

Policy: The Involvement of human subjects in medical research

If a Diabetes UK funded study involves human subjects, the administering Institution, the Grantholder and any other personnel involved in the study must treat such subjects in accordance with all applicable laws and regulations including, where relevant, the World Medical Association Declaration of Helsinki and the MRC Guidelines for Good Clinical Practice in Clinical Trials.

Before a Diabetes UK grant award can be activated, researchers are required to have all relevant regulatory and ethical approvals in place. Researchers may apply for funding before these approvals are in place, but the research may not commence until all necessary approvals are received.

It is the responsibility of the administering Institution to ascertain whether regulatory and/or ethical approval is required.

Evidence of all necessary regulatory and/or ethical approval must be submitted to Diabetes UK before the grant award can be activated. If, during the period of the grant award, there are any changes to protocol or to applicable laws and regulations that require an amendment to regulatory and/or ethical approvals, copies of the amendment approval documentation must be submitted promptly to Diabetes UK.

Diabetes UK requires that all eligible clinical trials are registered on the [International Standard Randomised Controlled Trial Number Register](#) (ISRCTN) or on another register listed on the [WHO International Clinical Trials Registry Platform](#) (ICTRP). Diabetes UK will meet the costs of registering the trial where this cost has been requested in the grant application.

Any serious incident arising in the course of the grant funded project must be reported immediately to Diabetes UK and the appropriate ethics committee. The grant funded project must be suspended until the relevant ethics committee has reached a conclusion on whether the project may continue. The Grantholder should notify Diabetes UK promptly of any decision by the ethics committee.