

# Identification of Neonates requiring BCG Immunisation

|  |                          |                      |  |
|--|--------------------------|----------------------|--|
| <b>Classification:</b>   | Guideline                |                      |  |
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| <b>Authors Job Title:</b>  | Maternity Matron         |                      |  |
| <b>Authors Division:</b>   | Women's and Children's   |                      |  |
| <b>Departments/Group this Document applies to:</b>   | Maternity, Neonates      |                      |  |
| <b>Approval Group:</b><br>Maternity Guidelines,<br>Women's Health CIG,<br>Children's Health PIG,<br>Children's Health CIG  | <b>Date of Approval:</b> | 26/02/2022           |  |
|  | <b>Last Review:</b>      | 26/02/2022           |  |
|  | <b>Review Date:</b>      | 26/02/2025           |  |
| <b>Unique Identifier:</b> MIDW/GL/147  | <b>Status:</b> Approved  | <b>Version No:</b> 3 |  |
| <b>Guideline to be followed by (target staff):</b> Midwives and neonatal staff   |                          |                      |  |
| <b>To be read in conjunction with the following documents:</b><br>None   |                          |                      |  |
| <b>Are there any eCARE implications?</b> No  |                          |                      |  |
| <b>CQC Fundamental standards:</b><br>Regulation 9 – person centered care<br>Regulation 10 – dignity and respect<br>Regulation 11 – Need for consent<br>Regulation 12 – Safe care and treatment<br>Regulation 13 – Safeguarding service users from abuse and improper treatment<br>Regulation 14 – Meeting nutritional and hydration needs<br>Regulation 15 – Premises and equipment<br>Regulation 16 – Receiving and acting on complaints<br>Regulation 17 – Good governance<br>Regulation 18 – Staffing<br>Regulation 19 – Fit and proper |                          |                      |  |

## Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

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The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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## Guideline Statement

BCG immunisation of neonates and children at risk of TB is a local and national requirement. From the 1<sup>st</sup> September 2021 there is a change in the neonatal BCG immunisation as part of the Severe Combined Immunodeficiency (SCID) screening at 5 days of age. The SCID screening evaluation is taking place in 6 areas across England It is necessary to move the BCG vaccination to when a SCID screening outcome will be available, which will be by 28 days of age. This will ensure that babies with SCID are not given the live attenuated BCG vaccine which is contraindicated in these babies.

4 Yellow Card reports regarding neonates who have died from disseminated BCG or tuberculosis infection after exposure to a TNF $\alpha$  antagonist in utero; they were probably not known to be immunosuppressed at the time of vaccination. As a precaution, any infant who has been exposed to immunosuppressive treatment from the mother either in utero during pregnancy or via breastfeeding should have any live attenuated vaccination deferred for as long as a postnatal influence on the immune status of the infant remains possible. In the case of in utero exposure to TNF $\alpha$  antagonists and other biological medicines, this period should be until the infant is age 6 months

Some cases of fatal BCG infection in infants after in utero exposure to TNF an antagonist have been reported through the Yellow Card scheme. Immunisation with live vaccines, including BCG, should be delayed for 6 months in children born of mothers who were on immunosuppressive biological therapy during pregnancy. If there is any doubt as to whether an infant due to receive a live attenuated vaccine may be immunosuppressed due to the mother's therapy, including exposure through breast-feeding, specialist advice should be sought.

The BCG vaccination will be provided by the Community School Aged Immunisation Service (CSAIS) Appendix 2

## Executive Summary

The BCG immunisation programme is a risk-based programme. The key part being a neonatal programme targeted at protecting those children most at risks of exposure to TB, particularly from the more serious childhood forms of the disease.

### 1.0 Roles and Responsibilities:

Community Midwives – identify babies at risk of TB and provide information to parents in the antenatal period.

Paediatricians/Advanced Neonatal Nurse Practitioner (ANNP) and Newborn Initial Physical Examination (NIPE) Midwives – identify babies at risk of TB and provide information to parents in the postnatal period and complete the information required as part of the NIPE in the local and national data section on the NIPE database

### 2.0 Implementation and dissemination of document

The guideline will be on the hospital intranet for all staff to access.

### 3.0 Processes and procedures

BCG vaccine contains a live attenuated strain derived from *M. bovis*. BCG Vaccine Statens Serum Institute (SSI) is the only available licensed vaccine in the UK. It contains live organisms that have been attenuated (weakened).

#### 3.1 Indication for BCG

- All infants (aged 0-12 months) living in areas of the UK where annual incidence of TB is 40/100,000 or greater
  - All infants (aged 0-12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater
  - those who are going to live with local people for more than three months in a country where the annual incidence of TB is 40/100,000 or greater

#### NOTE:

- Immunisation for travel purposes is the responsibility of a travel clinic.
- People seeking vaccination for themselves or their children should be assessed for specific risk factors for TB. Those without risk factors should not be offered BCG vaccination but should be advised of the current policy and given written information. Further information is available at [www.nhs.uk](http://www.nhs.uk)

#### 3.2 Maternity

- Unborn babies eligible for BCG vaccine should be identified during the pregnancy by their midwife and/or doctor to allow adequate information sharing and preparation of the parents. Documentation of this conversation and provision of leaflet to be documented in eCARE pregnancy booking
- On identification of the babies who are at higher than average risk (Appendix 1), parents should be given information on BCG vaccination and the NHS Immunisation Information leaflet titled "TB, BCG vaccine and your baby" (dH.gov.uk September 2021)  
<https://www.gov.uk/government/publications/tb-bcg-and-your-baby-leaflet>
- If the mother receives immunosuppressive biological therapy during pregnancy and the baby is eligible for BCG, please complete a Baby Alert as the BCG vaccine should be delayed until the infant is age 6 months
  - Following results of the routine newborn screening test at 5 days (usually expected within 10-12 days), Child Health where the diagnostic tests are negative Child Health a letter confirming the outcome of the investigations will be issued to parents and copied to GP and Health Visitor. This letter also confirms that vaccinations can now be given as usual including BCG and rotavirus vaccine.
  - Following the birth, the practitioner completing the Newborn Initial Physical Examination (NIPE) should document the requirements in the local and national section on the NIPE database.

- If a woman has received immunosuppressive treatment during pregnancy or while breastfeeding, the information should be included on the neonatal discharge paperwork so that the BCG can be delayed until the infant is 6 months of age

### 3.3 Neonatal Unit

- If a baby is still in NNU at 28 days old, their BCG vaccine will be delayed until they are discharged unless there is a clinical requirement for them to be vaccinated earlier, in which case the Trust can deliver the vaccine.
- For babies still unvaccinated at discharge, the NNU unit will be responsible for sending the referral form (Appendix 3) to the immunisation service for BLMK area BCGs to [epunft.bcgimmunisations@nhs.net](mailto:epunft.bcgimmunisations@nhs.net)

### 3.4 Contraindications

The vaccine should not be given to:

- Neonates in a household where an active TB case is suspected or confirmed.
- BCG is contraindicated in symptomatic HIV-positive individuals. In countries such as the UK where the risk of TB is low, it is recommended that BCG is also withheld from all those known to be or suspected to be HIV positive, regardless of clinical status. Where vaccination is indicated, for example infants born to HIV-positive mothers, this can be administered after two negative postnatal PCR tests for HIV infection.

### 3.5 Premature infants

It is important that premature infants have their immunisations at the appropriate chronological age, according to recommendations. There is little evidence that premature babies are at an increased risk of adverse reactions from vaccines.

## 4.0 Statement of evidence/references

### References:

[BCG vaccine for tuberculosis \(TB\) overview - NHS \(www.nhs.uk\)](#) accessed on 05/10/2021

[Who should have the BCG \(TB\) vaccine - NHS \(www.nhs.uk\)](#) accessed on 05/10/2021

[Tuberculosis by country: rates per 100,000 people - GOV.UK \(www.gov.uk\)](#) accessed on 05/10/2021

[BCG immunisation programme: changes from September 2021 letter - GOV.UK \(www.gov.uk\)](#) accessed on 05/10/2021

[BCG vaccination | Information for the public | Tuberculosis | Guidance | NICE](#) accessed on 05/10/2021

<https://www.gov.uk/drug-safety-update/live-attenuated-vaccines-avoid-use-in-those-who-are-clinically-immunosuppressed> - accessed on 24/12/2021

NICE Postnatal Care NG194 April 2021

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## 5.0 Governance

### 5.1 Document review history

| Version number | Review date | Reviewed by  | Changes made    |
|----------------|-------------|--------------|-----------------|
| 3              | 24/12/2021  | Mary Plummer | Complete review |

### 5.2 Consultation History

| Stakeholders Name/Board   | Area of Expertise            | Date Sent  | Date Received | Comments  | Endorsed Yes/No |
|---------------------------|------------------------------|------------|---------------|---|-----------------|
| Kiki Erskine              | Neonatal Nurse               | 10/01/2022 | 21/01/22      | Change modified to weakened (attenuated vaccine)<br>Typo corrected  | Yes             |
| Gillian Mallows           | ANNP                         | 10/01/2022 | 21/01/22      | Question on GP role in BCG.<br>Regional pathway added to identify pathway<br>Documentation requirements in NIPE | Yes             |
| Denise Campbell           | Governance - paediatric      | 10/01/2022 | 21/01/22      | Question on whether GP role.<br>Regional pathway added to identify pathway                                      | Yes             |
| Shveta Chana              | Paediatric Consultant        | 10/01/2022 | 21/01/22      | incorporating a flowchart to delineate the pathway easily.  | Yes             |
| Sophie Conneely           | Community Matron             | 10/01/2022 | 18/03/22      | Changes made at booking for identification of BCG requirement   | Yes             |
| Rebecca Lemon             | Practice Development Midwife | 10/01/2022 |               |   | Yes             |
| Natalie Lucas             | Practice Development Midwife | 10/01/2022 |               | Sentence rewording  | Yes             |
| Janice Styles             | Consultant Midwife           | 13/01/2022 |               | Read Guideline  |                 |
| Erica Puri                | Audit and Guideline Midwife  | 25/02/2022 |               | Flow chart into the appendices  | Yes             |
| Maternity Guideline Group | Maternity                    | 26/02/2022 |               |   |                 |
| Maternity CIG             | Maternity                    | 02/03/2022 |               |   |                 |

### 5.3 Audit and monitoring

| Audit/Monitoring Criteria | Tool | Audit Lead | Frequency of Audit | Responsible Committee/Board |
|---------------------------|------|------------|--------------------|-----------------------------|
| Pending- Reviewer aware   |      |            |                    |                             |

## 5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

| Equality Impact Assessment   |                     |  |                  |
|--|---------------------|--|------------------|
| Division   | Women and Children  | Department   | Women's Health   |
| Person completing the EqIA   | Mary Plummer        | Contact No.  | Ext 85130        |
| Others involved:   |                     | Date of assessment:  | 24/12/21         |
| Existing policy/service  | Yes                 | New policy/service   | No               |
| Will patients, carers, the public or staff be affected by the policy/service?    |                     | Yes  |                  |
| If staff, how many/which groups will be affected?                                |                     | N/A  |                  |
| Protected characteristic   | Any impact?         | Comments   |                  |
| Age  | YES                 | Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff |                  |
| Disability   | NO                  |  |                  |
| Gender reassignment  | NO                  |  |                  |
| Marriage and civil partnership   | NO                  |  |                  |
| Pregnancy and maternity  | YES                 |  |                  |
| Race   | NO                  |  |                  |
| Religion or belief   | NO                  |  |                  |
| Sex  | NO                  |  |                  |
| Sexual orientation   | NO                  |  |                  |
| What consultation method(s) have you carried out?                                |                     |  |                  |
| <i>Emails and meetings</i>   |                     |  |                  |
| How are the changes/amendments to the policies/services communicated?            |                     |  |                  |
| <i>Email and meetings</i>  |                     |  |                  |
| What future actions need to be taken to overcome any barriers or discrimination? |                     |  |                  |
| What?  | Who will lead this? | Date of completion   | Resources needed |
|  |                     |  |                  |
|  |                     |  |                  |
|  |                     |  |                  |
| Review date of EqIA  | 26/02/2025          |  |                  |



## Appendix 1: List of the countries where the incidence of Tuberculosis is higher than 40/100,000

<https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people> (Accessed 5/10/2021)



Public Health  
England

Table 1: High incidence countries (estimated incidence rate of 40 per 100,000 or greater)

| Country/Territory                     | WHO Region            | Estimated rate per 100,000 population | Number of cases | Rate ≥150 per 100,000 |
|---------------------------------------|-----------------------|---------------------------------------|-----------------|-----------------------|
| Afghanistan                           | Eastern Mediterranean | 189                                   | 72,000          | ✓                     |
| Algeria                               | Africa                | 61                                    | 26,000          |                       |
| Angola                                | Africa                | 351                                   | 112,000         | ✓                     |
| Azerbaijan                            | Europe                | 60                                    | 6,000           |                       |
| Bangladesh                            | South-East Asia       | 221                                   | 361,000         | ✓                     |
| Benin                                 | Africa                | 55                                    | 6,000           |                       |
| Bhutan                                | South-East Asia       | 165                                   | 1,300           | ✓                     |
| Bolivia (Plurinational State of)      | The Americas          | 106                                   | 12,000          |                       |
| Botswana                              | Africa                | 253                                   | 5,800           | ✓                     |
| Brazil                                | The Americas          | 46                                    | 96,000          |                       |
| Brunei Darussalam                     | Western Pacific       | 64                                    | 280             |                       |
| Burkina Faso                          | Africa                | 47                                    | 9,600           |                       |
| Burundi                               | Africa                | 107                                   | 12,000          |                       |
| Cabo Verde                            | Africa                | 46                                    | 250             |                       |
| Cambodia                              | Western Pacific       | 287                                   | 47,000          | ✓                     |
| Cameroon                              | Africa                | 179                                   | 46,000          | ✓                     |
| Central African Republic              | Africa                | 540                                   | 26,000          | ✓                     |
| Chad                                  | Africa                | 142                                   | 23,000          |                       |
| China                                 | Western Pacific       | 58                                    | 833,000         |                       |
| China, Hong Kong SAR                  | Western Pacific       | 63                                    | 4,700           |                       |
| China, Macao SAR                      | Western Pacific       | 65                                    | 420             |                       |
| Congo                                 | Africa                | 373                                   | 20,000          | ✓                     |
| Côte d'Ivoire                         | Africa                | 137                                   | 35,000          |                       |
| Democratic People's Republic of Korea | South-East Asia       | 513                                   | 132,000         | ✓                     |
| Democratic Republic of the Congo      | Africa                | 320                                   | 278,000         | ✓                     |
| Djibouti                              | Eastern Mediterranean | 234                                   | 2,300           | ✓                     |
| Dominican Republic                    | The Americas          | 42                                    | 4,500           |                       |
| Ecuador                               | The Americas          | 46                                    | 7,900           |                       |
| El Salvador                           | The Americas          | 58                                    | 3,800           |                       |
| Equatorial Guinea                     | Africa                | 181                                   | 2,500           | ✓                     |



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|                                  |                          |     |           |   |
|----------------------------------|--------------------------|-----|-----------|---|
| Eritrea                          | Africa                   | 86  | 3,000     |   |
| Eswatini                         | Africa                   | 363 | 4,200     | ✓ |
| Ethiopia                         | Africa                   | 140 | 157,000   |   |
| Fiji                             | Western Pacific          | 66  | 590       |   |
| Gabon                            | Africa                   | 521 | 11,000    | ✓ |
| Gambia                           | Africa                   | 158 | 3,700     | ✓ |
| Georgia                          | Europe                   | 74  | 3,000     |   |
| Ghana                            | Africa                   | 144 | 44,000    |   |
| Greenland                        | Europe                   | 128 | 72        |   |
| Guam                             | Western Pacific          | 54  | 91        |   |
| Guinea                           | Africa                   | 176 | 22,000    | ✓ |
| Guinea-Bissau                    | Africa                   | 361 | 6,900     | ✓ |
| Guyana                           | The Americas             | 79  | 620       |   |
| Haiti                            | The Americas             | 170 | 19,000    | ✓ |
| India                            | South-East Asia          | 193 | 2,640,000 | ✓ |
| Indonesia                        | South-East Asia          | 312 | 845,000   | ✓ |
| Iraq                             | Eastern<br>Mediterranean | 41  | 16,000    |   |
| Kazakhstan                       | Europe                   | 68  | 13,000    |   |
| Kenya                            | Africa                   | 267 | 140,000   | ✓ |
| Kiribati                         | Western Pacific          | 436 | 510       | ✓ |
| Kyrgyzstan                       | Europe                   | 110 | 7,100     |   |
| Lao People's Democratic Republic | Western Pacific          | 155 | 11,000    | ✓ |
| Lesotho                          | Africa                   | 654 | 14,000    | ✓ |
| Liberia                          | Africa                   | 308 | 15,000    | ✓ |
| Libya                            | Eastern<br>Mediterranean | 59  | 4,000     |   |
| Lithuania                        | Europe                   | 42  | 1,200     |   |
| Madagascar                       | Africa                   | 233 | 63,000    | ✓ |
| Malawi                           | Africa                   | 146 | 27,000    |   |
| Malaysia                         | Western Pacific          | 92  | 29,000    |   |
| Mali                             | Africa                   | 52  | 10,000    |   |
| Marshall Islands                 | Western Pacific          | 483 | 280       | ✓ |
| Mauritania                       | Africa                   | 89  | 4,000     |   |
| Micronesia (Federated States of) | Western Pacific          | 100 | 110       |   |
| Mongolia                         | Western Pacific          | 428 | 14,000    | ✓ |
| Morocco                          | Eastern<br>Mediterranean | 97  | 35,000    |   |
| Mozambique                       | Africa                   | 361 | 110,000   | ✓ |
| Myanmar                          | South-East Asia          | 322 | 174,000   | ✓ |
| Namibia                          | Africa                   | 486 | 12,000    | ✓ |
| Nauru                            | Western Pacific          | 182 | 20        | ✓ |
| Nepal                            | South-East Asia          | 238 | 68,000    | ✓ |
| Nicaragua                        | The Americas             | 43  | 2,800     |   |
| Niger                            | Africa                   | 84  | 20,000    |   |
| Nigeria                          | Africa                   | 219 | 440,000   | ✓ |
| Northern Mariana Islands         | Western Pacific          | 103 | 59        |   |

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|                                    |                       |     |         |   |
|------------------------------------|-----------------------|-----|---------|---|
| Pakistan                           | Eastern Mediterranean | 263 | 570,000 | ✓ |
| Papua New Guinea                   | Western Pacific       | 432 | 38,000  | ✓ |
| Paraguay                           | The Americas          | 46  | 3,300   |   |
| Peru                               | The Americas          | 119 | 39,000  |   |
| Philippines                        | Western Pacific       | 554 | 599,000 | ✓ |
| Republic of Korea                  | Western Pacific       | 59  | 30,000  |   |
| Republic of Moldova                | Europe                | 80  | 3,200   |   |
| Romania                            | Europe                | 66  | 13,000  |   |
| Russian Federation                 | Europe                | 50  | 73,000  |   |
| Rwanda                             | Africa                | 57  | 7,200   |   |
| Sao Tome and Principe              | Africa                | 114 | 250     |   |
| Senegal                            | Africa                | 117 | 19,000  |   |
| Sierra Leone                       | Africa                | 295 | 23,000  | ✓ |
| Singapore                          | Western Pacific       | 41  | 2,400   |   |
| Solomon Islands                    | Western Pacific       | 66  | 440     |   |
| Somalia                            | Eastern Mediterranean | 258 | 40,000  | ✓ |
| South Africa                       | Africa                | 615 | 360,000 | ✓ |
| South Sudan                        | Africa                | 227 | 25,000  | ✓ |
| Sri Lanka                          | South-East Asia       | 64  | 14,000  |   |
| Sudan                              | Eastern Mediterranean | 67  | 29,000  |   |
| Tajikistan                         | Europe                | 83  | 7,700   |   |
| Thailand                           | South-East Asia       | 150 | 105,000 | ✓ |
| Timor-Leste                        | South-East Asia       | 498 | 6,400   | ✓ |
| Turkmenistan                       | Europe                | 45  | 2,600   |   |
| Tuvalu                             | Western Pacific       | 296 | 34      | ✓ |
| Uganda                             | Africa                | 200 | 88,000  | ✓ |
| Ukraine                            | Europe                | 77  | 34,000  |   |
| United Republic of Tanzania        | Africa                | 237 | 137,000 | ✓ |
| Uzbekistan                         | Europe                | 67  | 22,000  |   |
| Vanuatu                            | Western Pacific       | 41  | 120     |   |
| Venezuela (Bolivarian Republic of) | The Americas          | 45  | 13,000  |   |
| Viet Nam                           | Western Pacific       | 176 | 170,000 | ✓ |
| Yemen                              | Eastern Mediterranean | 48  | 14,000  |   |
| Zambia                             | Africa                | 333 | 59,000  | ✓ |
| Zimbabwe                           | Africa                | 199 | 29,000  | ✓ |

Sources: World Health Organisation (WHO) TB burden estimates

Data accessed: October 2020

Prepared by: TB Surveillance Team, TB Unit, National Infection Service, Public Health England

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## Appendix 2 – East of England BCG Pathway



EoE Pathway  
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## Appendix 3 – BCG Referral Form BLMK

Please complete the following questions and send to:

Essex Partnership University NHS Trust (EPUT) – [epunft.bcgimmunisations@nhs.net](mailto:epunft.bcgimmunisations@nhs.net)  
For telephone, inquiries please contact – 0300 790 0594

### BCG Referral Assessment Form for Babies up to 12 months of age (born on or after 1<sup>st</sup> September 2021) – Hertfordshire, Bedford, Luton and Milton Keynes

#### Child's Name:

Date of birth: \_\_\_\_\_ NHS number (if known): \_\_\_\_\_

Parent/Care name(s): \_\_\_\_\_

Parent/Carer daytime contact number: \_\_\_\_\_

Parent/Carer address: \_\_\_\_\_

GP name & practice address: \_\_\_\_\_

Which hospital was the child born at? \_\_\_\_\_

#### Referrer's details

Referrer's name: \_\_\_\_\_ Designation: \_\_\_\_\_

Referrer's address: \_\_\_\_\_

Referrers NHS email address: \_\_\_\_\_ Referrers contact number: \_\_\_\_\_

#### Child's clinical information - Please answer **all** questions (Incomplete referrals may be sent back)

|   |          |
|---|----------|
| Has the <u>child</u> received a vaccination for TB (BCG)?                                       | YES / NO |
| Was the <u>child</u> born in the UK?  | YES / NO |
| If <b>NO</b> please state country of birth:   |          |
| Was the <u>child's birth mother</u> born in the UK?   | YES / NO |
| If <b>NO</b> please state country of birth:   |          |
| Was the <u>child's birth father</u> born in the UK?   | YES / NO |
| If <b>NO</b> please state country of birth:   |          |
| Were all of the <u>child's grandparents</u> born in the UK?                                     | YES / NO |
| If <b>NO</b> please state country/countries of birth:   |          |
| Have any members of the immediate family had TB in the last <b>FIVE</b> years?                  | YES / NO |
| Has the <b>child</b> lived or stayed in any Country other than the UK for longer than 3 months? | YES / NO |
| If YE If <b>YES</b> please state the Country:   |          |
| Has the child been screened for SCID? YES / NO  |          |
| If YES, please state result: Positive / negative  |          |
| <b>Please detail any significant clinical information (E.G. any details of PCR tests):</b>      |          |
|   |          |

Referral Date: .....