CONSENT TO TAKE PART IN RESEARCH

Dartmouth-Hitchcock Medical Center

A Phase II Study to Establish the Efficacy of Synthetic Human SecretiN in Human Acute Pancreatitis (SNAP) Study

Principle Investigator: Timothy B. Gardner MD MS

Introduction: You are being asked to take part in a research study. Taking part in research is voluntary.

You are being asked to take part in this study because you have been admitted to the hospital with acute pancreatitis.

Taking part in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information to help patients in the future.

Your decision whether or not to take part will not influence your current or future medical care, Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of the study is to learn about using a drug called SECRETIN for the treatment of acute pancreatitis. Currently there are no drug treatments for acute pancreatitis that have been shown to improve the disease. Besides controlling your pain and giving you fluids through your intravenous catheter, no treatments have been shown to be beneficial to improving acute pancreatitis.

In order to learn about SECRETIN and its effect of acute pancreatitis, 30 patients will receive SECRETIN and 10 will be observed receiving standard treatments, which is meant to have no effect. We would like you to participate in the study so that we can observe your treatment in the hospital – YOU WILL NOT BE RECEIVING ANY NEW DRUGS. We will compare your treatment in the hospital with those patients who will be given SECRETIN later. We will then evaluate how each group does in terms of how long it takes for your pain to improve and

whether or not patients develop any side effects from SECRETIN. We will also study some of the blood drawn daily while you are in the hospital.

Will you benefit from taking part in this study?

There is little chance you will personally benefit from being in this research study. We hope to gather information that may help people in the future.

What does this study involve?

While you are in the hospital, we will observe you for three days. Each day we will test some of your blood that will be drawn as part of your routine medical care. We will ask you every day how much pain you are having.

If you agree to be in the study, you will be visited 2-4 times per day by the study nurse. We will ask you every day to rate your pain on a 1-10 scale. We will use the blood drawn every morning as part of your medical care to examine different chemicals to see how you are responding to the medication.

Your participation in the study will last only while you are in the hospital.

Screening Tests:

There are no screening tests to enter the study. You are being approached because you have been hospitalized with acute pancreatitis. If you choose to take part, then you will enter the study and we will ask you how you are feeling once daily.

What are the options if you do not want to take part in this study?

Instead of being in this study you have the following options:

- The standard or common plan for someone in your situation is to receive pain medication and intravenous fluids. These will be given to you regardless of whether or not you participate in the study

If you take part in this study, what activities will be done only for research purposes?

If you take part in this study, the following activities will be done only for research purposes:

- Completing a daily pain survey
- Each day at the same time you are having your regular blood draws, we will take an additional small amount of blood, approximately 5 mls or 1 teaspoon for the study, to be analyzed for changes in some of the chemicals which your body makes when you have acute pancreatitis.

What are the risks involved with taking part in this study?

We do not anticipate any risks with your participation in the study because we will just observing your regular medical care. You should report any problems to your doctor or to the director of this study**:**

Timothy B. Gardner MD
603-650-6472

Other important items you should know:

- **Leaving the study:**

You may choose to stop taking part in this study at any time for any reason. If you decide to stop taking part, it will have no effect on the quality of your medical care.

- A description of this clinical trial will be available on www.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.

- If the results of this research are used to develop a product sold for a profit, you will not share in the profit.

- New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

- **Funding:** The ChiRhoClin Research Foundation provides funding for this research. ChiRhoClin, Inc. is the company which makes and sells SECRETIN.

- **Number of people in this study:** We expect 20 people to enroll in this study here and 20 at other study sites.

How will your privacy be protected?

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. We will not release any of your personal information to any agency or insurance group. All of your information will be kept in a locked filing cabinet and your data will be encrypted on the computer.

The information collected for this study will be used only for the purposes of research as stated earlier in this form.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere.

You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Committee for the Protection of Human Subjects (CPHS) at Dartmouth College
- ChiRhoClin, Inc.
- The United States Food and Drug Administration
- Ohio State University

In order to conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware *if your* PHI is disclosed to others, it may no longer be protected by federal privacy laws.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research director for this study: Dr. Timothy Gardner at (603 650-6472) during normal business hours.

If Dr. Gardner is not available, other members of the section of Gastroenterology will be available to answer your questions 24 hours per day at 603-650-5000.

If you have questions, concerns, complaints, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-6482 during normal business hours.

What about the costs of this study?

All additional tests/visits/procedures as described in the "If you take part in this study, what activities will be done only for research purposes?" section will be paid for by the study sponsors.

Insurance plans are billed only for study procedures that are the usual care for your condition.

Some of the medical care that you will receive during this study is the usual care a doctor would recommend for your condition. You or your insurance plan will be expected to pay for the costs of this usual medical care.

For assistance in determining your coverage, please call the billing specialist in DHMC Patient Financial Services at 603-653-1047 or 800-368-4783. Please provide the billing specialist with the protocol number, CPHS 30252.

Will you be paid to take part in this study?

You will not be paid for participating in this study.

What happens if you get sick or hurt from taking part in this study?

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- National Institutes of Health

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 650-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

Your responsibilities as a person taking part in this study

(1) Be aware it is important for your safety that the research team knows about your medical history and current condition.
(2) Notify the research team in advance if you plan to undergo any other medical treatment during this study, or are taking or plan to start taking any medications.
(3) Notify the research team immediately if you suffer any injury or unexpected reaction to the study medication or procedures.
(4) Seek treatment with the help of the research team if you suffer any injury or unexpected reaction to the study medication or procedures.
(5) Make reasonable efforts to follow the instructions of the research team.

CONSENT

I have read the above information about A Phase II Study to Establish the Efficacy of Synthetic Human SecretiN in Human Acute Pancreatitis (SNAP) Study and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this signed consent form.

Participant's Signature and Date PRINTED NAME

- Researcher or Designee Signature and Date PRINTED NAME