HRA consultation on Transparency – Registration and Reporting (Archive)

**UKCRC Registered CTUs Network Response:**

Whilst we are supportive of the HRAs commitment to increase transparency in clinical trials by making trial registration a condition of favourable ethics opinion for future trials, the proposals do not take into account the framework within which academic trials are conducted in the UK. The host institution of the CI (university or NHS) may provide the mechanism for sponsor oversight and approval and have legal responsibility for the trial from a regulatory perspective, however, it is the CI (or the CTU engaged by the CI) who is responsible for the set up and the conduct of the trial, including obtaining a favourable ethics opinion, and for registering the trial and reporting the results. By setting the conditions of favourable opinion at the sponsor level, rather than at the CI level, the proposal risks penalising individual CIs due to the actions of others within their host institution or, where the trial is co-sponsored, at another institution. This seems totally unreasonable. We would suggest that it is the CI declaration rather than the sponsor declaration that requests confirmation that all trials for which they are responsible have been registered. Otherwise the proposals risk impeding research across an entire institution due to the practices of one individual.