Permission to Take Part in a Human Research Study

Protocol Title: Trauma-Informed Care Competency Set Validation
Principal Investigator: Jennifer Potter
Description of Study Population: HMS Faculty, HMS students, Community Members
Version Date: 8-28-2020

About this consent form
Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. A copy of the form will be provided to you for your record.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at taylor_brown@hms.harvard.edu.

This research has been reviewed by the Harvard Longwood Campus Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Regulatory Affairs and Research Compliance (ORARC) at 617-432-2157 (or toll-free at 1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary
You are invited to take part in this research because of your expertise or lived experience in the domain of trauma-informed care. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

Participation will have no effect on employment status and supervisors will not have access to employees' responses. For participating students, participation will have no effect on participants' grades or academic standing, and academic supervisors will not have access to individual responses.

How many people will take part in this research?
About 60 people will take part in this research.

What can I expect if I take part in this research?
As a participant, you will be expected to complete 3 rounds of surveys. You will have 2 weeks to complete each survey. Each survey has approximately 60 questions and will take 60-90 minutes to complete. Your total commitment is estimated at 4 hours over a period of 12 weeks.

What are the risks and possible discomforts?

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Participants may have personal trauma histories or PTSD and may become distressed with the subject matter seen in the competencies. There are no explicit descriptions of trauma in the competencies, however the subject matter itself can be upsetting. It is probable that participants will experience some distress, however we anticipate that most participants will only have mild and temporary discomfort.

Are there any benefits from being in this research study?
There are no direct benefits to you from your taking part in this research. Possible benefits to society and medical education include increased adoption of trauma-informed care, and a greater number of medical students being trained to provide trauma-informed care.

What happens if I say yes, but I change my mind later?
You can leave the research at any time and it will not be held against you.

Will I be compensated for participating in this research?
You will not be compensated for your participation in this research.

What will I have to pay for if I participate in this research?
It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

There is always the risk of breach of confidentiality/privacy. All efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. No one except members of the research team will see the personal information. Your data will be de-identified once you complete each survey. Your information will be stored in a password protected file on encrypted computers during the study and destroyed after completion of the study. Each participant will be assigned a unique (anonymous) identifier (ie, P1, P2, P3), and only this de-identified information will be used during the research and publication process.