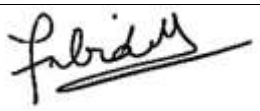
Birmingham and Solihull Mental Health NHS Foundation Trust

NEW CLINICAL PROCEDURES POLICY

Policy number and category	**C 14**	**Clinical**
Version number and date	**5**	**November 2021**
Ratifying committee or executive director	**Clinical Governance Committee**	
Date ratified	**December 2021**	
Next anticipated review date	**October 2025**	
Executive director	**Medical Director**	
Policy lead	**Head of Clinical Governance and QI**	
Policy author *(if different from above)*	**As above**	
Exec sign off signature (electronic)		
Disclosable under freedom of information act 2000	**Yes**	

POLICY CONTEXT

Any major new clinical intervention needs to be assessed for safety, efficacy and cost effectiveness before it is offered as a treatment by the trust. The intervention should be agreed by the Clinical Governance committee before it is undertaken by any member of Trust staff as part of routine care and practice.

POLICY REQUIREMENT

All clinical staff intending to carry out any new interventional procedure or significant new clinical procedure should seek the approval of the Clinical Governance Committee before undertaking the procedure.

The Clinical Governance Committee will only agree the use of the procedure when it is assured those adequate arrangements are in place to ensure it can be provided safely and that arrangements are in place to monitor its safety and effectiveness.

Contents

1: Introduction

1.1 RATIONALE (why):

1.1.1 Birmingham and Solihull Mental Health Foundation Trust recognises the need for new techniques and procedures. Properly researched and evidenced improvements in care can offer better outcomes to service users. However, the introduction of new procedures comes with an inherent risk, and this policy aims to detail the arrangements for ensuring there is robust governance in place so that it can be done safely, sustainably and always in the best interests of the service users.

1.1.2 This policy details arrangements for ensuring Trust compliance with national guidance. It aims to ensure that new approaches to treatment are evaluated and adopted to provide the best care possible using the resources available. It ensures there is a governance framework that supports safe and effective care and that this is a sustainable part of treatment pathways.

1.2 SCOPE (who, where and when):

All Clinical staff need to be aware of this policy.

The policy applies to the proposed introduction of any new clinical procedure or intervention which has not previously been undertaken within the organisation and also to the use of any new interventional procedure which an individual has not undertaken before within the Trust. This applies to proposed treatments for both staff and service users, the principle being that any new procedure being applied to a person, should be reviewed for its efficacy and risks This may include for example:

- An interventional procedure which is used for the treatment or diagnosis which involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy, irrespective of its use in other healthcare organisations.
- A new mental health treatment / intervention which has not been used in the trust before, and irrespective of its use in other healthcare organisations.
- An intervention which has been used before but is now proposed for a new indication.

The policy does not apply:

- To any procedure which is part of a research study when the research governance procedure would apply, and such procedures should only be performed when research proposals have been formally agreed. Once the research project has ceased, this policy should be followed if the new treatment is recommended for the trust to adopt into practice.
- For any drug used which will be reviewed through the Pharmacological therapies committee / Trust Medicines code.
- For any existing treatment being delivered by a new service. Any change to a service model should undertake a due diligence review. (Appendix B)
- The adoption of a new tool to diagnose, assess or support clinical care. As this isn't directly applied to the patient this policy will not apply. However, if there are implications, such as changes to Rio or changing established clinical practice, it should be discussed in appropriate forums to ensure governance oversight.

This could include Local Governance Committee, professional groups / committees or Trust Clinical Governance Subcommittees. For example, a new diagnostic tool that cuts out part of the usual diagnostic pathway should be considered by the relevant Governance committee to weigh up potential risks / benefits and practice implications.

1.3 PRINCIPLES (beliefs):

1.3.1 The use of any form of interventional procedure is most likely to have some form of direct risk to patient because of the intervention. Introduction of new procedures should be based on evidence-based practice, risk assessment, monitoring to ensure success and avoidance of harm and a sound business case.

1.3.2 The requirements of clinical governance place a requirement of accountability for clinical practice on all clinicians –this is overseen by clinical governance committee structures. Where any significant new intervention / procedure is proposed to be undertaken by the Trust such proposals should be formally agreed to ensure that risks to patients are minimised and that appropriate support is given to staff undertaking the intervention.

1.3.3 The "First do no Harm" report states that innovation has done may wonderful things, but "innovation without comprehensive pre-market testing and post marketing surveillance and long-term monitoring of outcomes is, quite simply dangerous. Crucial opportunities are lost to learn about what works well, what does not, what needs special measures put around its use, and what should be withdrawn because the risks over time outweigh the benefits" (point 1.15, page 5). This policy aims to address the relevant recommendations outlined in the report.

1.3.4 The Trust positively supports individuals with learning disabilities and ensures that no-one is prevented from accessing the full range of mental health services available. Staff will work collaboratively with colleagues from learning disabilities services and other organisations, in order to ensure that service users and carers have a positive episode of care whilst in our services. Information is shared appropriately in order to support this.'

2 POLICY

2.1.1 All clinical staff intending to carry out any new interventional procedure or significant new clinical procedure should seek the approval of the Clinical Governance Committee before undertaking the procedure.

2.1.2 The Trust Clinical Governance Committee will only agree the use of the procedure when it is assured those adequate arrangements are in place to ensure it can be provided safely and that arrangements are in place to monitor its safety and effectiveness.

3 THE PROCEDURE

3.1 A significant new clinical procedure should be interpreted as any clinical intervention which involves new techniques which have not been undertaken by the Trust. It may include the use of new equipment and new techniques.

3.2 Any clinician or clinical team who wishes to undertake a new procedure or who has not undertaken the procedure before is required to seek agreement from the Service Area Clinical Governance Committee / professional committee or Trust Clinical Governance Subcommittee, prior to presentation to the Trust Clinical Governance committee. An indication of this can be found in the flow diagram in appendix 1, although the process may be different for different interventions.

3.3 Where there is ambiguity or disagreement as to if a procedure falls under the remit of this policy, or the required committee scrutiny, the Head of Governance and QI / Medical director will provide guidance and their decision will be final.

3.4 In making a request to undertake a new procedure the clinician / clinical team will be required to provide the following information:

- Outline the details of the procedure to be undertaken.
- Clinical guidance / protocol to be followed.
- Evidence base of the procedure
- Skills and training required to undertake the procedure.
- Equipment required to undertake the training.
- Supervision arrangements of those undertaking the procedure.
- Risks associated with the procedure.
- Availability of information for patients on the procedure
- Arrangements for clinical audit

3.5 Financial implications are not covered by this procedure and would be required to be undertaken and agreed separately. Financial support for a procedure should not prejudice consideration of the procedure through this policy and equally agreement by the Clinical Governance Committee should not imply that financial support for a new procedure will be given.

3.6 The Service Area (Local) Clinical Governance Committee (or relevant professional committee) will consider the request and if it is supported will refer the request to the Trust Clinical Governance Committee.

3.7 The Clinical Governance committee will consider the request and agree whether it feels adequate clinical governance arrangements are in place to support the use of this procedure.

3.8 Where the procedure has been reviewed by NICE the Clinical Governance Committee will assure itself that the proposal meets all the requirements set out by NICE.

3.9 In the exceptional event that a new procedure is required to be undertaken in an emergency, where no other treatment options are viable and the patient is at serious risk, the clinician must seek agreement from the Medical Director. The Medical Director can provide an emergency agreement in principle, which will be reported to the next Trust Clinical Governance Committee. The committee will agree a date by which this policy will then be enacted for formal review and

approval as per this policy. This may include individual treatments and events such as outbreaks or major incidents.

3.10 Following agreement by the Trust Clinical Governance Committee, the new procedure, date of approval, lead clinician and sponsor will be added to the register of new clinical procedures. This register is kept and maintained by the Medical Director.

3.11 Twelve months after implementation of the new procedure, the lead clinician and sponsor will present an evaluation of the new procedure to the identified lead committee. This is the committee which represents the services / clinicians "most" impacted by the new procedure. Should there be any evidence of adverse events or harm, the lead committee can call for this evaluation sooner or direct additional evaluations take place after the 12-month period.

3.12 Almost every procedure carries an element of harm, which are overall outweighed by the benefits. However, the "First do no harm" report highlighted that without a mechanism to record and monitor adverse events, it took significantly longer to determine that very real harm was occurring in patients and delayed a review. Any additional adverse effects, which are above and beyond the known about harms or incidents, must be recorded on Eclipse. They must be clearly identified as being part of a new clinical procedure and the number and type be included in the evaluation. It is also incumbent on the clinical lead and sponsor to escalate any unexpected near misses / harm. The key principle is that we "do no harm" and if there is evidence that harm is occurring this must be escalated to the lead committee for due consideration.

4 Responsibilities

Posts	Responsibilities	Ref
All Staff	To ensure that any new clinical procedure is supported by Trust Approval priori to commencement.	
Policy Lead	To ensure that any new clinical procedure is approved through the proper systems.	

5 Development and Consultation

Consultation summary	
Date policy issued for consultation.	April 2021
Number of versions produced for consultation.	1
Committees / meetings where policy formally discussed.	**Date(s)**
PDMG	September 2021 & November 2021

6: Reference documents

- Health Service Circular HSC 2003 / 011 ‘Safe clinical innovation’
- Letter from Under Secretary of State 2004 ‘Implementing NICE guidance’
- Standards for Better Health (Healthcare commission) Core Standard 3
- First Do No Harm. The report of the independent medicines and medical safety review. July 2020

7: Bibliography

- none

8: Glossary

- none

9: Audit and Assurance

Element to be monitored.	Lead	Tool	Frequency	Reporting Committee
Any new clinical procedure identified goes through the approval process.	Head of Clinical Effectiveness and QI	Ad hoc report when new procedure identified.	When new procedure identified	Clinical Governance Committee

Appendix 1

Equality Analysis Screening Form

A word version of this document can be found on the HR support pages on Connect
http://connect/corporate/humanresources/managementsupport/Pages/default.aspx

Title of Proposal	New Clinical Procedures Policy		
Person Completing this proposal	Heather Hurst	**Role or title**	QI Lead
Division	Corporate	**Service Area**	Corporate
Date Started	April 2021	**Date completed**	April 2021

Main purpose and aims of the proposal and how it fits in with the wider strategic aims and objectives of the organisation.

The proposal ensures that there is a robust governance process around new treatment and interventions. This protects vulnerable service users from harm.

Who will benefit from the proposal?

Patients and staff receiving treatment from the trust

Impacts on different Personal Protected Characteristics – *Helpful Questions:*

Does this proposal promote equality of opportunity? *Eliminate discrimination?* *Eliminate harassment?* *Eliminate victimisation?*	*The Cumberlage "Do no harm report" report highlighted the potential risks and importance of listening to service users regarding harm. This policy reduces the risk of this occurring*

Please click in the relevant impact box or leave blank if you feel there is no particular impact.

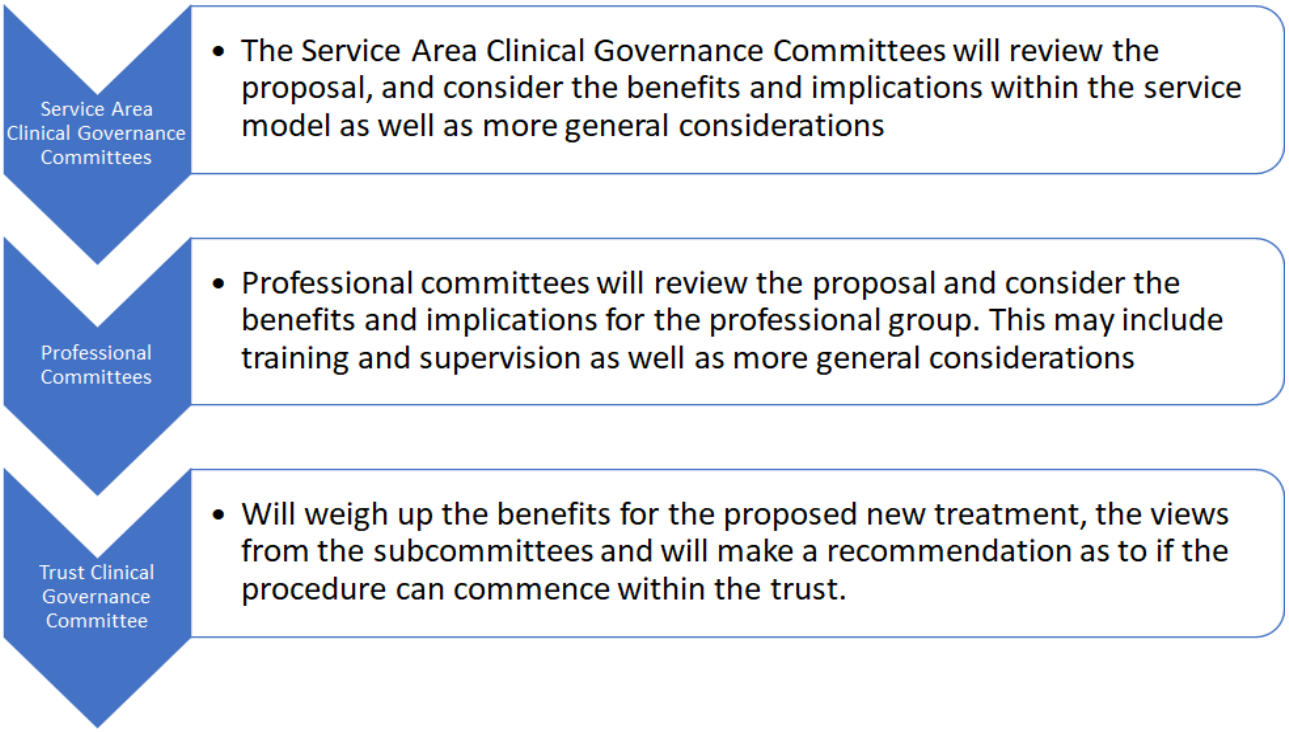
Personal Protected Characteristic	No/Minimum Impact	Negative Impact	Positive Impact	Please list details or evidence of why there might be a positive, negative or no impact on protected characteristics.
Age				
Including children and people over 65 Is it easy for someone of any age to find out about your service or access your proposal? Are you able to justify the legal or lawful reasons when your service excludes certain age groups				
Disability				
Including those with physical or sensory impairments, those with learning disabilities and those with mental health issues				

Do you currently monitor who has a disability so that you know how well your service is being used by people with a disability? Are you making reasonable adjustment to meet the needs of the staff, service users, carers and families?				
Gender				
This can include male and female or someone who has completed the gender reassignment process from one sex to another Do you have flexible working arrangements for either sex? Is it easier for either men or women to access your proposal?				
Marriage or Civil Partnerships				
People who are in a Civil Partnerships must be treated equally to married couples on a wide range of legal matters Are the documents and information provided for your service reflecting the appropriate terminology for marriage and civil partnerships?				
Pregnancy or Maternity				
This includes women having a baby and women just after they have had a baby Does your service accommodate the needs of expectant and post natal mothers both as staff and service users? Can your service treat staff and patients with dignity and respect relation in to pregnancy and maternity?				
Race or Ethnicity				
Including Gypsy or Roma people, Irish people, those of mixed heritage, asylum seekers and refugees What training does staff have to respond to the cultural needs of different ethnic groups? What arrangements are in place to communicate with people who do not have English as a first language?				
Religion or Belief				
Including humanists and non-believers Is there easy access to a prayer or quiet room to your service delivery area? When organising events – Do you take necessary steps to make sure that spiritual requirements are met?				
Sexual Orientation				
Including gay men, lesbians and bisexual people Does your service use visual images that could be people from any background or are the images mainly heterosexual couples? Does staff in your workplace feel comfortable about being 'out' or would office culture make them feel this might not be a good idea?				
Transgender or Gender Reassignment				
This will include people who are in the process of or in a care pathway changing from one gender to another Have you considered the possible needs of transgender staff and service users in the development of your proposal or service?				

Human Rights				
Affecting someone's right to Life, Dignity and Respect? Caring for other people or protecting them from danger? The detention of an individual inadvertently or placing someone in a humiliating situation or position?				
If a negative or disproportionate impact has been identified in any of the key areas would this difference be illegal / unlawful? I.e. Would it be discriminatory under anti-discrimination legislation. (The Equality Act 2010, Human Rights Act 1998)				
	Yes	**No**		
What do you consider the level of negative impact to be?	**High Impact**	**Medium Impact**	**Low Impact**	**No Impact**
If the impact could be discriminatory in law, please contact the **Equality and Diversity Lead** immediately to determine the next course of action. If the negative impact is high a Full Equality Analysis will be required. If you are unsure how to answer the above questions, or if you have assessed the impact as medium, please seek further guidance from the **Equality and Diversity Lead** before proceeding. If the proposal does not have a negative impact or the impact is considered low, reasonable or justifiable, then please complete the rest of the form below with any required redial actions, and forward to the **Equality and Diversity Lead.**				
Action Planning:				
How could you minimise or remove any negative impact identified even if this is of low significance?				
How will any impact or planned actions be monitored and reviewed?				
How will you promote equal opportunity and advance equality by sharing good practice to have a positive impact other people as a result of their personal protected characteristic.				

Please save and keep one copy and then send a copy with a copy of the proposal to the Senior Equality and Diversity Lead at bsmhft.hr@nhs.net . The results will then be publihed on the Trust's website. Please ensure that any resulting actions are incorporated into Divisional or Service planning and monitored on a regular basis.

Appendix 2- Flowchart of the review and decision process for a new clinical procedure



Appendix 3 Proposal for the introduction of a new procedure / technique

Proposal for the Introduction of a New Procedure / Technique/ Intervention

Title of new procedure	
Name of lead clinician	
Title of lead clinician	
Contact number and email of lead clinician	
Sponsor	*This may be a Clinical Director, Executive, someone from the senior management team or professional lead. They must be in a position to support / lead on the implementation of the new procedure and all other implications, such as training or financial needs.*
Outline of the Proposed New Procedure	
Brief description of what is involved.	*Briefly describe the proposed new treatment / procedure*
Target patient / staff group & the intended benefits	*Who will be in receipt of the new treatment? How will they benefit?*
Who would be delivering the new intervention?	*Describe the staffing model. How many staff/ from which team. Is it being absorbed into an existing role or are there new staff / teams to recruit?*
Staffing Implications	
Evidence of training competence of the lead	*As the lead clinician, suggesting this treatment, what is your level of training expertise in the treatment already.*
Ongoing training needs for lead and any other staff	*What are the training requirements to ensure staff delivering the procedure are trained to the required standards? Detail what the training is, how long it takes, the frequency required, cost and who will be delivering the training.*
Ongoing supervision requirements	*Who can / will be delivering ongoing supervision in this new treatment? What skills / training do they need. How often will it be required?*
Policy / protocols or guidance to be followed.	*What guidance will be in place to set standards and requirements for the new intervention. How will standards be agreed and maintained.*
Impact on other teams / services and dissemination of information	*Who / how will other services refer service users for the new treatment. Who / how will aftercare be provided. Please describe all the teams / services that will be impacted in any way and are therefore an "interested" party.*

List the "lead committee" and all of the committees which are going to/ have reviewed the proposal, the date of the meeting and the outcome.	*The lead committee will be the one which represents the service users and / or staff "most" effected by the new procedure. i.e., the group with a vested interest in the outcome. The 12-month evaluation will be presented to this committee, and this should be tabled on to the business cycle of the committee and reported to Trust CGC following receipt of the evaluation.* *For advice on which committees should be considered, contact the Head of Effectiveness and QI or the Medical Director* *All other interested parties should have an opportunity to scrutinise the proposal and reach an agreement as to if the proposal is agreed to / agreed with conditions / not agreed and the reasons for this.*
What patient information is going to be available and used?	*Describe the information that will need to be conveyed to anyone receiving treatment and how this will be done and evidenced. Will this be verbal / written? What are the arrangements to ensure informed consent? How will service users raise any adverse effects and what arrangements will be put in place to ensure they know about this.*
Evaluation	
Effectiveness	*If the treatment has been assessed by NICE, briefly outline the key NICE recommendations and if the proposal is compliant. Ensure the relevant guidance is listed in the reference list.* *Outline any supporting research / audit.* *If this treatment is already widely adopted and used elsewhere, describe this.*
Risks	*Outline the possible potential risks. The following lists are possible areas to consider.* *What are the potential risks to the patient in terms of side effects? What happens in the event it isn't "successful" etc.* *What are the potential risks to staff such as limited training / support options, for example?* *Are there any environmental risks such as equipment maintenance / breakdown / storage / ligature risks?* *What are the implications for indemnity insurance?*
Audit / evaluation	*Outline the plans for how the impact will be evaluated. Evaluation must include:* - *Clinical audit to demonstrate the new intervention is being implemented as per the standards set.* - *Outcome measures and evaluation of effectiveness.* - *Patient feedback both positive and negative* - *Any adverse events or incidents*
Resource Implications	
Capital cost.	*Cost of equipment/ training/ environment and staff to implement the new procedure.*
Recurring cost	*What are the ongoing costs including equipment maintenance / staffing and training?*
Efficiency gains or cost savings	*Are there any efficiencies that will be made elsewhere as a result of the new procedure? Are there any cost savings or income generation?*
Funding source	*Has funding been agreed already or plans for where funding will be obtained?*
Evidence	
Conflicts of Interest	*Please detail any possible conflicts of interest of the clinical lead and sponsor or declare there are none. Declare industry links such as authorship of manuals etc. Include private practice and any impact should this be utilised by the NHS.*

Glossary of the evidence (either embedded files or working hyperlinks)	*Proper scrutiny requires that the committees are able to review the available evidence for themselves before consideration of the proposal. Ensure all available evidence is listed here either as a working hyperlink or a reference that can be followed online or through the library.*

Appendix 4- Due Diligence Review to be completed before the implementation of a new team / service or service model.

DUE DILIGENCE CHECKLIST

For changes to new and pre-existing services within the Trust – please note that a CQEIA must be completed for all such projects/ changes.

Outline of the proposed changes inc. anticipated benefits and possible risks.	
Project Lead:	
Contact Email:	
Contact Telephone Nº:	
NB: All the following points need to be considered:	
CQC regulation	• Does this change affect our CQC registration? Does the service need to be registered? • Ensure a ratings certificate is displayed as appropriate **If you do not know contact Head of Regulatory Compliance (ext. 1076) to review the change and confirm.**
Risk Assessment and CQEIA	• Have you assessed the risks of the changes for the project? • Are these risks being reviewed regularly? By whom? • Which senior manager would you escalate the risks to? • What committee would own these risks? • How do the risks get escalated?
Policy Mapping	• Do the changes impact on any existing policies within the Trust? Would they mean that the service was no longer compliant with the policies? If so decisions would have to be made about altering the policy or the service. These issues will need escalating. **Contact Compliance Manager (ext.1030) for support.** Key policies to review are (this is not an exhaustive list): • Care Programme and Care Support Policy • Medicines Code • Resuscitation • Referral Management and Appointment policy • Care Records Management • Incident Reporting and Management • Lone Working • Health and Safety policy • Risk Management • Infection Prevention and Control • Admission, Transfer, Discharge and Follow Up Policy

<table>
<tr><td>Clinical Procedures</td><td>• Are there any clinical procedures and/or equipment which will be introduced by the service which are not currently used by the Trust?
Contact Clinical Governance Manager (ext.1090) for support.</td></tr>
<tr><td>Governance</td><td>• How does this new service fit into the clinical governance arrangements for the service area and the Trust?
• How will we continue to be assured that it is safe and providing a quality service?</td></tr>
<tr><td>Records management</td><td>Are there any changes required in the electronic record for the new service? Systems to consider include RiO, ESR, Eclipse etc
• Teams to be set up/altered
• Forms to be built
• Reporting arrangements reviewed</td></tr>
<tr><td>Internal relations</td><td>• How will the rest of the Trust know about the changes to the new services?
• Do the changes affect other services? If so how are these being communicated and agreed?
• Does Connect need to be updated? (including information about the service, telephone numbers and location)
• Which operational policy does the service come under does it need amending or a new one constructing?

• Have all relevant departments been contacted/ notified? Add any not listed:

<table>
<tr><th>Team contacted/ notified?</th><th>Yes/ No/ N/A</th></tr>
<tr><td>Estates Team</td><td></td></tr>
<tr><td>Facilities Team</td><td></td></tr>
<tr><td>Fire Officer</td><td></td></tr>
<tr><td>Health & Safety/ Risk Team</td><td></td></tr>
<tr><td>IT Team</td><td></td></tr>
<tr><td>Local Security Management Specialist</td><td></td></tr>
<tr><td>Project Management Office</td><td></td></tr>
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</td></tr>
<tr><td>Estates</td><td>• Detailed Project Brief available?
• Confirmation on budget expectations.
• Is there an associated budget available for the works?
• What are the anticipated time frames?
• Do the changes impact any other services?
• Are estates expected to escort, can security / clinical teams help?
• Are there any lessons learnt from similar projects in other areas?
• Handover and ongoing maintenance requirements / warranties confirmed and in place?</td></tr>
</table>

	• Cost implications on operational budgets moving forward in terms of PPM's confirmed? • Where water services are included – have changes to water systems been approved via Water Safety Group, provision for plans to be updated put in place?
Fire	• Annual review or miscellaneous changes to a sites Local Operating Procedure, to be submitted to local H&S meeting for ratification with the reviewed copy forwarded to the Trust Fire Safety Advisor. • Actions following a Fire Risk Assessment to be complied and returned to Fire Safety Advisor on two month review/request • Fire incidents will be fully investigated by the Trust Fire Safety Advisor, with outcomes submitted to the 'Responsible Person'. A review of which will be undertaken by the Trust within two months of receipt. • Actions from un-announced Fire Evacuation Drills to be used when reviewing the LOP • Staff nominations for F2F Training to be submitted to Adam Lee via email to bsmhft.healthandsafety@nhs.net
Health & Safety	• A request must be submitted for a new/ updated environmental, ligature, COVID-19 risk assessment for the service or change (contact the Health and Safety Team for support with this) bsmhft.healthandsafety@nhs.net • Responsibilities need to be defined/ agreed – who is managing the building/ point of contact for any queries/ concerns • Trained staff identified i.e. First Aiders • DSE Assessments updated where required
Security	There will need to be a Security Risk assessment of any building and/or service provision to ensure that appropriate levels of security commensurate with the proposed service provision are in place or implemented, as necessary. Such considerations are the requirement for: • anti-barricade/vision panels, • lone working, • staff assistance alarm systems, • reception desk safety, • access control into and within the building, • drug storage provision and • CCTV for example.
Staffing	• Arrangements for staffing • Arrangements for training • HR support • Local induction • Welfare facilities • DSE assessments
Equipment	• PPE, uniforms, medication bags, lone working devices, pinpoint alarms, laptops, mobile phones (Ordered through procurement system only)
Medication Safety	• Appropriate fridges, controlled drugs management, stock check processes etc