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Protocol #: 4 Subject ID: Version #: 1

Version Date: Feb. 2017

# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** The Impact of Professional Coaching on Emergency Physician Well-Being, Burnout, Leadership Strengths, and Goal Attainment: A Pilot Randomized Controlled Trial.

**IRB#:** 16-010192

Principal Investigator: Richard C. Winters, MD, MBA and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family and friends before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep.



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## **CONTACT INFORMATION**

| You can contact             | At                                   | If you have questions about   |
|-----------------------------|--------------------------------------|---|
| Principal Investigator:     | Phone:                               | <ul> <li>Study tests and procedures</li> </ul>                          |
| Dr. Richard C. Winters      | (507) 255-7002                       | Research-related injuries or emergencies                                |
| <b>Study Team Contact:</b>  | Phone:                               | <ul> <li>Any research-related concerns or</li> </ul>                    |
| Emergency Department        | (507) 255-9353                       | complaints  |
| Research                    |                                      | <ul><li>Withdrawing from the research study</li></ul>                   |
|                             | E-mail:                              | <ul><li>Materials you receive</li></ul>                                 |
|                             | rstemergencydeptres@mayo.edu         | ■ Research-related appointments   |
|                             | Institution Name and Address:        |   |
|                             | Mayo Clinic                          |   |
|                             | RO_GE_GR_410ER                       |   |
|                             | 200 First St SW                      |   |
|                             | Rochester, MN 55905                  |   |
|                             | Phone:                               | ■ Rights of a research participant                                      |
| Mayo Clinic                 | (507) 266-4000                       |   |
| <b>Institutional Review</b> | Toll-Free:                           |   |
| Board (IRB)                 | (866) 273-4681                       |   |
|                             | (000) 273 1001                       |   |
|                             | Phone:                               | <ul> <li>Rights of a research participant</li> </ul>                    |
| Research Subject            | (507) 266-9372                       | <ul> <li>Any research-related concerns or<br/>complaints</li> </ul>     |
| Advocate                    | Toll-Free:                           | <ul><li>Use of your Protected Health</li></ul>                          |
| (The RSA is independent     | (866) 273-4681                       | Information   |
| of the Study Team)          | (333, 273, 1331                      | <ul> <li>Stopping your authorization to use</li> </ul>                  |
|                             | E-mail:                              | your Protected Health Information                                       |
|                             | researchsubjectadvocate@mayo.edu     | ,   |
| Research Billing            | <b>Rochester, MN:</b> (507) 266-5670 | <ul> <li>Billing or insurance related to this research study</li> </ul> |



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#### 1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are an academic emergency physician who has expressed interest in participating in this research study.

#### 2. Why is this research study being done?

The purpose of this research study is to evaluate the impact of professional coaching of academic emergency physicians on goal attainment, psychological well-being, burnout, leadership style, and adult level of development.

### 3. Information you should know

#### Who is Funding the Study?

James H. and Helen F. Crossingham Emergency Medicine Award is the funding source for the study. The Crossingham Endowment covers costs related to professional coaching.

#### **Information Regarding Conflict of Interest:**

Richard C. Winters, MD MBA is the Principal Investigator for this research study. Dr. Winters does not have direct authority for the hiring, promotion, or termination of employment for any potential participant.

## 4. How long will you be in this research study?

You will be in this research study for approximately 12 months.



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#### 5. What will happen to you while you are in this research study?

If you agree to participate you will be **randomized** to one of three groups: One-to-One Coaching, Group Coaching, or a Group Coaching Waitlist (control group). You will have a 1 in 3 chance of being assigned by chance to any of the three study groups. You and the Principal Investigator cannot choose your study group.

If you choose to take part in this study, you will be required to pay a fee of \$250 to partially cover the actual cost of the professional coaching. You will pay this fee just prior to the initiation of your coaching sessions.

Participants randomized to **One-to-One Coaching** meet for an initial 2-hour coaching session, followed by seven 1-hour coaching sessions every 3-weeks via private video conference. These eight sessions will take place over the course of 6 months.

#### Additional requirements for **One-to-One Coaching:**

- Complete a 30-minute online assessment of goal attainment, well-being, burnout, and leadership strengths (a) at study enrollment, (b) at 6-months after study enrollment, and (c) 12-months following study enrollment.
- Complete a 15-minute VIA Character Strengths Test online prior to One-to-One Coaching.
- Following the completion of the final coaching session, you will participate in a phone call with a co-investigator that assesses your experience of coaching.

Participants randomized to **Group Coaching** will begin group coaching approximately 6-months after your enrollment in the study. Group Coaching participants meet for 90-minutes each month for 6 months for facilitated professional coaching by video conference with a group of colleagues who hold academic appointments in Emergency Medicine.

#### Additional requirements for **Group Coaching:**

- Complete a 30-minute online assessment of goal attainment, well-being, burnout, and leadership strengths (a) at study enrollment, (b) at 6-months after study enrollment, and (c) 12-months following study enrollment.
- Complete a 15-minute VIA Character Strengths Test online prior to Group Coaching.
- Prior to your initial group coaching session, participate in a 75-minute private phone interview with the primary investigator to discuss the how you make decisions and make sense of the world.



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• Following the completion of the final coaching session you will participate in a phone call with a co-investigator that assesses your experience of coaching.

Participants randomized to the **Waitlist Control Group** will be offered group coaching at the completion of the 12-month study period. If you chose to participate at that time, six 90-minute group coaching sessions will occur over the course of six months. These group coaching sessions will be facilitated by Richard Winters, MD at no additional cost to participants.

#### Requirements for Waitlist Control Group:

• Complete a 30-minute online assessment of goal attainment, well-being, burnout, and leadership strengths (a) at study enrollment (b) and at 6-months after study enrollment.

How are coaching sessions conducted? Professional coaching will be provided by Richard Winters, M.D., M.B.A., a Senior Associate Consultant and Assistant Professor of Emergency Medicine at Mayo Clinic and an International Coach Federation (ICF) certified professional coach. Dr. Winters will conduct the coaching sessions via Skype Video. Coaching sessions are structured using the GROW (Goal, Reality, Options, Will) model. Dr. Winters will audio record each coaching session. The audio recording will be transcribed, anonymized, and analyzed to identify common themes.

#### If you agree to participate by signing this informed consent form:

- 1. You understand that participation in the study is strictly voluntary. Additionally, you understand that you have the right to drop out of coaching and the study at any time without prejudice.
- 2. You understand and agree that you are fully responsible for your physical, mental and emotional well-being during coaching, including your choices and decisions. You are aware that the process of coaching may bring up areas that cause emotional discomfort.
- 3. You understand that coaching is a comprehensive process that may involve all areas of your life, including work, finances, health, relationships, education and recreation. You acknowledge that deciding how to handle these issues, incorporate coaching into those areas, and implement my choices is exclusively your responsibility.
- 4. You understand that coaching does not involve the diagnosis or treatment of mental disorders as defined by the American Psychiatric Association. You understand that coaching is not a substitute for counseling, psychotherapy, psychoanalysis, mental health care or substance abuse treatment and will not use it in place of any form of diagnosis, treatment or therapy.
- 5. You agree that if you are currently in therapy or otherwise under the care of a mental health professional, to first consult with your mental health care provider regarding the advisability of working with a coach and that this person is aware of your decision to proceed with the coaching relationship.



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- 6. You understand that Dr. Winters will maintain the strictest levels of confidentiality with all information unless release is required by law and that coaching is not a protected setting for Peer Review.
- 7. You understand that coaching is not to be used as a substitute for professional advice by legal, medical, financial, business, spiritual or other qualified professionals. You must seek independent professional guidance for legal, medical, financial, business, spiritual or other matters. You understand that all decisions in these areas are exclusively yours and acknowledge that your decisions and actions regarding them are your sole responsibility.
- 8. You will contact Dr. Winters for each session on the agreed upon day at the specified time arranged through his secretary and will treat his secretary with the dignity and respect she deserves.
- 9. You understand that you should come to each session prepared to give your undivided attention. You will turn off call waiting, computer applications, and do your best not to be distracted.
- 10. You understand that if you wish to re-schedule a session, you must give 24-hour notice. You understand that Dr. Winters is willing to accommodate schedule changes; however, he cannot promise that he will always be able to work it into his schedule.
- 11. You understand that if you miss a session because of an emergency, the missed session will be rescheduled at a convenient time.
- 12. You understand that repeated absences or tardiness may result in elimination from the study and cessation of coaching.
- 13. You agree to keep confidential any discussions that occur during Group Coaching to protect the anonymity of the other participants being coached, their colleagues, their personal and professional contacts, and their institutions.

All data collected about you in this research study will be maintained for future research. Other researchers at Mayo Clinic who aren't involved with this study may ask to use your de-identified data for future research. Researchers at other institutions may also ask for a part of your de-identified data for future studies.

## 6. What are the possible risks or discomforts from being in this research study?

The possible risks or discomforts of this research study include possible invasion of privacy and probing for personal information in surveys and interviews. The process of coaching may bring up areas that cause emotional discomfort for the participant. The Principal Investigator/professional coach, Dr. Winters, will work to minimize such occasions.



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#### 7. Are there reasons you might leave this research study early?

Participation is strictly voluntary. You may decide to stop at any time without prejudice. You should tell the Principal Investigator or study staff members if you decide to stop.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time if it is in your best interest, if you don't follow the study procedures, or if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected. Additionally, if you request, we will destroy and exclude from the research data any specific information or all information collected from you during the course of the study.

We will tell you about any new information that may affect your willingness to stay in the research study.

## 8. What are the possible benefits from being in this research study?

You may not benefit from taking part in this research study. It is for the benefit of researching the effects of professional coaching on emergency medicine physician faculty goal attainment, leadership strengths, well-being, and burnout.

## 9. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.



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#### 10. Will you be paid for taking part in this research study?

There is no remuneration for participants in this research study.

#### 11. How will your confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Extensive measures are being taken to limit the risk of the subject being identified. Please review the following steps will be taken at each stage of the research process to protect your rights and welfare:

- When participants enroll in this research study, each one signs Informed Consent. Please refer to section 5. What will happen to you while you are in this research study?, which contains 12 things the participants must agree to, number 12 being, "I agree to keep confidential any discussions that occur during Group Coaching to protect the anonymity of the other participants being coached, their colleagues, their personal and professional contacts, and their institutions." Any participant found to have violated this agreement will be removed from the study immediately.
- At the beginning of every Group Coaching session, Dr. Winters will remind each
  participant to keep any discussion confidential to protect the anonymity of other
  participants.
- All coaching discussions take place via video conferencing. Audio recordings of the sessions will be anonymized (names and identifying particulars are erased) and then transcribed. All recordings will be destroyed immediately after proofread of transcription.
- Pseudonyms will be substituted in the transcripts for all names of persons, departments, organizations, cities, towns, and counties.
- The transcripts are then coded and analyzed using Grounded Theory Methodology and ATLAS.ti qualitative data analytic software to identify common themes for theory generation on physician well-being, burnout, leadership strengths, and goal attainment.
- The following serves as a sample transcript excerpt:

Coach: "What is on your mind?"

Physician: "I have been having difficulty delegating tasks. As you know, I asked physician-x to work on the efficiency of the OR schedule at hospital-x. We have been having difficulty with physician-y's specialty-y group putting on emergent cases that disrupt our workflow. And it is not getting taken care of."

Coach: "What would you like to have happen?"



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- To preserve the privacy of participants, participant names will not be on assessments or other study documents. Instead, each participant will create a unique 6-letter code name to be used as an identifier. The first 3 letters of the code will be the first 3 letters of their mother's maiden name. The last 3 letters of the code will be the first 3 letters of their father's first name.
- All documents will be stored in electronic format (REDCap) and access will only be granted to authorized study team members.
- Any coaching transcripts, recordings, or assessments for participants who dropout will be destroyed and excluded from research data.
- The reporting results of will be done at the group level. Every step will be taken to adequately disguise the participant's identity in any published materials or presentations.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

If the results of the research are made public, information that identifies you will not be used.

Your permission lasts forever, unless you cancel it.



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## **ENROLLMENT AND PERMISSION SIGNATURES**

| Your signature documents your permission to take part in this research. |      |      |              |  |  |
|---|------|------|--------------|--|--|
|   | / /  |      | AM/PM        |  |  |
| Printed Name  | Date | Time | 7 1141/1 141 |  |  |
| Signature   |      |      |              |  |  |