



Study Change-in-Status Form Guidelines

1. INTRODUCTION

The following notes are intended to assist the researcher with the completion and submission of a Study Change-in-Status Form.

The information provided on this form is used by the Research Ethics Board to monitor any changes that may impact the safety of the study for participants.

Closed studies that will remain active for treatment or long-term follow-up and/or data analysis are still required to undergo a continuing review each year, up until the time of the final study closure. This form should not be used for a complete/final study closure notification. Investigators must submit a Final Report form. Please see the Annual Renewal/Final Report Form Guidelines for more information.

2. PROCEDURES

- 1) A Study Change-in-Status form + 4 copies must be completed and forwarded to the Research Services Office on the 15th of the month prior. Also, please forward 1 scanned copy to reb@hsnsudbury.ca. If your study involves an outside sponsor, attach correspondence as appropriate.
- 2) Changes-in-status that may occur are:
 - a. Target accrual met: This is usually when the Sponsor has closed recruitment when global recruitment is attained.
 - b. Accrual/recruitment prematurely closed: This occurs when the study is closed locally. The study may be discontinued by the sponsor or a regulatory authority. It may also be a closure initiated by the sponsor due to the fact that the study site has not met the recruitment goals set out by the contract.
 - c. Study suspended: The study may be temporarily stopped for a period of time by either the sponsor, or a regulatory authority. This is more than just a suspension of recruitment and potentially has greater impact for participants who are already enrolled in the study and taking part in study related activities. If this is the situation with your study, please provide detailed information on what actions have or will be taken to maintain participant safety and to inform current participants. **This is a significant change that will require detailed reporting to the REB.**
 - d. Study re-initiated: A study that has been suspended is now being re-initiated. Please provide details on how this process will occur, particularly what actions have or will be taken to advise participants who were taking part at the time of study suspension. **This is a significant change that will require detailed reporting to the REB.**
 - e. Recruitment suspension: This most often occurs when there is an amendment to the protocol by the sponsor that necessitates recruitment of potential participants be put on hold until the amendment is approved. Ongoing study participants continue in the study as usual.
 - f. Recruitment re-initiated: Recruitment activities are reinstated. This most often occurs after an Amendment of a protocol has been approved by the REB.
- 3) It is necessary to advise all parties involved in the study of any change to ensure that they are up to date on the status of the study. The information regarding the change impacts each area differently depending on the working relationship that has been established with the department, nursing unit or office. (For departments providing a “service”, it impacts the workload requirements for services provided, for nursing units it may impact recruitment or participant care, and for Research Administration, it may impacts billing/invoicing).