

**STANDARD OPERATING PROCEDURE 40
WCTU Business Continuity Plan**

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4.0	12 Jun 2026	Urgent amendment: inclusion of signpost to trial level BCPs in section 7.1 in line with UoW Policy.
3.0	31 Dec 2025	Biennial review. Re-write based on continuity test. Added in processes and responsibilities related to trial level incidents and strengthening the responsibilities around trial-based business continuity.
2.0	18 Jan 2023	Scope increased to include all priority activities. Changes based on continuity test: Strengthened the need for study specific priorities are to be identified and contingency included in working instructions
1.0	21 July 2020	New document



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1 Purpose and Scope

This SOP describes the procedures for responding to unexpected incidents that may disrupt operations within the Warwick Clinical Trials Unit (WCTU). It aims to:

- Enable prompt and effective responses to service disruptions.
- Ensure each trial identifies critical activities and maintains continuity through back-up and handover plans.
- Prepare WCTU for disruptions such as staff absences, system failures, or other operational issues.

It supports compliance with external standards, including the Data Security and Protection Toolkit, and aligns with the University’s Risk Management Procedures and Major Incident Plan. For broader guidance, refer to: <https://warwick.ac.uk/services/gov/businesscontinuity/>

This SOP is part of WCTU’s risk management framework and helps protect essential trial functions such as safety reporting, randomisation, and recruitment.

It applies to all WCTU staff. For the purposes of this SOP, the term ‘trial’ is used to refer to both clinical trials and non-trial studies, unless otherwise specified. References to ‘study’ should be interpreted in the same way.

2 Acronyms

BC	Business Continuity
BIA	Business Impact Assessment
CI	Chief Investigator
HR	Human Resources
QA	Quality Assurance
RA	Risk Assessment
R&IS	Research & Impact Services
SIRO	Senior Information Risk Owner
SOP	Standard Operating Procedure
TM/TC	Trial Manager / Trial Coordinator
UoW	University of Warwick
WCTU	Warwick Clinical Trials Unit

3 Definitions

Business Continuity	The process of identifying priority activities and the resources needed to carry them out. It refers to an organisation’s ability to maintain delivery of products and services within acceptable timeframes during a disruption
Business Continuity Plan	A document outlining recovery actions and alternative arrangements to help departments continue operations and restore normal service following major disruption
Incident	A localised event requiring a response but not classified as a major disruption or requiring University-wide intervention.

	<i>Example: Loss of systems managed by the Programming Team, localised flooding of the WCTU building or temporary loss of staff on a single trial.</i>
Major Incident	An event or situation that poses serious risk to human welfare, the environment, or national security. <i>Example: COVID-19 pandemic.</i>
Priority Activity	Activities that must be prioritised in the event of an incident to mitigate serious impacts. <i>Example: Safety reporting systems or time-critical central monitoring activities that support participant safety.</i>
Senior Risk Owner	A senior staff member accountable for the organisation’s information risk policy and overall information risk management.
Data Custodian	The individual responsible for the use, security and management of all data generated by a study. This role is delegated to the study’s CI.

4 Background

The University’s Business Continuity Planning policy requires all Heads of Department to complete a continuity plan for their area.

The core principle of business continuity is to ensure the delivery of priority activities during disruptions, such as ICT failures, severe weather, or infectious disease outbreaks.

Priority activities are identified through a Business Impact Assessment (BIA) and will differ across departments, faculties, and buildings.

This localised plan for WCTU outlines:

- The unit’s approach to incident response
- Identified priority activities
- Short- and long-term contingency measures

It supports the restoration of critical WCTU functions for local and major incidents. This SOP complements the University’s Major Incident Plan where it is implemented.

5 Responsibilities

Head of Operations/SIRO	Oversee the development and maintenance of the WCTU Business Continuity (BC) Plan, ensuring alignment with University of Warwick’s Business Continuity Strategy. Authorised to make decisions on behalf of the department during an incident. Responsible for managing, implementing and review of the plan.
QA Managers	Coordinate and maintain the BC Plan on behalf of the Head of Operations. Ensure annual testing of the plan is carried out.
Data Custodian	Usually, the CI or WCTU Academic Lead. Ensure business continuity requirements are documented for all owned information assets. Enable recovery processes for those assets in the event of disruption.

WCTU Programming Team Manager	Manage business continuity procedures related to WCTU’s trial data infrastructure. Oversee the development and maintenance of the WCTU Disaster Recovery Plan
Line Managers	Ensure staff are aware of and follow the procedures outlined in the BC Plan.
TM/TC	Identify study specific priority activities and ensure working instructions are in place to detail continuity for the identified activities
SPMs	Ensure teams under their portfolio maintain up-to-date continuity documentation, including team-level contingency plans where applicable. Maintain oversight of priority activities within their portfolio. Assess the impact of staffing or resource changes on these activities. Ensure handover documentation is available and accessible.
WCTU Staff	Review and follow this procedure during an incident. Be aware of where to access continuity resources and contact lists.

6 When

The WCTU Business Continuity Plan should be activated under the following circumstances:

Disruption to Priority Activities

When any activity identified as a priority (see Section 7.1) is at risk of interruption due to staffing, system, or facility issues.

Incident Classification

When an event is classified as either a WCTU-Level Incident or Study-Level Incident (see Section 7.2), requiring coordinated response.

Loss of Access to Critical Systems or Premises

When access to essential infrastructure (e.g. M-Drive, trial databases, WCTU building) is compromised.

Staff Absence or Handover Requirement

When key personnel are unavailable and handover documentation must be enacted to maintain continuity.

University-Wide Major Incident Declaration

When the University activates its Major Incident Plan, WCTU will support the broader response and enact relevant continuity measures.

Annual Testing or Scheduled Review

When conducting planned continuity tests or reviews as part of QA oversight (see Section 7.4).

7 How

7.1 Identifying, documenting and planning for priority activities

To ensure resilience during disruptions, each study must identify and document its priority activities that must be restored first to avoid significant impact. These should be determined early, ideally during the risk

assessment. The assessment of risk and priority activities should be revisited regularly at a time that is proportional to the risks.

Trial-Level Business Continuity:

It is good practice for each study to have a trial specific BC plan aligned with the Risk Assessment. But this could also be achieved through inclusion of continuity considerations within Working Instructions. At a minimum, the risk assessment should be signposted to the WI's which contain priority activities.

Continuity at a study level should:

- Identify study-specific priority activities
- Outline key risks and potential impacts
- Define back-up processes and handover arrangements
- Include key contacts and escalation routes
- Consider people, equipment and systems which are essential for priority activities.

Trial level BCPs are located within each projects individual risk assessments which are located on the Quality Assurance SharePoint Site: <https://livewarwickac.sharepoint.com/sites/WMS-WCTUQualityAssurance/RAMPs/Forms/AllItems.aspx>

Effective Handover:

In the event of expected disruption (e.g. staff absence), handover documentation should be used to transfer accountability for ongoing risks. Templates include:

- **T67**: SPM Handover Document
- **T36**: TM/TC Handover Document

Considerations for Priority Activities:

The table below outlines examples of WCTU-wide priority activities, associated dependencies, and infrastructure. Each study should adapt this framework to reflect its own specific needs.

For a comprehensive list of systems used across WCTU (including trial databases, M-Drive, online applications, and communication platforms), refer to the **WCTU Software Asset Register**. This register supports continuity planning by identifying system owners, access methods, and backup arrangements.

Table 1 – Considerations for WCTU Priority Activities

Priority Activity	People & Processes	Tech/Systems/Equipment	Premises
Preservation of paper documentation	n/a	n/a	WCTU Building/ CSRL Building
Preservation of digital documentation / data	Named archivists Programming Team	Mdrive Online applications	Server Building
Randomisation	Programming Team	Telephone/Micollab MS Teams Online applications	n/a
Safety Reporting	QA Team Clinical Causality Assessors (<i>site and WCTU</i>) SAE Triage Process	Mdrive Email Online applications	n/a
Emergency Unblinding	Trial clinical cover or 3 rd Party Service Providers	Mdrive Email Teams Online applications Telephone Unblinding system	WCTU Building/CSRL Building
Critical safety checks	Study team Investigator site data team	Mdrive Email Teams Online applications Telephone	WCTU Building/CSRL Building
Non-compliance & Breach reporting	TM QA Head of Operations	Mdrive Email Staff Intranet	n/a
Data Entry	Data Entry Clerk	Online applications Mdrive Email	WCTU Building

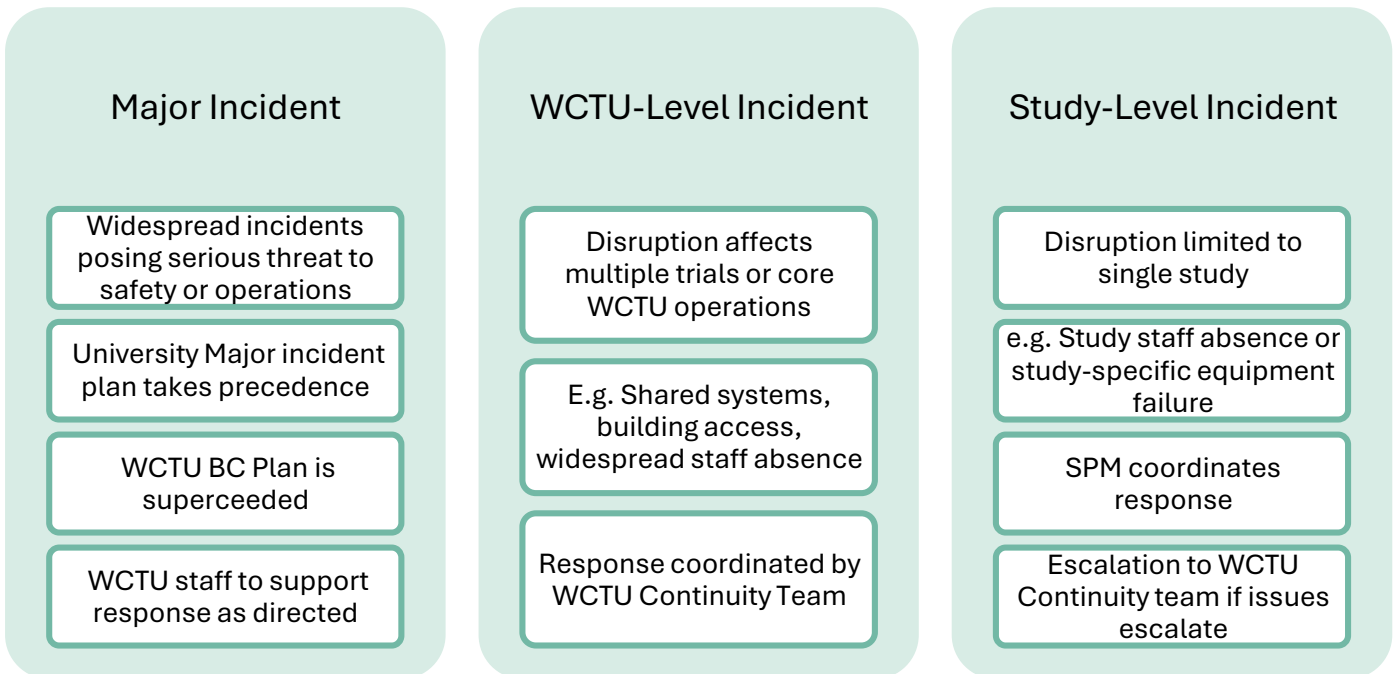


Sample Processing	Postal service / Couriers	Online applications Mdrive	n/a
Maintenance of CI oversight*	CI	Email Teams	n/a

*There are procedures for the loss of a CI in [SOP 12 \(part 1\)](#)

7.2 Assessment and response to incidents

When a disruption occurs, an initial assessment must determine the appropriate level of response. This is summarised below:



7.2.1 WCTU-Level Incident Response

In the event of a WCTU-Level disruption, a WCTU Continuity Team will be convened to manage the local response and maintain priority activities. Enacting the BC plan should be logged as per the section below.

Team Composition:

The core Continuity Team includes:

- Head of Operations (or delegate)
- Deputy Head of Operations
- QA Manager(s)

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- Senior Project Manager(s) (SPMs)
- Divisional Support Officer

Additional members may be invited based on the nature of the incident, such as:

- IT or Programming Team representatives
- Clinical Leads
- Information Governance or QA specialists

If key staff are unavailable, responsibilities must be delegated to ensure continuity of leadership and decision-making.

For details of current staff in the above roles visit:

<https://warwick.ac.uk/fac/sci/med/research/ctu/aboutus/team/>

Activation and Coordination:

- The Head of Operations (or delegate) will initiate the Continuity Team, ideally within 24 hours of the incident.
- Meetings will be held at a frequency appropriate to the severity and duration of the incident and may be conducted remotely.
- All decisions and actions must be documented in a Continuity Action Plan (see Appendix 1).

Initial Meeting Objectives:

At the first meeting, the team should:

1. Review the known details of the incident
2. Identify urgent risks or concerns
3. Agree on immediate actions
4. Assign roles and responsibilities
5. Determine communication needs, see considerations in table 2 below.
6. Confirm next meeting time and communication method

Table 2 – Considerations of potential parties to contact

Campus Security <i>(and Emergency Services)</i>	Internal Staff
Risk & Resilience Team	Study Oversight Committees
Senior Management	Regulatory Bodies <i>(e.g. HRA, CAG, NHS England)</i>
Media & Communications	Insurance Team
External partners	Estates
Visitors (on-site or en route)	Health & Safety
HR	Funding Body

7.2.2 Study-Level Incident Response

If disruption affects a single study, the SPM may lead the response using:

- The studies Business Continuity information
- BC Plan
- Trial-specific Working Instructions
- Relevant handover documentation

This ensures trial-level risks are addressed promptly and aligned with the broader WCTU response. Enacting these should also be logged as per section below.

7.2.3 Logging and Communication

Activation of the BCP and communication at any of these levels must be logged, and relevant stakeholders notified. This will be done primarily using [General | WCTU Business Continuity Team | Microsoft Teams](#).

7.3 Continuity Action Plan

Following the activation of the WCTU Continuity Team or recognition of a study level incident, a Continuity Action Plan should be created and maintained to guide the response and recovery process.

This plan should:

- Document team membership and assigned roles
- Define the frequency of meetings and communication methods
- Set out the objectives of the response
- Detail the implementation plan, including immediate and longer-term actions
- Identify resource implications, including staffing, systems, and facilities
- Outline cover arrangements for critical processes and assets affected by the incident

The plan should be updated regularly throughout the incident and used to record decisions, actions taken, and justifications. It serves as the central reference point for managing the disruption and ensuring accountability.

A template Continuity Action Plan is provided in **Appendix 1** of this SOP. This can be adapted for study-level incidents depending on which sections apply.

7.4 Testing the Plan

The QA Managers are responsible for coordinating the testing of the BCP, with support from the University's Risk and Resilience Team as needed.

Frequency and Format

- Testing should be conducted annually, where feasible.

- Accepted formats include:
 - **Tabletop Exercise:** A scenario-based discussion to familiarise staff with roles, responsibilities, and decision-making.
 - **Live Test:** A real-time simulation to assess operational and technical responses.
 - **Enacting the plan:** enacting the plan can also serve as a test but shouldn't replace the above.

Scope of Testing

- Scenarios should reflect both operational and technical disruptions.
- Where appropriate, study-level continuity plans should be included.

Documentation and Reporting

- A test report or a summary of the findings should be communicated to the WCTU Governance Committee.
- The QA team will maintain the following within the [General | WCTU Business Continuity Team | Microsoft Teams](#) and will include:
 - Attendance records
 - Summary reports
- **Appendix 1** provides a potential template that can be adapted for the scenario or to guide the production of meeting reports or slides.

7.5 Post-incident or Post-test Review

Following any incident or test, lessons learned must be reviewed and used to strengthen WCTU's business continuity planning and operational resilience.

Review Process

- A meeting should be held to:
 - Review the response or test
 - Identify successes and areas for improvement
 - Agree on corrective and preventative actions
- Updates to continuity documentation (e.g. WCTU BCP, study-level BC Summaries, working instructions, and escalation procedures) should be tracked and shared with relevant teams.

Closure and Governance

- The incident or test is considered closed once all agreed actions are completed.
- A summary of the event, actions taken, and outcomes should have appropriate oversight from the Governance Committee.

Non-Compliance and Data Breaches

- If the incident involves non-compliance, it must be managed in accordance with:
 - [SOP 31: Handling Non-Compliance](#)
 - [SOP 36: WCTU Data Breach Incident Management Procedure](#) (if applicable)



- Resulting non-compliances will be reviewed at the next Governance Committee meeting to:
 - Identify systemic issues
 - Assess the adequacy of current preventative measures

Knowledge Sharing

- Where appropriate, lessons learned will be shared across WCTU and, if relevant, with the wider University to support organisational learning and improvement.

8 Appendix 1: Continuity Action Plan Template

Insert background

Continuity team

Continuity Team; (insert names)

Meet: (insert frequency)

Summary of Incident:

Date BCP engaged:

Objective(s)

Describe objectives

Table 1 Implementation Plan

Number	ACTION	LEAD	DATE PLANNED	DATE COMPLETED
1	Establish a WCTU Continuity Team and meet (insert frequency)			
2				
3				
4				
5				

8.1

Table 2 Essential activity to be prioritised

The expertise and processes that without them in place, WCTU could not continue to operate and conduct clinical research:

Reference	Process/Support	Minimal staff required	Minimal systems / access required
Priority-1			
Priority-2			
Priority-3			
Priority-4			
Priority-5			
Priority-6			
Priority-7			
Priority-8			
Priority- 9			
Priority- 10			
Priority- 11			

8.2

Additional resource required

Resource	Estimated costs

USEFUL LINKS

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9 Appendix 2: Study Business Continuity Summary Template

Trial Title:
Trial Acronym:
Chief Investigator:
Trial Manager:
Date Completed:
Next Review Date:

1. Priority Activities

Activity	Description	Impact if Disrupted	Back-Up / Contingency
e.g. Safety Reporting	Reporting SAEs to sponsor	High – regulatory breach risk	Shared inbox access, SOP 34 WI, backup staff trained

2. Key Contacts

Role	Name	Contact Info	Cover Arrangements
Trial Manager			
CI			
Data Custodian			
QA Contact			

3. Critical Systems & Data

System / Data	Location	Access Method	Back-Up Location
e.g. Trial Database	Online App	Username + MFA	Server backup / M-Drive

4. Escalation & Handover

- **Escalation Route:**
e.g. Trial Manager → SPM → Head of Operations
- **Handover Documentation Location:**
e.g. T67 SPM Handover saved in SharePoint → [Insert Link]

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5. Additional Notes

- Any known risks, dependencies, or planned mitigations
- Reference to SOPs or templates used (e.g. SOP 34, T65, T36)