

## STANDARD OPERATING PROCEDURE 40

### WCTU Business Continuity Plan

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<b>Revision Chronology:</b>	<b>Effective date:</b>	<b>Reason for change:</b>
V2.0	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.
V1.0	21 July 2020	New document

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### WCTU Business Continuity Plan

#### 1. Purpose and scope

The purpose of this Standard Operating Procedure (SOP) is to detail procedures to follow to enable an immediate response to be made to an incident that could disrupt normal service in Warwick Clinical Trials Unit (WCTU). It also details the requirements for individual trials to document back-up processes in the event of an incident that could impact on priority activities.

This procedure is designed to define WCTU specific processes and should not replace the Universities' central Risk Management Procedures or Major Incident Plan. Further information on Business Continuity Planning at Warwick is available via: <https://warwick.ac.uk/services/gov/businesscontinuity/>

This plan is part of a wider risk framework that should enable WCTU to identify and manage risks that could disrupt our normal processes involved in the delivery of clinical trials, such as safety reporting, randomisation and recruitment.

This SOP is applicable to all WCTU staff and includes:

- Responsibilities – identification of roles and their responsibilities
- Management – to include:
  - Continuity Team
  - Identification of critical processes and assets
  - Business Continuity Action Plan
- Test Schedule
- Learning - Post incident lessons learnt.

#### 2. Definitions

<b>Business Continuity</b>	The process of identifying priority activities and the underpinning requirements for carrying them out
<b>Business Continuity Plan</b>	A document to outline recovery activities and alternative arrangements to enable departments to continue operating and restore normal service in the event of major disruption
<b>Major Incident</b>	An event or situation that threatens serious damage to human welfare, the environment, or the security of the state (UK)
<b>Priority Activity</b>	Activities that are essential for supporting the business needs of WCTU
<b>SIRO</b>	A senior staff member with overall responsibility for an organisation's information risk policy. The SIRO is accountable and responsible for information risk across the organisation.
<b>IAO</b>	Staff with responsibility to ensure that Information Assets are managed in compliance with the organisation's policies and to ensure procedures are developed, implemented, followed and regularly reviewed.

### 3. Background

All organisations have a responsibility to put in place continuity arrangements that enable priority activities to be maintained during any disruption or recovered to as soon as possible.

### 4. Procedure

#### 4.1 Responsibilities

The following roles undertake the responsibilities listed:

<b>Head of Operations (or delegate)/ Senior Risk Owner (SIRO)</b>	Oversee the development and maintenance of the WCTU Continuity Plan – ensuring it relates to the overall University of Warwick Business Continuity Strategy. Ensure reviews of plans are completed.
<b>QA Managers</b>	Coordinate and maintain the Plan on behalf of the WCTU ensuring that regular testing is undertaken.
<b>Information Asset Owners (IAOs) (Usually Chief Investigator or Warwick academic lead)</b>	Ensure that the requirements from the Business Continuity plan are adequately considered and documented for all information assets of which they have ownership. Enable the recovery of assets to be enacted.
<b>Warwick CTU Programming Team Manager</b>	Management of business continuity procedures relating to the WCTU Trial data infrastructure. Oversee the production and maintenance of the WCTU disaster recovery plan.
<b>Line Managers</b>	Ensure that staff are aware of and follow the Continuity Plan procedures.
<b>Trial Managers/Coordinators</b>	Identify study specific priority activities and ensure working instructions are in place to detail continuity for the identified activities
<b>All WCTU staff</b>	To be responsible for reviewing and following this procedure in the event of an incident.

#### 4.2 Priority Activities and Contingencies

The table below defines some of the considerations for priority activities for WCTU, however, this is not an exhaustive list. These are activities to which recovery priority must be given in an incident to prevent serious impacts. The table also details the other departments and stakeholders that the priority activities rely upon and/or influence. Where processes differ between studies, each study is expected to understand their priority activities. Study level priority activities should be detailed in clear working instructions which should be produced and approved in line with SOP 34: Generation, Review and Approval of Trial Specific Working Instructions. A template is available which prompts inclusion of key business continuity considerations is available (T65). Where back-up processes are planned at an organisational level, the QA team should maintain working instructions on behalf of WCTU.

**Table 1 – Considerations for WCTU Priority activities**

Priority Activity	People & Processes	Tech/ICT/Equipment	Premises
<b>Preservation of paper documentation</b>	n/a	n/a	WCTU Building/ CSRL Building
<b>Preservation of digital documentation / data</b>	<ul style="list-style-type: none"> <li>- Named archivists</li> <li>- Programming Team</li> </ul>	<ul style="list-style-type: none"> <li>- Mdrive</li> <li>- Online applications</li> </ul>	Server Building
<b>Randomisation</b>	<ul style="list-style-type: none"> <li>- Randomisation cover team</li> <li>- Programming Team</li> <li>- QA Team</li> </ul>	<ul style="list-style-type: none"> <li>- Telephone/Micollab</li> <li>- MS Teams</li> <li>- Online applications</li> </ul>	n/a
<b>Safety Reporting</b>	<ul style="list-style-type: none"> <li>- QA Team</li> <li>- Clinical Causality Assessors (<i>site and WCTU</i>)</li> <li>- SAE Triage Process</li> </ul>	<ul style="list-style-type: none"> <li>- Mdrive</li> <li>- Email</li> <li>- Online applications</li> </ul>	n/a
<b>Emergency Unblinding</b>	<ul style="list-style-type: none"> <li>- Trial clinical cover</li> </ul>	<ul style="list-style-type: none"> <li>- Mdrive</li> <li>- Email</li> <li>- Teams</li> <li>- Online applications</li> <li>- Telephone</li> <li>- Unblinding system</li> </ul>	WCTU Building/CSRL Building
<b>Critical safety checks</b>	<ul style="list-style-type: none"> <li>- Study team</li> <li>- Investigator site data team</li> </ul>	<ul style="list-style-type: none"> <li>- Mdrive</li> <li>- Email</li> <li>- Teams</li> <li>- Online applications</li> <li>- Telephone</li> </ul>	WCTU Building/CSRL Building
<b>Non-compliance &amp; Breach reporting</b>	<ul style="list-style-type: none"> <li>- WCTU Building</li> </ul>	<ul style="list-style-type: none"> <li>- Mdrive</li> <li>- Email</li> <li>- Staff Intranet</li> </ul>	n/a
<b>Data Entry</b>	<ul style="list-style-type: none"> <li>- Data Entry Clerk</li> </ul>	<ul style="list-style-type: none"> <li>- Online applications</li> <li>- Mdrive</li> </ul>	WCTU Building
<b>Sample Processing</b>	<ul style="list-style-type: none"> <li>- Postal service / Couriers</li> </ul>	<ul style="list-style-type: none"> <li>- Online applications</li> <li>- Mdrive</li> </ul>	n/a

## 4.3 Responding to an Incident

### 4.3.1 Assessment of Incident

In the event of a MAJOR INCIDENT this local plan will be superseded by the University Major Incident Plan and a strategic level 'Major Incident Team' meeting will be held to coordinate how the incident is managed.

In the event of an INCIDENT / SIGNIFICANT INCIDENT, this can be managed at the local level. It is recommended that the WCTU Continuity Team (see below) convene an incident management meeting. The initial meeting should assess the following:

1. Assess what is known about the incident so far
2. Urgent concerns/issues
3. Immediate actions
4. Assign Roles and responsibilities
5. Consider communication with the following as appropriate:
  - Emergency services and authorities (*if not already liaised with*)
  - Campus Security (*if not already liaised with*)
  - Risk & Resilience Team (*if not already liaised with*)
  - Senior management
  - Media & Comms
  - Internal staff
  - External partners
  - Visitors – on site or en-route
  - Human Resources
  - Health and Safety
  - Estates
  - Insurance
6. Agree when the group will next communicate and how

The template Continuity Action Plan should be used to record the assessment and associated outcomes. This can be located as an appendix to this SOP.

### 4.3.2 Management of Continuity Team

A Continuity Team consisting of the Head of Operations, Deputy Head of Operations, QA Managers, Senior Project Managers, the Business Support Officer and Divisional Support Officer will be convened in the event of an incident.

The Head of Operations will instigate this Continuity Team, ideally within 24 hours of the incident arising or sooner where possible.

The team will consider if any additional expertise should be brought into the Continuity Team to reflect the nature of the incident. For example, Clinical, IT or Programming expertise.

The Continuity Team will meet regularly and at an interval that is appropriate to the incident until it is deemed no longer necessary. Decisions and justifications should be recorded in a Continuity Action Plan (see section 4.3.3). In the case that face-to-face meetings are not possible, alternative arrangements for remote/online meetings should be made.

#### **4.3.3 Continuity Action Plan**

The Continuity Team will create and follow a Continuity Action Plan.

The plan should include membership, frequency of meetings, objectives, implementation plan, resource implications and cover arrangements for critical processes and assets as applicable to the incident.

See the template at the end of this document.

#### **4.4 Testing the Plan**

The QA Managers will coordinate the testing of the Plan. The University Risk and Resilience Team may be contacted to support with this activity. The testing should be completed annually where possible. Testing may take one of the following forms:

- Tabletop (disaster role-playing sessions that allow action plan participants to “walk through” the facets of the plan, to gain familiarity with their responsibilities given a specific emergency scenario).
- Real-time Live Test

Testing is critical to ensure that the Plan is fit for purpose and a testing report will be provided to the WCTU Governance Committee. Documentation of the testing should be maintained by the QA team. This should include attendance logs and a summary report which should feed into the lessons learnt (see section 4.4 below).

#### **4.5 Learning**

Following an incident or Test, any learnings should be considered, to include corrective and preventative actions. Once the actions have been completed, the incident or Test will be considered closed.

Any incidents that could be categorised as non-compliances should follow SOP 31 ‘Handling Non-Compliance’ and SOP 36 ‘WCTU Data Breach Incident Management Procedure’ if relevant to the incident. Resulting non-compliances will be reviewed after each incident is closed at the following WCTU Governance Committee to ensure there are no systematic issues and that current preventative measures are appropriate.

Any lessons learnt from incidents will be shared where appropriate to improve operations across WCTU and the wider University as necessary.

### List of abbreviations

IAO	Information Asset Owner
QA	Quality Assurance
R&IS	Research & Impact Services
S/TMF	Study/Trial Master File
SIRO	Senior Information Risk Owner
SOP	Standard Operating Procedure
TM/TC	Trial Manager / Trial Coordinator
WCTU	Warwick Clinical Trials Unit

### Appendix 1: Continuity Action Plan Template

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## APPENDIX 1: Contingency Action Plan Template

*Insert background*

### Continuity team

**Continuity Team; (insert names)**

**Meet: (insert frequency)**

### Objective(s)

*Describe objectives*

### Table 1 Implementation Plan

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

### 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			

<b>Priority-4</b>			
<b>Priority-5</b>			
<b>Priority-6</b>			
<b>Priority-7</b>			
<b>Priority-8</b>			
<b>Priority- 9</b>			
<b>Priority- 10</b>			
<b>Priority- 11</b>			

**Additional resource required**

<b>Resource</b>	<b>Estimated costs</b>

**USEFUL LINKS**

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