UNIVERSITY of LOUISVILLE

COMBINED BIOMEDICAL ICF/RESEARCH AUTHORIZATION
INSTRUCTIONS - Revised 12-2012

HUMAN SUBJECTS PROTECTION PROGRAM OFFICE

University of Louisville
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*An asterisk following the item number indicates that the information is to be included in the informed consent if it is relevant to the study.

Item#	Statement Descriptions	Source of Requirement
	PRE-CONSENT INFORMATION – Include those that are applicable. Delete those that are not. Sponsor assigned protocol number: Industry Contracts assigned number: Office of Grants Management assigned number: Sponsor(s) Name and Address: IRB assigned number: Investigator(s) Name, Degree University Department, and Address: Site(s) where study will be conducted: Phone number for Subjects to call with Questions:	Local IRB
	INTRODUCTION AND BACKGROUND INFORMATION	
1.	State that the subject is invited (not asked) to participate. If the consent is for a parent to sign, use "You/Your child (referred to as you in the rest of this document) are…"	Local IRB
2.	Indicate the subjects are participating in a research study and explain why this subject is being invited.	Federal, basic
3.	Name the University investigator and list their degree. If there are Co-investigators, also list their names and degrees. .	Local IRB
4.*	Indicate the approximate number of local subjects in the study. If this is a multi-center study, include a statement on the number of subjects expected to be enrolled across all sites.	Federal, when appropriate
	PURPOSE	
5.	Include a lay term description of the scientific purpose of the study. This description should be written so subjects reading at the eighth grade level can understand the terms.	Federal, basic
	PROCEDURES	
6.	Indicate the expected duration of the subject's participation in the study. If appropriate, give the amount of time in hours, days, months or years. If the study involves multiple sessions, estimate the amount of time for each session. ▪ As much as possible, describe in lay terms all study and screening procedures that may be required. ▪ Clearly explain in an itemized fashion which procedures are standard of care and which are experimental (research). ▪ If questionnaires are used (e.g., Quality of Life), state that the subjects may decline to answer any question that may make them uncomfortable, or, if applicable, which may render them prosecutable under law. If you wish to add a procedures table or schema to show the subjects a timeline of study visits and when study procedures will be done, use a statement like the following: "See Appendix __ (page __) for the procedures table that gives a timeline of study visits and when study procedures will be done. "	Federal, basic, Local IRB interpretation
7.	State whether hospitalization is required and, if so, where the subject will be hospitalized.	Local IRB
8. *	If the study involves randomization, state this and explain the term; e.g., a process 'like flipping a coin'.	Local IRB, interpretation of federal

Item#	Statement Descriptions	Source of Requirement
	POTENTIAL RISKS	
9.	Describe any reasonably foreseeable physical risks and/or discomforts to subjects. Include information on known side effects of the specific drugs, devices or procedures. In a tabular form, list probable and possible physical risks and their frequency of occurrence. Select the header line you wish to use and delete the other line. List either a percentage or a descriptive term such as "likelihood greater than 40%, less likely (1 – 39%), rare (less than 1%) and severity (mild, moderate, severe, unknown). Describe all risks in lay terms. Medical terms should be stated in lay language. The table included in the template is a suggested method of displaying research risks. It is not the only way to display risks, but it is a method favored by the local IRB. If you use this tabular format and give percentages by each entry, you are much less likely to have the IRB return your consent form with the request that you display risks in some other manner. If you do not have enough information to give percentages, then state this in your application as justification for not applying the percentages. NOTE: You may also insert a statement like: "See Appendix __ (page __) for a table of foreseeable risks associated with this study." There may also be risks with associated procedures performed as part of the research study. List procedures and the related risks associated with the clinical procedures that are part of the study. Describe the procedures in lay terms. If additional consents for procedures are required, state that the subject may need to sign more than one consent. If applicable, include risks of blood draws, contrast dye, and radiation exposure.	Federal, basic; Local IRB interpretation
10.*	Other risks that should be included are: psychological risks, social risks, economic risks, and/or legal risks. These should be addressed as appropriate to the protocol for the study.	Federal, when appropriate
11.*	If there is little or no human risk data available, include information acquired on studies in animals.	Federal, when appropriate
12.*	Include a statement concerning unforeseeable risks: "In addition, you may suffer harms that we have not seen before."	Federal, when appropriate
	POSSIBLE PREGNANCY RISKS	
13.*	If there are no risks to pregnant females or females of child bearing age, you do not need to include any of the following statements in the informed consent. If pregnant or nursing women are excluded from the study, state this and add a statement supporting the rationale for not including pregnant women. For studies that involve the use of drugs, devices or procedures with risks to the fetus in females of child bearing potential, add one of the following statements (a, b, or c): a. There is evidence of potential for birth defects b. Animal studies have shown potential for birth defects and there are no human studies; c. There are no known animal or human data on the potential for birth defects. The following statements are the template language to be used in this section. If the template language is not applicable to your study, remove it from the informed consent. State: "You should discuss pregnancy risks with your doctor before signing this consent form. Women who are pregnant or breast feeding may not participate in this research study. If you are pregnant or become pregnant, your unborn child may suffer harms that we have not seen before. If you or your partner becomes pregnant while in this study, the sponsor may ask to follow the outcome of the pregnancy. If you agree to allow the study doctor to follow your pregnancy, you will be asked to read and sign a separate consent form for permission to follow the outcome of your pregnancy." **(A separate pregnancy consent template is available from the HSPPO website.)**	Federal, when appropriate; Local IRB interpretation

	If applicable state: "If you are a man taking part in the study and your partner becomes pregnant, the study doctor may ask you to ask your partner for permission to follow her pregnancy. If she agrees, she will be asked to sign a separate consent form mentioned above." State: "Before starting this research study, females able to have children will have a pregnancy test. Talk to your doctor about the best method of birth control to use while you are in this study (**tailor this instruction to the needs of the study**). It is important that you call your study doctor at _____ right away if you become pregnant or father a child during the course of the study. If you or your partner becomes pregnant, you may have to decide whether or not to end your pregnancy.	
14.*	If applicable state: "We do not know the effects of <study drug name> on an unborn baby. There is a risk that your unborn baby could be harmed if you become pregnant during your participation in the study. (If you ask, your study doctor will discuss the possible risks to your unborn child and your options should you become pregnant while in this study.)"	Federal, when appropriate; Local IRB interpretation
	RESEARCH INVOLVING GENETIC INFORMATION	
15.*	*****Include only if the research involves genetic testing. **This paragraph should be inserted before the Benefits Section.** If the research involves a separate consent form for genetic testing, include the following paragraphs in the separate consent form. A new 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. This law generally will protect you in the following ways: 1. Health insurance companies and group health plans may not request your genetic information that we get from this research or use your genetic information when making decisions regarding your eligibility or premiums. 2. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Employers with 15 or more employees, health insurance companies, and group health plans must follow this law. This new law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.	Federal, when appropriate
	BENEFITS	
16.	List the benefits of participating in the study. If there are none, state: "You may not benefit by participating in this study. The information collected may not benefit you directly; however, the information may be helpful to others."	Federal, basic
	ALTERNATIVES	
17.*	List <u>alternative procedures or courses of treatment</u>, if any, that might be advantageous to the subject. If these treatments are available without participating in the study, state that the treatment is available without being a part of the study. Also state that the subject may choose to receive standard of care treatment or comfort care treatment, and not participate in this study..	Federal, basic
18.*	**RESEARCH RELATED INJURY – Review the options and use the template language to choose the correct option on who pays for injury.** Pick the option that best matches the proposed contract language and remove the other options. You may have to edit some language in the selected paragraph to make an exact fit to the contract language. **If the sponsor pays for injury, include this paragraph.** If you are injured by being in this research study, the study doctor will arrange for you to get medical treatment. The sponsor will pay for any reasonable medical costs related to	Federal, basic; local interpretation

	the treatment of your injury. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call your study doctor (provide/insert PI's name and 24 hour phone number). Instruction: a. If limiting treatment sites, the investigator must state specifically where the treatment will be provided. **If the Sponsor does not pay for injury, include this paragraph.** If you are injured by being in this research study, the study doctor will arrange for you to get medical treatment. The sponsor, the study site, or your study doctor has not set aside money to pay for treatment of any injury. You and your insurance will be billed for the treatment of these injuries. Before you agree to take part in this research study you should find out whether your insurance will cover an injury in this kind of research. You should talk to the study doctor or staff about this. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call your study doctor (provide PI's name and 24 hour phone number here)..	Federal, basic; local interpretation
	COMPENSATION	
19.*	**Choose one of the following options:** **S**tate: You will not be compensated for your time, inconvenience, or expenses while you are in this study. **(or)** You will be paid **(state the form or method of payment; $ in cash, given a gift card, other)** for your time, inconvenience, or expenses while you are in this study. **(If subjects will be compensated, state how much. Explain how payments to study subjects are pro-rated and distributed equally, if appropriate, or distributed according to time commitment and potential discomfort for each visit.) (The following sentences must be in the consent if subjects are paid.)** Because you will be paid to be in this study the **[University of Louisville and/or the sponsor (select the appropriate one or both if both will pay)]** may collect your name, address, social security number, and keep records of how much you are paid. You may or may not be sent a Form 1099 by the University. This will only happen if you are paid $600 or more in one year by the University. We are required by the Internal Revenue Service to collect this information and you may need to report the payment as income on your taxes. You can still be in the study even if you don't want to be paid.	Local IRB
	COSTS	
20.*	**Choose the appropriate information from the options listed below.** Pick the option that best matches the proposed contract language and remove the other options. You may have to edit some language in the selected paragraph to make an exact fit to the contract language. Where you see the following symbol below **[**]**, insert the following KRS language for any study that is a cancer trial: "According to Kentucky State Law (KRS Chapter 304.17A-136, Coverage for Cancer Clinical Trials) insurance plans may not deny coverage for routine treatment costs incurred during your participation in a cancer study if your insurance plan would have covered those costs had you not been in the study. This law is for your protection. For more information about this law, ask your study doctor." **<u>Option A: Sponsor pays for all costs AND there will be no co-pays or deductibles AND Sponsor pays for Research Related Injury:</u>** "There will be no additional costs to you for participating in this research study over the usual costs of your routine care outside of this research study. You will not be billed for	Federal, when appropriate

the tests, medications and procedures that are done for this research study. The charges for these items will be paid for by the Sponsor. These include (list all).

However, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance."

Option B: Sponsor pays some costs AND Sponsor pays for Research Related Injury

"There may/will **(choose one or the other*)*** be additional costs to you for participating in this research study over the usual costs of your routine care outside of this research study. You will not be billed for the following office visits, tests, medications, and procedures that are done for this research study: (list all not billed). The charges for these items will be paid for by the Sponsor. However, you or your insurance company will be billed for all other office visits, tests, medications and procedures related to this research study which may total approximately (state the approximate $$ amount billed to the subject).

Additionally, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study. You will be responsible for paying your co-pay that is associated with any office visit, test, medication or procedure. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance. If your insurance company does not pay for your bills associated with this study, you will be responsible for paying them." **[**]**

Option C: Sponsor pays for all costs, there will be no co-pays or deductibles BUT Sponsor does NOT pay for Research Related Injury

"Unless you are injured, there will be no additional costs to you for participating in this research study over the usual costs of your routine care outside of this research study. You will not be billed for the office visits, tests, medications and procedures that are done for this research study. The charges for these items will be paid for by the Sponsor. These include (list all research related procedures).

However, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study, and for treatment of any research related injury you experience. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance. If your insurance company does not pay for your bills associated with this study, you will be responsible for paying them. **[**]**

If you are injured by this research, there will be additional costs for participating in this research study."

Option D: Sponsor pays some costs BUT Sponsor does NOT pay for Research Related Injury

"There may/will **(choose one or the other*)*** be additional costs to you for participating in this research study over the usual costs of routine care outside of this research study. You will not be billed for the following office visits, tests, medications and procedures that

are only done for this research study: (list all not billed). The charges for these items will be paid for by the Sponsor. However, you and your insurance company will be billed for all other office visits, tests, medications and procedures related to this study which may total approximately (state the approximate $$ amount billed to the subject).

Additionally, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study, and for treatment of any research related injury you experience. You will be responsible for paying your co-pay that is associated with any test, medication or procedure. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance. If your insurance company does not pay for your bills associated with this study, you will be responsible for paying them. **[**]**

If you are injured by this research, there will be additional costs for participating in this research study."

Option E: Sponsor pays for nothing

"There will be additional costs to you for participating in this research study over the usual costs of your routine care outside of this research study. You and/or your insurance company will be billed for all office visits, tests, medications and procedures involved in this research study and as part of your routine medical care outside of this research study. Examples include doctor's office visits, blood tests, x-rays, CT scans, EKGs, medications, and hospital stays. You will be responsible for paying your co-pay that is associated with any office visit, test, medication or procedure. None of the charges from the doctor's office, pharmacy or hospital during your participation in this study will be paid for by the Sponsor. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If your insurance company does not pay for your bills associated with this study, you will be responsible for paying them. **[**]**

If you are injured by this research, there will be additional costs for participating in this research study."

Option F: Insurance is billed for everything AND the Sponsor will pay ALL denied charges upon insurance denial

[Note: Some affiliated study sites do not allow the use of this option-check with the Research Office at your study site(s)]

You and/or your insurance company will be billed for all office visits, tests, medications and procedures involved in this research study. Additionally, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study. Examples include doctor's office visits, blood tests, x-rays, CT scans, EKGs, medications, and hospital stays. You will be responsible for paying your co-pay that is associated with any test, medication or procedure. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance.
[**]

If your insurance company does not pay for your medical bills associated with this study, please bring them to the study doctor for payment by the Sponsor. The Sponsor will pay for all bills related to this research study which are denied by your insurance company.

	<u>Option G: Insurance is billed for everything and the Sponsor will pay some denied charges upon insurance denial</u> [Note: Some affiliated study sites do not allow the use of this option-check with the Research Office at your study site(s)] "There may/will **(choose one or the other*)*** be additional costs to you for participating in this research study over the usual costs of you routine care. You and/or your insurance company will be billed for all office visits, tests, medications and procedures involved in this research study. Additionally, you or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care outside of this research study. Examples include doctor's office visits, blood tests, x-rays, CT scans, EKGs, medications, and hospital stays. You will be responsible for paying your co-pay that is associated with any office visit, test, medication or procedure. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance. **[**]** If your insurance company does not pay for your bills associated with this study, please bring them to the study doctor. The Sponsor may pay for some of the bills related to this research study denied by your insurance company. Otherwise, you will be responsible for paying them."	

Item#	Statement Descriptions	Source of Requirement
	HIPAA RESEARCH AUTHORIZATION	
21.*	**This section should only be included if the PI will access PHI. Use the statement shown below exactly.** "The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). Examples of PHI are your name, address, and birth date together with your health information. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this research study. Your PHI may not be used or shared without your agreement, unless it meets one of the HIPAA exceptions." State and federal privacy laws protect your health information. In most cases, health information that identifies you can be used or shared by the research team only if you give your permission by signing this form. If you sign this form your health information will be used and shared to answer the research questions described above and to make sure that the research was done correctly. The time period when information can be used or shared ends when all activities related to this study are completed. **Choose the following statement that is applicable for your research:)** "Your access to your health information will/will not **(choose will or will not)** be limited during this study. **(If "will not" is chosen, delete the following sentence)** When the study is over, you will have the right to see your health information related to this research." **(If applicable, add the following if there are sub-studies with this protocol:)** **"**This research has an optional sub-study. If you agree to take part in this sub-study you may be asked to sign a separate informed consent and "Research Authorization" form. This allows the use and sharing of your PHI by those listed in the "Research Authorization." **(State: "**You do not have to sign this form. If you do not sign this form you may not participate in the study and health information that identifies you will not be shared with the research team." **Site(s) where health information about you will be used or shared for this research:** (List the appropriate affiliated and/or non-affiliated sites where the research will take place. You may use a table or a simple list.. For a list of choices, we have provided for your reference the ULRF Clinical Sites and Faculty Practice Group Sites at the end of this document in Appendix II. Choose and include any of the sites that will participate as part of your research study.)	Federal, when appropriate
	PROTECTED HEALTH INFORMATION (PHI) THAT WILL BE USED OR SHARED FOR RESEARCH	
22.*	(List any PHI that will be used or shared for research. Some choices are listed at the end of these instructions. Only include the choices that are applicable for your research.)	Federal, when appropriate

Item#	Statement Descriptions	Source of Requirement
	CONFIDENTIALITY	

23.	"Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.
	
	Your information may be shared with the following:
	• The sponsor **(name the sponsor, and CRO if applicable)** and others hired by the sponsor to oversee the research
	• The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Privacy Office and others involved in research administration at the University
	• The local research team
	• Researchers at other sites participating in the study **(if applicable)**
	• People who are responsible for research and HIPAA oversight at the institutions where the research is conducted
	• People who are responsible for billing, sending and receiving payments related to your participation in the study
	• Government agencies, such as: **(Add to or remove from this list as needed)**
	  o Office for Human Research Protections (OHRP),
	  o Office of Civil Rights,
	  o Food and Drug Administration (FDA) **(include only if study involves a drug or device),**
	• Data Safety Monitoring Board(s) related to the study **(include only if study involves a drug**, **device, or procedures greater than minimal risk)**
	Others: **(If other are added, include this heading. If not, remove it.)**."	

	REVOCATION OF RESEARCH AUTHORIZATION	

24.	**State: "**You may cancel the permission you have given us to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you cancel your permission:
	
	• We will stop collecting information about you.
	• You may not withdraw information that we had before you told us to stop.
	  o We may already have used it or shared it.
	  o We may need it to complete the research.
	• Staff may ask your permission to follow-up with you if there is a medical reason to do so.
	
	To cancel your permission, you must complete a written "Revocation of Research Authorization" form located at the end of this document. You may also obtain a copy from your study doctor, designated personnel or from the Human Subjects Protections Program Office website (http://louisville.edu/research/humansubjects/subject-information). "
		Federal, when appropriate

	INFORMATION AVAILABLE ON CLINICALTRIALS.GOV	
25.*	**(Include this section if this study is an applicable clinical trial that is published or required by law to be published on ClinicalTrials.gov.)** "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time." **(Remove "as required by U.S. Law" if this study is registered because of ICMJE**	Federal, when appropriate

	guidelines. A copy of the ICMJE guidelines is posted on the HSPPO website at: http://louisville.edu/research/humansubjects/investigator-research-team-information)	
25.	•	Federal, basic; Local IRB interpretation
	SECURITY	
26.	"The data collected about you will be kept private and secure in a _____". **(Finish this sentence by describing how the subject information will be protected from disclosure and physically secured, e.g., locked cabinet, encrypted, password protected computer or secured server, limited access, locked area, etc.).**	Federal, basic; Local IRB interpretation
	CONFLICT OF INTEREST – (Include this section if this is a sponsored study.)	
27.	"This study involves a conflict of interest because ***(Select one of the following three options. Delete the remaining options and instructions prior to submission.)*** (1) the institution, (2) the investigator or (3) the institution and investigator will be compensated for your participation in it. This compensation is used to pay for the costs of doing this study. If you want to know, ask the investigator how ***Select one of the following three options. Delete the remaining options and instructions prior to submission.*** (1) the institution, (2) the investigator or (3) the institution and investigator) will benefit by your participation in the study."	Local IRB
	VOLUNTARY PARTICIPATION	
28.	**State:** "Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, you won't be penalized or lose any benefits for which you qualify. If you decide to be in this study, you may change your mind and stop taking part at any time. If you decide to stop taking part, you won't be penalized or lose any benefits for which you qualify. You will be told about any new information learned during the study that could affect your decision to continue in the study. "	Federal, basic; Federal, when appropriate
	TERMINATION	
29.*	State: "Your study doctor or the study sponsor has the right to stop this study at any point. Your study doctor may take you out of this study with or without your okay. Reasons why this may occur include: **(disclose anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent)** " **(Include the following language if there are adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.)** "If you stop taking part in this study, it could harm you. You will be asked to follow these steps for your own safety: **(Describe all procedures for orderly termination of participation.)"**	Federal, when appropriate
	PARTICIPATION IN OTHER RESEARCH STUDIES	
30.*	(Indicate whether or not the subject may participate in this study if they are currently participating in another research study. Add:) "It is important to let your study doctor know if you are in another research study."	Local IRB
	CONTACT PERSONS	
31.	Template language is mandatory for this section. This language is already listed in the ICF template.	Federal, basic
	RESEARCH SUBJECT'S RIGHTS	
32.	Template language is mandatory for this section. This language is already listed in the ICF template.	Federal, basic; Local IRB interpretation
	CONCERNS AND COMPLAINTS	
33.	Template language is mandatory for this section. This language is already listed in the ICF template.	Local IRB

Item#	Statement Descriptions	Source of Requirement
	ACKNOWLEDGMENT AND SIGNATURES	
34.	Template language is mandatory for this section. This language is already listed in the ICF template.	Federal, basic; Local IRB
35.	Provide a line and caption for "Subject Name (Please Print)" and provide a line for the Subject to Sign and date. Beneath this, provide a line and caption for the "Printed Name of Legal Representative." To the right add a line and caption for "Signature of Legal Representative" and then "Date Signed". Beneath this provide a line and caption for "Relationship of Legally Authorized Representative to Subject"	Local IRB
36.*	Provide lines for the printed names and signatures of the parties involved (Person Explaining Consent Form, and Investigator). Include a separate "date signed" line for each signature line. In studies involving minors aged seven or above, the minor involved will sign an assent form to indicate awareness of his/her role in the study.	Federal, basic
38.*	Below the last signature line, provide a list of Investigators, their Degrees, and their 24 hour phone numbers with area code.	Local IRB
	REVOCATION OF AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR HEALTH INFORMATION FOR RESEARCH	
39.	Final page of the combined document. Information required by OCR	Federal, basic; Local IRB interpretation

APPENDIX I: CHOICES TO INCLUDE IN THE RESEARCH AUTHORIZATION SECTION OF THE COMBINED CONSENT/RESEARCH AUTHORIZATION, if applicable

Site(s) where health information about you will be used or shared for this research. Any of these choices may be listed under the appropriate heading in the combined consent/authorization.

Affiliated Sites:

University of Louisville (Do not delete this site.)
Jewish Hospital & St. Mary's Healthcare (Kentucky One Health)
Norton Healthcare, Inc., including Kosair Children's Hospital
University of Louisville Hospital/J. Graham Brown Cancer Center

Unaffiliated Sites:

Louisville Metro Public Health & Wellness
KY Cabinet for Health & Family Services
Seven Counties Services
List Others:

University of Louisville Research Foundation (ULRF) Clinical Sites –

Children & Youth Clinic
Dentistry Clinics (Undergraduate DMD; Graduate, Perio, Endo and Ortho; Oral Surgery and GPR at ACB; Faculty Practice, Graduate Pedodontic Clinic)
Neonatal Follow Up Program
UL Pathology Flow Cytometry Lab (BCC)
UL Pathology Special Procedures Lab
University Health Services (HSC and Belknap)
Weisskopf Child Evaluation Center
WINGS Clinic – (ACB)

Faculty Practice Group Sites –

University of Louisville Physicians (ULP)
Orthopedic Trauma Associates, PSC
University Cardiothoracic Surgical Associates, PSC
University Urology, PLLC
Other:

APPENDIX II: Protected health information (PHI) that will be used or shared for research

Consultation reports
Diaries and questionnaires
Discharge summaries
Specimens
Healthcare provider orders
History and physical exams
Laboratory, x-ray, and other tests
Records of your operation(s)
Medical progress notes
Photos, videotapes, or digital or other images
Records about the study device
Records about the study drug and other drugs you may be taking
Other:

If not looking at any of the data listed below, do not include in the consent.

THE INFORMATION WE MAY LOOK AT OR GATHER FOR THIS RESEARCH MAY ALSO INCLUDE:

HIV / AIDS status
Hepatitis infection
Sexually transmitted diseases
The diagnosis and treatment of a mental health condition
Other reportable infectious diseases
Drug and Alcohol Use History

Add this sentence to the ICF for the above reportable infections: "This study involves testing for _____. If you have a positive test, we are required by Kentucky law to report the results to the local Health Department nearest where you live or to the Kentucky Department for Public Health.

Add any other Appendices applicable to your study. If you choose to have a study schema **or** procedures table that gives a timeline of study visits and when study procedures will be done, you may add an Appendix for the timeline.

You may also choose to have a Risks Table included as an Appendix.