

N2/CAREB-ACCER SOPs v4

List of changes

SOP Code	Effective Date	Summary of Changes
SOP 105B.004	15-May-2023	Changed his/her to their
SOP 108.004	15-May-2023	Responsibility for the SOP revised to indicate the responsibility for the management of the SOPs is with the N2/CAREB REB SOP Committee
SOP 201.004	15-May-2023	Changed his/her to their
SOP 203.004	15-May-2023	Changed his/her to their
SOP 302.004	15-May-2023	5.6: deletion of approval 5.6.1: deletion of 'are presented at the meeting for REB approval'; inclusion of 'members are requested to review the minutes and to note any errors for correction' 5.6.2: deletion 5.6.3: deletion 5.7.1: deletion of 'or' replaced by 'and'; 'Number(s) voting for, against and abstaining....'
SOP 303.004	15-May-2023	5.4.4: remove specific reference to HC retention requirement
SOP 701.004	15-May-2023	5.2.2: addition of French 5.6.3 addition of "and dated" as per GCP 4.8.11? "Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects"
SOP 801.004	15-May-2023	Replaced his/her with their

Addendum	Effective Date	Purpose of the Addendum	Summary of Changes
SOP-Research-REB-303.003-Document-Management-Addendum	15-May-2023	Revise the language regarding the retention of documents to be more inclusive of different types of research	Minor revisions to wording and numbering
SOP-Research-REB-402.003-REB-Review-Decisions-Addendum	15-May-2023	Clarifies the language regarding approvals	Minor revisions to wording and numbering
SOP-Research-REB-106.004-REB-Signatory-Authority-Addendum	03-Sep-2024	Delegates and defines signing authority to members of the REO	Newly created