Pharmacokinetic Informed Consent Form

INFORMATION TO PARTICIPANTS

NAME OF STUDY:	A Phase 4, Open-Label, Single-Dose, Parallel-Group Study to Evaluate the Safety of 1 g of Cefazolin in Pediatric Subjects With a Weight of at Least 25 kg but Less Than 60 kg Scheduled for Surgery and the Safety of 2 g of Cefazolin in Pediatric Subjects With a Weight of at Least 60 kg Scheduled for Surgery
STUDY NUMBER:	HC-G-H-1601
STUDY SPONSOR:	B. Braun Medical Inc. 824 Twelfth Avenue Bethlehem, PA 18018 USA
STUDY DOCTOR (INVESTIGATOR):	[Investigator Name] [Site Address] [Office Hours Tel] [Out of Hours Tel]
[ETHICS COMMITTEE (EC) or INVESTIGATIONAL REVIEW BOARD (IRB):]	[EC/IRB Name] [EC/IRB Address] [Office Hours Tel] [Out of Hours Tel]

Why are you receiving this information?
You have already agreed to allow your child to participate in the clinical research study assessing the safety of cefazolin doses in children scheduled for surgery - the safety study.

As the parent, Legally Authorised Representative (LAR), the legal guardian(s), of _____ (enter patient/child's name), you are being asked to consider whether you would allow your child to participate in the pharmacokinetic (PK) part of the clinical research study. Pharmacokinetics, which is abbreviated PK, is described as what the body does to a drug, including the movement of the drug into, through, and out of the body. Your child is being asked to participate because the FDA has asked that approximately 40 children from this study agree to 4 additional blood collections taken during and after surgery to check the levels of the study drug in the blood. This additional consent form is required for participation in the PK part of the study.

This consent form does not repeat information contained in the consent form for the safety study. It focuses only on the PK part of the study. Participation in the PK part of the study is optional. You/ your child do not have to agree to take part in this PK part of the study. The following information describes the PK part of study and your child's role as a possible participant. Please read this information carefully and do not hesitate to ask your study doctor any questions to ensure that you are able to make an informed decision as to whether your child may participate. The PK part of this clinical research study is sponsored by a company called B. Braun Medical Inc., and B. Braun Medical Inc. is also sponsoring the safety study providing the study drug.

What is the purpose of this clinical research study?

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PK blood samples taken during and after surgery will be used to measure the amount of study drug that is in your child's body during different time points after the study drug is given. This will determine what the body does to the study drug, cefazolin, and will help confirm the safest and best doses of this drug in children who have surgery.

It is expected that approximately 40 children will participate in the PK part of the study. Within this group of 40 PK subjects, a minimum of 10 children are planned to be in the 10 to 13 years old age bracket to make sure that there is an adequate representation of this age group.

What procedures are involved?
If you provide consent for your child to participate in the PK part of the study, the following study procedures will be done:

- The legally authorized representative (LAR), for example: the parent, will be required to sign this Informed Consent Form (ICF).
- Depending on age, your child may also be required to sign a form that confirms his or her agreement to participate in the PK part of the study.
- Blood samples will be collected at the following 4 times after the study drug has been started on the day of surgery:
    - 0.5 to 1.0 hours
    - 2.0 hours
    - 3.0 hours
    - 4.0 hours

If the surgery is extended unexpectedly beyond 3 hours, the study doctor may decide that an additional dose of study drug is required. Depending on the timing of when the additional dose of study drug is given, the 4.0 hour PK blood sample may or may not be collected. It will not be collected if the additional dose of study drug is given before the 4-hour collection time. The study doctor will make that decision. Valuable research information will be obtained from each of the 4 planned PK blood collections so it will be ok if the 4th blood sample cannot be collected.

If you are not familiar with any of these procedures, please ask your study doctor to explain how they are performed.

If you decide for your child to participate in the PK part of the study, your child will not be required to make any extra visits in addition to the study visits required in the safety study.

How will the PK blood samples be collected?
The PK blood samples will be collected through a separate thin needle into a vein in your child's arm (or leg) on the opposite side of the body from where the study drug will be given. The needle will stay in place over a period of time, for about 4 hours after your child is given the study drug.

The amount of blood to be collected for each of these PK samples will be about ¾ teaspoon (4 mL). This adds up to a total of 3 teaspoons (16 mL) for all 4 PK blood samples. The total amount of blood collected for the PK samples plus the samples for the safety study is still well within the guidelines for safe blood collection amounts for children.

What is expected from you?
Permission to collect 4 blood samples is all that is expected from your child in the PK part of the study. The study rules are no different from the ones in the safety study.

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What will happen at the end of the PK part of the study?
At the end of the PK part of the study your child will continue their participation in the safety study as planned.

What are the potential risks and discomforts?
There may be some temporary discomfort, bruising, swelling and/or, in rare circumstances, infection at the place where the needle for PK sample blood collection is inserted into the body.

Are there any reproductive risks?
There are no known reproductive risks for participation in the PK study.

Pregnancy: If your child becomes pregnant during your participation in the study, her participation may be stopped. However, details about the pregnancy may be collected.

What are the advantages and disadvantages of participation in the study?
By taking part in the PK part of the study, your child will provide new information that may benefit other patients in the future.

Will you be informed if new information becomes available during the study?
Your study doctor will inform you and your child in a timely manner of any new information learned during the study that may affect your willingness to continue your participation.

Who can you contact with further questions?
You or your child may ask questions about this consent form or the study at any time (before or during the course of the study). If you have additional questions, or if your child experiences a study-related injury, contact the study doctor using the details provided in the table on the first page of this information sheet.

If you have a complaint or question about your child's rights as a research subject, you may contact the [Ethics Committee (EC) or Institutional Review Board (IRB)] using the details provided in the table on the first page of this information sheet. This is a group of scientific and non-scientific individuals who review research studies with the safety and welfare of research subjects in mind.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What happens if you change your mind?
Your child's participation in the PK part of this study is voluntary. Your child does not have to take part, and may discontinue at any time and for any reason without prejudice to his or her future medical care by the investigator or at the study site, and without penalty or loss of benefits to which he or she is otherwise entitled. If you or your child decide to withdraw from PK participation at any time, tell the study doctor and follow instructions. It may be helpful if you/your child could explain your reasons. No prejudice will be shown toward your child for medical care or participation in future research.

In addition, your study doctor or the sponsor may withdraw your child from the PK part of the study for your child's own safety, even if you/your child wish to continue to participate, for example:

- If your child does not meet the protocol eligibility criteria
- If you/your child do not follow the study rules

- If your child experiences a serious or intolerable reaction that in the study doctor's opinion requires withdrawal from the study
- If your child becomes pregnant
- If you or your child request to withdraw informed consent or Health Insurance Portability and Accountability Act (HIPAA) authorization
- Any other reason warranting withdrawal at the discretion of the study doctor with approval of B. Braun Medical Inc.

If your child's participation in the PK part of the study is stopped early there will be no additional procedures for you to follow.

Are there any costs if you decide to participate?
There is not cost to participate in the PK part of the study.

Is there a payment if you decide to participate?
You/your child will not receive payment for participation in the PK part of this study.

Will you receive compensation if you are injured as a result of the study?
If any injury or illness should occur to you that is reasonably judged by the Investigator and Sponsor to be a direct result of the PK part of the study, medical treatment will be provided. The Sponsor of this study will pay for reasonable and routine costs of such treatment (a) if not covered by your personal insurance, by a governmental program or by any third party and (b) provided you have followed the directions given by the study doctor. The sponsor does not offer to provide compensation other than that described above. If you would like further information about compensation for research-related injuries, please contact the study doctor. Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information. You and your child do not give up any of your legal rights by agreeing to this and signing this form.

Will the personnel involved in the study receive any payment?
The [investigator] receives payment from B. Braun Medical Inc. who is the sponsor of this study.

Statement of Consent
- I have read and understand the statements in this informed consent form
- I have had the opportunity to ask questions and I am satisfied with the explanations provided
- I agree to allow my child to take part in the PK part of this study.
- I will receive a copy of this signed consent form to keep. I understand that the signed original will remain on file with the study doctor

_____

Legally Authorized Representative or Legal Guardian
Printed Name Signature Date

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Witness (if applicable)

Printed Name Signature Date

- I have presented the study and answered the Legally Authorized Representative or Legal Guardian's questions
- I will give the subject/legal representative a copy of this signed and dated Informed Consent

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Presenter (Investigator/Delegate)

Printed Name Signature Date