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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.
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| 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.
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