebitanii gulaaluu hin dandeenye dha. |
| Once the study is completed, you will be able to review and obtain copies of your records related to the study. | Qorannoon al tokko yoo xumuramutti qoranicha waliin kan wal-simatu irra deebitanii ilaaluunii fi garagalcha isaa argachuun kan dandeessan ta’a. |
| If you decide not to sign and date this form, you will not be able to take part in the study. | Yoo unka kana guutuudhaan mallateessuuf hin murteessitan ta’e, qorannoo kana keessatti hirmaannaa taasisuu hin dandeessan. |
| [1]You will receive a signed and dated copy of this form for your records. | [1] Garagalchi unka mallatteeffame kanaa isiniif kan kennamu ta’a. |
| If you are receiving an electronic copy of your signed and dated consent form and/or storing or viewing this document on a personal electronic device (PED), there is a risk that an unauthorized individual or individuals may access this form, especially if the PED is shared with others or is lost, hacked, or subject to a search warrant or subpoena. | Yoo isin unka waliigaltee mallateeffame kana garagalcha dookumantii kanaa kompiyuutera keessan irraa keewwattanii fi / ykn kompiyuutera dhuunfaa keessanii irra keewwattan, salphaadhumatti namni akka ilaaluuf hin hayyamaminiif arguu kan danda’uu yoo ta’u, keessumaa yoo kompiyuutera dhuunfaa keessanii namaaf ergifamee ykn badee argameef ykn akka sakatta’amuuf barbaadame. |
| [1]Authorization (Permission) To Use and/or Share Your Protected Health Information[2][3] | [1] Aangoo kennuu (Hayyamuu) akka gargaaramuu fi / ykn odeeffannoo Fayyaa keessanii isa Dhorkaa ta’e ilaalchisuuf [2] [3] |
| [1]The Health Insurance Portability and Accountability Act (HIPAA) requires protection of your health and medical information so that it is kept private and confidential to the greatest extent possible. | [1] Inshuuraansii Fayyaa sosocho’uu fi Gochi Itti gaafatamummaa /The Health Insurance Portability and Accountability Act / kan inni barbaadu eeggannoo fayyaa fi odeeffannoo al’aansa keessanii waan ta’eef hamma danda’amaa ta’etti kan dhuunfaa fi kan iccitiin eegamu ta’uu barbaachisa. |
| Protected health information (PHI) is any health information that identifies you. | Odeeffannoon Fayyaa Ittifamanii (OFI) jechuun odeeffannoo fayyaa kamiin iyyuu taanaan kan isin ibsuu dha. |
| PHI includes both information we will collect about you as part of this study as well as health information that is stored in your medical record. | OFI kan inni of keessatti haammatu odeeffannoo nuti waa’ee keessan walitti qabnu, akka qaama qorannoo kanaatti akkasumas, odeeffannoo fayyaa kan galmee wal’aansaa keessan keessatti galmeeffamee dha. |
| [1]Before we can use your information or share it with others for research purposes, we need your permission to do so. | [1] Nuti odeeffannoo keessanitti osoo ofii itti hin fayyadamin ykn warra biroofis dhimma qorannootiif hin dabarsin, dursinee hayyama keessan argachuu barbaadna. |
| If you sign this document, you give authorization (permission) to the MMCORC[2][3]researchers and research staff conducting this study to use and share your health information for the research study described in this document. | Dookumentii kana yoo mallatteessitan, dhaabbata qorannoo “MMCORC”[2][3] jedhamuuf hayyama fayyadamummaa odeeffannoo fayyaa dookumentii kana keessatti argaman kennuu keessan agarsiisa. |
| Your health information that may be used and/or shared will include the following: | Odeeffannoon Fayyaa keessanii kan gargaaramanii fi /ykn dabarfamanii qorannoof hiraman kan itti aananii jiran of keessatti haammata: |
| All the information collected during the research that is described in the consent document | Odeeffannoo yeroo qorannoo sassabaman kan dookumantii waliigaltee keessatti ibsaman hunda. |
| Health information in your medical records that is relevant to the research described in the consent document | Odeeffannoon fayyaa kan galmee wal’aansaa keessan keessatti argamu qorannoo jedhameef fudhatama kan qabuu dha. |
| Parties who may share your health information for the purpose of this research include the following: | Qaamoleen odeeffannoo fayyaa keessanii qorannoodhaaf hirmaachuu danda’an warra armaan gadii of keessatti haammata: |
| Healthcare providers who are part of this research | Kunuunsa fayyaa kan gumaachan warra qaama qorannoo kanna ta’an. |
| Other healthcare providers who are not part of this research (other doctors, hospitals and/or clinics) who are involved in your care | Kunuunsa fayyaa kan gumaachan kan biroo kan qaama qorannoo kanaa hin taane (dokteerota kan biroo, Hospitaalota fi / ykn Kilinikoota) warra gumaacha kanatti hirmaannaa taasisan. |
| Your health information may be used and/or shared for the following purposes: | Odeeffannoo fayyaa keessanii gargaaramuun tarii itti fayyadamuu fi /ykn qorannoodhaaf dabarsuun kaayyoon isaa kan itti aanee jiryyf ta’a: |
| Verify that you are eligible to enroll in the study. | Qorannichatti hirmaachuuf ga’aa ta’uu keessan adda baafachuuf. |
| Conduct the study and make certain that the study is being carried out properly. | Qorannoo geggeessuu fi qorannichi sirriitti geggeeffamuu isaa raggaasisuuf. |
| Ensure that the information collected during the study is accurate and complete. | Odeeffannoon walitti qabame kun yeroo walitti qabamaa turetti sirrii ta’uu isaatii fi guutuu ta’uu isaa raggaasisuudhaaf. |
| Analyze the study results. | Firii qorannichaa gamagamuuf. |
| Help to make sure that your safety and rights as a research subject are protected. | Akka mata duree qorannoo dhorkamaa ta’e tokkootti nagummaa fi mirgi keessan eegamaa ta’uu isaa raggaasifachuuf. |
| If applicable, bill responsible parties for services or procedures related to your participation in the study. | Yoo, qorannoo kana keessatti kutaawwan tajaajilaa murteessoo ta’an kan isin waliin ykn kan adeemsa hirmaannaa keessaniin walitti dhufu ta’e. |
| The researchers may share your health information with the following: | Qorattootni odeeffannoo fayyaa keessanii kanneen armaan gadii waliin hirmaachuu danda’u: |
| Strata Oncology and their representatives such as study monitors and Clinical Research Organizations | Istiraataa Onkoloojii fi bakka buutota kan akka qindeessitoota qorannoo fi Dhaabbata Qorannoo Kilinikaa |
| Data coordinating centers (a group that is organized to handle data management throughout the study) | Giddu-gala qindoomina odeeffannoo (waliigala qorannoo kanaa keessatti odeeffannoo sirriitti to’achuuf gumii gurmaa’e) |
| Representatives of federal or state government agencies such as the Food and Drug Administration (FDA), when required by law | Bakka buutotni Federaalaa yookaan dhaabbiileen mootummaa kan naannoo kan akka Bulchiinsa Nyaataa fi Dhugaatii (BND), yeroo seeraan gaafatamutti. |
| The HealthPartners Institute Institutional Review Board (IRB) for the Community Oncology Programs | Sagantaalee Onkoloojii Hawwaasaa kan ‘HealthPartners Institute Institutional Review Board (IRB)’ |
| Chesapeake IRB | Chesapeake IRB |
| [1]The researchers and the sponsor agree to protect your health information by using and sharing it only as authorized by you under the Protected Health Information section of this document and as required by law. | [1] Qorattoonnii fi ispoonsara odeeffannoo fayyaa keessanii balaa irraa ittisuuf kan walii-galan namoota ittisa odeeffannoo Fayyaa galmee fi akka seerri barbaadutti namoota hayyama keessan jalaati. |
| For example, your health information may be disclosed to proper authorities in order to prevent serious harm to yourself or others or to meet state law reporting requirements of positive test results, including but not limited to Hepatitis and HIV. | Fakkeenyaaf, odeeffannoo fayyaa keessanii namoota aangoo qabaniif ifa gochuun balaa hamaa isin irraa ykn namoota biroo irraa ittisuuf, ykn gabaasa ulaagaa seera mootummaa naannoo kan guute kan of keessatti hammatu, garuu kan dhibee Tiruu fi HIV qofaa irratti hin murtoofne. |
| Once your PHI is shared with someone outside the research team or if you choose to share your information with others outside of the study, your information may no longer be protected by HIPAA regulations. | Yeroo tokkoof Odeeffannoon Qorannoo keessanii kan Ittifamaa ta’e kana nama gurmuu qorannoo kanaa keessa hin jirreef yoo dabarfamee ykn odeeffannoo dhuunfaa keessanii nama qorannoo keessa hin jirreef hiruun yoo filannoo keessan ta’eef, odeeffannoon keessan akka seera “HIPAA” irratti ibsamee jirutti to’atamuu hin danda’u. |
| Right to refuse to give authorization (permission) | Mirga, aboo diddaa hayyama kennuu |
| [1]You can choose to give or not to give your permission to use and share your PHI. | [1] Odeeffannoo Fayyaa Ittifame (OFI) keessanitti akka fayyadamani fi hirataniif hayyama kennuu fi dhiisuu keessan filachuu dandeessu. |
| If you choose not to give permission and not to sign this document, you will not be able to take part in this research study. | Yoo hayyama kennuu dhiisuu filattani fi galmee kana irratti mallaatteessuu-dhaabaattan qorannoo kana keessatti qooda fudhachuu hin dandeessan. |
| Your decision will not affect your access to standard medical care. | Murtoon keessan wal’aansa fayyaa dhaabbataa ta’e kan isin argattan irrattii dhiibbaa geessisu hin qabu. |
| Right to revoke (take back) authorization (permission) | Mirga aangoo (hayyama dhowwachuu) qabaachuu. |
| [1]You may change your mind and take back your permission at any time. | [1] Yeroo kamitti iyyuu yaada keessan geeddaruun hayyama keessan dhowwachuu dandeessu. |
| If you take back your permission in the future, information that has already been obtained may remain as part of the research record, but no additional information will be added to the research record. | Yoo gara fuula duraatti hayyama kennuu keessan irraa duuba deebitan, odeeffannoon argamee jiru akka qaama qorannichaatti galmaa’ee kan turu yoo ta’u, garuu galmee qorannoo kanatti odeeffannoon dabalataa hin dabalamu. |
| If you take back your permission, you will not be allowed to continue participating in the study. | Yoo hayyama keessan irraa gara boodaatti deebitan itti fuftaniiqorannoo kaana irratti hirmaachuun isiniif hin hayyamamu. |
| [1]To take back your permission, you must send a letter to the principal investigator to inform him of your decision. | [1] Hayyama keessan irraa boodatti deebi’uuf murtoo keessan gara qorataa olaanaatti xalayaa erguun itti beeksisuu qabdu. |
| If you wish to take back your permission, send a letter to the principal investigator listed below: | Yoo hayyama keessan irraa duubatti deebi’uu feetaniif, gara qorataa olaanaa armaan gadiitti xalayaa keessan ergaa: |
| Daniel Anderson, MD | Daniel Anderson, MD |
| MMCORC | MMCORC |
| 3800 Park Nicollet Boulevard | 3800 Park Nicollet Boulevard |
| St. Louis Park, MN 55416-2699 | St. Louis Park, MN 55416-2699 |
| Access to personal health information | Odeeffannoo fayyaa kan dhuunfaa argachuu |
| [1]You have the right to see and copy your medical records and PHI related to the research study for as long as this information is held by the study team or institution where the research is conducted. | [1] Odeeffannoo Fayyaa Ittifamee kan qorannicha waliin walitti dhufeenya qabu faana odeefannoon kun garee qorannoo ykn dhaabbata qoranichi keessattii geggeeffamu keessatti mirga galmeewwan fayyaa keessanii ilaaluu fi garagalchuu ni qabaattu. |
| However, to ensure the scientific integrity of the study, you will not be able to see or copy some of the study information until after the study has been completed. | Haata’uiyyuu malee, haqummaa qorannoo Saayinsaawwaa ta’e mirkaaneeffachuuf, hanga adeemsi qorannichaa goolabumutti odeeffaannoo tokko tokko ilaaluu fi garagalfachu (koppii godhachuu) hin dandeessan. |
| The Notice of Privacy Practices available in the hospital, clinic, or office where the research was conducted provides general information on your rights to review, copy, and amend your health information. | Beeksisi akkaataa hojii dhuunfaa kan argamuu danda’an: hospitaala, Kilinika, ykn waajjiira qorannichi keessatti geggeeffamu kan isaan dhi’eessan odeeeffannoo waliigalaa kan haala mirga irra deebitanii ilaaluuf, koppii godhachuu fi fooyyessuu ni dhi’eessa. |
| Expiration of authorization (permission) | Xumura kennama Aangoo (hayyamaa) |
| Your permission to use and share your PHI in connection with this study does not have an expiration date. | Odeeffannoo Fayyaa Ittifamee kan wal qabatu gargaaramuu fi kan biraatiif hiruun yeroo hayyama isaatii kan yeroon itti darbu miti. |
| Consent/Authorization | Walii galtee / kennama aangoo |
| [1]By signing this form, I acknowledge that this study has been explained to me, including the potential risks and discomforts. | [1] Unka kana mallatteessuudhaan, rakkoo fi mijachuu dhiisuu isaa dabalachuun waa’een qorannoo kanaa naaf ibsamu isaa beekamtiin itti kenna. |
| I have read this consent form in its entirety and have spoken to the study doctor or his/her representative and have had all questions answered to my satisfaction. | Unka waliigaltee kana tartiibaan jalqaba hanga xumuraatti hunduma isaa dubbisuun, dokteera qorannichaa ykn bakka bu’aa isaa /isheetti haasa’uudhaan gaaffii koo hundaaf deebii quubsaa ta’e argadheen jira. |
| I will receive a completed signed copy of this document. | Garagalcha unka mallatteeffamee xumurame harkatti naaf kan kennamu ta’a. |
| My signature indicates my agreement to voluntarily participate in this study. | Mallattoon koo, walii-galtee qorannoo kana keessatti fedhaan hirmaachuu koo agarsiisa. |
| By signing this form, I also give permission to access, use, and disclose my health information in the way described in this consent document. | Akkuma galmee hayyamaa kana keessatti caqafamee jirutti, odeeffannoo fayyaa kootii kana ilaaluun, fayyadamuunii fi ibsa kan biroof gargaaramuun akka danda’amuuf Unka kana mallatteessuudhaan hayyameera. |
| [1]Signature of Patient [2]Date[3] | [1] Mallattoo Dhukkubsataa [2] Guyyaa [3] |
| Printed Name of Patient | Maqaa Dhukkubsataa kan Maxxanfame |
| [1]Research Representative’s Statement[2]: | [1]Yaada Bakka bu’aa Qorannoo[2]: |
| I have explained this research study to the subject and have answered any questions he/she had. | Waa’een qorannoo kanaa naaf ibsamuudhaan, gaaffiiwwan inni/isheen anaan gaafatan hundaaf deebii kenneera. |
| Signature of Research Representative | Mallattoo Bakka-bu’aa Qorannoo |
| Printed Name and Title of Research Representative | Maqaa Maxxanfamee fi Aankii Bakka bu’aa Qoraannoo |