INFORMED CONSENT

Department of Nursing

TITLE OF STUDY: Fear of Recurrence as a Mediator of Illness Perception and Perceived Stress in Acute Myocardial Infarction Survivors.

INVESTIGATOR(S): Reimund Serafica, Sarah Zvonar

For questions or concerns about the study, you may contact
Sarah Zvonar at **(317)759-1487** or **Dr. Reimund Serafica at (702) 895-5746.**

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact **the UNLV Office of Research Integrity – Human Subjects at 702-895-2794, toll-free at 877-581-2794, or via email at IRB@unlv.edu.**

Purpose of the Study
You are invited to participate in a research study. The purpose of this study is to understand the thoughts and feelings of those who have had a cardiac event, such as a heart attack.

Participants
You are being asked to participate in the study because you fit these criteria:
(1) admitted with one of the following diagnoses: confirmed AMI-STEMI, confirmed AMI-non-STEMI, confirmed AMI-STEMI/non-STEMI unspecified, unstable angina, or coronary artery disease;
(2) aged 18 years or older;
(3) able to read and understand English;
(4) willing to be contacted for a six-week follow-up.

Procedures
If you volunteer to participate in this study, you will be asked to do the following: Complete surveys in the hospital and complete the surveys again six weeks after you were in the hospital.

Ph.D. candidate Zvonar will also look in your medical record for information about your heart attack. This information includes the type of heart attack, lab levels, and vital signs when you entered the hospital, any infections or viruses at admission, catheterization lab or surgery, and outcomes at 6 weeks including readmissions to the hospital, and death.

Benefits of Participation
There will not be direct benefits to you as a participant in this study. However, we hope to learn how fear of recurrence or fear of another heart attack occurs after surviving a heart attack or heart-related event.

Risks of Participation

There are risks involved in all research studies. This study may include only minimal risks. While participating in the study, the risks, side effects, and discomforts include:

- Fatigue (physical or mental) while answering the questions
- Possible loss of confidentiality
- Uncomfortable answering personal questions

We will minimize these risks by:

- Having nurses who have the education and experience working with people with health conditions
- To minimize possible fatigue, you will be asked every 20 minutes during the interviews if you would like to take a break.
- We are keeping all files in a locked, secure location available only to the research team.
- If you are uncomfortable with questions, tell the researcher you do not want to answer that question.

Cost /Compensation

There will not be a financial cost to you to participate in this study.

The study will take 20 minutes of your time. As a thank you for your time, you will be compensated $5 in gift cards. You will also receive a $5 gift card if you take another survey six weeks later, which will also take 20 minutes.

Confidentiality

All information gathered in this study will be kept as confidential as possible. No reference will be made in written or oral materials that could link you to this study. All records will be stored virtually at the University of Nevada, Las Vegas (UNLV) for three years after completion of the study. After the storage time, the information gathered will be deleted.

Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate in this study or any part of this study. You may withdraw at any time without prejudice to your relations with the University of Nevada, Las Vegas (UNLV), IUH (Indiana University Health), or any of its partners. You are encouraged to ask questions about this study at the beginning but may ask at any time during the research study.

Participant Consent:

I have read the above information and agree to participate in this study. I have been able to ask questions about the research study. I am at least 18 years of age. A copy of this form has been given to me.

Signature of Participant Date

Participant Name (Please Print)

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to Sarah Zvonar, at Indiana University Health to use or disclose (release) your health information that identifies you for the research study described above. The health information that we may use or disclose (release) for this research includes

Information in your health record about the current admission including date of diagnosis, diagnosis code, vital signs and labs, the outcome of your heart attack including any interventions performed, such as a percutaneous coronary intervention (PCI) or surgery. Information will also be collected on previous diagnoses or health conditions. Information will again be collected at 6 weeks after the cardiac event including length of stay in the hospital, any admissions or emergency room visits to the facility with reasons for admission, and death.

The health information listed above may be used by and/or disclosed (released) to
Sarah Zvonar

Indiana University Health is required by law to protect your health information. By signing this document, you authorize Indiana University Health to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission if permitted by laws governing them.
Please note that:

- You do not have to sign this Authorization, but if you do not, you may not receive research-related compensation.
- Indiana University Health may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that:

- You may change your mind and revoke (take back) this Authorization at any time, except to the extent that University of Nevada, Las Vegas (UNLV) & Indiana University Health has already acted based on this Authorization. To revoke this Authorization, you must call: Indiana University IU Human Subjects Office at 317-278-3458 or 800-696-2949.
- If you change your mind about this specific research study, please call **Sarah Zvonar** at **(317)759-1487** or **Dr. Reimund Serafica at (702)895-5746.**

OTHER ELEMENTS:
Disclosures to the recipient about protected health information:

- Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information that could identify you will be

removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent. If information is used in future research, it will be de-identified before sharing. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

- The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:
  (1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
  (2) if you consent to the disclosure, including for your medical treatment;
  (3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
  (4) for the purpose of auditing or program evaluation by the government or funding agency.

- No publication or public presentation about the research described above will reveal your identity without another authorization from you.

- To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that Indiana University Health maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Indiana University Health to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by Indiana University Health. If it is necessary for your care, your health information will be provided to you or your physician.

- If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization, nor receive compensation as outlined above.

This Authorization will expire at the end of this research study or December 31, 2022.

Signature (participant or participant's personal representative)	Date
Printed name (participant or participant's personal representative)	If applicable, a description of the personal representative's authority to sign for the participant