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.
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 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, assent, HIPAA template language into that document.

4. When the PI obtains PRMC approval, the Pediatric Oncology staff and the PI complete and submit the required CIRB application documents to the NCI CIRB. The protocol title 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 the most recent version of the study protocol and submits it to the MCC PRMC chair for expedited review.
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 personnel 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 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: If appropriate, the PI submits a request for a Waiver of Authorization on the UK form to the UK IRB for review.

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 their determination.

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.

The following are sections and/or wording that the UK ORI requires to be added to the NCI CIRB informed consent form template before enrolling subjects at the University of Kentucky.

WHO IS DOING THE STUDY?

The person in charge of this study is _________________ (Principal Investigator, PI) of University of Kentucky, Department of ________________(list department). If the PI is a student they should disclose this fact, and, add the following sentence: He/She is being guided in this research by _______________ (Advisor). There may be other people on the research team assisting at different times during the study.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

State in basic lay language reasons a subject could be excluded from volunteering, such as being a smoker, being under 18 years of age, being pregnant, etc.). Include only those events/conditions which would not be pre-determined by a review of records or by the decision of an attending physician. Include those events/conditions of which the potential subject would ordinarily be aware.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky AB Chandler Medical Center in Lexington, Kentucky. You will need to come to its [specify name of clinic and/or UK inpatient facility where subject will report for study exams and procedures] [choose one: one time/ several times/ many times] during the study.

[If pediatric bone marrow transplant is specified in the study design, insert the following section: 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.]

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research.

Please note that what is considered the usual treatment for your cancer may vary at different institutions. Therefore the procedures/tests listed in the section titled ‘What extra tests and procedures will I have if I take part in this study?’ may not reflect what are considered extra tests at the University of Kentucky. At the University of Kentucky the following are considered extra tests/procedures done for this research study: (insert the tests/procedures that are considered above standard of care at UK)

Therefore, these costs:
will be your responsibility; or
will be paid by the sponsor (insert sponsors name here); or
the sponsor (insert sponsors name here) has agreed to pay $XXX of those costs; 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 these costs); 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 at 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.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

Include the following information if participating in other studies could put your subject at risk:
You may/may not (please indicate choice) take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call _____________ (PI’s or medical supervisor’s name) at _____________ immediately. [For greater than minimal risk research add information for one (or a combination) of the following as a contact for subjects to use in case of illness or injury during his/her participation in the study:
1. a dedicated pager number;
2. a dedicated cell phone number;
3. other reliable 24-hour contact option at your discretion, and/or
4. as deemed necessary, in addition to one or more of the above, referral to 911 for an emergency.]

__________________ (PI’s or medical supervisor’s name) will determine what type of treatment, if any, that is best for you at that time.

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 (add study specific language by selecting appropriate options… e.g.,

will 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.

You do not give up your legal rights by signing this form.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, ______________________ at ___________. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

• (List all of the protected health information* to be collected for this protocol/study such as demographic information, results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures as well as medical history. Also include Medicare Health Insurance Claim Numbers (HICN), Social Security Numbers (SSN) and Employer Identification Numbers (EIN) if regulated by Medicare reporting provisions)

The Researchers may use and share your health information with:

• The University of Kentucky's Institutional Review Board/Office of Research Integrity.
• Law enforcement agencies when required by law.
• University of Kentucky representatives.
• (UK Hospital if applicable. You must include this item if you are providing financial compensation for study participation or obtaining lab results from UKMC.)
• (If your research fall under the purview of a government agency (i.e., FDA, NIH, etc) list them in this section of the authorization form.)
• (Investigational Drug Service (IDS) if investigational drugs are dispensed through IDS.)
• (Center for Clinical and Translational Science (CCTS) if CCTS staff are involved in the study.)
• (National Cancer Institute (NCI) for cancer related studies only)
• (List any collaborators, outside laboratories, etc.)
• (If applicable – list the sponsor's name and its agent(s) or government agency funding your research.)
• (List any other groups with whom the information may be shared.)
• (If applicable - statement that primary physician will be contacted if researcher in the course of the project learns of a medical condition that needs immediate attention.)

The researchers agree to only share your health information with the people listed in this document.

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.
You may not be allowed to participate in the research study if you do not sign the form. If you decide not to sign the form, it will not affect your:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky
- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: (name and contact information) to inform (him/her) of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

[Optional item: You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information.]

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky’s Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

[Insert any CIRB consent template signature statement here, e.g. “I agree to take part in this study”.]

(When developing the consent/authorization form, please format to ensure the signature lines fall on a page containing text.)

_________________________________ __________________________
Signature of research subject (if applicable:) Date
or *research subject’s legal representative

_________________________________ __________________________
Printed name of research subject (if applicable:) Representative’s relationship to or *research subject’s legal representative research subject

*(If, applicable) Please explain Representative’s relationship to subject and include a description of Representative’s authority to act on behalf of subject:
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

Name of [authorized] person obtaining informed consent/HIPAA authorization Date

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. Wagner, 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
CONSENT TO CONTINUE PARTICIPATION AND HIPAA AUTHORIZATION (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. We also are requesting 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). It protects individually identifiable health information (protected health information) that doctors and nurses transmit to others as part of the normal conduct of these studies.

All of the elements of informed consent in the attached 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.

In order for you to continue your participation in this research study, UK XXX Department Name XXX must first obtain your written authorization to use or disclose your protected health information (PHI) for the research purposes described during the informed consent process and in the attached consent form. This form provides that authorization. By signing it, you authorize the use and/or disclosure of your PHI described below.

WHAT PROTECTED HEALTH INFORMATION WILL BE USED OR DISCLOSED?

Patient Identifiers to continue to be collected:

For follow-up in most cooperative group studies, the collection of patient identifiers is limited to the following items. However, for certain studies it may be necessary to collect additional information. The
collection of this information is critical to maintain acceptable levels of data quality as well as scientific validity.

Patient Identifiers Reason

Patient Name Allows researchers to verify the accuracy of research case numbers across multiple pieces of information submitted throughout the life of the study.

Zip Code Federal Requirement

Country Federal Requirement

Elements of Dates All dates relevant to the study will be collected to insure the appropriate analysis of the data including dates of diagnosis, treatment etc.

Social Security Number The SSN allows for more efficient searching of patient data and provides a means of tracking patients for study follow-up data collection. Additionally, the SSN is required to access the national health death index, used by researchers.

Medical Record, Prescription and Other Unique Identifying Numbers This allows the researchers another level of information to ensure the accuracy of the data. It also maintains the appropriate link to the institution submitting the data and ensures that the appropriate records are audited.

What personal health information do the researchers want to continue to use in follow-up?

The entire research record and any medical records held by the University of Kentucky that are needed for the research may be used and disclosed, including:

• The history and diagnosis of your disease
• Current and previous treatments you received
• Other medical conditions that may affect your treatment
• Laboratory, radiology and pathology test results
• Follow-up information about your general health, the status of your disease, and late effects from treatment.
• (If applicable) Blood or tissue samples may have already been sent for research testing as part of this study. If you prefer not to have the study doctors save or use your samples for future testing, you should notify XXX Principal Investigator NameXXX at the University of Kentucky XXX Department name and address XXX that you would like those samples thrown away.

WHAT WILL YOUR PROTECTED HEALTH INFORMATION BE USED FOR?

If you consent to continue to participate, your protected health information can continue to be used to meet the goals of XXXProtocol TitleXXX the study for which your parent or guardian gave their permission for you to enroll. Those goals are described in the copy of the original consent that we are giving you with this document.

WHO WILL RECEIVE, AND/OR USE OR DISCLOSE THE INFORMATION?

This form will continue authorization for the following person(s) and/or organization(s) to disclose, use, and receive the information specified in this form:

• The Principal Investigator and the University of Kentucky employees involved with the research study
• The Institutional Review Board and the Office of Research Integrity at the University of Kentucky
• (If applicable) XXX Cooperative Group or Study Sponsor XXX
• (If applicable) The Data and Safety Monitoring Board, an independent group of experts assigned to review the data from this research throughout the study
• (If applicable) The National Cancer Institute (NCI), the National Institutes of Health (NIH) and the Office for Human Research Protection (OHRP), and the Federal Food and Drug Administration (FDA)
• (If applicable) The Pediatric Central IRB of the National Cancer Institute (NCI-CIRB)
• (If applicable) The National Cancer Data Base (NCDB) and the Kentucky Cancer Registry

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.

You do not have to sign this consent and authorization. If you decide not to sign this consent/HIPAA authorization:

• You will not be able to take part in the research study for which you have already enrolled, as described above.
• It will not affect general medical care, payment or enrollment in any health plans or affect eligibility for benefits.

After signing the Authorization, you can change your mind and:

• Not let the researcher disclose or use your protected health information (revoke the Authorization).
• If you revoke the Authorization, you will need to send a written letter to: XXX Principal Investigator Name, Address, City, State, Zip XXX to inform him/her of your decision.
• If you revoke this Authorization, researchers may only use and disclose the protected health information already collected for this research study.
• If you revoke this Authorization your protected health information may still be used and disclosed should you have an adverse event (an ill effect).
• If you change your mind and withdraw the authorization, you will not be allowed to continue to participate in the study.

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 Kentucky Clinic 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.

Date:
Subject’s signature indicating consent

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

XXX PI Name XXX
Principal Investigator (Signature)

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