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| Background pattern  Description automatically generated**A picture containing sky, outdoor, blue  Description automatically generated**  **OHSN-REB TOP 10 Updates**  **JULY 28, 2021**  A picture containing text, sign, red  Description automatically generated | |
| ***Please share the following important REB Top 10 list with your research study teams.*** | |
| **1** | **Reminder to Provide Study Information in Email to REB**  In general email correspondence with the REB, please ensure to provide the following information so that we may better assist you and provide a prompt response:   1. **Subject Line**:  * CRRF Number, Protocol Number, Acronym, purpose of email (i.e., inquiry of…)  1. **Body of email**:  * Regarding: CRRF number, protocol number, study acronym and title, PI and Co-I, study staff, if applicable * Purpose for correspondence (use bullets to summarize) |
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| **2** | **New Temporary Process for Amendments when Documents Require  Translation or Verification by OHRI French Translation Services (Eric Lepine)**  OHRI French Translation Services (Eric Lepine) is currently experiencing a higher than usual volume. The following temporary measures have been put into place to ensure Amendment Forms will be approved in a timely fashion:   * If **Eric Lepine is translating:**   + When an amendment form is approved, the letter will indicate approval for the English documents.   + The REB will then send the applicable documents to Eric Lepine directly for translation on the study team’s behalf.   + Eric Lepine will return the translated documents directly to the REB, and an approval letter for the French documents will be processed and forwarded to the study team along with the translated versions and certificate of translation. * If **PI/Study Team is translating:**   + When an Amendment Form is approved, the study team will receive an Amendment approval letter for the English documents.   + The email in which the approval letter is enclosed will detail when the French documents are due and instruct to forward the translated documents to the REB Office.   + The REB will send the applicable documents for verification on the study team’s behalf.   + An approval letter for the French documents will be processed and forwarded to the study team along with the certificate of verification. If the REB deems changes are required, tracked (showing the changes) and clean copies will also be enclosed with your approval letter.   **The REB’s** [**Amendment Form**](http://www.ohri.ca/ohsn-reb/forms/Amendment%20Form,%20revised%20July%2028,%202021.docx) **has been updated to reflect these changes**. At the time of every Amendment submission, be sure to access the form directly from the OHSN-REB website to ensure you are completing the most recent version.  If you have any questions, please contact your Research Ethics Coordinator. |
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| **3** | **Platform Change for Ethics Applications Reviewed under the  CHEO and OHSN REB Harmonization Agreement**  In an effort to continuously improve the CHEO/OHSN REB Harmonization Agreement workflow, all ethics applications will now be submitted through the CTO Stream platform when research activities are conducted at both sites. This allows the CHEO and OHSN REBs to further streamline review and decision-making processes. The REBs are working with CTO to make changes to adjust questions to fit both retrospective and prospective applications.   Reminder that the ethics application platform to be used will be communicated to study teams via email after CHEO and OHSN REB review of the completed [TOH & CHEO REB Harmonization REDCap Survey](https://redcap.cheori.org/surveys/?s=RPXAKKC8PD). |
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| **4** | **Updates to REB Application Multi-Centre Question in Ethics Tab 1**  OHSN-REB’s definition of a “multi-centre” study has changed:   * **Old definition:** Research involving several hospitals/research institutions, where each location is overseen by a local investigator. * **New definition:** Research involving recruitment at 2 or more sites (e.g.: hospital, institution, clinic and/or medical centre).   **What does this mean?** For new applications, if 1 Investigator is recruiting from multiple locations, the study should now be classified as multi-centre. |
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| **5** | **Updates to REB Application Recruitment (Tab 5) and Consent (Tab 6) Tabs**  **CRRF Ethics Tab 5 - Recruitment:**   * Addition of instruction regarding initial contact with TOH and UOHI patients: *In review with The Ottawa Hospital (TOH) and University of Ottawa Heart Institute (UOHI) Privacy Offices, it was determined that email addresses recorded in a patient’s EPIC medical record have been collected for specific use (only to be used by the Foundation, Alumni and Patient Experience Survey), and not for research purposes.*   *Even when the Permission to Contact (PTC) for research purposes is on file in EPIC, initial contact via email with patients for research purposes is not permitted. Prior to communicating with patients via email, the “*[*Research* *Participant Consent to Communicate by Email*](http://www.ohri.ca/ohsn-reb/covid19/Research%20Participant%20Consent%20to%20Communicate%20by%20Email%20(English).pdf)*” form must be used.*  **CRRF Ethics Tab 6 - Consent:**   * Now allows for multiple types of consent (written, verbal, implied and/or waiver of consent) to be selected.   + This is particularly useful for projects involving multiple groups of participants for which a different type of consent will be sought. For example, a study involving an in-person interview with patients from whom written consent will be obtained, as well as an online survey of staff from whom implied consent will be obtained. * Addition of questions about alterations in the consent procedures and participant debriefings, to better align with CTO Stream’s revised forms. * Improved question logic; now better tailored to study design. |
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| **6** | **Updates to OHSN-REB ICF Templates**  Minor changes to the Main Clinical Trial, Minimal Risk, Main Oncology, Optional and Pregnant Partner Consent Forms have been made. Revised versions, as well summaries of changes are posted on the [OHSN-REB website](http://ohri.ca/ohsn-reb/consent_forms.htm). |
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| **7** | **Summary of Implied Consent and NEW Implied Consent Template**  **What is implied consent?**   * With implied consent, participants indicate that they knowingly agree to participate in the study by completing a research activity (e.g., by completing a survey/questionnaire). * It does not require a signature from the participant, but it does require provision of information to the research participant to make an informed choice.   **When can implied consent be used?**   * Acceptable in certain **minimal risk** research studies. * Most commonly used in research that involves the completion of a simple, onetime survey/questionnaire, where the act of completion and return of the survey/ questionnaire implies their consent to participate.   **What documents do I need to include in my REB application?**   * An Implied Consent Form (use OHSN-REB’s template) **“NEW”**   **Resources:**   * [OHSN-REB Implied Consent Form Instructions and Template](http://ohri.ca/ohsn-reb/forms/Implied%20Consent%20Form%20Template,%20December%2003,%202020.docx) |
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| **8** | **Summary of Verbal Consent for Minimal Risk Studies**  **What is verbal consent?**   * With verbal consent, a participant states their consent to participate orally but does not sign any written form.   **When can verbal consent be used?**   * Acceptable in certain **minimal risk** research. * Generally obtained over the phone, and it is not generally acceptable to use when obtaining consent in person.   + Verbal consent over the phone may be considered when it is the only feasible method of obtaining consent from participants when there is not going to be any in-person interaction (e.g., completing a telephone interview).   + For particular in-person circumstances where written consent cannot be obtained, verbal in-person consent may be obtained, subject to approval by the REB.   **What documents do I need to include in my REB application?**   * A Verbal Consent Script (use OHSN-REB’s template) that will be read to the potential participant in its entirety * An Information Sheet that will be given to the potential participant in advance of the consent discussion   **Resources:**   * [OHSN-REB Verbal Consent Script Instructions and Template](http://ohri.ca/ohsn-reb/forms/Verbal%20Consent%20Script%20Template,%20December%2003,%202020.docx) |
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| **9** | **Reminder for Post Approval Submissions**  **Local IRIS ethics application:**  All post approval submissions must be submitted on an OHSN-REB Form (Amendment Form, Continuing Review Form, Reportable Event Form or Study Closure Form). Submissions received without one of the REB’s forms will be returned to the study team.   * This includes Product Monographs, Investigator Brochures and Device Manuals, which must be submitted with an Amendment Form. * The REB forms can be found in the ‘Forms’ tab of the [OHSN-REB website](http://ohri.ca/ohsn-reb/forms.htm). * **Reminder:** The OHSN-REB Office continues to work remotely; all post approval submissions must be submitted via email to [REBAdminstration@ohri.ca](mailto:REBAdminstration@ohri.ca) (do not submit in hardcopy).   **Local IRIS registration application (for studies submitted in CTO Stream or Romeo under CHEO & OHSN-REB harmonized review):**  All post approval submissions must be submitted to the board of record (BOR) through CTO Stream or ROMEO due to the CHEO & OHSN REB harmonized review.  As you are aware, **ALL** studies submitted through CTO Stream or ROMEO must be registered in the Clinical Research Registration Form (CRRF). In order to update the registration information, the following documents must be submitted via email to [REBAdminstration@ohri.ca](mailto:REBAdminstration@ohri.ca) so the study status/details can be updated in IRIS:  BOR's approval letter for PI change  BOR's approval letter for continuing review  BOR's acknowledgement letter for study closure  Privacy breach at TOH or UOHI |
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| **10** | **Reminder for Use of Email in Clinical Research**  In review with The Ottawa Hospital (TOH) and University of Ottawa Heart Institute (UOHI) Privacy Offices, it was determined that email addresses recorded in a patient’s EPIC medical record have been collected for specific use (to be used only by the Foundation, Alumni and Patient Experience Survey), and does not include for research purposes.  Even if the Permission to Contact (PTC) for research purposes is on file in EPIC, initial contact via email with patients for research purposes is not permitted. Prior to communicating with patients via email, the “Research Participant Consent to Communicate by Email” form must be used.  **Resources:**   * [Guidance for Use of Email in Clinical Research](http://ohri.ca/ohsn-reb/forms/Guidance%20for%20Use%20of%20Email%20in%20Clinical%20Research,%20November%2020,%202020.pdf) * [Guidance for Obtaining Consent from Participants to Communicate by Email](http://ohri.ca/ohsn-reb/forms/Guidance%20for%20Obtaining%20Participant%20Consent%20Using%20the%20Research%20Participant%20Consent%20to%20Communicate%20by%20Email%20Form,%20November%2020,%202020.pdf) * Consent Form: Research Participant Consent to Communicate by Email:  [English](http://www.ohri.ca/ohsn-reb/forms/Research%20Participant%20Consent%20to%20Communicate%20by%20Email%20November%2020,%202020%20(English).docx) | [French](http://www.ohri.ca/ohsn-reb/forms/Research%20Participant%20Consent%20to%20Communicate%20by%20Email%20November%2020%202020%20(French).docx) * [OHSN-REB Email Templates](http://ohri.ca/ohsn-reb/consent_forms.htm) |
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**For complex studies, it is recommended that you meet   
with the REB prior to REB submission.**

**If you would like to request a virtual meeting with the REB Chair or REB Manager, please contact** [**REBAdministration@ohri.ca**](mailto:REBAdministration@ohri.ca)