STANDARD OPERATING PROCEDURE

Guidance to researchers on the support and necessary management of self-harm, suicidal ideation and intent, in patients accessing research opportunities with the aim to minimise the risk of serious injury to self or others and death of those accessing research opportunities.

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LCRF

RESEARCH AND DEVELOPMENT

BACKGROUND

The NIHR Lancashire Clinical Research Facility (LCRF) is a dedicated unit to support multidisciplinary clinical research, providing a safe and quality environment for the delivery of clinical research. Participants attending the facility suffer from all disease areas and will be from all age ranges.

Participants attending the facility may attend acutely unwell or may develop symptoms whilst in the facility. The support and necessary management of a patient experiencing mental health crisis is based on clinical assessment by appropriately qualified medical and clinical nursing personnel. The LCRF staff include a team of registered general nurses, a registered mental health nurse and other allied health care professional who receive a

regular mental health scenario training session as part of the training in managing emergencies and BLS/ILS.

PURPOSE/OBJECTIVE

To describe the process for assessment and treatment of patient attending the LCRF with new or worsening mental health symptoms.

SCOPE

It is the responsibility of all staff involved in the care of those accessing research opportunities to ensure that patients are able to access the necessary support and treatment when there is a risk of severe self-harm and/or suicidal intent and/or harm to others, which could cause serious distress, harm or even death. It is important that the person deemed at greater risk is able to access the necessary support in a timely manner to minimise any risks identified.

It is important that the research team have a good oversight of the patients' individual mental health needs and management plan, if applicable. It is important to note that not all patients who present with a serious risk may be under a mental health service or have a recorded history of mental illness.

PROCEDURE

Patients involved in investigational Mental Health studies at the research facility will have been assessed by mental health services within Lancashire and South Cumbria Mental Health Trust and will have a care co-ordinator , a care plan and a current risk assessment/management plan which will be adopted to support their involvement within the trial by a study co-ordinator and stored within their patient records- any necessary adaptations to the environment will be discussed as a team prior to their attendance at the LCRF and any risk factors will be identified beforehand so that involved staff are informed. Contact numbers provided to participants will be for research staff that are knowledgeable about that participant's clinical detail and in the unlikely event that a service user contacts the LCRF reception the guidance above should be adhered to where there is no LSCFT

staff available. A copy of LSCFT staff mobile numbers will be provided to reception so that calls can be passed on.

If in the unfortunate event that harm is caused whilst a participant is on site, then the medical management of that patient should take precedence. Staff should follow routine pathways for physical health, obtaining support from hospital colleagues where necessary and appropriate. If the harm caused is superficial then first aid should be provided and the participant should be taken to the nearest A and E for assessment of their mental health, staff should follow the guidelines above.

If a patient attends the NIHR **Lancashire Clinical Trials Facility based at Royal Preston Hospital (LCRF)** and presents with an immediate risk of self-harm and/or suicidal intent and/or harm to others, which could cause serious distress, harm or severe changes to their health, then the following actions must be adhered to:

Research staff: -

- The patient must not be left alone.
- The shift co-ordinator and clinical lead must be informed.
- If there is a psychiatrist or Medic available, then advice must be sought.
- If the patient is already under the care of mental health services, then their key worker or duty team member should be contacted and informed, advice can be sought before any action if appropriate. All patients attending the LCRF for a Mental Health study will be under a clinical team- details will be documented on the first page of their research file.
- In the event the nurse/team are not available, the LTHTr Mental Health Liaison Team should be contacted for advice. The Mental Health Liaison Team at LTHTr have access to RiO (LSCFT Medical records electronic system). This team is based within the Avondale unit and operates 24/7. Tel: 01772 773499.
- In the event that physical intervention is deemed necessary and ward staff need to implement an immediate longer term care plan then they must contact the on duty Doctor / Consultant via the Preston Hospital switch hub on 01772 716565 asking to

be put through to the "on duty doctor for mental health or alternatively the psychiatric consultant"– if this deemed appropriate, arrange 1-1 supervision for the patient. Once physical intervention is implemented, and the situation is appropriately controlled it would be advised the patient's vital signs are monitored & documented for an agreed time frame with the Doctor.

- If a service user is unco-operative, aggressive, or demonstrating imminent intent to harm themselves or others then security must be called. Distress to the service user should be minimised as much as possible. At this point two members of staff known to the service user is preferable to support them. This decision must be documented, with rationale. Emergency contact number from any internal phone is 2222, inform the operator you require emergency security assistance and of the Location assistance is required. On arrival of security ensure as much information is shared with the team as possible including- Voluntary status, capacity, physical ailments, etc.
- A detailed entry onto the patient's electronic record must be completed on the same day.
- The Principal Investigator (PI) of the study must also be informed within 24 hours of the care escalation or as detailed in the study protocol.
- All safety reporting processes should be followed as per study protocol.
- A Datix form must be completed within 24 hours.

Security staff: -

- To attend and assist with bringing the situation under control by means of De-escalation and will only use physical intervention as a last resort where it is deemed Necessary, Reasonable, and Proportionate in the circumstances.
- Any physical intervention will be the least restrictive, not effecting airways, breathing, or circulation and will not last beyond the point of crisis.
- To act in accordance with current legislation and not deviate. They include the following: Mental capacity Act, Mental Health Act, Criminal Justice and immigration Act and Common Law. It is unlikely that a patient will be detained whilst receiving treatment at the research facility. If the Patient is detained under any of the relevant

powers, then Security officers will take appropriate action in accordance with those legislations / Powers. If the Patient is a voluntary Patient the Security Team will have no holding powers and will only take action to protect themselves / others or property in this instance Security officers will only be able to detain a person pending arrival of the Police who will then make the decision regarding any possible criminal offences.

If a patient is seen at **home** for research purposes and presents with an immediate risk of self-harm and/or suicidal intent and/or harm to others that could cause serious distress, harm or severe change to their health then the following actions should be adhered to:

- The patient must not be left alone unless there is a risk to the researchers own personal safety.
- If you are worried that the person is at immediate risk of harm due to deterioration in the patient's mental health, then dial the Mental health Crisis Line on 0800 953 0110 available. During this period the patient should not be left alone, unless there is a risk to the researchers own personal safety.
- If the patient is already under the care of mental health services, then their key worker or duty team member should be contacted and informed. This information is available on Rio and the team can be contacted beforehand to get any additional or up to date risk information.
- A detailed entry onto the patient's electronic record must be completed on the same day.
- The PI of the study must also be informed.
- All safety reporting processes must be followed as per study protocol.
- A research manager must be informed.
- A Datix form should be completed.

In the event that a person who has or is involved in research expresses thoughts **over the telephone** of intent of self-harm or suicide and/or harm to others that could cause serious distress, harm or there is a severe change to their health then the following actions should be adhered to:

- Try and stay on the phone to the person where possible, ask a colleague to help if someone is nearby.
- Ascertain the study and what researchers the patient is known to- try and access familiar staff if possible whilst staying on the phone.
- Give clear instructions to the person about what is going to happen e.g. 'I am worried about what you have just told me and feel that you need some more support right now, my colleague is ringing an ambulance to come to you so you can get some help to feel better. I will stay on the phone with you until they get there, let's talk through what's been going on for you. . .' and provide reassurance.
- Find out where the person is and dial the mental health Crisis Line on 0800 953 0110 If the person does not disclose where they are located or hangs up. Give as much information as you can to the emergency services including any information we have on our records.
- If the patient is already under the care of mental health services, then their key worker or duty team member must be contacted and informed of any risks identified and what actions have been taken. This will also ensure that the patient is followed up as required.
- A detailed entry onto the patient's electronic record must be completed on the same day.
- The PI of the study must also be informed within 24 hours of the care escalation.
- All safety reporting processes must be followed as per study protocol.
- A research manager must be informed within 24 hours.
- A Datix form should be completed within 24 hours.

4. OTHER RELATED PROCEDURES

Both trusts policies

CONSULTATION WITH STAFF AND PATIENTS

Name	Role
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LCRF Operational Group	

Sign Off Lancashire Teaching Hospitals			
Lead Author:			
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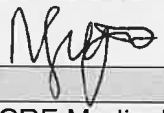
Signature		**Date**	12-06-2023
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Name and Position	LCRF Medical Director		
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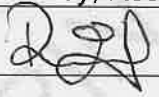
Authorised for release by:			
Name and Position	Rebecca Wilby, Research Access Project Manager		
Signature		**Date**	12-06-2023

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