

CONTROLLED DOCUMENT

Introduction of Novel Therapeutic Interventions Policy

CATEGORY:	Policy
CLASSIFICATION:	Governance
PURPOSE	To set out the agreed policy for the submission of a Novel Therapeutic Intervention proposal to and the agreement by the Novel Therapeutics Group.
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<ul style="list-style-type: none"> • Essential Reading for: All those introducing or planning to introduce a Novel Therapeutic Intervention to the Trust • Information for: Risk and Compliance Staff 	

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1. Policy Statement

- 1.1 University Hospitals Birmingham NHS Foundation Trust (the 'Trust') must ensure that when novel therapeutic Interventions are introduced, they are appropriate, effective, and that staff undertaking these procedures are appropriately trained in order to ensure patients are not exposed to unnecessary risk. The purpose of this policy is to detail a clear mechanism by which the Trust can achieve these aims.
- 1.2 This policy ensures the Trust's compliance with the Care Quality Commission's Standards for Quality and Safety, ensuring Interventions are safe and that processes are effective.
- 1.3 Novel therapeutic Interventions (see 3.2 for the National Institute of Clinical Excellence (NICE) definition of an Intervention), are those which have previously undergone clinical trials or other forms of systematic evaluation to demonstrate safety and likely or proven efficacy, but which have not yet been used previously at the Trust.

2. Scope

- 2.1 This policy outlines a formal structure whereby the Trust can ensure:
 - 2.1.1 Novel therapeutic Interventions introduced within the Trust are appropriate and effective;
 - 2.1.2 All staff who undertake novel therapeutic Interventions and other staff who support them, have an appropriate level of skill and training to perform these techniques; and
 - 2.1.3 Patients are not exposed to unacceptable clinical risk when a novel therapeutic Intervention is introduced to the Trust.
- 2.2 The Novel Therapeutics Group acts on behalf of the Executive Medical Director. The Chair of the Novel Therapeutics Group is authorised to grant approval for novel therapeutic Interventions to be introduced.
- 2.3 This policy is not proposed for use when a clinical Intervention is new to an individual clinician but is already established within the Trust.
 - 2.3.1 In such circumstances, when an individual clinician wishes to undertake Interventions/procedures they have not performed previously they must learn the new technique by assisting a competent practitioner until judged by that practitioner to be competent to operate independently.

- 2.3.2 It is the individual responsibility of each practicing clinician to ensure that they are competent to carry out procedures they undertake.
- 2.3.3 If appropriate, the clinician will be required to attend a structured course and evidence of accreditation will need to be provided.
- 2.4 Drug Interventions are not considered a novel therapeutic Intervention in this context if they do not meet the definition of an Intervention laid out in 3.2. These must be dealt with by the Trust Medicines Management Advisory Group (MMAG).
- 2.5 Staff must note that Expanded Practice Protocols (EPPs), used by health professionals are processed through a separate framework. Further advice pertaining to these processes can be obtained from the Practice Development Team.
- 2.6 If there is any doubt as to the procedure's status as a novel therapeutic Intervention, further advice must be sought from the Clinical Risk and Compliance Unit.
- 2.7 In addition any general queries relating to this policy must be directed to the Novel Therapeutics Group Chair or Group Administrator whose contact details can be obtained through the Clinical Risk and Compliance Unit.

3. Framework

- 3.1 The Trust recognises the need for innovation and views the introduction of novel therapeutic Interventions as a vital part of practice to enhance the quality of patient care. However, this must be balanced with the Trust's responsibility for ensuring the safety of the patients involved in the introduction of these Interventions.
- 3.2 An Intervention is defined by the National Institute for Health and Clinical Excellence (NICE) as:
 - 3.2.1 "Making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel;
 - 3.2.2 Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth; or

- 3.2.3 Using electromagnetic (which includes X-rays, lasers, gamma-rays and ultraviolet light), ionising or acoustic energy - for example, using a laser to treat eye problems.”
- 3.3 This definition provides useful guidance for proposals to the Novel Therapeutics Group, but cannot cover every eventuality. The Group Chair can provide advice where there is uncertainty.
- 3.4 All novel therapy proposals require the following information to be provided in the proposal proforma (available in Appendix 2 of the associated procedural documentation) before they will be considered for use at the Trust:
- 3.4.1 Evidence of safety and efficacy must be provided, including an explanation of the intended benefit to the patient. This must, where available, include guidance from NICE or other bodies.
- 3.4.2 Medicines must have Market Authorisation with a summary of product characteristics that includes the proposed use,
- 3.4.3 Medical devices must be CE marked for the intended use,
- 3.4.4 Clinicians wishing to introduce new techniques to the Trust must be able to demonstrate that they are trained in their delivery, that patients are fully informed about the nature of the Intervention including risks, and that practice is audited, with reports to the Novel Therapies Group,
- 3.4.5 A methodology for auditing performance of the proposed novel therapy must be included. This may include, where applicable, relevant device or other registries.
- 3.5 Any staff undertaking a Novel Therapeutic Intervention are required to submit an incident form, if an adverse event occurs, clearly stating that it relates to a novel therapeutic Intervention. They are also required to inform the Novel Therapeutics Group any deviation from the agreed protocol.
- 3.6 The Novel Therapeutics Group will agree, on a case by case basis, an appropriate point (either based on time passed or number of the Novel Therapeutic Intervention undertaken) to review the outcomes of the audit of the intervention and make a decision regarding the ongoing use of the Novel Therapeutic Intervention within the Trust.

4. Duties

4.1 Medical Director

The Executive Medical Director, on behalf of the Chief Executive, is responsible for implementing and monitoring this policy through the Novel Therapeutics Group, the relevant advisory groups and the Clinical Quality Monitoring Group.

4.2 Novel Therapeutics Group

4.2.1 The Novel Therapeutics Group is a sub-group of the Trust Clinical Quality Monitoring Group. The Novel Therapeutics Group reports and is accountable to the Board of Directors through that Group.

4.2.2 The role of the Group is to review proposals for the introduction of novel therapeutic Interventions within the Trust and ensure they are appropriate and clinically safe. Only when all factors have been fully reviewed to the satisfaction of the Group will approval be given. A list of considerations is available in the associated procedural document to this policy.

4.2.3 The Group will not advise on the ethical or financial implications of novel therapeutic Interventions. Assessment of the financial implications is the responsibility of the Divisional Management Team. Advice regarding ethics can be sought from the Local Research Ethics Group, whose contact details can be obtained through Research and Development.

4.3 Chair of the Novel Therapeutics Group

The Chair of the Novel Therapeutics Group has delegated authority from the Executive Medical Director to authorise the introduction of novel therapeutic Interventions, and is responsible for ensuring that:

4.3.1 All novel therapeutic Interventions proposals are thoroughly reviewed by the Group;

4.3.2 Audit data is submitted and reviewed by the Group once novel therapeutic Interventions have commenced;

4.3.3 NICE are notified of any plans to carry out procedures not listed on the NICE website under the guidance of the Head of Clinical Risk and Compliance;

- 4.3.4 The Group works to time scales as set out in the procedural document associated with this policy; and
- 4.3.5 Membership of the Group is reviewed on an ongoing basis to ensure there is a sufficient and broad enough representation.
- 4.3.6 Respond to any queries relating to this policy and advise on where there is uncertainty about a novel therapeutic Intervention.

4.4 Risk and Compliance Unit

- 4.4.1 Members of the Clinical Risk and Compliance Unit will monitor the implementation of new novel therapeutic Interventions including adherence to any conditions stipulated by the Novel Therapeutics Group and the timely request of audit data as stated in this policy or otherwise by the Group.
- 4.4.2 Members of the Risk and Compliance Unit will also provide a quarterly report to the Trust's Clinical Quality Monitoring Group detailing any new novel therapeutic Interventions, progress with agreed novel therapeutic Interventions and any exceptions or concerns.

4.5 Novel Therapeutics Group Administrator

The Novel Therapeutics Group Administrator will, jointly with the Chair of the Novel Therapeutics Group Chair, respond to any general queries relating to the this policy.

4.6 Clinicians Proposing or undertaking Novel Therapeutic Interventions

- 4.6.1 All clinicians proposing or undertaking novel therapeutic Interventions are responsible for familiarising themselves with the details of this policy and its associated procedure.
- 4.6.2 When clinicians wish to introduce new, but validated Interventions, they must submit a proposal directly to the Novel Therapeutics Group, using the proposal form detailed in the associated procedure.
- 4.6.3 Clinicians are responsible for ensuring that any conditions stipulated by the Group are met and that there is a robust audit undertaken of the novel therapeutic Intervention.
- 4.6.4 In the event of an adverse event resulting from an Intervention, clinicians must submit an incident form clearly stating that it

relates to a novel therapeutic Intervention. The clinician must also inform the Novel Therapeutic Group of any deviation from the agreed protocol.

4.7 Divisional Management Team/Divisional Directors/Clinical Service Leads

4.7.1 Members of Divisional Management Teams/Divisional Directors/Clinical Service Leads are responsible for ensuring that novel therapeutic Interventions within their areas of responsibility are referred for review to the Novel Therapeutics Group.

4.7.2 They are responsible for ensuring appropriate liaison has taken place regarding the implications for implementation at an operational level, including financial requirements.

4.8 Clinical Staff

All Clinical staff carrying out the Novel therapeutic Interventions within the Trust are responsible for familiarising themselves with this policy and ensuring that they comply with the policy and procedures set out within this document.

5. Implementation and Monitoring

5.1 Implementation

This policy will be available on the Trust's intranet site. The policy will also be disseminated through the management structure within the Trust.

5.2 Monitoring

Appendix A provides full details on how this policy will be monitored by the Trust.

6. References

HSC 2003/011: The Interventional Procedures Programme, National Institute for Health and Clinical Excellence (2009)

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (2014)

Medical devices regulations: compliance and enforcement, Medicines and Healthcare products Regulatory Agency (2017)

7. Associated Policy and Procedural Documentation

Clinical Standards and Audit Policy

Procedure for the Introduction of Novel Therapeutic Interventions within University Hospitals Birmingham

Appendix A

Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Number and status of all novel therapeutic Interventions	Clinical Risk and Compliance	Clinical Quality Monitoring Group	All new proposed novel therapeutic Interventions, progress with agreed Interventions including audit progress and any exceptions or concerns as undertaken by the Risk and Compliance Unit.	Quarterly
Adverse incident as a result of a novel therapeutic Intervention	Head of Clinical Risk and Compliance	Novel Therapeutics Group	Report on monitoring of Trust incidents.	On an exception basis
Efficacy of the novel therapeutic Intervention	Individual Clinician	Novel Therapeutics Group Executive Medical Director	Monitoring of outcomes of the novel therapeutic Intervention, dependant on the type of Intervention, skill of the practitioner and patient throughput.	To be agreed on case-by-case basis