Cambridge Clinical Research Facility

National Institute for Health Research

Developing a study risk assessment tool

Stewart Fuller on behalf of the UKCRF Network study risk assessment tool group

Background and Aim

Clinical Research Facilities (CRF's) are required to submit risk data for their annual reports to National Institute for Health Research (NIHR) on studies undertaken in their facilities.

The need for consistent approach across all CRF's when assessing and reporting risk was identified.

A working group was set up representing 19 (NIHR) CRF's. The Study Risk Assessment Tool was developed to assess and quantify each study's risk.

Methodology

A working group was convened with representation from a diverse group of research professionals. Clinical research nurses, clinical research nurse managers and quality assurance managers collaborated to develop the tool.

Following an initial face to face meeting and drawing on a risk assessment tool from NIHR Birmingham CRF, the group developed a pilot tool.

The pilot tested the tool across a variety of CRF's and study types. e.g. Early phase I/II, experimental medicine, late phase and imaging studies The group shared their pilot results with the working group via a series of teleconferences.

A guidance document was also produced to assist in completion of the risk assessment.

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Risk Area	Description (Risk Significance Score*)				Score
Study Design & Management					
1. Complexity of study design / methodology	*First in Human /Phase 1 Pilot/proof of concept Double blinded / adaptive / multiple arms* (9)	*Randomised Controlled Trial* (6)	*Clinical Trial (Open Label)* (3)	*Cohort / Cross-Sectional* (1)	
	Pilot/proof of concept Double blinded / adaptive / multiple arms (9)	*Experimental Medicine/Phase 2/2a/2b* (6)	*Phase III Phase IV* (4)	*Observational Epidemiological Studies Clinics* (1)	
2. Trial management & Data capture structure		*Non-commercial study* (4)	*Commercial study* (2)		
Study Procedures					
3. Interventions (including IMP administration)	*New or Non-standard procedures not previously undertaken in the Trust* (9)	*Invasive procedure(s) currently undertaken within Trust that are new to the CRF* (6)	*Invasive procedures currently undertaken by CRF Staff* (4)	*Study limited to blood samples and/or questionnaire only* (1)	
4. Study Visits	*Any visit outside core hours* (9)	*Outreach / Lone Working / Home Visit* (5)		*Outpatient visits within core working hours* (1)	
Investigational Medicinal Product					
5. IMP Involvement	*Advanced therapy IMP or GMO* (8)	*CTIMP or Device (6)*	*No IMP dosing* (2)	*No IMP* (0)	
Participants					
6. Participant Group	*Adults lacking capacity / Children / Complex or specialist care needs* (8)	*Patients* (6)	*Healthy Volunteers with chronic conditions* (4)	*Healthy Volunteers* (1)	
Investigator					
7. Investigator Experience	*PI with no research experience* (9)	*No previous clinical studies in the NHS* (6)	*No previous studies in the CRF* (4)	*Adequate training and experience to support this study* (1)	
Resources					
8. Intensity Score		*High* (6)	*Medium* (4)	*Low* (1)	
Laboratory					
9. New or hazardous samples or processing methods	*Yes High Risk* (9)	*Medium* (6)	*Low* (4)		
Any Other Perceived Risk					
	(9)	(6)	(4)	(2)	
Risk Minimisation Strategies					
Residual Risk					
Comments					

If score <15 consider if appropriate for implementation on the CRF	High >44	Medium 30-44	Low 15-29	Overall score:
Completed by:		Date:		
Checked by:		Date:		

Results

Designed to be simple to use, the tool assesses risk across 7 categories. Risk assessment is made by attributing scores to each category via sub category descriptors.

Categories are; Study Design and Management, Study Procedures, Investigational Medicinal Product, Participants, Investigator, Resource and Laboratory Risks.

The assessor is able to document any risk minimisation strategies and residual risk. The completed risk tool provides a risk score as well as a High, Medium or Low risk status for each study.

Study Risk Assessment Tool

Overview of Risk Scoring Tool

Each study implemented in the Clinical Research Facility (CRF) must be given an overall risk score (High/Medium/Low) which is reported as part of the annual metrics return to NIHR.

The risk assessment tool provides a method for generating an overall estimate of risk significance (consequence x likelihood) for each study, and also for identifying individual significant risks that may require further review and or action(s).

Use of a standardised tool across the CRF network ensures that there is consistency in the risk scores reported. The tool should be used in addition to risk assessment and management procedures, as required by individual Trusts.

Using the Risk Scoring Tool

The score should be calculated before risk controls or other mitigation activities have been undertaken.

A member of the CRF team can complete the scoring tool using the current version of the study protocol and the CRF application form or Site Specific Information (SSI) form.

The risk score is calculated from seven risk areas associated with study delivery and there are twelve specific risk categories to be considered. These are shown below:

Risk Area	Risk Category
Study Design & Management	Study Complexity
	Study Management / Data Capture
Study Procedures	Interventions
	Study Visits
Investigational Medicinal Product	IMP
Participants	Participant group
Investigator	Investigator Experience
Resources	Intensity Score
Laboratory	New or hazardous samples / processing

Each row is scored separately, and the score is inputted into the end column.

Once a score has been given for each of the 10 rows, a total score can be calculated, which will correspond to one of the 3 risk bands (High/Medium/Low).

Conclusion

The working group achieved consensus despite diverse clinical trial professional representation. The pilot process allowed for CRF's with very different types of studies to test the tool in their own facilities to ensure it met local needs, as well as providing standardised metrics for reporting purposes.

The tool is now in use across the 19 NIHR CRF's. It is easy and quick to use and can be applied to a wide variety of clinical research studies.

The group now plans to perform a final review of the tool and its guidance document following the submission of this years annual reports to NIHR.

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