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GUIDANCE NOTES FOR NOTIFICATION OF STUDY CLOSURE

1. PURPOSE

This Guidance Note explains the information that must be submitted to the FHREB upon completion of a study.

2. CRITERIA FOR STUDY CLOSURE

2.1. Studies Involving Human Subject Recruitment

A study is considered closed only when ALL data collection procedures as per the approved protocol have been completed. Studies that have completed subject recruitment [i.e. closed to accrual] are not considered closed if data related to the subject is still being collected. This type of data collection activity can include the following:

i) post-treatment contact with research subjects; for example, when data is collected via imaging reports, blood analysis reports, etc. and incorporated into the research study database.
ii) indirect collection of data for follow up purposes after treatment with the study intervention is completed; for example, quality of life/late side effects/survival data. As an example, this type of data might be collected by telephone contact with the research subject or via a third party such as a family physician.

2.2 Studies That Do Not Involve Direct Subject Participation

Studies that do not involve direct subject participation, for example, secondary use of data, are considered closed when data acquisition is completed.

Studies that involve the analysis of tissue only are considered closed when no more tissue samples are being withdrawn from the tissue bank or acquired from another research group for studies which analyze human tissue.

2.3 Study Renewal

Once a study is closed, annual renewal of the study is not required. Please ensure that an up to date renewal is in place until the study is closed.

3. NOTIFICATION OF STUDY COMPLETION

3.1 Obligations of the Principal Investigator

The principal investigator/designate for any study involving human subjects must affirm that data collection has been completed so that there is no direct or indirect contact with the subject for purposes of collecting data related to that individual.

3.2 Procedure for Notifying the FHREB of Study Closure

Updated 2017 November 17: The principal investigator/designate should email the Integrated Post-Approval Application Form Section B Renewals, as applicable, to REB@fraserhealth.ca or the current FHREB Coordinator.

The information that must be included in the notification varies for different types of studies and is detailed below in Guidance Notes 3.3, 3.4 and 3.5.

3.3 Clinical Trials

Reference: ICH GCP 4.13 "Final Report(s) by Investigator"[1]

Once the study has been completely closed by an industry sponsor at the site close-out visit, the "Close-out Notification Form for Clinical Trials and Industry Sponsored Research" must be submitted to the FHREB. Essential elements of this form include:

- the Principal Investigator's affirmation that subject data collection is completed;
- total number of research subjects enrolled at the FH site;
- the number of Serious and Unexpected Adverse Events, if applicable;
- the date of the study monitor's final close-out visit, for industry sponsored research;
- the final disposition /storage of all research-related study documents;
- the final disposition of any electronic data (i.e. locked), and;
- any other information required by the study sponsor.

3.4 Non Clinical Research

Once all study data has been collected from any source (e.g. subjects, secondary data/tissue banks), the Integrated Post-Approval Application Form Section C Close-Out must be submitted to the FHREB. Essential elements of this form include:

- the Principal Investigator's affirmation that data collection is completed.
- total number of research subjects enrolled at the FH site, if applicable;
- the final disposition of all research-related study documents, and;
- the final disposition of any electronic data (i.e. locked).

4. FHREB ACKNOWLEDGEMENT OF NOTIFICATION

The FHREB office will email an acknowledgement of the closure notice within five business days to the contact person identified in the closure notice and the Principal Investigator.

[1] Canada: Good Clinical Practice: Consolidated Guideline. ICH Harmonised Tripartite Guideline. 1997. Available at http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/ich/efficacy/goodclin_e.pdf .