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| **PAR Visit Checklist** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Study Title**: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Protocol:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Faculty Supervisor:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Student Investigator:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Start time: End time: Duration:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Location:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Attendees** | Student Investigator:  Faculty Supervisor: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Introduce the post-approval program and PAR visit process (introduction meeting, protocol discussion, study materials review (checklist sections), summary meeting, final report, PI response and close-out) | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| CER reminders | | Submit annual renewal applications at least two weeks prior to the ethics expiry date  If a lapse in ethics approval occurs, research activities contemplated under the protocol must be put on hold unless permission is given by the HREP  Submission of a study completion report is a UofT requirement  Submit adverse/unanticipated event reports should be submitted to the HREP in a timely manner  Evaluation Survey  Post-Approval package  Have you ever been audited  Has anyone in your lab completed the TCPS2 Tutorial | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PAR Visit Discussion** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Before we begin, could you please provide a summary of your study, focusing on the goal, method, and population? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Before we begin do you have any project related issues, concerns, or potential areas of interest that you would like to discuss? Have there been any changes since the most recent ethics approval? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| What training do you require your research staff/graduate students to complete for this project (e.g., research ethics, confidentiality/privacy, qualitative methodologies)? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have any members of your team completed formal ethics training? | | | | | | | | | | | | | | | | | Yes | | | | | | | | | | | No | | | | | | | |
| If yes, what kind of training (indicate team member for each training type)?  TCPS2 on-line tutorial  Research ethics 101 workshop  Visiting lecture from the HREP  Other: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Oversight (Supervisor/Lead Investigator)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| How do you stay up to date on the current progress of the project, provide ongoing support during the study and ensure the current ethics protocol is being followed? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (CERS) Does this project involve any potential conflicts of interest? | | | | | | | | | | | | | Yes | | | | | | | | | | | | | | No | | | | | | | | |
| If so, let’s talk about how this is managed: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Recruitment, Compensation & Informed Consent** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Was consent sought for participation? | | | | Yes | | | | | | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | |
| If no, provide justification: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If yes, how was consent obtained and documented? | | | Written consent  Verbal consent  Documentation of the process in field notes  Other: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Who is responsible for obtaining consent? Describe any training/experience completed to assist in fulfilling this role. Describe the procedures followed for conducting the consent discussion. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Are compensation and/or reimbursement provided for this study? | | | | | | | | | | | | | | | Yes | | | | | | | | | | | | No | | | | | | | | |
| Please describe the recruitment and compensation process for this project. Also explain how you monitor/track these activities: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Proxy consent and Debriefing** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Was proxy (ex: parental) consent given for participation? | | | | | | Yes | | | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| If yes, what procedures were followed in determining capacity? Describe the procedures that are/will be followed to involve the participants in the decision-making process to the greatest extent possible: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Was any deception or intentional non-disclosure involved in the research procedures? | | | | | | | | | | | | Yes | | | | | | | | | | | No | | | | | | | | | | | | |
| If yes, describe the procedures followed for debriefing study participants: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have any participants expressed concerns about the use of deception or intentional non-disclosure? | | | | | | | | | Yes | | | | | | | | | | No | | | | | | | | | | | N/A | | | | |
| Following debriefing, have any participants withdrawn themselves and their data from the study? | | | | | | | | | Yes | | | | | | | | | | No | | | | | | | | | | N/A | | | | |
| **Dissemination of Study Results** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is member checking incorporated in this protocol? | | | | | | | | Yes | | | | | | | | | | | No | | | | | | | | | | N/A | | | | |
| If yes, please describe what information/feedback will be provided to participants and how they will access to this data: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Was/will a final report or research summary be provided to study participants? | | | | | | | | | | | | | | | | | | Yes | | | | | | | | | | | | | No | | | | |
| If yes, describe the method of distribution: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Privacy and Confidentiality Procedures** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Does the project involve the collection and/or use of identifiable (direct or indirect) information (excluding the consent form)? | | | | | | | | | | | | | | | | Yes | | | | | | | | | | | No | | | | | | | | |
| If yes, list below: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Describe the procedures in place to preserve confidentiality (ex: prevent loss or unauthorized access, physical safeguards, encryption etc.) for both identifiable and de-identified data:  - | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| How long will data and/or biosamples be retained following study completion? Describe the safeguarding procedures. If data is not retained indefinitely, describe the destruction or disposal procedures that will be followed: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Are study participants given the option of withdrawing their data? | | | | | | | Yes | | | | | | | No | | | | | | | | | | | | N/A | | | | | | | | | |
| Discuss any limitations to data protection or data withdrawal: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have any participants withdrawn from the study? | | | | | | | | | | | | | | | Yes | | | | | | | | | | | No | | | | | | | | | |
| If yes, describe any reasons for withdrawal provided by participants: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Adverse/unanticipated events** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have there been any adverse/unanticipated events over the course of the project? | | | | | | | | | | | | | | | | | | | | Yes | | | | | | | | | | | | No | | | |
| If yes, have all events been appropriately reported to the REB? | | | | | | | | | | Yes | | | | | | | | No | | | | | | | | | N/A | | | | | | | | |
| Have any research participants complained about their experience in this project (verbally or in writing)? | | | | | | | | | | | | | Yes | | | | | | | | | | | | | No | | | | | | | | | |
| If yes, please provide details: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **General Discussion Topics** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Now that you have had a chance to conduct the research, what are your thoughts on the research related risks that were anticipated during the initial REB review (specifically in relation to participant vulnerability and research related risk? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Please discuss any barriers to research oversight that you think would be relevant to future HREP recommendations for best practice: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Overall Assessment** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Satisfactory, No recommendation(s) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Satisfactory, with recommendation(s) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Significant findings with recommendation(s) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Significant findings with required corrective action(s) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Review of Study Materials** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **General study materials and** **REB documents** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Completion of any research personnel training (TCPS2, GCP, NIH etc.) | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Documentation of other institutional and/or administrative approvals/agreements | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Current REB approval letter | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Current REB-approved ethics protocol | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Current REB-approved supporting documents | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Documentation of any site-specific study procedures (data retention plan, consent process etc.) | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Most recent annual renewal submission and associated REB approval letter | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| REB amendment approval letter(s) | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Are study materials and REB documents being stored appropriately? | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| **Study materials related to recruitment** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Are the currently approved versions of the recruitment materials being used? | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Documentation of enrolment numbers | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Documentation of participant compensation/reimbursement | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Documentation of participant requests for withdrawal and/or drop-out procedures | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| **Study materials related to consent** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is the currently approved version of the consent document being used? | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Is the consent process sufficiently documented for each enrolled study participant? | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Are signed and dated copies of the consent document on file for each study participant? | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Are signed consent documents maintained appropriately? | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| **Study materials related to data confidentiality** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Confirm that all identifiable electronic data that is maintained outside of a secure server environment is encrypted appropriately | | | | | Yes | | | | | | No | | | | | | | | | | | N/A | | | | | | | | | | |
| Are hard copy records stored in a locked cabinet in a restricted access room? | | | | | Yes | | | | | | No | | | | | | | | | | | N/A | | | | | | | | | | |
| **Study materials related to adverse events** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adverse event/ unanticipated issue reports | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| REB acknowledgement letters | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |
| Verify follow-up activities | | | | | Yes | | | | | | No | | | | | | | | | | N/A | | | | | | | | | | | |