

Protocol registration requirements for NIHR funded systematic reviews

Principle Investigators are requested to send their registration number, or proof that they do not need to register, as part of the pre-contracting processes. Only once all approvals are in place does the NIHR HTA programme issue the contract. A tick box for approvals gained is being incorporated in the new HTA programme information management system which will allow monitoring of status and prompts to be sent if required.

For Technology Assessment Reports (TARs) which are carried out by affiliated groups under a capacity contract, the registration number is required after final protocols are approved by NICE or NIHR HTA and are part of the going 'live' process; prompts would be sent if registration details were not forthcoming.

Changes to internal processes have been limited to updating the website and guidance to applicants to reflect the requirement to register systematic review protocols; and the monitoring team alerting project teams who are commissioned to undertake a systematic review that requires registration. NIHR HTA programme also promote the benefits of registration and encourage participation to all relevant projects that are already active and receiving funding and meet the PROSPERO inclusion criteria.

The following guidance was used in the pilot and is to be included in information to all NIHR project fund holders:

“Applications Involving Evidence Synthesis

Applicants undertaking systematic reviews should note the commitment of NIHR to registration in the PROSPERO database. PROSPERO was developed by the NIHR's Centre for Reviews and Dissemination (CRD), and is the first international online facility to prospectively register systematic reviews for research about health and social care. Access is free of charge and open to the public.

PROSPERO registration is a condition of NIHR funding for systematic reviews. It is accepted that not all systematic reviews commissioned by the HTA programme will fall in to the scope of the register. The immediate focus is on reviews of the effects of interventions and strategies to prevent, diagnose, treat, and monitor health conditions for which there is a health related outcome. A review should also only be registered once it is in receipt of confirmed funding, and not before.

The timing of registration should be at the point when the protocol is complete/stable but before screening studies for eligibility has begun. It is at this point where intentional, or inadvertent, bias could come in to play i.e. manipulating the inclusion criteria to capture those studies that show a particular desired result.

Researchers are required, once registered on PROSPERO, to keep their protocol up to date, this includes mirroring any major protocol amendments, updating status when completed (or abandoned) and adding publication details when published.

Registration should take place on the PROSPERO website, which can be accessed at <http://www.crd.york.ac.uk/PROSPERO>.”