CONSENT TO TAKE PART IN RESEARCH

Dartmouth-Hitchcock Medical Center

Study Title: D19033 - An Education and Behavioral, Single-Center, Observational Cohort Study Evaluating the Effect of Emotion Regulation and Burnout on Medical Trainees' Learning and Documentation of Serious Illness Communication

Principal Investigator: Garret Wasp, MD

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 are a second-year internal medicine resident or a first-year hematology fellow at Dartmouth-Hitchcock Medical Center.

Your decision whether or not to take part in this study will have no effect on your academic standing or job status at Dartmouth-Hitchcock Medical Center. You will not be penalized or lose benefits to which you are otherwise entitled.

Please read this form carefully and ask questions if there is anything about this study that you do not understand.

Background and Purpose

It is important for physicians to have effective discussions with their patients about serious illnesses. Unfortunately, research has shown that physician communication during these discussions is often lacking key prognostic information and physicians often fail to discuss patient values. Barriers to effective communication about serious illness include physician's lack of training and difficulty dealing with the emotions of the patient.

Psychological theory suggests that emotion regulation is necessary for effective discussion about prognoses because both the physician and patient have emotional responses to the information being presented. Emotion regulation can be impaired by the emotional exhaustion ("burnout"), feelings of depersonalization, and feelings of low personal accomplishment commonly found in physicians completing their residency and fellowship training.

Because it is difficult to change behavior and communication style in humans, we hope to learn more about how to teach physicians to have effective discussions about serious illnesses. There are two goals of this study. The first goal is to test the relationship between the physician's skill in emotion regulation and level of burnout and them enacting learned communication skills during discussions. The second goal is to evaluate the efficacy of communication skills training on physician documentation, confidence, and observed communication skills over 12 months.

We expect approximately 42 residents and fellows to take part in this study. We also expect that more than half of these individuals will also consent to be part of the behavioral research study.

This study is partially funded by Norris Cotton Cancer Center and Dr. Maxwell Vergo.

Will you benefit from taking part in this study?
Taking part in this study may or may not benefit you. We hope to gather information that may help people in the future.

What will happen during this study?
As part of your graduate medical education, you are rotating with the palliative care team. Part of this rotation includes a formal communication skills training, participation in three simulated patient encounters with actors and structured feedback, and voluntary surveys on your communication confidence and other aspects of the training. These activities are not study activities.

Participating in this study would mean that in addition to your rotation and training you would also take part in the following study activities which will be done only for research purposes:

- Complete two questionnaires about your emotion regulation at training start, six, and twelve months after elective completion.
- Participate in a semi-structured interview three months after elective completion where you are asked about barriers and facilitators to having effective serious illness conversations. Interviews will be about 20-40 minutes and will be recorded.
- Review a list of patients that you have seen and indicate whether or not they are candidates for serious illness conversation.
- Receive electronic communications about your documentation habits relating to serious illness conversations.

You will take part in this study for 12 months (or less if DHMC employment ends before 12 months).

What are the risks involved with taking part in this study?
There is a risk of loss of confidentiality of your information that is used in this study. The research team will make every possible effort to keep your information private. More detail about how we use your personal information and protect your privacy is later in this form.

Faculty study team members responsible for the academic and professional evaluation of study participants will have only limited access to the study data and will not have access to identifiable information. By necessity, these faculty will take part in rating and providing feedback to participants during simulated patient encounters, so they will have access to the identifiable study data that they originate.

What if you no longer want to take part in this study?
Being in this study is voluntary. You can choose not to be in this study at any time. Leaving the study will not affect your academic standing or job status in any way. You will not be penalized or lose benefits to which you are otherwise entitled. Please tell the study staff if you are thinking about leaving the study.

Any new information related to this research will be made known to you if and when it becomes available. This may affect your decision to stay in this study.

Possible Study Termination
It is important for you to know that the study staff may stop the study at any time for any reason. It is also possible that you will be asked to leave the study.

How will your privacy be protected?
We are careful to protect the identities of the people in this study. We keep the information collected for this study secure and confidential.

In order to conduct this study, researchers need to use your personal information. The information collected as data for this study includes:

- Personal information that identifies you such as your name and your birth date.
- Information collected for research purposes such as survey/questionnaire responses and recorded interviews.

The information and identifiable collected for this study will be used only for the purposes of research as stated earlier in this form. Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes.

No publication or public presentation about the research described above will identify you.

By signing this form, you allow the research team to use your 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, Dartmouth College, and elsewhere.

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, and
- The Committee for the Protection of Human Subjects (CPHS) at Dartmouth College.

Your permission to use your 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.

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

Electronic information will be kept in a secure, password-protected, research database indefinitely. After the study is completed, research information is stored in Dartmouth College Records Management off-site storage. Documents are shredded on site after 50 years.

What if you decide not to give permission to use and share your personal health information?
If you do not allow use of your 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 information. You should let the researcher know if you want to cancel your permission. The research 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 with questions about this study?
You have the right to ask questions about the study at any time for any reason. If you have questions about this study you may call the principal investigator for this study: **Dr. Garret Wasp**, at **603-650-4344** during normal business hours.

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 (CPHS), at 603-646-6482 during normal business hours. The CPHS is the Institutional Review Board (IRB) for research at Dartmouth. An IRB is a group of people who reviews research to protect your rights as a study participant.

A description of this clinical trial will be available on 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.

What about the costs of this study?
There are no financial costs to you for taking part in this study. There could be costs associated with travel and time

Will you be paid to take part in this study?
Each participant will receive a $20 gift card at four timepoints throughout the course of their participation in the study, for a total of $80.

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

CONSENT

I have read the above information about: ***D19033 - An Education and Behavioral, Single-Center, Observational Cohort Study Evaluating the Effect of Emotion Regulation and Burnout on Medical Trainees' Learning and Documentation of Serious Illness Communication*** and have been given time to ask questions. I agree to take part in this study and understand that I will be given a copy of this signed consent form.

Participant's Signature	Date	PRINTED NAME

Researcher or Designee's Signature	Date	PRINTED NAME