DIVISION OF RESEARCH AND INNOVATION

Quick Guide: Completing Datix for Research Participants

Open an 'Incident Reporting - Datix' form from GOSHweb 'Quick links' (at the bottom of each page).

At the top of the form there are instructions that highlight useful policies, give guidance on the icons used in the form and provide useful contacts in case you need further assistance.

Within the form you can also click the ❓ icon for help with a particular field.

Section	Guidance
People Affected	• Complete for ALL people affected by the incident. • If more than one person was impacted, 'Add another' to include their details. • This is the ONLY place where the person affected should be identified. • Select 'Yes' the patient is involved in a research study and complete the R&D number. If multiple studies are impacted, write 'multiple' for R&D number and upload a word document with a full list of R&D numbers in 'additional information'.
Other contacts	• Complete if other people were involved but not affected by the incident (e.g. witnesses, police officers, family, other staff members). • This is the ONLY place where the person involved should be identified.

Incident Details	• Complete Incident date and time.
	• Complete Division and Speciality – It's important to get this right during reporting or the right people won't be notified of the incident.
	  ○ **For CRF**, Division is 'Research & Innovation' and Speciality is 'Research'.
	  ○ **For research outside of the CRF**, select your Trust Division and Specialty and then select 'Yes' that additional specialities are involved. For the Additional Specialty/Department involved, select 'Research' by double clicking on it.
	• Complete Location (type) and Location (exact) – It's important to get this right during reporting or the right people won't be notified of the incident.
	  ○ **For CRF**, Location (type) is 'Ward/Adjacent areas' and Location (exact) is 'Clinical Research Facility'.
	  ○ **For R&D Office**, Location (type) is 'Office' and Location (exact) is 'R&D Office'.
	• Complete the Description and Immediate Action Taken.
	  ○ Be factual and as succinct as possible, consider using the SBARD model.
	
	  ○ '**R**ecommendation' and '**D**ecision' will be completed by the incident manager as part of the investigation.
	  ○ Do not include any person identifiable or study identifiable information here.
	  ○ You can check spelling by clicking on the 📝 icon (bottom right of each box).

Incident coding	• Complete this section; if you need any help speak to your manager, the incident manager or the contacts at the top of the incident form.
Additional information	• Select if you want/don't want to attach any documents to the incident. If you do want to attach documents; complete the document information. If multiple studies are impacted, upload a word document with the full list of R&D numbers here.
Reporter	• Complete your information
Responsible Manager	• Complete the person who is responsible for managing this incident. This doesn't have to be your manager but should be the most appropriate person to investigate the incident. Discuss with the Nurse in Charge/Clinical Band 7 if you're not sure.

DO NOT MAKE UNAUTHORISED COPIES