Supplemental Material

Consents (Phases 2B and 3)\

Patient Information and Consent Form
Phase 2B

Principal Investigator:
Dr. Monica Parry, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto
Phone: (416) 946 – 3561
Email: monica.parry@utoronto.ca

Co-Investigators:
Ms. Tina Ceroni – Clinical Trials Ontario
Ms. Hafsa Ansari – University of Toronto
Dr. Ann Kristin Bjørnnes – Oslo Metropolitan University
Dr. Sabrina Cavallo – Université de Montréal
Mr. Andrew Day – Kingston General Hospital
Dr. Anne Ellis– Queen's University
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Ms. Heather Burnside – University of Toronto
Ms. Adhiyat Najam – Diabetes Action Canada
Ms. Marianne Park – Network of Women
Dr. Dawn Richards – Clinical Trials Ontario
Dr. Karine Toupin-April - University of Ottawa
Dr. David Wells – Diabetes Action Canada

Title of Project: Patient Engagement Partnerships in Clinical Trials (PEP-CT): Systematic Development and Testing of Patient Partner and Investigator Decision Aids

Purpose and Background
The overall goal of this 2-year project is to build capacity for sex/gender uptake and patient engagement in clinical trials. A clinical trial is a research study used to compare a new drug to a harmless pill, or placebo. In Canada, we are changing our approach to clinical trial studies. We now believe that patients (men and women) should be partners in deciding on the importance of research, designing studies, and sharing study results. However, investigators do not know how to work with patients, and patients do not know how to work with investigators. Our work will refine and test two decision aids to build capacity for sex/gender uptake and patient engagement in clinical trials. Decision aids can assist patients and investigators weigh their own potential benefits and risks of engaging patients as partners in clinical trial research. This particular study (Study 2B) involves face-to-face usability testing of the Patient Engagement Partnerships in Clinical Trials (PEP-CT) Patient Partner Decision Aid.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a baseline demographic form describing my age, sex, gender, education, and employment. To protect my privacy and confidentiality, I will have a study ID number instead of

my name on the form.

2. I will be asked to use the PEP-CT Patient Partner Decision Aid and work through the information, my values and my decision to engage as a patient partner on a clinical trial research team. As I use the decision aid, I will describe my experiences using a 'think aloud' approach. I will be observed during the session that will last for 1-1.5 hours and it will take using video conferencing (ZOOM). At the end of the session I will be asked four short questions and asked to complete a short survey. The session will be audio-recorded and to protect my privacy and anonymity, my last name will not be used.

Potential Benefits
I understand that by participating in this study I may have a better understanding of the patient partner role in clinical trial research.

I understand that I can get a plain language summary of the study results by checking the box below:

- ☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. If I find that working through the PEP-CT Patient Partner Decision Aid upsets me, I can discuss this with the researchers who are conducting this study.

Cost
I understand that there is no charge for participating in this study.

Financial Compensation
I understand that I will be compensated for my time to complete on-line usability testing. Compensation is based on recommendations for patient engagment compensation as outlined by the Strategy for Patient-Oriented Reseach Networks in Chronic Disease (https://diabetesaction.ca/wp-content/uploads/2018/07/TASK-FORCE-IN-PATIENT-ENGAGEMENT-COMPENSATION-REPORT_FINAL-1.pdf). I will receive $25/hour for my participation in the Phase 2B usability testing.

Confidentiality
I understand that information will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Research Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

I understand that if I participate in a usability testing session, my anonymity will be preserved through the use of my first name only.

The research study with which you are participating may be reviewed for quality assurance to ensure that required laws and guidelines are followed. If chosen, representatives of the Human Research Ethics Program (HREP), may access study related data and/or consent materials as part of their review.

All information accessed by the HREP will be upheld to the same standard of confidentiality that has been stated by the research team.

Right to Refuse or Withdraw
I understand that my participation in this study is entirely voluntary and I am free to refuse to take part in the usability testing or to withdraw at any time prior to the usability testing without penalty. During the usability testing, I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly request this to be done. I also understand that during and after the usability testing, it will not be possible for me to withdraw my data from the study.

Contact
I understand that if I have any questions about the study, I can contact Dr. Monica Parry at 416-946-3561 (Principal Investigator). I understand that if I have question about my rights as a research participant, I can contact the University of Toronto, Office of Research Ethics at ethics.review@utoronto.ca or 416-946-3273. I may keep this copy of the information and consent letter for my own reference.

SUBJECT STATEMENT AND SIGNATURE SECTION
I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me. I have been given enough time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form.

_____ _____
(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION
I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to subjects in this study.

_____ _____
(Signature of study personnel) (Date)

Investigator Information and Consent Form
Phase 2B

Principal Investigator:
Dr. Monica Parry, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto
Phone: (416) 946 – 3561
Email: monica.parry@utoronto.ca

Co-Investigators:
Ms. Tina Ceroni – Clinical Trials Ontario
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Title of Project: Patient Engagement Partnerships in Clinical Trials (PEP-CT): Systematic Development and Testing of Patient Partner and Investigator Decision Aids

Purpose and Background
The overall goal of this 2-year project is to refine and evaluate two innovative bilingual (English and French) decision aids (patient partner and investigator) designed to improve patient engagement partnerships in clinical trials (PEP-CT). Patient-oriented research (POR) is research designed to engage patients as partners with a focus on patient-identified priorities and outcomes. A 2017 systematic review suggested little active patient engagement in trial design, data analysis/interpretation and dissemination. We have completed **Phase 1 (CIHR-funded)** of this project and have used CIHR's Strategy for Patient-Oriented Research (SPOR) Capacity Development Framework, SPOR Patient Engagement Framework, and partnered with Clinical Trials Ontario (CTO). Activities included: 1) conducting a scoping review, and 2) hosting a 1-day consultation workshop. Based on the plethora of existing POR resources it was unanimously decided at the consultation workshop that next steps would include collating relevant POR information into two decision aids; one for patients and one for investigators. The tools are intended to help each weigh potential benefits/risks of patient engagement partnerships in clinical trials. The International Patient Decision Aid Standards (IPDAS) mandates a systematic process for decision aid development that includes consultation with end-users. Guided by the IPDAS, User-Centered Design and the Ottawa Decision-Support Framework our specific aims of this project are to refine and evaluate the decision aids through: 1) alpha (usability) testing (Phase 2), and 3) beta (field) testing (Phase 3).

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a baseline demographic form describing my age, sex, gender, education,

and employment etc. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

2. I will be asked to use the PEP-CT Investigator Decision Aid and work through the information, my values and my decision to engage a patient partner on a clinical trial research team. As I use the decision aid, I will describe my experiences using a 'think aloud' approach. I will be observed during the session that will last for 1-1.5 hours and it will take place using video conferencing (ZOOM). At the end of the session I will be asked four short questions and asked to complete a short survey. The session will be audio-recorded and to protect my privacy and anonymity, my last name will not be used.

Potential Benefits
I understand that by participating in this study I may have a better understanding of the patient partner role in clinical trial research.

I understand that I can get a plain language summary of the study results by checking the box below:

- ☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. If I find that working through the PEP-CT Investigator Decision Aid upsets me, I can discuss this with the researchers who are conducting this study.

Cost
I understand that there is no charge for participating in this study.

Financial Compensation
I understand that I will be compensated for my time to complete on-line usability testing. I will receive $25/hour for my participation in the Phase 2B usability testing.

Confidentiality
I understand that information in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Research Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

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The research study with which you are participating may be reviewed for quality assurance to ensure that required laws and guidelines are followed. If chosen, representatives of the Human Research Ethics Program (HREP), may access study related data and/or consent materials as part of their review. All information accessed by the HREP will be upheld to the same standard of confidentiality that has been stated by the research team.

Right to Refuse or Withdraw
I understand that my participation in this study is entirely voluntary and I am free to refuse to take part in the usability testing or to withdraw at any time prior to the usability testing without penalty. During the usability testing, I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly request this to be done. I also understand that during and after the usability testing, it will not be possible for me to withdraw my data from the study.

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SUBJECT STATEMENT AND SIGNATURE SECTION
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(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION
I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to subjects in this study.

_____ _____
(Signature of study personnel) (Date)

Patient Information and Consent Form
Phase 3

Principal Investigator:
Dr. Monica Parry, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto
Phone: (416) 946 – 3561
Email: monica.parry@utoronto.ca

Co-Investigators:
Ms. Tina Ceroni – Clinical Trials Ontario
Ms. Hafsa Ansari – University of Toronto
Dr. Ann Kristin Bjørnnes – Oslo Metropolitan University
Dr. Sabrina Cavallo – Université de Montréal
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Title of Project: Patient Engagement Partnerships in Clinical Trials (PEP-CT): Systematic Development and Testing of Patient Partner and Investigator Decision Aids

Purpose and Background
The overall goal of this 2-year project is to build capacity for sex/gender uptake and patient engagement in clinical trials. A clinical trial is a research study used to compare a new drug to a harmless pill, or placebo. In Canada, we are changing our approach to clinical trial studies. We now believe that patients (men and women) should be partners in deciding on the importance of research, designing studies, and sharing study results. However, investigators do not know how to work with patients, and patients do not know how to work with investigators. Our work will refine and test two decision aids to build capacity for sex/gender uptake and patient engagement in clinical trials. Decision aids can assist patients and investigators weigh their own potential benefits and risks of engaging patients as partners in clinical trial research. This particular study (Phase 3) involves on-line testing of the Patient Engagement Partnerships in Clinical Trials (PEP-CT) Patient Partner Decision Aid.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a baseline demographic form describing my age, sex, gender, education, and employment. I will also be asked to complete a survey at the start of the study. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

2. I will be asked to use the PEP-CT Patient Partner Decision Aid and work through the information, my values and my decision to engage as a patient partner on a clinical trial research team. After using the decision aid, I will be asked to fill out the same survey as I did before I used the decision aid. In addition, I will be asked to complete two additional surveys and participate in a 30-minute telephone interview, scheduled at a convenient time for me. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the questionnaires.

Potential Benefits
I understand that by participating in this study I may have a better understanding of the patient partner role in clinical trial research.

I understand that I can get a plain language summary of the study results by checking the box below:

- ☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. If I find that working through the PEP-CT Patient Partner Decision Aid upsets me, I can discuss this with the researchers who are conducting this study.

Cost
I understand that there is no charge for participating in this study.

Financial Compensation
I understand that I will be compensated $100 for my time to complete the Phase 3 field testing. Compensation is based on recommendations for patient engagment compensation as outlined by the Strategy for Patient-Oriented Reseach Networks in Chronic Disease (https://diabetesaction.ca/wp-content/uploads/2018/07/TASK-FORCE-IN-PATIENT-ENGAGEMENT-COMPENSATION-REPORT_FINAL-1.pdf).

Confidentiality
I understand that information about specific individuals in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Research Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

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Right to Refuse or Withdraw

I understand that my participation in this study is entirely voluntary and I am free to refuse to take part in the testing or to withdraw at any time prior to the study without penalty. I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly request this to be done. I also understand that during and after testing of the PEP-CT Patient Partner Decision Aid, it will not be possible for me to withdraw my data from the study.

Contact

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SUBJECT STATEMENT AND SIGNATURE SECTION

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(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION

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(Signature of study personnel) (Date)

Investigator Information and Consent Form
Phase 3

Principal Investigator:
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Phone: (416) 946 – 3561
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Co-Investigators:
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Title of Project: Patient Engagement Partnerships in Clinical Trials (PEP-CT): Systematic Development and Testing of Patient Partner and Investigator Decision Aids

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The overall goal of this 2-year project is to refine and evaluate two innovative bilingual (English and French) decision aids (patient partner and investigator) designed to improve patient engagement partnerships in clinical trials (PEP-CT). Patient-oriented research (POR) is research designed to engage patients as partners with a focus on patient-identified priorities and outcomes. A 2017 systematic review suggested little active patient engagement in trial design, data analysis/interpretation and dissemination. We have completed **Phase 1 (CIHR-funded)** of this project and have used CIHR's Strategy for Patient-Oriented Research (SPOR) Capacity Development Framework, SPOR Patient Engagement Framework, and partnered with Clinical Trials Ontario (CTO). Activities included: 1) conducting a scoping review, and 2) hosting a 1-day consultation workshop. Based on the plethora of existing POR resources it was unanimously decided at the consultation workshop that next steps would include collating relevant POR information into two decision aids; one for patients and one for investigators. The tools are intended to help each weigh potential benefits/risks of patient engagement partnerships in clinical trials. The International Patient Decision Aid Standards (IPDAS) mandates a systematic process for decision aid development that includes consultation with end-users. Guided by the IPDAS, User-Centered Design and the Ottawa Decision-Support Framework our specific aims of this project are to refine and evaluate the decision aids through: 1) alpha (usability) testing (Phase 2), and 3) beta (field) testing (Phase 3).

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and employment etc. I will also be asked to complete a survey at the start of the study. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

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Potential Benefits
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I understand that I can get a plain language summary of the study results by checking the box below:

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Potential Risks
I understand that there are no known risks to participating in this study. If I find that working through the PEP-CT investigator Decision Aid upsets me, I can discuss this with the researchers who are conducting this study.

Cost
I understand that there is no charge for participating in this study.

Financial Compensation
I understand that I will be compensated $100 for my participation in the the Phase 3 field testing.

Confidentiality
I understand that information in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Research Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

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