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Guidelines for Providing New Information to Study Participants

The TCPS, the ICH-GCP Guidelines, and the US Code of Federal Regulations require that research participants be provided with any significant new findings that develop during the course of the research that may impact their willingness to continue to participate in the research. These "significant new findings" are evaluated on a case-by-case basis by the REB. While the Belmont Report does not specifically address re-consenting, it does provide an additional ethical requirement that research participants be notified of significant new findings that might affect their long-term health even after they have completed participation in the research study. Neither the TCPS, nor the regulations provide guidance on the manner or extent of documentation required to satisfy these regulatory and ethical responsibilities.

Significant new findings often result in changes to the consent form or to the protocol after participants have signed a consent document. The purpose of this document is to provide guidance regarding the types of information the REB considers to constitute significant new findings, what changes to the protocol or consent form should be conveyed to participants, and the means by which the REB expects significant new findings or changes to be conveyed to current or past participants.

What constitutes significant new findings requiring reporting to current/past participants

Significant new findings generally include, but are not limited to:

- Changes in potential or actual risks or benefits to participants.
  Examples:
  - Changes in standard of care, such that participation in research can increase the risk to participants (i.e., participants would be deprived of the standard of care by continuing to take part in the research study);
  - Identification of new risks to participants currently receiving the study treatment;
  - Identification of potential late-term effects for participants who completed study treatment;
  - Discovery that a life threatening or severely debilitating side effect occurs more frequently than previously expected.
- Addition or deletion of study procedures or change in number of visits required.
  Examples:
  - Addition of monitoring procedures;
  - Addition of new instruments or questionnaires;
  - Collection of new or different information from participants.
- Substantive alterations to the experimental/study treatment.
  Examples:
  - The frequency of dosing is increased or decreased;
  - The route of study drug administration is altered.
- Substantive changes in potential costs or payments to participants.
  Examples:
  - A drug previously paid for/provided by the study will no longer be provided;
  - Reimbursement for costs of study participation are increased or decreased.

How to report significant new information

Significant new information should be conveyed to current and past participants (when applicable) using a consent update form. Use of a consent update form rather than revising the consent document is mandatory for participants already enrolled in a research study (current and past).

The consent update form must be implemented (i.e., method of providing the document to participants) according to the relevance and urgency of the new information. For example:

1. **Recall participant** (i.e., schedule for an ad hoc visit asap): recall the participant immediately if new information reflects significant changes in potential or actual risks or benefits;
2. **A telephone call to participants**: inform the participant via telephone. This should be documented in the health record to indicate when and who provided the new information to the participants. This method is encouraged to verify that participants received this information (e.g., due to potential increased risks) for those participants who are no longer being seen in person, or when a significant gap in time would occur between when the new findings are discovered and the next scheduled contact with the participant;
3. **A letter to participants**: this mode of communication may be suitable for informing those participants who are no longer seen by the researcher in person, and when the new information is not life threatening or time sensitive.

REB review of significant new information

Significant new information that the researcher proposes to disseminate should be submitted for review (by the Provincial Applicant) using a provincial amendment (PAM) application. The recommended method for implementing the consent update form (as noted above), should be included in the amendment application.

In general, the REB must review the new information to be provided to participants prior to its dissemination, unless the information must be provided urgently to eliminate an apparent immediate hazard to participants or others (i.e., urgent new safety information). In the case where this information is provided to participants urgently prior to REB approval, the researcher must report the dissemination of this information to the REB as soon as possible.

When the new findings are urgent (i.e., to eliminate/address an immediate hazard), and the applicant is requesting approval for an oral update, the Provincial Applicant (or participating centre applicant) should contact the responsible OCREB Research Ethics Coordinator prior to submitting the request. The following information must be provided to assist in determining if the request for an oral update should be submitted:

1. Confirmation that the new information presents an immediate safety risk, and the rationale for its immediate implementation;
2. Confirmation that the sponsor is recommending urgent provision of this information to study participants;
3. Confirmation that the PI has reviewed the information and is recommending urgent provision of this information to study participants;
4. The recommended process for disseminating the information (e.g., by phone); and
5. The content of the information (script or text) that will be provided orally to the study participants.

Once reviewed and approved, the oral script is available to all participating centres for implementation.

In the subsequent submission related to the new information (amendment) the Provincial Applicant should note that the new information required urgent oral dissemination to the study participants and the submission should include the OCREB approved oral text.

Note. When the study remains open to enrolment, the amendment also will include the submission of a revised main consent, which includes the new information (see Table below).

When a Consent Update Form is not required

The REB is aware that study sponsors often request that researchers present revised consent documents to participants to sign ("re-consent") when they have been revised, regardless of the significance of the new information or change. In many cases informing participants by providing them with a revised main consent is inappropriate, and may result in needless burdens for the participants, the presentation of irrelevant information, and the potential dilution of the impact of any significant new findings.

Consequently, the REB does not require the use of a Consent Update Form when the revisions to consent documents are unlikely to affect the participants' willingness to continue participation in the research study. Examples of situations for which the REB generally would not require a consent update form include:

- A minor increase in number of participants to be enrolled in the study;
- New risk information about the study drug is discovered, but is not related to late effects and all participants have completed study treatment;
- Addition of new study procedures or study visits that do not pertain to participants already enrolled in the study (e.g., changes made to screening procedures that only affect new participants).

Guidelines on the appropriate method for providing the new information

The following guidelines indicate the appropriate methods to use when providing significant new findings to research participants, and the required documentation for notification. The format for disclosure will be dependent on the applicant's selection, followed by the REB's review of the new information, the new risks identified and the overall risk of the research. REB approval will include specific information related to the notification processes for the consent update form based on the review of the new information.

Document Required for A Revised Consent Form for future enrolment	**Participant/Study Status**	**Best Practice: Process for provision of new information**
Revised consent form: Amend the original ICF to include new information *(required if the study is open to enrolment at any of the centres using OCREB)*	Open to enrolment at **any** of the study centres using OCREB	Sign new (revised) consent form at enrolment
Document Required for Consent Update	**Participant/Study Status**	**Best Practice: Process for provision of new information**
Consent Update Form: A brief form containing **ONLY** the new findings/changes to the ICF. *(required if there are any currently enrolled participants on active treatment /intervention at **any** of the centres using OCREB, and/or for completed participants if the study is closed to follow-up but the new findings might affect the long term health of the participants)*	Participants on active treatment or intervention at any of the study centres using OCREB	1. Recall participant immediately to provide consent update form and obtain signature. 2. Contact participant (via phone) - obtain signature on consent update form at next visit. 3. At next visit, provide consent update form and obtain signature. 4. At next visit, provide consent update form. No signature is required on the form (document in health record).
	Participants on follow up with occasional visits	1. Contact participant (via phone) – provide consent update form at next visit. 2. Mail consent update form – confirm receipt at next visit. 3. At next visit provide consent update form.
	Participants on follow up via phone contact	Mail consent update form & document receipt at next phone contact.
	Closed to follow-up. New findings affect the long term health of the participant	Send consent update form by certified mail; include a contact for participants requesting additional information.