An Introduction of Principal Investigator Pathway, Improving 'out of hours' Contact

A successful collaboration between the CRF Administration Department & Principal Investigators on securing availability and an 'out of hours' contact service for all clinical trials carried out of the Clinical Research Facility, based at the University Hospital of Wales.

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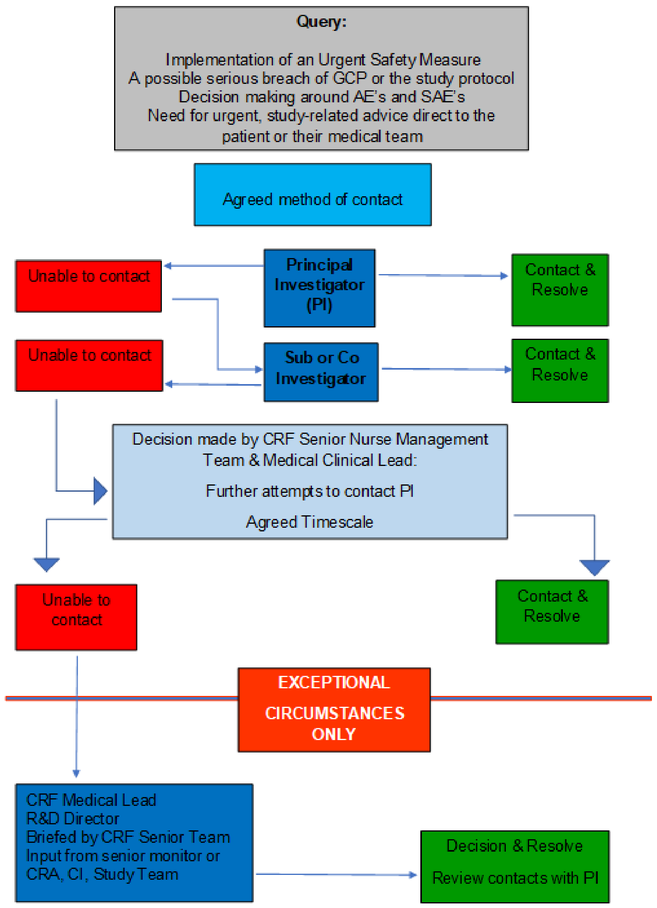
Background: The University Hospital of Wales (UHW) Clinical Research Facility (CRF) conduct clinical trials from Phase I to Phase III across many adult hospital specialities. The portfolio of clinical trials includes first in man studies and other agents not yet licensed. Should issues arise relating to such studies requiring Principal Investigator (PI) contact the flowchart opposite is to be followed. These could include the following; queries from other clinicians caring for patients, requests for action or response from agencies including regulatory & sponsors in the event of an Adverse Event (**AE**), Serious Adverse Event (**SAE**) or Suspected Unexpected Serious Adverse Reaction (**SUSAR**).

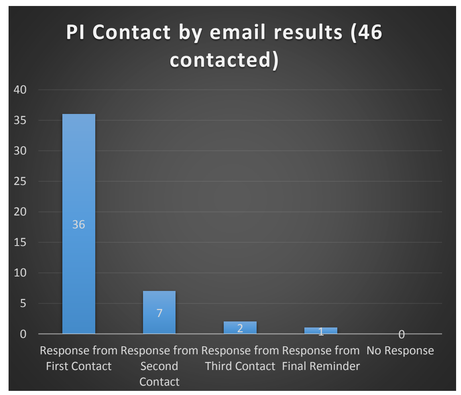
Methodology: PI contact details and preferences of contact are recorded during the study set up stages by the CRF Admin Team and are held electronically on a shared drive for ease of use. The minimum information required is one or more telephone numbers for urgent contact and an email address for non-urgent contact. Studies may also have sub-investigators (SI) capable of acting as a nominated deputy for the PI. To be part of this contact pathway such SI must be appropriately named on the delegation log.



Aims & Objectives: Our aim is for the CRF to implement a new structure within the facility, in line with Standard Operating Procedures (SOP) that ensures up to date contact details for PI & SI. In order to achieve this I have created a generic e-mail to capture any change in circumstances which is automated and issued monthly to all PI's & SI's that carry out Clinical Trials within the CRF. Details are then updated onto CRF Manager® and in addition we notify UHW switchboard.

Study Name: Clinical Trial (Haematology)						
Principal Investigator	**Co- Investigator**	**Email**	**Mobile**	**Office Hours**	**Out of Hours**	**Secretary Contact**
Professor/ Dr Name		Name.Name@email.com	07967109874	02920740000	02921000000 (home)	02920749999
	Dr J Watson	J.Watson@email.co.uk	07875123456			
	Dr S Holmes	S.Holmes@email.com	07791012345	02920747747	02920123456 (home)	

Results & Conclusions:
Results for this implementation are ongoing and data is still being analysed. Early reports show that since implementation we have been able to identify 3 changes in PI circumstances that may not have been reported or advised without this procedure being in place.



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