UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

Title of this study: Scaling Interoperable Clinical Decision Support for Patient-Centered Chronic Pain Care

Researchers:

Christopher Harle, Ph.D.	Ramzi Salloum, Ph.D.
352-294-5797	352-294-4997
charle@ufl.edu	rsalloum@ufl.edu

You are being asked to participate in a research study.

Before you agree to take part in this study, Dr. Salloum or his representative will tell you:

- **Why the study is being done and what will happen to you if you take part in the study:**
  The purpose of this study is to better understand what information a primary care clinician needs to appropriately treat a patient with chronic pain and to design decision support tools that will provide this information to clinicians in an efficient and helpful manner. To answer this question, researchers from the University of Florida, Wake Forest, Applied Decision Science, LLC, Alphora, LLC, and Dr. Laura Marcial would like to conduct a workgroup with a diverse group of stakeholders to guide the study team in the process of adapting and tailoring Pain Manager to UF Health. Pain Manager, is an existing computed program that is publicly available from Agency for Healthcare Research and Quality. The goal of this study is to improve Pain Manager so it is most useful to patients and doctors at UF Health. We will use your feedback to improve this program. All adaptations or improvements to the software made in the course of this study will be publicly accessible.

  Participate in an up to 6-hour workshop with up to 10-15 workgroup members. This workgroup will include decision support design exercises and providing feedback on prototype decision support designs. Participants will also allow investigators to audio and video record the focus group. The workgroup will also meet monthly after the initial workshop to continue improve the user-centered design.

- **How long you will be in the study:**
  Your participation in this study will last approximately 3 months.

- **How many people will be in the study:**
  There are 10-15 workgroup members.

- **The possible foreseeable risks, discomforts, and benefits of this research:**
  While on the study, the risks are minimal but include: unauthorized personal outside of the study viewing the video recording of your participation in the workgroup. To mitigate this risk, all information collected will be stored in a password protected database and none of your information will be connected with your name.

By participating in this study, you will help improve how doctors and other health care providers get new information on how to best treat and care for people who have chronic pain. This will include treatment guidelines and decision support tools made for patients with chronic pain.

- **Alternatives to being in the study:**
  Instead of being in the study, you have the right to refuse participation and not be in the study today.

- **How your study records will be maintained and who will have access:**
  Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. All video recordings will be saved into a password protected database. Only authorized investigators affiliated with the project will have access to this information for the purpose of analyzing the data. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

  Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the University of Florida Institutional Review Board or its designees, and the study sponsor, the Agency for Healthcare Research and Quality

- **If it will cost you anything to take part in this study:**
  There is no cost to you to participate in this study.

- **If you will be compensated for taking part in this study:**
  You will receive payment for taking part in this study. You will receive a $300 honorarium at the end of the workgroup.

  If you are paid more than $199 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

  Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

  If you have any problems regarding your payment contact the study coordinator.

- **When or if you may be told about new findings which may affect your willingness to keep taking part in this study:**
  This is not applicable to this study.

If you agree to participate in this study, you will be given a signed copy of this document.

You may contact Dr. Salloum at 352-294-4997 at any time if you have questions about the research or if you think that you have been hurt by the research.

You may contact the Institutional Review Board at the University of Florida Health Science Center at (352) 273-9600 if you have questions about your rights as a research subject or what to do if you are injured.

You may choose not to be in this study or you may quit being in the study at any time and there will be no penalty and no loss of any benefits you are entitled to. Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise, your research records will not be released without your permission unless required by law or a court order.

If any identifiable information was collected as part of this research, it is possible that your research information with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Signature of Person Consenting Date

CONSENT TO BE VIDEO AND/OR AUDIO RECORDED

With your permission, you will have the following done during this research (check all that apply):

☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.
The Principal Investigator (PI) of this study, _____, or *[his/her]* successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.
Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):
_____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):
_____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

_____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date