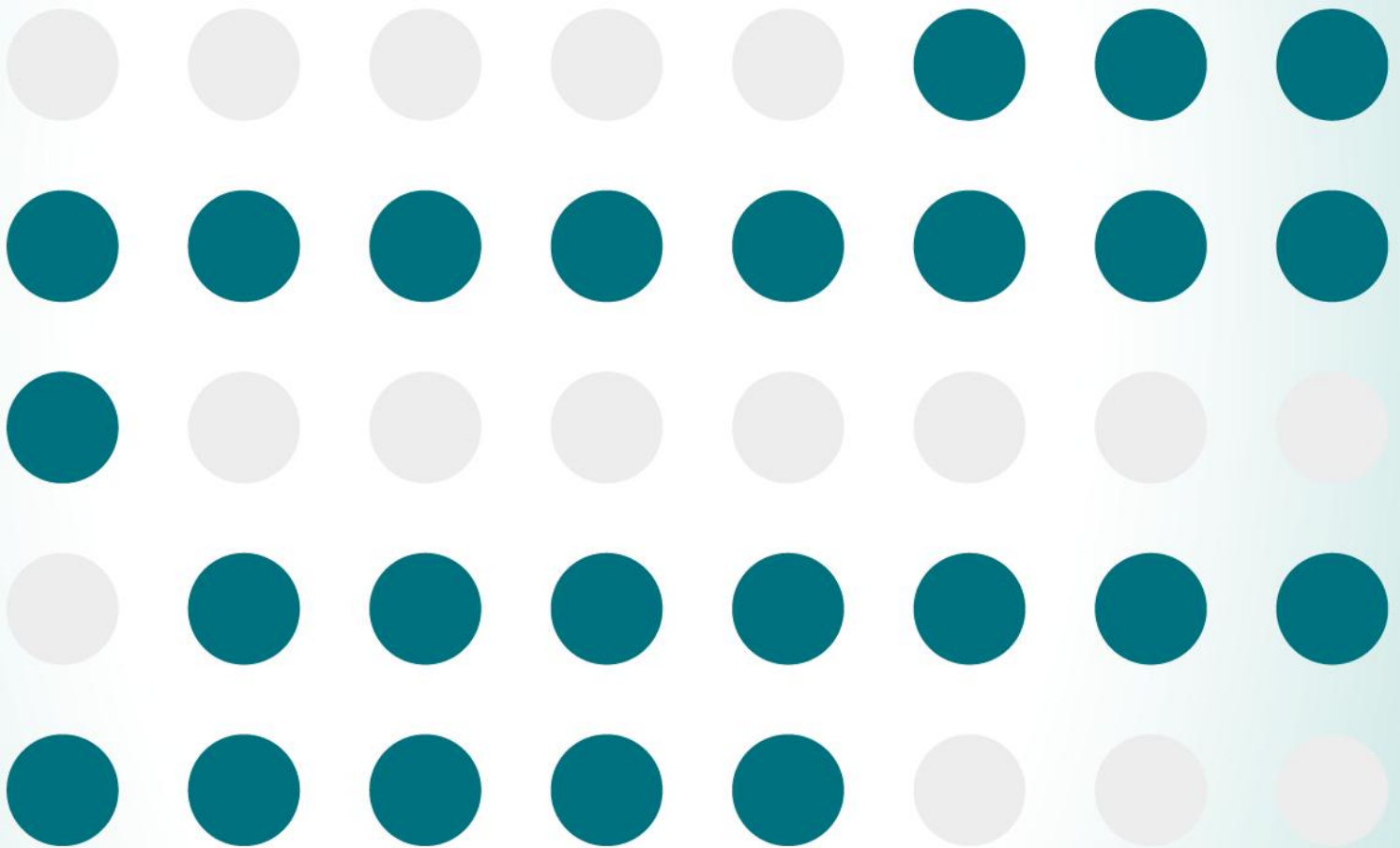


West and South Yorkshire and Bassetlaw Commissioning Support Unit



Individual Funding Request (IFR) Procedure

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March 2013



LOCAL DECISION MAKING ABOUT INDIVIDUAL FUNDING REQUESTS (IFRs) FOR MEDICINES AND OTHER INTERVENTIONS

An Individual Funding Request (IFR) is a request to fund a healthcare intervention for an individual who falls out of the range of services and treatments that the local Clinical Commissioning Group has agreed to commission.

WEST AND SOUTH YORKSHIRE AND BASSETLAW COMMISSIONING SUPPORT UNIT (WSYB CSU) INDIVIDUAL FUNDING REQUEST (IFR) PROCEDURE

1. Introduction

This procedure describes the guiding principles and framework by which the IFR process operates, the processes by which NHS Clinicians make funding requests on behalf of their patients, and refers to the commissioning policies which guide the IFR Panel through their decision making. It sets out a framework which is designed to ensure consistently fair and equitable consideration of requests for funding or treatment outside routine contractual agreements. The procedure is informed by, and complies with, the Yorkshire and Humber Regional IFR Policy.

For the purpose of this procedure, and in common with the Secretary of State's Directions to Primary Care Trusts and NHS Trusts concerning decisions about drugs and other treatments 2009, the term 'healthcare intervention' includes use of a medicine or medical device, diagnostic technique, surgical procedure and other therapeutic intervention.

This procedure applies to all employees of the West and South Yorkshire and Bassetlaw Commissioning Support Unit (WSYB CSU), contract and agency staff and any other individual working on behalf of WSYB CSU.

2. Overview

West and South Yorkshire and Bassetlaw CCGs make decisions about the funding of medicines and other interventions on a population basis for the majority of interventions. Contracts for these routinely commissioned interventions are then put in place. Where a clinical need is identified for interventions that sit outside routine commissioning, these requests are subject to a process called Individual Funding Requests (IFR). The NHS Constitution (January 2009) states:

- You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor/registered health practitioner says they are clinically appropriate to you.
- You have the right to expect local decisions on funding of other drugs and treatment to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor/registered health practitioner feel would be right for you, they will explain that decision to you.

An Individual Funding Request is therefore normally regarded as being appropriate for a treatment, intervention or drug not routinely commissioned by West and South Yorkshire and Bassetlaw CCGs.

These requests, for exceptional funding, are considered by the Individual Funding Request (IFR) Panel. The Panel meets on a weekly basis to decide upon funding requests for medical and general health interventions that sit outside that which is routinely commissioned.

The IFR Panel business centres around requests which are either where:

- There is a commissioning policy not to fund a health care intervention for the specified indication but a referring clinician considers their patient to be exceptional to that policy, those requests will be considered for funding by the IFR Panel. In addition the IFR Panel will consider a request where the clinical circumstances are so unique that it is unlikely that other patients will require this intervention.
- There is no policy in place for the requested health care intervention or indication and the clinical circumstance is so rare that it is unlikely that other patients will routinely require this intervention. Usually these requests are for a new intervention which has become available and which has not previously been considered by WSYB CSU, then the IFR Panel will identify whether this request is likely to apply to a population of patients. The overall aim is to reduce the number of requests to the IFR Panel and to concentrate on developing policies for new and existing interventions and treatments.

The IFR process has three key stages for dealing with individual funding requests;

- The triage process during which requests are filtered to ensure they are appropriate IFR requests (this process is not a decision making process).
- The IFR Panel during which funding decisions are made.
- The West and South Yorkshire and Bassetlaw Commissioning Support Unit (WSYB CSU) Appeals Panel which is convened when a request has been declined and the referring clinician or their patient believes that there has been a failure to follow due process or to interpret the policy.

3. Exceptionality

Exceptionality should be considered in the context of the CCGs policies for a health care indication. In general, WSYB CSU must justify the grounds upon which it chooses to recommend funding a healthcare intervention for a patient when that intervention is unavailable to others with the condition.

A patient may be considered exceptional to the general policy if **both** the following apply:

- He/she is different to the general population of patients who would normally be refused the healthcare intervention, and
- there are good grounds to believe that the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.

In assessing exceptionality, WSYB CSU will not consider social, demographic or employment circumstances.

Where a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage nor disadvantage the patient. However, response to an intervention will not be considered to be an exceptional factor.

4. Principles and Values

West and South Yorkshire and Bassetlaw CCGs have a statutory duty to maximise the health of the local population by ensuring the provision of accessible, quality health care services within available resources. However, demand for services for patients may exceed the capacity and resources available. There is, therefore, a constant need to prioritise spending on clinical and cost effective interventions and with due consideration to equity of access. WSYB CSU therefore applies a fundamental set of principles to all such decision making and these are reflected in the work of the IFR department as outlined below:

- The IFR department must ensure that all processes potentially involving patient identifiable information are managed confidentially and comply with data protection standards.
- The IFR Panel must ensure that the intervention requested is likely to be provided where the patient may gain easy access, will be affordable, and have sound evidence of clinical and cost effectiveness.
- The IFR Panel should promote the use of more effective services over less effective (giving due consideration to equity and accessibility) and utilise existing proven pathways of care over new or experimental technologies.
- The IFR Panel will seek to identify interventions producing the greatest health outcomes, and will consider all national and local guidance and local funding priorities.

WSYB CSU is committed to ensuring that decision making is transparent, fair, equitable and open to scrutiny. Application of this policy in practice should ensure that the IFR process stands up to external scrutiny. The policy is available on the WSYB CSU website and accessible to all.

At all times decisions to fund treatments will be based upon both national guidance and locally adopted policies. Interventions recommended in NICE technology appraisals will be implemented on publication of guidance unless previously prioritised. Patients have the right to have funding made available where the drug or treatment requested through the IFR is recommended in NICE Technology Appraisal Guidance. Where NICE has yet to issue guidance, or where NICE will not be appraising a drug, the IFR Panel should make decisions based upon rational and proper consideration of all evidence available.

5. Consideration of Individual Funding Requests

5.1 Pre-requisites

The following criteria need to be met prior to the consideration of an IFR request:

- The patient must be registered with a WSYB General Practitioner
- The request for funding must be made by an NHS clinician, or a medical consultant within the independent or private sector with whom one of the West and South Yorkshire and Bassetlaw CCGs hold a contract.

5.2 Process

5.2.1 Triage

The purpose of triage is to ensure that only appropriate requests go forward for Panel consideration and is not a decision making process. Requests may be redirected if they are not appropriate IFR requests (for example requests for removal of benign skin lesions that should follow the dermatology pathway or requests for Low Priority Procedures) or the pre-requisites above are not met. Occasionally requests are received for healthcare interventions that are part of the contracted activity between a specific provider and CCG. These will be triaged out of the process and the clinician making the request will be informed that no prior approval is required.

5.2.2 Panel

Preparation

The agenda and paperwork for the panel is prepared in advance, including all requests triaged from those received by the end of the week prior.

Meeting structure

The meeting is held weekly and considers all requests that are received on (up to and including) the Friday of the previous week. The Terms of Reference can be found at Appendix 1.

Membership

- 2 GP Medical Advisors¹ (clinical advice, research, clinical liaison and decision-making)
- 1 IFR Lead Manager or deputy (compliance with IFR and commissioning policy and communication of further commissioning actions)
- Other clinicians as required, including Complex Neurology and Rehabilitation Advisor, Pharmacist.
- IFR Assurance Officer or deputy (to record decisions and actions and aid compliance with policy)

Procedure

Each case is considered in turn, with reference to all the available information, and with participation of additional clinical advisors as required. The outcome for each case will be one of the following:

- Approved
 - Patient meets procedure criteria
 - Patient does not meet procedure criteria but evidence of exceptionality has been provided
- Declined
 - Patient does not meet procedure criteria
 - Patient does not meet procedure criteria and evidence of exceptionality has not been provided
- Pended
 - The Panel have considered the information provided and have requested additional information to support the request

Actions are agreed appropriate to the outcome. Standard processes and template documents are in place to facilitate effective communication of outcomes to the requesting clinician and directly to the patient when appropriate. Cases that are pended in order to receive additional information are reconsidered or closed within a specified timeframe (30 days).

Cases will always be reconsidered if new information is presented, even outside the specified timeframe.

¹ Specifically employed and inducted into this role – one advisor may be virtual

5.3 Notifications

Cost per case interventions subject to notification are also logged and trends monitored by the IFR team. These are ratified by the IFR GP Medical Advisors at the end of each Panel meeting.

5.4 Appealing Against a Decision

Where a decision has been made by the IFR Panel not to fund a healthcare intervention and the clinician that made the request feels that all the relevant information has been provided and considered but is concerned that there has been a failure to follow due process or to interpret the procedure correctly, the patient or the clinician can appeal against the IFR Panel decision. (Appendix 2)

6. OTHER PROCESSES MANAGED BY THE IFR DEPARTMENT

6.1 Requests for Complex rehabilitation

The IFR Panel apply the same standard of robust decision-making to other requests made by NHS clinicians for placements for adults outside of routinely commissioned services, primarily for those with complex rehabilitation needs, such as neuro-rehabilitation. This process has been put in place to ensure placements (which may be provided within the independent sector) are of the correct standard, are closely monitored as to achievement of anticipated benefits, are concluded at the clinically appropriate time and wherever possible ensuring that patients remain linked to local service provision or are reconnected as soon as possible.

6.2 Procedures subject to threshold and prior approval

West and South Yorkshire and Bassetlaw CCGs from time to time will identify the need to manage referrals for specific indications, in line with achieving evidence-based balanced use of resources. This requires a process of peer assessment of referral or treatment requests against a set of predefined criteria. This process is serviced by the IFR team and requires the same level of GP clinical support as the IFR process.

Where a treatment requested requires commissioner prior approval an appropriate decision on whether to approve funding will be made by the IFR Panel. This is not the same as an IFR request but will follow the same robust decision making process. Where multiple requests for a specific treatment are received then these requests should be taken forward for a service and policy development.

6.3 Equipment

The IFR Panel also consider requests for bespoke and standard equipment for adults and children which cannot be provided via the Sheffield Community Equipment Loan Service (SCELS) and considers all equipment requests for Continuing Health Care (CHC) patients.

7. SPECIFIC EXCLUSIONS

IFRs in the following circumstances will normally be refused:

- Where an IFR results from a patient who has paid for treatment who then wishes to have their treatment continued by the same provider but funded by the NHS for whatever reason (e.g. an insurance company refuses to pay the treatment costs or a patient can no longer afford treatment). The provider and/or the GP will be asked to refer the patient to NHS funded services for an assessment of whether the requested care is clinically required and available within existing service agreements held by West and South Yorkshire and Bassetlaw CCGs.
- Where the IFR requested is also available elsewhere within a Trust with which West and South Yorkshire and Bassetlaw CCGs have a contract, this will be handled within normal contractual processes. Where the IFR is made retrospectively unless it can be demonstrated that treatment was needed as an emergency.
- Where the patient does not take up treatment within one year of approval being given, then the case will be closed and a new application for funding must be made.
- Where an IFR is made by a non NHS clinician based in a private provider with whom West and South Yorkshire and Bassetlaw CCGs do not hold a contract.
- Where an IFR is made for a treatment within a private provider, when equivalent NHS services are available.

8. REFERRALS TO PROVIDERS IN THE INDEPENDENT SECTOR

IFRs to providers in the independent sector must meet the criteria specified above. The independent sector includes private providers with whom West and South Yorkshire and Bassetlaw CCGs already hold a contract or where clinical evidence states that this is the only provider which is suitable for the treatment requested.

9. Low Priority Procedures

Low Priority Procedures (LPPs) are managed by the IFR Team and are submitted via the IFR Safe Haven. They are considered on a weekly basis by an IFR GP Medical Advisor and the outcome for each case will be one of the following:

- Approved – the request meets the procedure criteria and is therefore approved
- Declined – the request does not meet the procedure criteria and is therefore declined
- Pended – the GP Medical Advisor requires additional information in order to make a decision

Standard processes and template documents are in place to facilitate effective communication of outcomes to the requesting clinical and directly to the patient when appropriate.

Any requests received for Pain Management Procedures follow the IFR process above and are considered at the weekly IFR Panel.

10. URGENT REQUESTS FOR FUNDING TREATMENT

The processes outlined below relate to the clinical urgency with which a funding decision must be made by WSYB CSU.

The urgency of the request will be determined by a member of the IFR team, i.e. that the request must be processed quickly in order to avert, alleviate or avoid any perceived significant harm to the patient, which may arise unless a decision is taken in a shorter timescale than might otherwise be expected within the IFR Process.

WSYB CSU will not retrospectively fund any care or treatment which has not been given prior approval, unless it can be demonstrated that the treatment was needed as an emergency or to avoid a life threatening situation, and that unsuccessful efforts were made to contact the IFR Team.

All applications for treatment or funding deemed urgent will be acknowledged by telephone, fax or email on the day of receipt.

Contact will be made with the applicant by telephone to agree a timescale within which a response must be provided in order to meet the patient's clinical need, this will be a maximum of two working days. In such cases one IFR Medical Advisor and the IFR Lead Manager will be required to make the decision to be ratified by a second medical advisor. The IFR Assurance Officer is notified of the outcome of the consideration of the request and will aim to seek approval from the appropriate CCG.

The IFR Assurance Officer will immediately notify the referring clinician of the decision, followed by written confirmation.

The IFR Assurance Officer will notify the panel for ratification at the next panel meeting.

While WSYB CSU will endeavour to respond to such urgent requests as quickly as possible, this should not compromise the quality and validity of the decision-making process.

11. General

Members of the IFR panel must declare interests that may be relevant and material to the consideration of any item of IFR Panel business. In such an event, the Member may not take part in discussions relating to any such item of business

All discussions within the context of the IFR Panel will be treated as strictly confidential amongst the IFR Panel members.

12. Approval and Reporting Arrangements

All recommendations made by the IFR Panel must be signed off by a nominated person with delegated authority at each CCG prior to the clinician who made the request being informed of the outcome. The arrangements around this sign off of decisions must be robust enough to ensure that the CSU Key Performance Indicators are adhered to.

Where urgent recommendations are made outside the usual IFR Panel meeting, the IFR Assurance Officer will aim to get CCG sign off. If sign off by the CCG cannot be achieved for any reason the referring clinician will be notified of the decision prior to sign off in order to meet the patients clinical need.

The IFR panel will operate at all times in accordance with the Standing Orders and the Standing Financial Instructions of WSYB CSU. The expenditure of the Panel will be reviewed and reconciled monthly with finance managers.

13. CONTRACTS

Subject to the conditions set out in this document, patients may be referred to NHS organisations with which the West and South Yorkshire and Bassetlaw CCGs hold a contract without the need for prior approval.

For NHS organisations with which West and South Yorkshire and Bassetlaw CCGs do not hold a contract, different arrangements apply.

If the referral is not to one of the 'specialised services' defined by the Department of Health, and it is covered by mandatory tariff, then there is no need for prior approval.



**West and South Yorkshire and Bassetlaw Commissioning Support Unit
(WSYB CSU)
Individual Funding Request (IFR) Panel
Terms of Reference**

1. Purpose

The IFR Panel will consider all requests for treatment that are not routinely commissioned including exceptions to the existing procedure and requests made in the absence of any procedure.

2. Membership

- At least 2 IFR GP Medical Advisors (clinical advice, research, clinical liaison and decision making – one advisor may be virtual)
- 1 IFR Lead Manager or deputy (compliance with IFR and commissioning policies and communication of further commissioning actions)
- Other clinicians as required, including Complex Neurology and Rehabilitation Advisor, Pharmacist etc.
- IFR Assurance Officer or deputy (to present cases and record decisions and actions and aid compliance with policies)

3. Quoracy

The Panel must be quorate to make decisions. 2 GP Medical Advisors and 1 IFR Lead Manager or deputy must be present.

4. Panel Decisions

The Panel will seek to make a majority decision. Where there is a difference of opinion the IFR Assurance Officer will seek further advice from another GP Advisor and the case will be discussed at the next available Panel meeting until a unanimous decision can be made.

5. Attendance at Meetings

Other members of staff (either from the CSU or CCG) may be requested to attend the Panel meetings in an advisory capacity as necessary to discuss particular issues or to offer advice to the Panel members.

6. Frequency of Meetings

The Panel will meet weekly and will consider all requests received up to and including the Friday prior to the meeting.

7. Duties and Operation

7.1 The duties of the IFR Panel will be to consider, and approve or decline, where appropriate, requests to fund treatment for individual patients.

7.2 The IFR Panel may seek additional or supporting information to further inform the request.

7.3 Patient identifiable information will be dealt with in confidence, and will not be used unless essential to the consideration of the request.

7.4 The IFR Panel will consider all the necessary information received from the clinicians involved in the patient's care.

7.5 The IFR Panel will assess and evaluate the evidence base for the clinical and cost-effectiveness of each intervention under discussion, and will consider the views of relevant stakeholders where appropriate.

7.6 The Panel will produce clear reasons for their decisions, using the checklist which will be based on current guidance, the overall resources available to the CSU and the CCG decision making values including evidence of effectiveness, equity and accessibility.

7.7 The IFR Panel will always consider national guidance when making decisions on individual cases.

8. General

Members of the IFR Panel must declare interests that may be relevant and material to the consideration of any item of IFR Panel business. In such an event, the Panel member may not take part in discussions relating to the case.

All discussions and paperwork within the context of the IFR Panel will be treated as strictly confidential amongst the IFR Panel members.

9. Review

These Terms of Reference should be reviewed one year from date of operation.

**West and South Yorkshire and Bassetlaw Commissioning Support Unit
(WSYB CSU)
Individual Funding Request (IFR) Appeals Panel
Terms of Reference**

1. Constitution

The West and South Yorkshire and Bassetlaw Commission Support Unit (WSYB CSU) Individual Funding Request (IFR) Appeal Panel (IFR Appeal Panel) can only discharge those duties specifically delegated in these terms of reference.

The Appeal Panel is authorised by the WSYB CSU to investigate any activity within its Terms of Reference. It is authorised to seek any information it requires from an employee and all employees are directed to co-operate with any request made by the Appeal Panel. The Appeal Panel is also authorised by WSYB CSU to obtain legal advice and to secure the attendance of other appropriate persons with relevant experience and expertise if it considers this necessary.

2. Duties

The Appeal Panel considers and decides on appeal applications which challenge due process by reference to local policies and the WSYB CSU IFR general policies.

The duties of the Appeal Panel are as follows:

- To consider and review the IFR Panel's decision in relation to the funding of an individual's treatment by reference to fair and appropriate application of the process. (A second appeal may be heard if it relates to new evidence).
- To receive and review all documentation considered by the IFR Panel and further submissions received from parties.
- To hear oral representations from an IFR Panel member or other appropriate WSYB CSU staff member in relation to the IFR Panel decision.
- To hear representations from the clinician or patient making the appeal or their representative if they wish to make oral representations.

- To consider additional information or specialist advice as necessary for example the individual's relevant clinical records and comments from the treating clinician(s) with the individual's written consent.
- To make a decision, in private, to uphold the original decision of the IFR Panel, or refer the case back to the IFR Panel for reconsideration.

3. Membership

3.1 The Appeal Panel shall consist of the following members:

Two Senior Managers from the appropriate CCG (one of which should be the Chief Officer or their nominated representative)
One Medical Advisor from the appropriate CCG
WSYB CSU Head of Clinical Services (or their nominated representative)
WSYB CSU Senior Manager (to present the case and act on the outcome)

3.2 The Appeal Panel will be chaired by the Chief Officer or their nominated representative.

3.3 Each member of the Appeal Panel will have a named deputy.

3.4 In order to be quorate all members or their deputies must be present.

3.5 All members and their deputies must not have an interest in the case being considered.

3.6 Other members of staff including members of the IFR Panel may be requested to attend the Appeal Panel to present a particular case and or to offer further information in respect of the case.

3.7 The appellant and/or their nominated representative may attend to submit oral or written evidence in support of their appeal. An appellant may not be legally represented at an Appeal Panel hearing.

3.8 A solicitor may be present to provide the Appeal Panel with legal advice and other specialist advisers may attend as required.

4. Frequency

The Appeal Panel will meet as and when required. The CSU will organise and administer the Appeal Panel.

5. Accountability and Reporting Arrangements

- 5.1 An appeal against a decision should be made within three months of notification of the decision.
- 5.2 Requests from a patient or clinician for an appeal will be acknowledged within two working days of receipt.
- 5.2 The chair of the Appeal Panel will brief the Chief Operative Officer of the appropriate CCG (or deputy) about the outcome of the Appeal Panel meeting immediately after the meeting.
- 5.2 The Appeal Panel will feedback to the IFR Panel decisions in relation to cases.
- 5.4 The Appeal Panel will ensure that, the appellant is notified of the Appeal Panel's decision within seven working days.

6. Other Matters

The Appeal Panel will be supported administratively through the WSYB CSU IFR Team. Duties in this respect will include:

- Agreement of agenda with the Chair.
- Collation and distribution of agenda papers.
- Taking minutes and keeping a record of matters arising and issues to be carried forward.

7. Review

These terms of reference should be reviewed one year from date of operation.