*Concise Summary*

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This is a research study to find out if a drug called ABC-123 is safe and to determine the safest, most effective dose of the drug.

Depending on when you enroll in this study, you will receive higher doses of ABC-123 until the safest and best tolerated dose is reached. ABC-123 is given via *i.v.* infusion in the clinic at MUSC. You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last 4-5 hours. Infusions of study drug will be given during week 1 of each 3-week cycle. After two cycles, you will be evaluated and you may be able to continue receiving ABC-123 if you have had no bad reactions to the study drug or disease progression.

If ABC-123 is proven effective, you may benefit from participating in this study, but that cannot be guaranteed. There are risks to this study drug that are described in this document. Some risks include: nausea, diarrhea, low white & red blood cell count, being tired & weak, fever, muscle pain and radiation risks from CT scans. You do not have to participate in this study to have your condition treated. Alternative treatments include X, Y or Z.

If you are interested in learning more about this study, please continue reading below.

*Concise Summary*

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patients with ABC.

Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to the pain clinic three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.

Participation in this study may improve your physical well-being, but that cannot be guaranteed. The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality. You do not have to participate in this study to have your condition treated. Alternative treatments include medications to treat your pain, steroid injections or surgery.

If you are interested in learning more about this study, please continue to read below.

*Concise Summary*

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate the safety and effectiveness of ABCD-123 compared to placebo (an inactive substance) in the treatment of XYZ.

If you agree to participate, you will undergo a screening visit where you will have blood drawn and a physical exam to assess your health. If your test results show you are able to continue, you will be randomly assigned to either ABCD-123 or placebo. You will have a 50:50 chance of being on ABCD-123 (like the flip of a coin). Neither you or your study doctor will know what group you are in. You will take the study medication once a day for 12 weeks, and will have study visits weekly for the 12 weeks, and a follow up visit 4 weeks later, so that the total duration you are in the study will be approximately 16 weeks. You will be asked to complete questionnaires about XXX at each visit, and blood will be drawn again at week 12.

There are risks to the study drug that are described in this document. Some of the risks include difficulty sleeping, nausea and dizziness. If you are randomized to placebo, you will go without treatment for your condition for 16 weeks. Also with randomization, neither you nor your doctor will decide to what group you are assigned. If you have a strong opinion about what treatment you receive or would like your doctor to decide what treatment you receive, you should not participate in this study.

It is unknown if this ABCD-1234 will help your condition, however you will be followed closely with weekly visits, and you can stop participating in the study at any time. It is possible that your symptoms will improve, but that cannot be guaranteed. You do not have to participate in this study to have your condition treated. Alternative treatments include X, Y or Z.

If you are interested in learning more about this study, please continue to read below.

*Concise Summary*

You are being asked to allow your child to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD).

Participants in this study will have a blood sample collected during their clinical blood draw and tissue that would otherwise be discarded from your clinical procedure will be obtained for research purposes. The tissue will be tested in the laboratory. Your child’s medical record will also be reviewed to collect information on current medications and previous medical procedures. Parents of participating children will also be asked to complete a questionnaire. Your child’s participation is complete once the medical record and questionnaire have been reviewed, and the tissue and blood sample have been collected.

There is a risk of loss of confidentiality, but the researchers will code the samples and research information to protect privacy. There are no direct benefits to you or your child, but it is hoped this information may help us to develop some target treatments for GI complications in children with IBD.

This is not a treatment study; if you choose not to have your child participate, you child will continue to undergo the regularly scheduled clinical procedure.

If you are interested in learning more about this study, please continue to read below.