

Appendix 4

Study Status Definitions

Study Status	Definition
<u>Abandoned</u>	The project owning organisation, site or sponsor has chosen to abandon the project at this site. It might have started to be worked up but it is no longer viable or has failed feasibility. It could be that the study is subject to competitive recruitment and the national target has been reached before UHL is set up. Could also be that it has received an unfavourable opinion from the REC
<u>Accepted</u>	The site has been approached to gauge interest in running the project and has been accepted. Not in use at UHL
<u>Archived</u>	The site has been archived. Use when the study is completely closed and has been officially archived and moved to relevant archive facility. The study should appear in the Stor-a-file Archive spreadsheet unless alternative archiving arrangements have been made.
<u>Closed</u>	The site is closed and no more patients can be recruited. Study has finished recruitment and all site activity. The study data may be in the process of analysis and follow up is not required.
<u>Closed – Follow up complete</u>	The site is closed and follow-up is finished. Study has finished recruitment and all site activity. The study data may be in the process of analysis and follow up has been completed.
<u>Completed</u>	The site is completed and published. This is the stage immediately before archive. A report must have been submitted & if possible publications have been made.
<u>Concept</u>	The site is in concept stage and is not in formal development. This should be used when the study is Sponsored by UHL and preliminary work is being undertaken to set the study up with UHL as the lead centre.
<u>Declined</u>	The site has been approached to gauge interest in running the project but has declined. In addition it may be that no response has been received from the specialty areas.
<u>Expression of Interest</u>	The site has been approached to gauge interest in running the project. Awaiting response from specialty areas.
<u>Feasibility</u>	The site is in a feasibility stage. This is site feasibility, part of initial stages of C&C – this is often coupled with Sponsor feasibility to assess site appropriateness.

<u>Not selected by sponsor</u>	The Sponsor has decided not to run the project at this site.
<u>Open</u>	The site is open and actively recruiting patients
<u>Project site in set up</u>	The site is still being set up before it is ready to be opened. This status means that the study has achieved a satisfactory feasibility and is being worked up to confirm Capacity & Capability.
<u>Rejected</u>	The site has been rejected or the site has rejected the study. This is subtly different to declined.
<u>Suspended</u>	The site is currently suspended. This is usually down to regulatory reasons. It is often done by either the Host organisation or Sponsor when situations have arisen that require the site to temporarily suspend activity. It can also be as a result of drug or device safety concerns. When a site is officially suspended, a formal notice must be received from the relevant regulators & HRA before re-opening.
<u>Withdrawn</u>	A regulatory authority has stopped the project at this site.
<u>Withdrawn by sponsor</u>	The sponsor has stopped the project at this site