

# Status Change

Medical University of South Carolina

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# What is Status Change?

- A Status Change is only submitted to the IRB to report an immediate change in study status that is outside of normal study progression and well before a Continuing Review is due.
- Often, it is used to report a temporary suspension in enrollment due to new safety information.
- May be submitted in conjunction with updates needed due to a reportable event.
- Cannot use Status Changes to permanently close a study with the IRB.

# Getting Started

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- In your inbox, select the study that needs a Status Update.
- Under “My Activities” select “New Status Change”

The screenshot displays a user interface with two main sections: 'Current State' and 'My Activities'. The 'Current State' section is titled 'Approved' and contains three buttons: 'View Study', 'Printer Version', and 'View Differences'. The 'My Activities' section contains a list of activities, each with a red 'SS' icon: 'Edit Guest Access', 'Log Public Comment', 'Copy Study', 'Edit Communication Leads', and 'Edit SC Research Studies Directory Posting'. Below these activities are four buttons: 'New Reportable Event', 'New Amendment', 'New Continuing Review', and 'New Status Change'. The 'New Status Change' button is circled in red.

# Statuses Explained

- **Enrolling Subjects and/or Collecting Data:** use this status if actively enrolling subjects and/or collecting data on enrolled subjects
- **Enrolling Subjects – No accrual/enrollment to date:** use this status if trying to enroll subjects, but at the time of continuing review, there are no subjects enrolled
- **Enrollment Closed – Subjects continue to receive study treatment/intervention:** use this status once enrollment has been reached or closed, but are still actively treating the subjects
- **Enrollment closed – Follow-up and collecting data only:** use this status when enrollment is closed but no active treatment is occurring. Subjects are just in follow-up.
- **Data Analysis Only – Identifiable:** use this status when enrollment is closed and only completing data analysis with identifiable data.
- **Data Analysis Only – De-identified:** use this status when enrollment is closed and only completing data analysis with de-identified data.
- **Enrollment Temporarily Suspended:** use this status when enrollment has been suspended by the sponsor/PI
- **Permanently Closed – All study activities are completed:** use this status when closing out/terminating the study with the IRB

# Selecting a Status

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- Select the **NEW** status, not what the status is right now.

2.0 – Make sure to explain the reason why the status is changing.

## Status Change

### 1. \* Current Study Status:

- Enrolling Subjects and/or Collecting Data
- Enrolling Subjects - No accrual/enrollment to date
- Enrollment Closed - Subjects continue to receive study treatment/intervention
- Enrollment Closed - Follow-up and collecting data only**
- Data Analysis Only - Identifiable
- Data Analysis Only - De-identified
- Transfer to External IRB
- Enrollment Temporarily Suspended

### 2. If enrollment status changed, explain why:

# Number of subjects

- Provide all of the requested information.

## Number of Subjects

- |     |  |   |              |
|-----|--|---|--------------|
| 1.0 | Number of subjects study-wide - proposed:                    |   | Study Value: |
| 2.0 | Number of subjects at local site - proposed:                 | * | Study Value: |
| 3.0 | Number of subjects enrolled study wide - actual:             |   |              |
| 4.0 | Number of subjects enrolled at local site - actual:          | * |              |
| 5.0 | Number of subjects enrolled at local site since last review: | * |              |

*Note: "last review" is the study's initial review or continuing review, whichever is most recent.*

## Number of Subjects (Continued)

- |     |   |
|-----|---|
| 1.0 | Subjects receiving treatment/intervention - local:                                |
| 2.0 | Subjects in follow-up only - local:   |
| 3.0 | Total subjects completed - local:<br>(Including death(s) as an expected endpoint) |
| 4.0 | Estimated date of study completion:   |

# General Comments

- Upload any correspondence from the sponsor or documents that will assist in the review of or explain the reason for the status change.

**General Comments**

1.0 **Add any additional comments to assist in the review**

2.0 **Add any miscellaneous documents that do not fit in other sections of the study application**  
Click Add to upload document(s)

Name	Description	Orig. Author	Orig.
There are no items to display			

# FINISH

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The PI will submit  
the completed  
Status Change!

