Levels of R&D Support for Researchers

This table outlines some of the specific support available to UHCW staff carrying out a trial defined as research requiring an IRAS submission. Support activities are carried out by different R&D teams which have been grouped into 3 levels of support. Activities not ticked will be the responsibility of the researcher. Please note this is not an exhaustive list of trial activities, and where appropriate, activities will be documented in a more detailed Division of Responsibilities. Early discussion with R&D at the grant application stage is essential to agree your required level of support, please contact researchsponsorship@uhcw.nhs.uk (Ext. 26053) in the first instance to discuss if you're less familiar with these R&D teams.

	Levels of R&D Support		
	1	2	3
Activities	**Governance Support**	**Institute Support**	**Trial Management Unit (TMU) Support**
Dedicated point of contact for advice & guidance throughout your trial	✓	✓	✓
Discussion of your research idea, initial feasibility assessment and signposting (e.g. Governance, PPI, Statistics, Clinical delivery, Randomisation, IP, Supporting departments)	✓	✓	✓
Arranging and Coordination of Site Initiation Visit (SIV) if required	✓	✓	✓
Submission of Integrated Research Application System (IRAS) Form (initial/modifications)	✓	✓	✓
Monitoring and oversight of finances, funder and trial milestones/reporting	✓	✓	✓
Support with close down & archiving activities	✓	✓	✓
Review & feedback to researcher of Protocol, IRAS Form and other trial records (initial/modifications) prior to Sponsor review submission		✓	✓
Oversight, review & feedback to researcher of data management procedures (e.g. Case Report Form (CRF) review)		✓	✓
Opening external trial locations for **multi-centre trials**		✓*	✓
Arranging regular meetings to discuss trial progress		✓	✓
Editing of Protocol, IRAS and other trial records (initial/modifications) prior to Sponsor review submission			✓
Coordinating the set-up of **trial interventions** e.g. drugs, devices			✓
Creation of trial specific documents required to set-up the Investigator Site File (ISF)			✓
Full **Data Management** (e.g. CRF review, database development, data validation)			✓
Arranging regular Trial Management Group (TMG) meetings (e.g. monitoring recruitment, safety reporting, deviations etc.) and other oversight committee meetings (e.g. TSC/DMC)			✓
Day-to-day coordination following approvals, during recruitment until the end of the trial			✓

**Limited to non-REC trials*