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| Examples of what comprise amendments | * Change to the study end date. * Inclusion of new sites and investigators. * Minor changes to the protocol or other study documentation. * Updates to investigator’s brochure (unless there is a change to the risk/benefit assessment for the study). * Minor changes in funding arrangements. * Changes in the documentation used by the research team for recording study data. * Changes in the logistical arrangements for storing or processing data. |
| Examples of what extend beyond amendments | * Significant changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value. * Changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment of the study. * Change of sponsor(s) or sponsor’s legal representative. * Change to the insurance or indemnity arrangements for the study. * Changes to the definition of the end of the study. * Any other significant change to the protocol or the terms of the REC application. |