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Appendix D LETTER OF INFORMATION / CONSENT

A Study of/about State of Practice of Medical Imaging Software

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Purpose of the Study: The purpose of this study is to conduct a current state of practice analysis of software in select research software domains for the purpose of understanding quality and assisting in the future development of such software.

Procedures involved in the Research: Participation in this study will involve a one-to-one semi-structured interview between a member of our research group and a lead developer of your software. The interview will be conducted, and audio-recorded, via Microsoft Teams and the questions will follow a transcript. The video-conference interview would include roughly 20 questions that focus on the software development process and the development group. The interview should not take longer than 90 minutes.

Potential Harms, Risks or Discomforts: The risks involved in participating in this study are minimal. You may feel uncomfortable or anxious if you perceive that your project is being scrutinized. Our questions will focus on your development team and the development process. The questions will not suggest that a specific course of action is better than another. The questions will focus on identifying what was done and not why it was done.

You do not need to answer questions that you do not want to answer or that make you feel uncomfortable. I describe below the steps I am taking to protect your privacy.

There is also a minimal risk of privacy breach in the event that someone deduces your identity from the interview responses, as well as data breach by virtue of the interview being conducted online and the answers being stored on an online repository. The privacy breach risk will be minimized by keeping your name confidential. Your name will never be shared outside of the research team. The data breach risk will be minimized by storing interviewee names and answers separately, and by gathering and storing all data on private password protected McMaster University systems.

We acknowledge that maintaining the privacy of interviewed sole developers, or members from a small developer team, may not be possible since such identities can be inferred. The interviewee will have to accept this risk if they choose to be interviewed.

Potential Benefits: The answers to these interview questions will help us analyze the current state of practice of software development, and provide insight into common or best practices for the benefit of future software development. However, participants may not benefit from participating in the study.

Confidentiality: You are participating in this study confidentially. Social risks surrounding identifiability are addressed in detail in the section of this document titled 'Potential Harms, Risks or Discomforts'. I will not publish your name. The data that will be collected will be stored separately from your identity. The data from all interviewees will be analyzed prior to the release of our study. We are planning on linking interview details to the software, and not to a developer. The raw data will be deleted after a retaining period of 3 years.

This study will use the Microsoft Teams platform to collect data, which is externally hosted cloud-based service. Please note that whilst this service is approved for collecting data in this study by the McMaster Research Ethics Board, there is a small risk with any platform such as this of data that is collected on external servers falling outside the control of the research team. If you are concerned about this, we would be happy to make alternative arrangements for you to participate, perhaps via telephone. Please talk to the researcher if you have any concerns.

Participation and Withdrawal: Your participation in this study is voluntary. If you decide to be part of the study, you can stop (withdraw), from the interview for any reason, even after giving consent or part-way through the study or up until March 31st 2021 when we expect to be analyzing the data into our report. If you decide to withdraw, there will be no consequences to you. You can request for your data to be removed via email. In cases of withdrawal prior to March 31st 2021 any data that you have provided will be destroyed unless you indicate otherwise. If you do not want to answer some of the questions you do not have to, but you can still be in the study.

Information about the Study Results: We expect to have this study completed by approximately May 2021. If you would like a brief summary of the results, please let me know how you would like it sent to you.

Questions about the Study: If you have questions or need more information about the study itself, please contact me at donga9@mcmaster.ca

This study has been reviewed by the McMaster University Research Ethics Board and received ethics clearance. If you have concerns or questions about your rights as a participant or about the way the study is conducted, please contact:

McMaster Research Ethics Secretariat
Telephone: (905) 525-9140 ext. 23142
C/o Research Office for Administrative Development and Support
E-mail: ethicsoffice@mcmaster.ca

Note

- Please feel free to ask questions about your involvement in this study.
- If you choose to participate in this study you may withdraw from the study at any time or up until March 31st 2021.

These questions will be asked at the time of the interview:

- Do you agree that the interview can be audio recorded?
- Would you like a copy of the study results?
 - Where to send the results?