ALBANY MEDICAL CENTER
ALBANY, NY 12208

CONSENT TO TAKE PART IN A HUMAN RESEARCH STUDY

AND

HIPAA Authorization (Health Information Privacy Rights)

Title of research study: Clinical Trial of the Treatment of Acute Sinusitis with Standard-Dose versus High-Dose Amoxicillin/Clavulanate (3968)

Principal Investigator: Paul Sorum, MD, Professor Internal Medicine and Pediatrics, Albany Medical College

Site: Albany Medical Center, Internal Medicine and Pediatrics, Latham, NY

Study-related phone number: (518) 262-7500

You are being asked to take part in a research study because you are being treated with antibiotics for acute sinusitis.

What you should know about a research study

- Please read this consent form carefully. The consent will explain the purpose, risks and possible benefits of taking part in this research study.
- The main goal of regular medical care is to help each patient. The main goal of a research study is to learn things to help future patients.
- We cannot promise that this research study will help you.
- Just like regular medical care, your taking part in this research study can result in harmful effects that may be minor or serious.
- Someone will explain this research study to you. Make sure all your questions are answered before you make a decision.
- Being in a research study is voluntary. Whether or not you take part in this research study is up to you. Also, if you agree to take part now, you can change your mind later on.
- Whatever you decide, it will not affect your access to health care, treatment and services not related to the research.

1 - Why is this research study being done and what is its purpose?

The Infection Disease Society of American currently recommends treating acute sinusitis in adults with a standard dose of amoxicillin combined with clavulanate. The amoxicillin does the work of killing the bacteria. The clavulanate is added to counteract some of the factors that can make bacteria

resistant to amoxicillin. There is good reason to think that a higher dose of amoxicillin would be more effective in killing bacteria in the sinuses than the standard dose. Indeed, a study in children has demonstrated this. No study has, however, been done in adults.

The purpose of this study is, therefore, to find out if high-dose amoxicillin will led to faster and greater improvement in symptoms in adults than standard-dose amoxicillin (both combined with the same amount of clavulanate). A secondary purpose is to see if the impact of high-dose amoxicillin/clavulanate depends on what types of bacteria are growing in people's noses.

2 - Who is doing the research study?

Paul Sorum, MD, is in charge of this research study. We expect that 300 patients at the Albany Med Medicine and Pediatrics office in Latham will be in this research study. You will be in this research study for one month.

3 - What can you expect if you take part in this research study?

You will fill out a questionnaire about symptoms that the nurses will give to all patients with respiratory symptoms (SNOT-16).

You will have a sample of nasal secretions collected on a nasal swab. The doctor, physician's assistant, or nurse will insert the swab into the front part of your nose and swirl it slightly. You may insert and swirl the swab yourself if you prefer; the clinician will make sure you insert it far enough.

You will receive 2 bottles of study medications. You will take 1 dose twice a day for 7 days (a total of 14 doses). A dose is 1 pill from each bottle, taken at the same time. You will thus take 2 pills twice a day for 7 days, a total of 28 pills. It is best to space each dose 12 hours apart.

The bottles contain two different medications: amoxicillin (either the standard or the high dose) and clavulanate. The pills in the two bottles will look different.

If you have trouble swallowing pills, you may break the pills in half along the score line (only). You may not crush or chew the pills.

Take each dose at the start of a meal or snack.

Take all 14 doses, even you feel better, unless you and our office decide otherwise (see below).

The dose of amoxicillin you get will be chosen by chance, like flipping a coin**.** Neither you nor the doctors and nurses will choose what dose you get. You will have an equal chance of being given each dose. Neither you nor the clinicians will know subsequently which dose you are taking.

You will be called by someone from the office to ask you questions about how you are doing. These calls will take place at 3 points: day 3 (48-72 hours after you take the first dose of antibiotics), day 10, and day 30. Each call should take no more than 5-10 minutes.

We will also give you a copy of the questions you will be asked at day 3. If, for any reason, we have not gotten in touch with you by 72 hours, please fill you the questionnaire by yourself. We will pick it up from you later.

If you become very ill, you need, of course, to go to the Emergency Department. If you are getting worse (but do not need to go to the Emergency Department) or if you develop disturbing side effects, please call the office at 518-262-7500. A doctor is on call at all times when the office is closed.

You may ask us at any time to change your treatment (and drop out of the active part of the study).

If you drop out of the active part of the study, we will still call you, if you do not mind, at days 3, 10, and 30.

4 - What are the risks and possible discomforts?

RISKS/SIDE EFFECTS OF amoxicillin/clavulanate

Common

- Diarrhea. This is caused largely by the clavulanate, which each treatment group receives in equal amount. In one study, 16.7% of people taking high dose amoxicillin with clavulanate for bronchitis got diarrhea, while 14.4% of those taking standard dose amoxicillin with clavulanate got diarrhea.
- Abdominal pain. This occurs less frequently than diarrhea. It is uncertain if it occurs more frequently if taking high dose than if taking standard dose.
- Vaginal discharge and itching (in women). This also occurs less frequently than diarrhea. It is uncertain but possible that it occurs more frequently if taking high dose than if taking standard dose. It can be treated quite easily.

Occasionally

- Mild-moderate allergic reactions, in particular, a rash or hives.

Rare but Serious

- Rarely in death (about 1 in 50,000 people taking amoxicillin). This risk is not greater with the high dose than with the standard dose of amoxicillin.Severe allergic reactions, in particular, difficulty breathing and/or a dangerous fall in blood pressure, resulting in a visit to the emergency department, possibly in hospitalization, and very

Like other antibiotics, the medication may reduce the effectiveness of birth control pills. It is advised to add another method of birth control for the duration of the pill pack.

In addition to these risks, you may have an unknown side effect that may be a minor problem or may be so severe as to cause death.

RISKS of nasal culture

The nasal culture may be mildly uncomfortable and, occasionally cause minor bleeding.

RISKS of disclosure of private information

We will keep your personal information private and protected. Nonetheless, it may be possible for others to find a way to get ahold of this information. We will not, however, be collecting sensitive data that, if inadvertently revealed, is likely to cause you any difficulties or embarrassment.

5 - What are the possible benefits?

We cannot promise any benefits to you or others from your taking part in this research. If, however, high-dose amoxicillin/clavulanate is more effective, your symptoms may improve faster if you are, by chance, in the high-dose group.

Possible benefits to others are, primarily, either a change in the treatment of acute sinusitis or a reaffirmation of standard treatment.

6 - If you do not want to take part in the research study, are there other choices?

You are free to choose not to take part in this research study. You and the clinician will then decide how best to treat your illness, including taking antibiotics if appropriate.

7 - If you have any questions or problems, whom can you call?

You should call Paul Sorum, MD, (or the doctor on call) at (518) 262-7500 if you have any questions or problems or think you have been injured**.**

If you cannot reach Dr. Sorum, and have complaints about this research study, or if you have questions about your rights as a research subject, you may call the Albany Medical College Office of Research Affairs at (518) 262-5182.

8 - What information will be kept private?

We cannot guarantee privacy. However, efforts will be made to keep your personal information and other health information, including research study records and medical records, private. You will be identified as a research subject for medical records and billing purposes.

Authorization (Permission) to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

If you have questions about your privacy rights, please call the AMC Research Privacy Officer at (518) 262-0671.

What information about you may be used and given to others?

Information that identifies or can be used to identify you such as your phone number, your date of birth, your health information, and other similar personal information may be collected for this study.

Your health information that may be used for this study and given to others can be in different forms and may include:

- Written information, such as the record of your initial visit and follow-up phone calls
- Electronic information, which is information stored in computer systems, such as your electronic health record and in the study's data base
- Verbal information, such as in phone calls made as part of this research study
- Information obtained during this research about

- Past and Present Medical History
- Physical exam
- Laboratory results
- Questionnaires
- Study procedures, treatments and follow up

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. 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.

Who will be able to use your health information and give it to others?

Information about your health may be used and given to others by the study doctor and his study team. They will see the research information during and after the study.

Who will be able to get your health information and how and why will they use it?

Information about you and your health that might identify you may be given to others to carry out the research study.

Information about you and your health that might identify you may be given to:

- US Food and Drug Administration (FDA) and or the Department of Health and Human Services (DHHS).
- The Albany Medical Center Institutional Review Board (IRB), which is a group of people responsible for protecting your rights and welfare and is not involved in the conduct of the clinical study.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be made known.

If you give written permission to release your health information, the information may be shared with others and no longer be protected by the privacy regulation.

Will you be able to see your research records?

You will not be able to see your research record until the end of the study. At that time, it will be scanned into your electronic health record, and you will be able to obtain a copy of it.

When will the research end and when will your health information no longer be used?

This permission will remain in effect until the study has been completed, which will take place within the next two years.

What if you don't want to give your permission to be included in the research and don't want anyone to give out and use your health information?

If you do not give us permission by signing the permission (authorization) form, you will not be able to be in this research.

You can give us permission to use and give out the health information listed above for the purposes described above by signing this permission (authorization) form.

Can you stop taking part in the study early?

You may decide to not continue in the research study at any time by telling Dr. Sorum or the other clinicians and staff at the Medicine and Pediatrics office. It will not affect your access to health care, treatment and services not related to the research.

You may cancel your permission for us to use and disclose your health information at any time. You do this by sending written notice stating you wish to cancel your permission. Send this to Dr. Sorum at the Albany Med Medicine and Pediatrics office (724 Watervliet-Shaker Road, Latham 12110). If you cancel your permission, you will not be able to continue being in this study.

When you cancel your permission, no new health information that might identify you will be gathered after that date. Information gathered before you cancel your permission may still be used and given to others. They might use the information to complete analysis and/or reporting for this research.

9 - Can anyone else remove you from the study?

Dr. Sorum or another of the clinicians may decide to remove you from the study if he or she determines that it is against your interests to continue in it or if we are not able to contact you for follow-up.

We will tell you about any new information that may affect your health, welfare or choice to stay in the research including any new findings that develop from this research during the course of the research.

10 - What else do you need to know?

We will give you a signed and dated copy of this form.
Taking part in this research study will lead to no added costs to you or your insurance company. The antibiotics and the nasal culture will be free of charge.

If you are injured as a result of taking part in this research study, medical services needed to treat such injury will be made available to you at our office and at Albany Medical Center Hospital. No funds have been set aside for the cost of the medical treatment, and it will be billed to you or your insurance company. AMC will not accept financial responsibility for the cost of such services. This paragraph relates only to billing and payment for services provided, and does not release AMC from responsibility for its negligence or intentional wrongdoing, if any. By signing this consent form, you have not given up any of your legal rights.

11 - Contact information

It is very important that we be able to contact you by telephone in 3, 10, and 30 days to find out how you are doing.

Please indicate the telephone number(s) we should call.

Day 3 Daytime: _____

Evening: _____

Day 10 (if different) Daytime: _____

Evening: _____

Day 30 (if different) Daytime: _____

Evening: _____

PERMISSION OF RESEARCH SUBJECT AND HIPAA AUTHORIZATION

Approval of research subject:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
Consent obtained by:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)		**Title**	
Witness:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
A witness is required when the subject cannot read and the consent document was read to the subject. The sponsor may also require a witness.			