Approved by South West London Medicines Optimisation Group: 18/03/2021

2021/22 Policy for patients on insulin pump therapy without baseline HbA1c and / or information on disabling hypoglycaemic events to assess NICE eligibility or patients who do not meet NICE eligibility criteria

This guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Background:
South West London Clinical Commissioning Group (SWL CCG) fund insulin pumps in line with NICE TA 151 (July 2008) as per SWL Commissioning Principles for PbR Excluded Drugs/Devices Appendix 1 (www.swlmcg.nhs.uk).

Patients with insulin pumps in situ, who are moving into SWL area with no evidence of having met NICE criteria at the time of starting treatment or who do not meet NICE eligibility criteria, require consideration whether they are eligible for further funding. It is important not to discriminate against local patients treated within the NHS who may not have access to this treatment as they have not met NICE criteria and to use the available financial resources responsibly.

Recommendations:
Provided the patient is under the care of a trained specialist team (comprising of a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietician), Trusts can seek funding from SWL CCG through submission of the proforma in appendix 3, for insulin pump consumables for an interim period of 6 or 12 months while patients are being assessed as per flow diagram in appendix 1A or 1B.

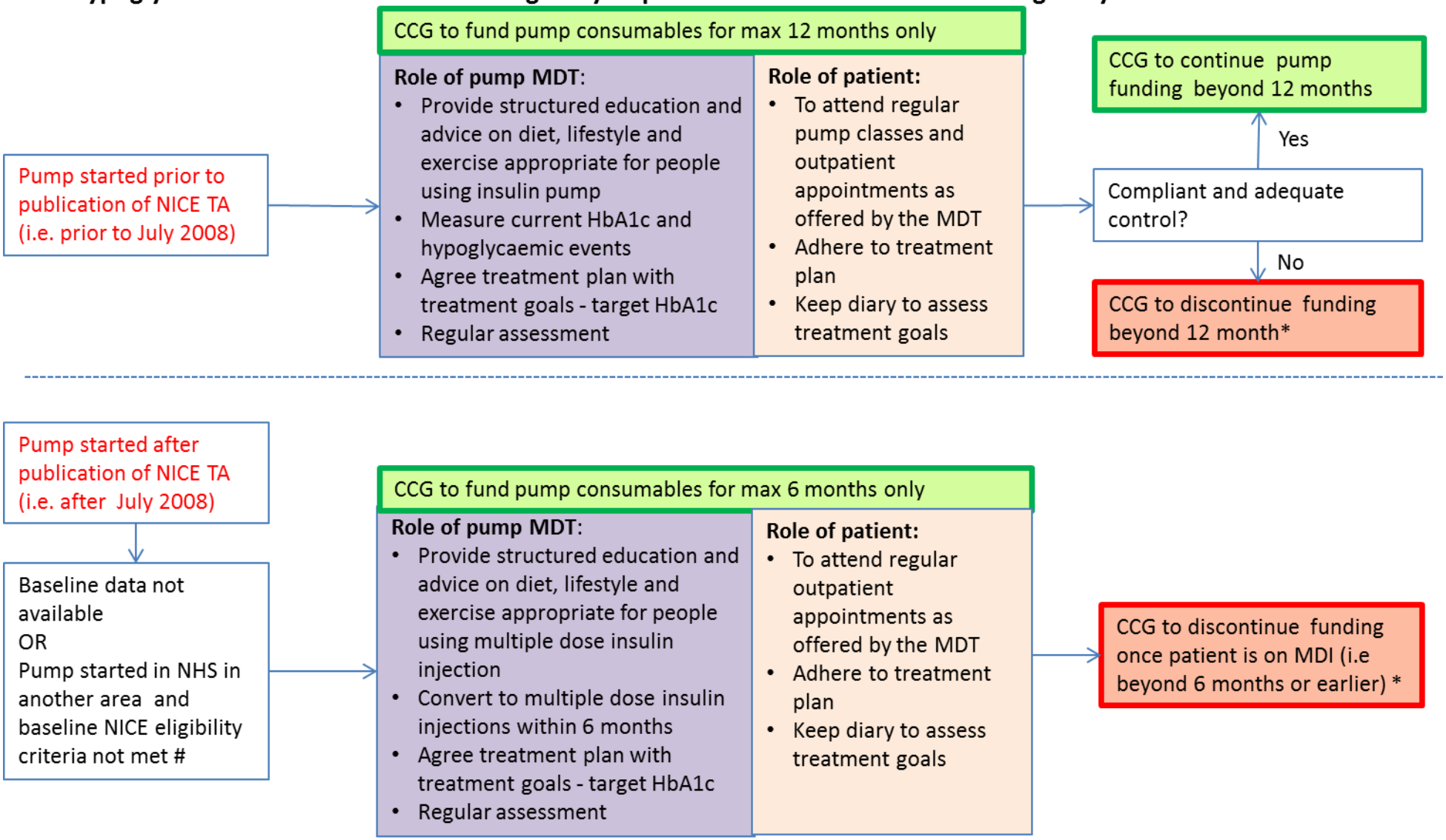
Patients who do not meet criteria for continuation of insulin pump and consumables funding:
If there are patient specific exceptional clinical circumstances requiring the patient to remain on a pump, funding may be applied for via IFR (nelcsu.ifrswlondon@nhs.net).

NOTE: This policy in not applicable to:

- Retrospective funding requests
- Patients started on pumps in the private healthcare sector

Appendix 1A: Patients started in UK:

Process map for patients on insulin pump therapy without baseline HbA1c and / or information on disabling hypoglycaemic events to assess NICE eligibility or patients who do not meet NICE eligibility criteria

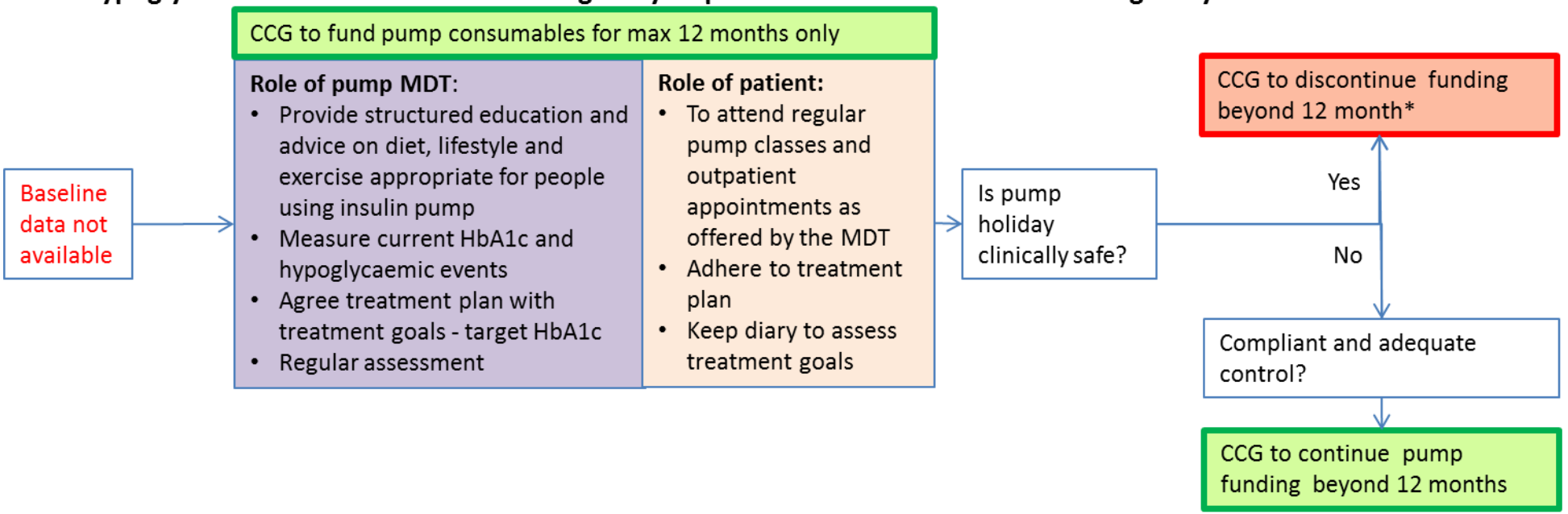


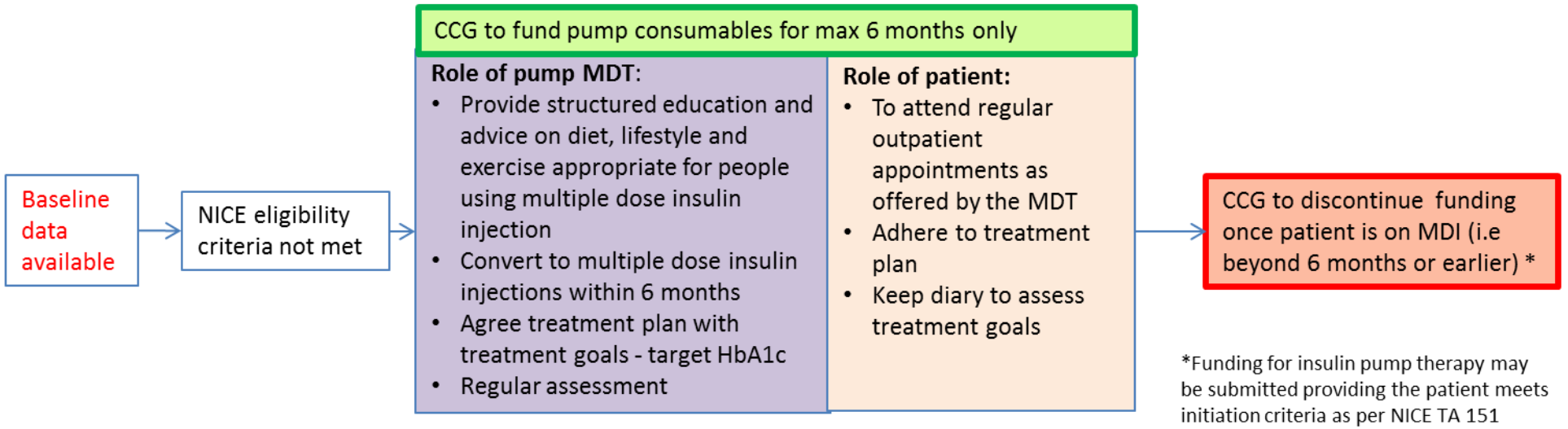
Not for patients started in private healthcare sector

*Funding for insulin pump therapy may be submitted providing the patient meets initiation criteria as per NICE TA 151

Appendix 1B: Patients started outside UK:

Process map for patients on insulin pump therapy without baseline HbA1c and / or information on disabling hypoglycaemic events to assess NICE eligibility or patients who do not meet NICE eligibility criteria





*Funding for insulin pump therapy may be submitted providing the patient meets initiation criteria as per NICE TA 151

Appendix 2:
NICE TA 151 (July 2008) – Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus

Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a possible treatment for adults with type 1 diabetes mellitus provided that:

- attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia (defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life)

OR

- HbA1c levels have remained high (that is, at 8.5% or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

CSII should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.

Appendix 3:

Temporary Funding Request Form 2021-22

For patients on insulin pump therapy without baseline HbA1c and / or information on disabling hypoglycaemic events to assess NICE eligibility or patients who do not meet NICE eligibility criteria started in the NHS or abroad

Please tick or select the corresponding borough that the patient is registered to:

Croydon borough (SWL CCG) ☐	**Kingston borough (SWL CCG)** ☐	**Merton borough (SWL CCG)** ☐
Sutton borough (SWL CCG) ☐	**Richmond borough (SWL CCG)** ☐	**Wandsworth borough (SWL CCG)** ☐
Other CCG ☐ **Please state name:**		

All forms must be typed and all fields must be completed (or n/a stated where field is not applicable). Incomplete mandatory fields and hand-written forms will result in the form being returned and may cause delays to consideration for funding.

Anonymity – Please ensure that in order to protect patient's identity, apart from Section A, the patient is not referred to by name or initials within the application form.

SECTION A: CONTACT INFORMATION		
1. NHS Approved Provider Name		
2. Address		
3. Applicant Details *The applicant should have clinical responsibility for this intervention for this patient for this specific clinical indication.* *Please ensure the declaration is signed and dated (Section H)*	**Name:**	
	Designation:	
	Tel:	
	nhs.net address: **(No other email accepted)**	
4. Patient Details	**Initials:**	
	NHS Number:	
	Hospital ID number:	
	DoB:	
	Patient Address:	
	Registered Consultant:	
	Registered GP name:	
	GP practice code:	
	Date of referral:	/ /

SECTION B: INTERVENTION REQUESTED

(NB: Intervention refers to requested treatment, investigation, etc)

5. Patient diagnosis or condition (for which intervention is requested)	Type I diabetes
6. Other relevant diagnosis or co-morbidities	
7. Name of pump for which consumables* are requested: (tick as appropriate) *Not including consumables associated with continuous blood glucose monitoring or insulin.	☐ Mylife ypsopump (Ypsomed) ☐ Accucheck insight (Roche) ☐ A6 Touch care (Medtrum) ☐ Accucheck combo (Roche) ☐ Omnipod (Insulet) ☐ Tandem T-Slim (Air liquid) ☐ Dana R (Advanced Therapeutics) ☐ Kaleido Pump (ViCentra) ☐ Minimed 640G (Medtronic) ☐ Dana RS (Advanced Therapeutics) ☐ MiniMed 670G (Medtronic) ☐ Other:
8. When and where was pump treatment started? **Clinical Urgency** The decision to treat in the event of immediate or life-threatening circumstances must be made in accordance with NHS Approved Provider (Trust) governance mechanisms.	**Pump treatment start date:** / / **Pump treatment was started by:** Hospital name: Place: Country: **Was treatment started in private healthcare sector?** **Your request will be acknowledged within 5 working days of receipt. A funding decision usually takes the CSU up to 4 weeks from the date of receipt of a full & accurately completed application with copies of supporting clinical papers and completion of section I.**
	Is the case more urgent than this?
	☐ **Yes** ☐ **No** **If 'YES' please state why**
9. Is requested intervention part of a clinical trial?	Tick as appropriate: ☐Yes / ☐No If **Yes**, **then STOP HERE.** This funding route is not appropriate. Please speak to your Trust Chief Pharmacist for drug trials. There is no need to complete the rest of this proforma.

SECTION C: COMPARISON WITH STANDARD COMMISSIONED INTERVENTION

10. Insulin Pump NICE eligibility criteria	**A. HbA1c (please tick one of 2 below):** ☐ Baseline HbA1c (prior to starting pump therapy) is less than 8.5%. Please

	provide baseline HbA1c: % and mmol/mol ☐ Baseline HbA1c (prior to starting pump therapy) is not available. Please explain why it is not available, describe all attempts undertaken to obtain this information and why all options have now been exhausted: **B. Disabling hypoglycaemic events (please tick one of 2 below):** ☐ Patient did not have disabling hypoglycaemic events# prior to starting pump therapy. ☐ Number of disabling hypoglycaemic events# (prior to starting pump therapy) not available. Please explain why it is not available, describe all attempts undertaken to obtain this information and why all options have now been exhausted: # Disabling hypoglycaemic events are defined by NICE as repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.

SECTION D: CURRENT STATUS OF PATIENT

11. Current patient status	**Current HbA1C level:** **Current number of hypoglycaemic episodes per week** **Current number of disabling hypoglycaemic episodes* per year:**
12. Current patient engagement in managing condition.	Please describe current patient engagement with pump MDT in detail including attendance at pump classes and outpatient appointments, adherence to treatment plan, use of diaries etc :
13. Reason for request	**P**lease explain why a request is made for temporary continuation of funding for pump consumables for this patient:

SECTION E: PREVIOUS TREATMENT/INTERVENTIONS

14. Summary of pump therapy intervention(s) this patient has received for the condition.	**Start Date:**	**Stop Date:**	**Name of Pump Intervention**	**Reason for stopping* / Response achieved or indicate if still continuing**
15. Has a previous application been submitted on behalf of this patient?			Tick as appropriate: ☐Yes / ☐No	

SECTION F: EVIDENCE FOR EFFECTIVENESS OF INTERVENTION REQUESTED

16. Planned intervention by pump MDT	Please describe the interventions planned by the pump MDT for this particular patient in detail (including treatment goals and targets if available, timescales by which time a decision on discontinuation / continuation of pump treatment can be reached):

17. Outcomes (a) What would you consider to be a successful outcome for this intervention in this patient? – include details of the parameters you intend to measure	
(b) How will you monitor this and how frequently will you monitor this?	
(c) What stopping criteria will be used to decide when the intervention is no longer effective?	
(d) Detail the current status of the patient according to these measures (if not already provided in question 11).	
18. What are the anticipated adverse effects and potential risks of the intervention for this patient?	
19. How do the benefits outweigh the risks?	

SECTION G: COSTS and REVIEW	
The completed form must be sent to the Trust Chief Pharmacist, for completion of Part A and to the Trust service manager for completion of part B).	
PART A – (to be completed by approved NHS provider Chief Pharmacist)	
20. Total Acquisition cost of pump consumables (inc VAT) for duration of treatment being applied for	£ per months
21. State the value of any offset costs	£
22. Please benchmark these costs against London Procurement Prices (if applicable)	
23. Application reviewed by Chief Pharmacist or nominated authorised deputy	**Name:** **Signature or email confirmation:**
PART B- (to be completed by approved NHS provider service manager)	
24. Application reviewed by Service Manager or nominated authorised deputy	**Name:** **Signature or email confirmation:**

SECTION H: APPLICANT'S DECLARATION	
25. Declaration I declare that this application is complete and accurate and that all necessary supporting information and evidence has been provided on this form (& attachments).	Tick as appropriate: ☐Yes / ☐No

<table>
<tr><td colspan="2">26. Patient Consent
I confirm that this funding request has been discussed in full with the patient, including an appraisal of the benefits/risks of the intervention and they have consented to the proposed treatment. I confirm the patient has consented to CCG & CSU staff involved in the preparation, consideration and funding of their case to access confidential clinical information about them (including their NHS no.) to enable full consideration of this request and payment of invoices. In the case of a minor or vulnerable adult I confirm I have complied with the relevant legislation guidance including the Children Act 2004 and Mental Capacity Act 2005.</td><td>Tick as appropriate:
☐Yes / ☐No

Patient signature (optional):</td></tr>
<tr><td colspan="2">27. Correspondence and Contact
The IFR team will copy the patient into correspondence concerning progress and outcome of their application. If you do not want the patient to be contacted or to receive correspondence please indicate this.</td><td>Please copy the patient into correspondence.

Tick as appropriate:
☐Yes / ☐No</td></tr>
<tr><td>Responsible Clinician Name:</td><td>Signature or email confirmation:</td><td>Date:
/ /</td></tr>
</table>

Equality Monitoring Data

This section is for data monitoring purposes only and will be removed from the application prior to consideration by the IFR Panel.

1	**Ethnic Origin**								
	White	British	☐	Irish	☐	Any other White background	☐		
	Mixed	White and Black Caribbean	☐	White and Black African	☐	White and Asian	☐	Any other Mixed background	☐
	Asian or Asian British	Indian	☐	Pakistani	☐	Bangladeshi	☐	Any other Asian background	☐
	Black or Black British	Caribbean	☐	African	☐	Any other Black background	☐		
	Other Ethnic Groups	Chinese	☐	Any other ethnic group	☐				
2	**Gender**								
		Male	☐	Female	☐	Transgender	☐	Not disclosed	☐
3	**Sexuality**								
		Heterosexual	☐	Bisexual	☐	Gay	☐	Lesbian	☐
		Not disclosed	☐						
4	**Age Group**								
		16-25	☐	26-35	☐	36-45	☐	46-55	☐
		56-65	☐	66+	☐				
5	**Do you consider yourself to have a disability?**								
		Registered disabled	☐	Unregistered disabled	☐	Not disabled	☐		
	Nature of disability								
		Hearing impairment	☐	Speech impairment	☐	Mobility Impairment	☐	Age related impairment	☐
		Visual impairment	☐	Learning disability	☐	Mental health	☐	Other	☐
6	**Religion**								
		No religion	☐	Christian	☐	Buddhist	☐	Other	☐
		Hindu	☐	Jewish	☐	Muslim	☐		

For South West London CCG(Croydon, Kingston, Merton, Richmond, Sutton and Wandsworth boroughs) - forms should be submitted to nelcsu.ifrswlondon@nhs.net; Tel. enquiries: 020 3668 1222