

| University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures | | | |
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| Revision #8 | TITLE: NCI CIRB Review | | Page 1 of 16 |
| Approved By: ORI Director | Signature | Date | Date First Effective: 07-24-06 |
| Approved By: Nonmedical IRB Chair | Signature | Date | |
| Approved By: Medical IRB Chair | Signature | Date | |
| Approved By: Markey Cancer Center Director | Signature | Date | Revision Date: 03-23-2023 |

OBJECTIVE

To outline the coordination procedures between the Markey Cancer Center (MCC), Office of Research Integrity (ORI), UK Institutional Review Board (IRB) and Principal Investigator (PI) for managing cooperative group pediatric or adult protocols with the National Cancer Institute (NCI) Central Institutional Review Board (CIRB).

GENERAL DESCRIPTION

The NCI CIRB reviews and oversees all its member cooperative group sponsored pediatric and adult research. The University of Kentucky (UK) is a member of several cooperative research groups, both adult and pediatric. In accordance with NCI CIRB regulations and UK policies and procedures, data collection of eligible NCI cooperative group sponsored pediatric or adult research must be reviewed by the NCI CIRB. It is the responsibility of each UK PI to evaluate cooperative group studies available and identify each study for UK's participation in accord with MCC review procedures. The PI and staff will prepare the cooperative group study according to the CIRB's requirements for initiation and continued conduct at UK.

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB Member, PI/Study Personnel, ORI Staff, ORI Director, ORI Research Education Specialist, ORI Research Compliance Officer (RCO), MCC Associate Director of Clinical Translation (ADCT), MCC Clinical Research Office (CRO), MCC Protocol Review and Monitoring Committee (PRMC), MCC Clinical Care and Research Teams (CCARTs), Pediatric Oncology staff.

| | | |
|---|-------------------------------|---------------------|
| University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures | | |
| Revision #8 | TITLE: NCI CIRB Review | Page 2 of 16 |

PROCEDURES

Submission for Pediatric Protocols

1. The PI identifies a Children’s Oncology Group (COG) study with NCI CIRB protocol approval available for member participation. The PI/study personnel downloads the CIRB protocol from the ‘Participants’ area on the CIRB website (www.ncicirb.org) and submits it to the to the MCC Clinical Research Office (CRO) for review by the MCC Protocol Review and Monitoring Committee ([PRMC](#)).
2. MCC PRMC reviews all cancer clinical trials. MCC PRMC coordinator facilitates review of CIRB studies with the Institutional Biosafety Committee (IBC), Radiation Safety Committee (RSC) and the Radioactive Drug Research Committee (RDRC). IBC, RSC and RDRC reviews will be conducted in parallel with CIRB review. If a study requires IBC, RSC and/or RDRC review it will not be opened to accrual by Pediatric Oncology until all issues have been resolved.
3. The PI/study personnel downloads the NCI-CIRB sample informed consent form from the CIRB website and incorporates the current UK approved informed consent local context and assent. If the NCI-CIRB age for signature request in Assent document requirements differ from UK’s requirements, the PI should follow the NCI-CIRB’s requirements.
4. When the PI obtains PRMC approval, the Pediatric Oncology staff (study team) and/or the PI submit an Abbreviated Application (AA) in E-IRB for UK HIPAA review. The AA will be reviewed and a HIPAA Determination Letter is generated. The PI/study team complete and submit the required CIRB application documents to the NCI CIRB. The protocol must contain the word “NCI-CIRB” at the beginning of the title. Pediatric Oncology staff place a copy of the PRMC approval in the study regulatory file.
5. The PI/study personnel complete the required CIRB application forms by submitting the Study-Specific Worksheet about Local Context to open the study with the CIRB.

Submission for Adult Protocols

1. The PI identifies a cooperative group study he/she would like to open. The PI notifies other physicians at the MCC Clinical Care and Research Team (CCART) meeting of a potential protocol through the NCI CIRB that he/she would like to open. This meeting is a discussion with potential co-investigators regarding their willingness to participate in the proposed study.
2. The PI completes a MCC PRMC new protocol submission form documenting MCC CCART approval and submits it to the MCC PRMC coordinator. The MCC PRMC coordinator searches the NCI CIRB website to determine if the study is CIRB eligible. If the study is CIRB eligible, the MCC PRMC coordinator adds the pre-fix “NCI-CIRB” to the title in OnCore. The MCC PRMC coordinator downloads most recent version of the study protocol and submits to the MCC PRMC chair for expedited review.

| | | |
|---|-------------------------------|---------------------|
| University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures | | |
| Revision #8 | TITLE: NCI CIRB Review | Page 3 of 16 |

3. The MCC PRMC reviews the protocol to confirm accrual estimates and local feasibility of the study
4. Upon receipt of MCC PRMC approval, PI/study team submit an Abbreviated Application (AA) in E-IRB for UK HIPAA review. The AA will be reviewed and a HIPAA Determination Letter is generated. The Oncology study staff and the PI confirm that the Annual Signatory Institution Worksheet about Local Context and the Annual Principal Investigator Worksheet about Local Context have been submitted and are approved by the CIRB using the IRB manager site.
5. The PI/study personnel update the NCI CIRB study personnel roster to include all sub-investigators and appropriate research staff. IRB manager access is requested for the PI (if a new investigator), all sub-investigators, clinical research associates and others as determined by the PI.
6. The PI/study personnel submit the Study Specific Worksheet about Local Context via the IRB manager site.
7. The PI/study personnel downloads the current CIRB study documents (protocol, NCI CIRB consent form, CIRB application including most recent CIRB approval memos) from the “Participants” area on the CIRB website. In addition, the study personnel download the current version of the UK IRB’s local context language from the NCI CIRB SOP located on the ORI website. The PI study staff combines the consent template and the UK IRB local context language to create the consent form to be used during the study.
8. The CIRB reviews and approves the Study-Specific Worksheet about Local Context. Once approved, the CIRB is the IRB of Record for the study.
9. MCC’s PRMC coordinator facilitates review of CIRB studies with the Institutional Biosafety Committee (IBC), Radiation Safety Committee (RSC) and the Radioactive Drug Research Committee (RDRC). IBC, RSC and RDRC reviews are conducted in parallel with CIRB review. If a study requires IBC, RSC and/or RDRC review it will not be opened to accrual by the MCC until all issue have been resolved.

Institutional Biosafety Committee

- a. The MCC PRMC coordinator adds the IBC as a management group within OnCore. This group receives all MCC PRMC approval notifications. The notifications are sent to a shared email address accessible by the IBC coordinators.
- b. If the IBC identifies an issue requiring their review they contact the Director of Clinical Research Operations. He/she identifies the regulatory coordinator who supplies the additional documentation to the IBC.

| | | |
|---|-------------------------------|---------------------|
| University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures | | |
| Revision #8 | TITLE: NCI CIRB Review | Page 4 of 16 |

University Radiation Safety Committee

- a. The MCC PRMC assigned reviewer decides if the study meets criteria for further review by the RSC.
- b. If the reviewer finds the study meets criteria for review by the RSC, the MCC PRMC coordinator provides the Radiation Safety Director with a copy of the protocol, the completed expedited review and the MCC PRMC approval memo.
- c. The Director of Clinical Research Operations identifies a regulatory coordinator who assists the PI in supplying additional documentation to address the concerns of the committee.

Radioactive Drug Research Committee

- a. The MCC PRMC asks the ORI staff and RDRC Chair to decide if the study meets criteria for further review by the RDRC.
 - b. The MCC PRMC coordinator provides the RDRC with copy of the protocol, the completed expedited review and the MCC PRMC approval memo.
 - c. The Director of Clinical Research Operations identifies a regulatory coordinator who assists the PI in supplying additional documentation to address the concerns of the committee.
10. MCC investigators follow the Conflict of Interest Policies of the University of Kentucky which is verified annually by the Office of the Vice President for Research. (see UK's *Conflict of Interest Policies*, <http://www.research.uky.edu/ospa/coi.html>).

Post-Approval Responsibilities

Once the NCI CIRB is designated as the IRB of record, the PI interaction with the UK IRB is minimal but includes the following:

1. HIPAA: The PI/study team is required to submit an Abbreviated Application (AA) in E-IRB for UK HIPAA review. If appropriate, the PI also submits a request for a Waiver of Authorization within their AA in E-IRB to the UK ORI/IRB for review. The PI/study team should submit HIPAA changes in the AA in addition to submission for review and approval by the NCI-CIRB.
2. Study Personnel: The PI/study team should submit study personnel changes in the AA in addition to submission for review and approval by the NCI-CIRB. Study personnel changes are submitted by updating the approved AA to reflect study personnel changes approved by the NCI-CIRB.
3. Study Closure: The PI/study team should notify the UK IRB Reliance team within two (2) weeks of the protocol being closed/inactivated with the NCI-CIRB by updating the AA to reflect that the study closure was approved by the NCI-CIRB. The "15-MCCCRO-KP:

| | | |
|---|-------------------------------|---------------------|
| University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures | | |
| Revision #8 | TITLE: NCI CIRB Review | Page 5 of 16 |

MCC-CRO Master SP List” (#43163) may be used to identify study personnel on the AA.

Once the NCI CIRB is designated as the IRB of record, the PI interaction with the UK MCC includes the following:

1. Unanticipated Problems involving Risk to Subject or Others, Serious or Continuing Noncompliance: The PI submits local UPs to the NCI CIRB and the MCC Data and Safety Monitoring Committee (DSMC). The MCC DSMC has the authority to suspend and/or terminate protocols based upon the committee’s review. The MCC DSMC, after completing their review, sends a letter summarizing the nature of the discrepancies and their resulting requirements and/or decisions to the UK IRB, as well as to the PI, the Director of the MCC CRO, the MCC Director, the MCC ADCT, and the MCC PRMC Chair.
2. Protocol Violations: The PI submits local protocol violations to the UK MCC DSMC in accord with DSMC requirements and the Cooperative Group, in accord with the Cooperative Group’s guidelines.
3. Adverse Events and Serious Adverse Events: The PI submits local adverse events to the UK MCC DSMC in accord with DSMC requirements and the Cooperative Group, in accord with the Cooperative Group’s guidelines.

Once the NCI CIRB is designated as the IRB of record, the UK ORI responsibilities include the following:

1. Qualifications of Investigators and Research Staff: The MCC provides UK ORI with a list of investigators and research staff who participate in NCI CIRB independent review research periodically. ORI staff verifies human research training with the Collaborative Institutional Training Initiative (CITI) and sends a report to the MCC.
2. Informed Consent Form Local Context Language: The UK ORI staff modifies the UK informed consent form template periodically as new federal, state and university rules and regulations require. At that time, ORI staff modifies the local context portion of the informed consent form that is on file with the NCI CIRB as part of the Annual Local Context Form and notifies MCC CRO staff of this update.
3. Unanticipated Problems involving Risk to Subject or Others, Serious or Continuing Noncompliance: The ORI NCI CIRB designee accesses the Unanticipated Problem and/or Noncompliance Forms through the NCI CIRB web portal periodically to monitor the submissions by UK PIs. The UK IRB has the authority to review, on a local level, any unanticipated problems or noncompliance issues that indirectly or directly affect protocols for which the UK IRB is responsible. The review may result in an institutional plan to manage incidents, experiences or outcomes including measures to prevent similar occurrences. UK IRB informs the PI, the DSMC and the MCC ADCT of any actionable determinations.

| | | |
|---|-------------------------------|---------------------|
| University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures | | |
| Revision #8 | TITLE: NCI CIRB Review | Page 6 of 16 |

Quality Assurance/Improvement Findings

1. At a minimum, the MCC Pediatric Oncology group reviews NCI CIRB pediatric protocols on a yearly basis and the MCC CRO reviews adult NCI CIRB protocols on a yearly basis at continuation review. The MCC Pediatric Oncology group and the MCC CRO review confirms the following:
 - the most current informed consent form was used;
 - the UK required HIPAA authorization or Waiver of Authorization form was used; and
 - the UK required informed consent form language was retained in the consent document. (See [NCI CIRB Review SOP](#) for *UK specific local context informed consent language and HIPAA authorization language to be added to the NCI CIRB informed consent template*).
 - the regulatory file for the study is maintained in accord with UK and sponsor policy. In addition, MCC CRO staff verifies these regulatory elements (listed above) during its quarterly auditing process. The MCC CRO staff notifies the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review.
2. The MCC CRO, and the MCC Pediatric Oncology group sends written reports of the findings to the RCO following review by the DSMC as outlined in the MCC DSMC SOP's. The DSMC Chair forwards a copy of the final audit report to the RCO. The RCO forwards the report to the IRB Chair and/or ORI Director. More immediate contact with the RCO is used when necessary.

REFERENCES

[21 CFR 50.25](#)
[21 CFR 56.111](#)
[45 CFR 46.108](#)
[45 CFR 46.111](#)
[45 CFR 46.116](#)
[45 CFR 46.117](#)
[45 CFR 46 Subparts C](#)

University of Kentucky (UK) specific informed consent language to be added to the National Cancer Institute, Central Institutional Review Board (NCI CIRB) informed consent template.

Note to preparer: The following is wording that the UK ORI/IRB requires to be added to the NCI CIRB consent document before enrolling subjects at the University of Kentucky. UK specific language should be added to the appropriate section of the NCI consent document. This language should not replace language in the NCI consent document, but should be presented as additional, site-specific information. Remove the word "SAMPLE" from the title of the approved form.

This document includes the University of Kentucky's local context language that was approved by the NCI-CIRB on **/**/****.

For pediatric oncology studies only: *If pediatric bone marrow transplant is specified in the study design, insert the following language into the section of the approved form that describes the Blood and Marrow Transplant procedure:*

Stem cell transplantation (SCT) for children, if indicated, will take place at another COG Hospital that is certified to perform that procedure on children. The University of Kentucky Children's Hospital is not a designated pediatric blood and marrow transplant (BMT) institution.

Insert the following language into the section entitled: What happens if I am injured because I took part in this study? Note: If this section does not appear in the approved consent, then also insert the UK section title: What happens if you get hurt or sick during the study?

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm may be your responsibility; or may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); or may be paid by Medicare or Medicaid if you are covered by Medicare, or Medicaid (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare [1-800-633-4227] or Medicaid 1-800-635-2570). A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

Use existing CIRB approved consent signature series, with the addition of the following signature lines, if applicable. Do not duplicate if signature lines are already present in the CIRB consent form.

*Signature of research subject's legal representative (if applicable)

Date

*Printed name of research subject's legal representative
(if applicable)

*If applicable, please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject

Signature of Principal Investigator or Sub/Co-Investigator

University of Kentucky (UK) specific assent language to be added to the National Cancer Institute, Central Institutional Review Board (NCI CIRB) informed consent template for pediatric protocols (assent for subjects age 12-17 years of age)

CHILD'S ASSENT FORM
CHILDREN'S ONCOLOGY GROUP

DIVISION OF PEDIATRIC HEMATOLOGY-ONCOLOGY
UNIVERSITY OF KENTUCKY MEDICAL CENTER

Title: NCI-CIRB- XXXX
Title of Study

Study-specific information is copied from the section of the COG/CIRB-approved protocol: Youth Information Sheet for 12-17 Year Old Subjects. It is then formatted using larger font and assent tense.

For studies involving reproductive risk, the following paragraph is added:

The doctors told you that you should not participate in this study if you are pregnant or breast-feeding, or planning to father a baby during the treatment. If it is possible for you to become pregnant or to father a child, you should only be in this study if you make sure to use reliable birth control. You can ask your doctor about birth control methods that are approved for use during this study.

(If parents will be informed of the results, this sentence will be used.) To treat you on this study, the doctors will perform a lab test to make sure that you are not pregnant, and these test results may be shared with your parents.

The following UK Assent Language will be added to the Youth Information text:

If something makes you feel bad while you are in the study, you will tell Dr. _____, or your other doctor, or your parent. Also you can ask them any questions you might have about being in the study.

Signing this paper means that you have read this or it has been read to you and that you want to be in the study. If you decide not to be in the study, you do not need to sign this paper. Being in the study is up to you and your parents and no one will be mad if you do not sign this paper or if you change your mind later. You have been told about this study and why it is being done and what to do, and you agree to be in the study.

Patient's Signature

Date Signed

Name of Individual Who Provided Explanation to the Subject

Date:

Signature of Investigator

Revised 8/6/2018

University of Kentucky (UK) specific informed consent language to be added to the National Cancer Institute, Central Institutional Review Board (NCI CIRB) informed consent template.

Note to preparer: The following is wording that the UK ORI/IRB requires to be added to the NCI CIRB consent document before enrolling subjects at the University of Kentucky. UK specific language should be added to the appropriate section of the NCI consent document. This language should not replace language in the NCI consent document, but should be presented as additional, site-specific information. Remove the word "SAMPLE" from the title of the approved form.

This document includes the University of Kentucky's local context language that was approved by the NCI-CIRB on **/**/****.

For pediatric oncology studies only: If pediatric bone marrow transplant is specified in the study design, insert the following language into the section of the approved form that describes the Blood and Marrow Transplant procedure:

El trasplante de células madre (SCT, por sus siglas en inglés) para niños, si está indicado, se llevará a cabo en otro hospital del COG que esté certificado para realizar ese procedimiento en niños. El Hospital de Niños de la Universidad de Kentucky no es una institución designada para hacer trasplantes de sangre y médula ósea (BMT).

Insert the following language into the section entitled: What happens if I am injured because I took part in this study? Note: If this section does not appear in the approved consent, then also insert the UK section title: What happens if you get hurt or sick during the study?

Es importante que comprenda que la Universidad de Kentucky no tiene fondos reservados para pagar el costo de cualquier atención o tratamiento que pueda ser necesario porque se lastima o se enferma mientras participa en este estudio. Además, la Universidad de Kentucky no pagará ningún salario que pueda perder si se ve perjudicado por este estudio.

Los costos médicos relacionados con su cuidado y tratamiento debido a daños relacionados con la investigación pueden ser su responsabilidad; o puede ser pagado por su asegurador si está asegurado por una compañía de seguros médicos (debe preguntarle a su asegurador si tiene alguna pregunta con respecto a la disposición a pagar de su asegurador en estas circunstancias); o puede ser pagado por Medicare o Medicaid si está cubierto por Medicare o Medicaid (si tiene alguna pregunta sobre la cobertura de Medicare / Medicaid, debe comunicarse con Medicare llamando al 1-800-Medicare [1-800-633-4227] o a Medicaid). 1-800-635-2570).

Su aseguradora o Medicare / Medicaid pueden requerir un copago / deducible de usted, incluso si su aseguradora o Medicare / Medicaid han acordado pagar los costos. El monto de este copago / deducible puede ser sustancial.

Use existing CIRB approved consent signature series, with the addition of the following signature lines, if applicable. Do not duplicate if signature lines are already present in the CIRB consent form.

*Firma del representante legal del paciente
de la investigación (si es aplicable)

Fecha

*Nombre en letras del representante legal del paciente de investigación
(si es aplicable)

* Si corresponde, explique la relación del representante con el paciente e incluya una descripción de la autoridad del representante para actuar en nombre del paciente.

Firma del Investigador Principal o Sub / Co-Investigador

"I, Michelle Gross hereby certify that I am fluent in the English and Spanish languages and that the above 4 pages is an accurate and complete translation of the attached document

09\08\2018

A handwritten signature in black ink, appearing to be 'MG' followed by a stylized flourish.

University of Kentucky (UK) specific assent language to be added to the National Cancer Institute, Central Institutional Review Board (NCI CIRB) informed consent template for pediatric protocols (assent for subjects age 12-17 years of age)

FORMULARIO DE CONSENTIMIENTO DEL NIÑO

GRUPO DE ONCOLOGIA PARA NIÑOS

DIVISIÓN DE HEMATOLOGÍA PEDIÁTRICA-ONCOLOGÍA
UNIVERSITY OF KENTUCKY MEDICAL CENTER

Título: NCI-CIRB- XXXX
Título del estudio

Study-specific information is copied from the section of the COG/CIRB-approved protocol: Youth Information Sheet for 12-17 Year Old Subjects. It is then formatted using larger font and assent tense.

For studies involving reproductive risk, the following paragraph is added:

Los médicos le dijeron que no debe participar en este estudio si está embarazada o en periodo de lactancia, o si planea tener un bebé durante el tratamiento. Si es posible quedar embarazada o tener un hijo, solo debe participar en este estudio si se asegura de usar un método anticonceptivo confiable. Puede consultar a su médico sobre los métodos anticonceptivos aprobados para su uso durante este estudio.

(If parents will be informed of the results, this sentence will be used.) Para tratarla en este estudio, los médicos realizarán una prueba de laboratorio para asegurarse de que no está embarazada, y los resultados de estas pruebas pueden compartirse con sus padres.

The following UK Assent Language will be added to the Youth Information text:

Si algo le hace sentir mal mientras estás en el estudio, le dirá al Dr. _____, a su otro médico o a sus padres. También puede hacerles cualquier pregunta que tenga sobre su participación en el estudio.

Firmar este documento significa que ha leído esto o que le han leído y que desea participar en el estudio. Si decide no participar en el estudio, no es necesario que firme este documento. Estar en el estudio depende de usted y de sus padres y nadie se enojará si no firma este documento o si cambia de opinión más adelante. Le informaron sobre este estudio y por qué se está haciendo y qué hacer, y usted acepta participar en el estudio.

Firma del paciente

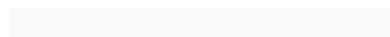
Fecha de Firma

Nombre del individuo que proporcionó la explicación al paciente

Fecha:

Firma del investigador

Revised 8/6/2018



"I, Michelle Gross hereby certify that I am fluent in the English and Spanish languages and that the above 1 page is an accurate and complete translation of the attached document

09\08\2018

A handwritten signature in black ink, appearing to be the initials 'MG' with a stylized flourish at the end.

University of Kentucky
Pediatric Hematology/Oncology
XXXStudy SponsorXXX
xxxSponsor Reference Numberxxx

Study Title: **XXX**

CIRB or UK IRB #: **XXX**

Consent to Continue Participation (For Follow-up Only)
For Subjects Previously Enrolled by Parent(s) or Legally Authorized Representative

Subject Name: _____ **Date of Birth:** ____/____/____
(please print) (mm) (dd) (yyyy)

INVESTIGATOR INFORMATION

XXX PI Name XXX _____ *****_***_******
Principal Investigator Name Telephone Number

INTRODUCTION

You have been participating in the above-titled **XXXCooperative Group or Study SponsorXXX** research study for which your parents or legally authorized representative signed a consent form. Now that you are able to act on your own behalf, we are asking for your consent to remain in the study for follow-up only. With a separate form, we will also request your permission to release your follow-up health information for research purposes, in accordance with the privacy law, the Health Insurance Portability & Accountability Act (HIPAA).

All of the elements of informed consent in the enclosed consent document signed by your parents or legally authorized representative remain the same. All the procedures listed in the original consent form have been completed with the exception of follow-up.

By signing this form, you agree to have your research study follow-up at the University of Kentucky **XX Department NameXXX**. If you do not wish to continue follow-up on this study, other options will be discussed with you. You do not have to continue to participate in the study. You will not suffer any penalty or loss of benefits by leaving the study.

WHAT ARE THE RISKS OF THE RESEARCH STUDY?

There is a small risk that your protected health information may be released to an unauthorized person. Every effort will be made to maintain the confidentiality of your medical and research information. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

WILL YOU BENEFIT FROM CONTINUING PARTICIPATION IN THE STUDY?

There probably will be no medical benefit to you from participating in the study. We hope that information collected on your response to your study treatment will help other people in the future who are diagnosed with your disease. There are no plans for you to share in any profits from products or discoveries that may result from your continued participation in the study.

WHAT WILL IT COST TO CONTINUE TO PARTICIPATE?

There will be no cost to you for continuing to participate in the follow-up phase of this study.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

If you choose to consent to continue to follow-up on this study, we would like to continue to collect follow-up data on you for up to ten years after the last patient started on this research study. We would like you to participate in this study until that time. However, you may withdraw at any time. If you decide to stop participating in the study, we will encourage you to talk to the researcher and your regular doctor first.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about this research study or to report a research-related injury, you can contact the researcher **XXX** PI Name **XXX** at **XXX** 859-PIs-Phone **XXX**, at the Department of **XXX** Department Name **XXX** during business hours. After hours, call 859-323-5321 and ask for the **XXX** UK Specialty **XXX** doctor on call. Research staff people are available at 859-***-**** to answer any questions you may have about the research at any time.

If you have general questions about your rights as a participant in this research study, you can call the University of Kentucky Office of Research Integrity at 859-257-9428 or toll free at 1-866-400-9428.

SIGNATURES

I have read the information given above. The investigator or his/her designee has personally discussed with me the research study and has answered my questions. I have been given sufficient time to consider if I should continue to participate in this study.

I hereby consent to continue to take part in this study as a research study subject.

Subject's signature indicating consent

Date: _____

Investigator or specific individual who has been designated to obtain consent (Signature)

Date: _____

XXX Investigator Name **XXX**
Investigator (Signature)