**Guidelines for Providing New Information to Study Participants**

**Background/Rationale**

The TCPS (2), the ICH-GCP, and the US Code of Federal Regulations (CFR) require that research participants be provided with any significant new findings developed during the course of the research, which may relate to the participants’ willingness to continue. Participants should also be notified of significant new findings that might affect their long-term health even after they have completed participation in the research study. These “significant new findings” will be evaluated on a case-by-case basis by the REB.

**Definitions**

1. **Information Letter:** A letter to be provided to participants when new information is not likely to affect their willingness to continue participation in the research study

Examples: decrease in frequency of follow up visits; change in Principal Investigator

1. **Consent Form Addendum:** An addendum to the original approved consent form signed by the participant; required for *current* research participants, when new research findings are considered significant.
2. **Updated Consent Form**: Revised version of the *entire* consent form; required for *new* participants entering the study, when new research findings are considered significant

**Significant New Research Findings**: Examples include but are not limited to

1. **Changes in potential risks or benefits to current research participants**
   1. Identification of significant adverse events related to the research intervention
   2. Identification of potential late-term effects
   3. Confirmation that a life threatening or severely debilitating side effect occurs morefrequently than previously anticipated
   4. Changes to standard of care, where access could be influenced by continuing research participation
2. **Addition/deletion of study procedures or change in number of visits required**
   1. Addition of monitoring procedures
   2. Addition of new instruments or questionnaires to the study
   3. Collection of new or different information from participants
3. **Substantive alterations to the current study intervention**
   1. The frequency of dosing is increased or decreased
   2. The route of study drug administration is altered.
4. **Substantive changes in potential costs or payments to participants.**
   1. A drug previously paid for/provided by the study will no longer be provided
   2. Reimbursement for costs of study participation are increased or decreased

**Documentation and Dissemination of Significant New Research Findings**

New information should be communicated to participants according to the relevance and urgency of the new information:

1. **Urgent Verbal Communication,** by phone or ad hoc “face to face” meeting.  
     
   Required if the new information reflects a significant change in risk, either real or potential (for example, a life-threating side-effect from the study intervention). This method is encouraged when it is necessary to verify that the research participant has received the information in person. The research file should document the nature of the new information and when and by whom it was provided.
2. **Communication at the next scheduled visit,** using an REB-approved document  
     
   Suitable if the new information is not of an urgent nature (for example, a change in the frequency of follow up visits; reduction in number of study procedures)
3. **Communication by mail,** using an REB-approved document  
     
   Suitable if the information is not time sensitive or is administrative in nature

**REB Review of Significant New Information**

1. Significant new information to be communicated to participants should be submitted to the REB in the form of an amendment, with all applicable written documents.   
   (***Note:*** If no written documents are available at the time of the submission, then the REB process for reporting unanticipated problems shall be followed)
2. Significant new information should be reviewed and approved by the REB before it is provided to participants, ***unless the information is of an urgent nature.*** The urgent dissemination of this information should be reported to the REB when the pertinent amendment is submitted for approval.

**Information for which a Consent Form Addendum is NOT Required**

The REB is aware that study sponsors often request researchers to present revised consent documents to participants to sign ("re-consent") when documents have been revised, regardless of the significance of the new information or change. In many cases informing participants is inappropriate and may result in additional needless burden. Consequently, the REB does ***not*** require the use of a Consent Form Addendum when the revisions would not or could not affect the participants’ willingness to continue participation in the research study:

* Correction of typographical errors has been corrected; revision of the version date on the consent form
* A minor increase in number of participants to be enrolled in the study
* Addition of new short term risk information about the study drug/intervention in participants no longer receiving the study drug/intervention
* Addition of new study procedures or additions of study visits that do not pertain to participants already enrolled in the study (e.g., changes made to screening procedures that affect only new participants).

**Summary Table:** The following table summarises the appropriate methods to use when providing significant new findings to research participants and the documentation required for notification. All pertinent documents require approval by the Research Ethics Board (**see previous comments regarding urgent verbal communication**)

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| **Document(s) Required for A Revised CF** | **Participant/Study Status** | **Best Practice: Process for Provision of New Information** |
| **Updated Consent Form**  Original Consent Form ***rewritten in its entirety*** when new findings are considered significant | Allparticipants ***to be actively enrolled in the given study*** | Participants to sign new (revised) consent form ***at time of enrollment*** |
| **Consent Form Addendum**  An addendum to the original approved consent form signed by the participant  Contains ***only the pertinent new findings/changes,*** and a discussion of their importance in the context of the original signed consent form | Participants ***currently enrolled/receiving the active study intervention*** | Immediate recall of the participants to review and sign the Consent Form Addendum  **OR**  Contact participants via phone etc with new information; pertinent documents reviewed and Addendum signed at next visit |
| Participants ***on follow up, with occasional visits*** | Contact participants via phone etc with new information; Addendum signed at next visit |
| Participants ***on follow up phone contact*** | ***Mail*** Addendum; enclose copy that participants can sign and return; confirm receipt at next phone contact; record in participants’ study records |
| Closed to follow-up. ***New findings affecting the long-term health of the participants*** | Contact participants with new information; mail Addendum; contact again to confirm receipt; record in participants’ study records |