Devon NHS
Primary Care Trust

Individual Patient and Restricted Treatments Funding Processes

1. Executive Summary

1.1 All PCTs need policies and processes for dealing with individual requests from patients or clinicians for NHS funding for specific treatments. The majority of health services for the Devon PCT population are funded via existing contracts (primary care, secondary care and tertiary care provided by a range of NHS, private or voluntary/charitable sector organisations). However, there will always be instances where a patient or clinician wants a treatment to be funded that is outside these arrangements. These cases generally fall into the following categories:

a. Health innovations – new drugs, devices and procedures (e.g. new drugs that NICE has not yet assessed)

b. Unusual treatments – treatments that may not be new, but which the PCT does not normally fund (e.g. treatments outside mainstream conventional medicine)

c. Restricted treatments – established treatments that are subject to a formal PCT policy that approves funding only in certain circumstances (e.g. cosmetic treatments, IVF, gender reassignment surgery)

1.2 These cases are very important for the patients and clinicians involved and are also important for the PCT in delivering on its obligation to commission effective healthcare for the population within the available funding. Such cases are also very significant in terms of organisational reputation. Although they account for only a tiny percentage of patients, treatments and expenditure, there is often a great deal of public and media interest in these cases. For all these reasons, clear and robust processes are required.

1.3 Meetings of a Review Group were held on 9th May 2007 and 6th June 2007 with clinical and managerial representatives to devise new processes for decision making and appeals. The report and recommendations have been considered by the Management Team and PEC and amendments made as required. This report summarises the recommendations arising from this work.

1.4 This paper is underpinned by the following appendices which provide an overview of the overall process and terms of reference for the panels:

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Board approved 27.06.07

2. Initial Decision-Making Panels

2.1 Panel arrangements are preferred to arrangements based on individuals making decisions as they enable a wider range of expert views to be considered, are more legally defensible and should help to ensure equity. However, panel arrangements do require a greater soccer predictions with odds commitment in terms of overall staff time and can only be held periodically, potentially leading to slower responses.

2.2 In order to balance these considerations, the following arrangements are recommended:

i) Cases falling into the categories of Health Innovations and Unusual Treatments will be considered by the Individual Patient Funding Panel (IPFP), based in the South Molton Office of the PCT. This Panel is a development of the existing Devon PCT IPFP arrangements that were themselves developed from the former North Devon PCT arrangements. These cases are usually the most urgent and so this Panel will meet weekly. These cases require clinical (medical, pharmaceutical and/or public health) expertise and will need to consider information from sources such as NICE in order to make decisions. The volume of cases is too great (about 40 per week) to allow shared arrangements with neighbouring organisations. However, it is important that a 'postcode lottery' is avoided, so the decision-making will be supported by shared guidance (e.g. NICE, Peninsula Cancer Network recommendations, Peninsula Cardiac Network recommendations, etc). In addition, the Panel will link into the proposed Peninsula Health Technology Appraisal process once this is established. Summaries of individual PCT decisions will also be shared between the PCTs.

ii) Cases falling into the category of Restricted Treatments will be dealt with by the Restricted Treatments Funding Panel (RTFP), based in the Dartington Office of the PCT. This Panel is built upon the former Teignbridge and South Hams & West Devon PCT "Low Priority Procedures Panel" arrangements which were shared with Torbay Care Trust and Plymouth PCT. The RTFP will meet monthly. Subject to agreement of the three Boards, it is recommended that Devon PCT continues to operate shared arrangements with the neighbouring organisations. This will allow for more efficient use of Panel and administrative time and will also help to ensure consistency between organisations and avoidance of a 'postcode lottery'. Separating the panel arrangements for Restricted Treatments from those for other types of case will help to reduce the workload of the IPFP. The nature of the decision-making is different as these cases are subject to existing policies and so cases are assessed against those policies rather than requiring the evaluation of research and other independent evidence. Therefore, although clinical expertise is necessary the number and range of clinicians required is less than for the IPFP and the panel membership reflects this.

2.3 Both panels will be managed within the Directorate of Provider Development. There will be a single route into these arrangements for all cases to make the process more straightforward for patients and clinicians. A database (with restricted password access) will be kept of all cases in order to facilitate tracking of cases through the process, recording of decisions, allowing similar previous cases to be identified to support decision-making, reporting to the PEC and Board and confirmation of correctness of invoices for payment. This database will also be used to identify

multiple requests for similar treatments to enable the PCT to develop formal policies in these areas.

3. Appeals Panel

3.1 It is recommended that appeals against a decision made by the IPFP or RTFP go through a single appeals process. The Treatment Decisions Appeals Panel will be chaired by a Non-Executive Director, but will have a clinical majority and will be held as required, normally within one month of the request for appeal. The members will be independent of any involvement in the IPFP or RTFP decision.

3.2 Prior to Appeal, the IPFP or RTFP will review the case to ensure that if there is any additional information that was not available at the first stage the case is reconsidered in the light of this; similarly, if the Appeal raises any concerns about process the IPFP or RTFP will review the case and ensure that any process issues are addressed. This review might avoid the need for an Appeal. As the RTFP only meets monthly, if the review stage would lead to undue delay the IPFP will undertake the review for RTFP cases.

3.3 All documentation to be considered at Appeal will be sent to the appellant and the appellant will be asked to confirm that this is comprehensive and that they are satisfied that the case should be considered on the basis of that information. This should minimise the risk of repeated Appeals for the same case. Patients (or their representatives) will be able to present their cases at the Treatment Decisions Appeals Panel.

3.4 In order to ensure a demonstrable separation of initial decisions and appeals, the appeals process will be managed by the Directorate of Communication and Corporate Affairs. In order to ensure that the appeals process is demonstrably independent of the complaints process, the two functions will be managed in different parts of the Directorate. This should also allow for the necessary links to Governance and Communications structures.

4. Peninsula Fertility Review Panel

4.1 The Peninsula Fertility Policy (primarily focused on IVF) has been a very positive development. It has minimised the risk of a local postcode lottery (unlike many other areas in which each neighbouring PCT has different access criteria) and has placed the Peninsula broadly in the middle ground of policies across the country, avoiding some of the more controversial restrictions that have been implemented elsewhere. However, despite this, the Peninsula Fertility Group have recognised that there are a number of ‘grey areas’ where it is difficult to draw a line between cases that should be funded and those that should not.

4.2 In order to address the risks that this presents, a Peninsula Fertility Review Panel has been established. This Panel meets quarterly and considers difficult borderline cases with the dual intentions of ensuring consistency and using these difficult cases to inform future policy refinements. This Panel makes recommendations to PCTs, but decision-making remains with PCTs. Fertility cases that are refused funding by the RTFP and are subject to a request for a review of the decision are reviewed by the

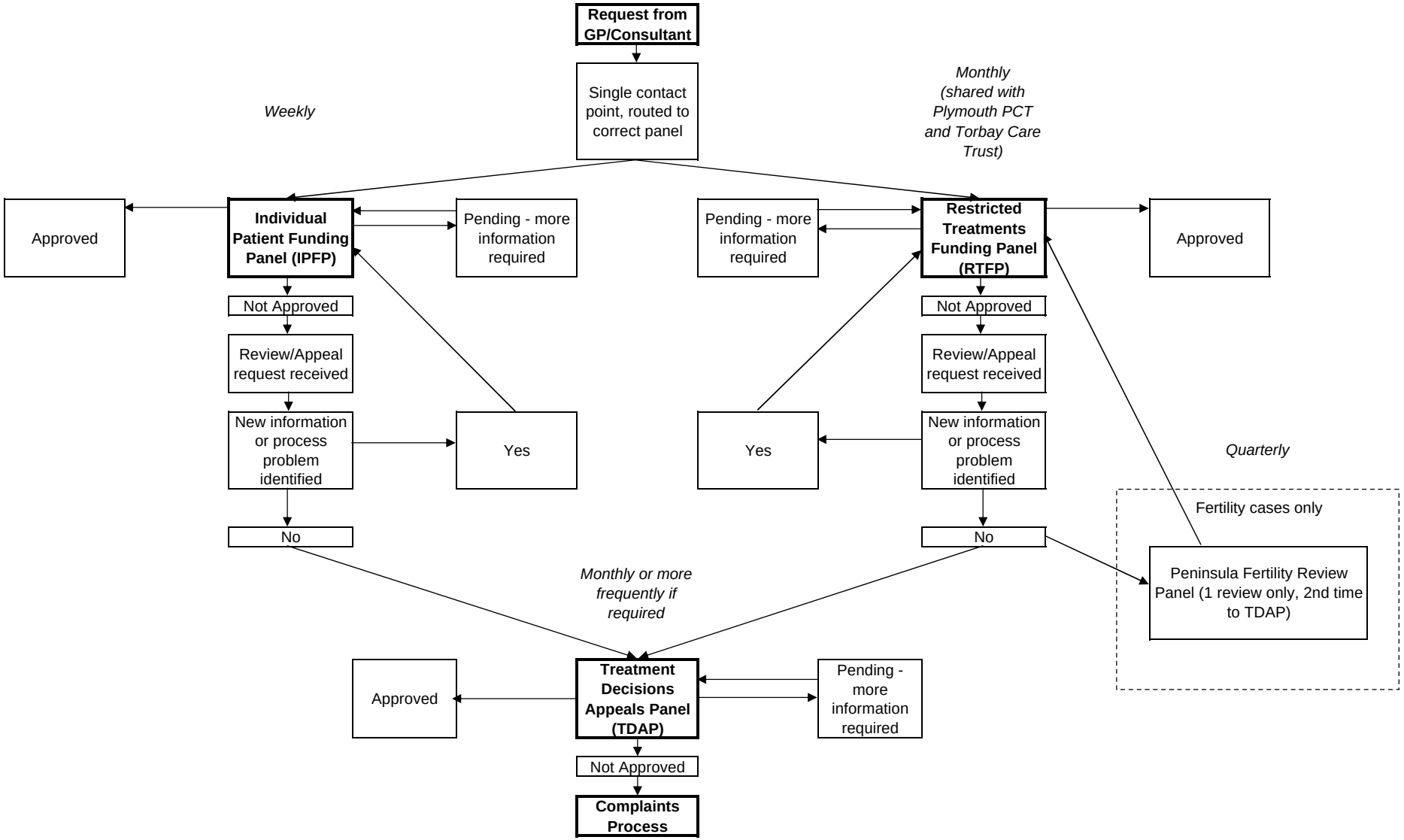
Peninsula Fertility Review Panel and a recommendation given to the RTFP for consideration. Patients may still appeal to the Treatment Decisions Appeal Panel after this stage.

5. Recommendations

5.1 The Board are asked to approve the recommendations contained within this report.

Warwick Heale
Assistant Director of Provider Development
June 2007

Devon PCT Individual Patient and Restricted Treatments Funding Request Process



Appendix a

Devon NHS
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Appendix B

INDIVIDUAL PATIENT FUNDING PANEL

Terms of Reference

1. Purpose of the Group

The role of the Panel is to consider approval of funding by the PCT for treatment on a case by case basis that is outside existing contracts or for which prior approval is required within existing contracts.

The Individual Patient Funding Panel is a sub-committee of the Primary Care Trust Professional Executive Committee.

2. Terms of Reference

To provide robust arrangements for the approval of treatments and care for patients funded on an individual named patient basis within an agreed commissioning policy for Specialist High Cost/Low Volume Procedures/Treatments.

To identify the costs associated with packages of care and monitor expenditure against planned budget.

To identify those services which could be developed and provided locally in a more cost effective way.

3. Membership

At least 2 of the following:
- One Public Health clinician
- Two PEC / GP clinician members (one to act as Chair)

At least 1 of the following:
- Commissioning Director / Manager
- Finance Director / Manager

In Attendance
- Panel Co-ordinator

4. Meetings and Conduct of Business

- The quorum of the committee will comprise two clinician representatives and one representative from Commissioning or Finance.

- Meetings of the Panel will be formal and appropriate agendas and minutes produced. Agendas and associated papers will normally be handed out on the day.

- Administrative support will be provided by the Panel Co-ordinator.

- Meetings will be held at least once every month.

- The membership of the Panel will need to reflect the nature of the case under consideration to ensure fair and robust decisions are made. The panel may co-opt members to provide specialist input when appropriate.

- Where a member of the Panel has knowledge of the patient, this will be formally declared and noted. It will be the decision of the Chair of the Panel as to whether the Panel should be reconvened with a different membership.

- The Panel will operate in accordance with Section 5 of the Primary Care Trust's Standing Orders and any proposed changes to its Terms of Reference, membership or procedural arrangements will require the approval of the Professional Executive Committee.

- Decision making will take account of the best available evidence available at the time, using sources such as the National Institute for Health and Clinical Excellence (NICE), The Scottish Medicines Consortium (SMC), local Clinical Networks and properly constructed published research trials. It is the responsibility of the requesting clinician to furnish appropriate evidence to support the request.

- The Terms of Reference will be reviewed annually.

5. Reporting Arrangements

Activity Reports of the Panel will be submitted to the Primary Care Trust Professional Executive Committee on a quarterly basis.

When the Panel considers that there is evidence of matters that constitute a high level of risk, they will be reported through the Primary Care Trust's risk reporting procedure.

The Panel will prepare an Annual Report for consideration of the Primary Care Trust Professional Executive Committee and the Board coincident with the annual Appeals Panel Report.

6. Communication and Involvement Plan

Key stakeholders, including clinicians, patients and the public, will be involved with the work of the Individual Patient Funding Panel where appropriate.

The Individual Patient Funding Panel will observe the requirements of the Freedom of Information Act 2000, which allows a general right of access to recorded information held by the Trust, including minutes of meetings, subject to the specified exemptions.

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Appendix C

RESTRICTED TREATMENTS FUNDING PANEL

Terms of Reference

1. Purpose of the Group

1.1 The role of the Panel is to consider approval of funding by Devon PCT, Plymouth PCT and Torbay Care Trust for treatment on a case by case basis either identified within the Low Priority Treatments Policy, the Gender Dysphoria Policy or the Peninsula Fertility Policy.

1.2 The Panel is a sub-committee of the Primary Care Trust Professional Executive Committee.

2. Terms of Reference

1.3 To provide robust arrangements for the approval of treatments and care for patients funded on an individual named patient basis within the agreed commissioning policies for Low Priority Treatments, Gender Dysphoria or Fertility Treatments.

1.4 To identify the costs associated with packages of care and monitor expenditure against planned budget.

3. Membership

1.5 Members may be drawn from Devon PCT, Plymouth PCT or Torbay Care Trust and will include:

- At least 1 of the following who will act as Chair:
  - One Public Health clinician
  - One GP

At least 1 of the following:
- Commissioning Director / Manager
- Finance Director / Manager

4. Meetings and Conduct of Business

1.6 The quorum of the committee will comprise three members in total, one of which must be a clinical representative and one managerial.

1.7 Meetings of the Panel will be formal and appropriate agendas and minutes produced. Agendas and associated papers will normally be handed out in advance of the meeting.

1.8 Administrative support will be provided by the Panel Co-ordinator.

1.9 Meetings will be held approximately once per month.

1.10 Where a member of the Panel has knowledge of the patient, this will be formally declared and noted. It will be the decision of the Chair of the Panel as to whether the Panel should be reconvened with a different membership.

1.11 The Panel will operate in accordance with Section 5 of the Primary Care Trust's Standing Orders and any proposed changes to its Terms of Reference, membership or procedural arrangements will require the approval of the Professional Executive Committee.

1.12 Decision making will take account of the agreed commissioning policies for Low Priority Treatments, Gender Dysphoria or Fertility Treatments.

1.13 The Terms of Reference will be reviewed annually.

5. Reporting Arrangements

1.14 Activity Reports of the Panel will be submitted to the Primary Care Trust Professional Executive Committee on a quarterly basis.

1.15 When the Panel considers that there is evidence of matters that constitute a high level of risk, they will be reported through the Primary Care Trust's risk reporting procedure.

1.16 The Panel will prepare an Annual Report for consideration of the Primary Care Trust Professional Executive Committee and the Board coincident with the annual Appeals Panel Report.

6. Communication and Involvement Plan

1.17 Key stakeholders, including clinicians, patients and the public, will be involved with the work of the Individual Patient Funding Panel where appropriate.

1.18 The Restricted Treatments Panel will observe the requirements of the Freedom of Information Act 2000, which allows a general right of access to recorded information held by the Trust, including minutes of meetings, subject to the specified exemptions.

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Appendix D

TREATMENT DECISIONS APPEALS PANEL
Procedure & Terms of Reference

1. Introduction

1.1 Current policy within the National Health Service reinforces the need for commissioning on the basis of effectiveness, sound evidence and central guidance. This guidance is available from a number of sources including the National Institute for Health and Clinical Effectiveness (NICE), National Service Frameworks (NSFs) and Health Technology Assessments.

1.2 Patients and their General Practitioners may sometimes request treatment which the PCT does not commission as standard, or this may be proposed by a consultant or other healthcare professional. Where such a request has been made under this process and the request has been refused by the Individual Patient Funding Panel or Restricted Treatments Funding Panel, an appeal may be made to the PCT's Treatment Decisions Appeals Panel.

1.3 A Treatment Decision Appeal Panel will consider appeals from patients (via their General Practitioner) who consider that a refusal of the Primary Care Trust to fund care or a course of treatment has been wrong in terms of process, adherence to the PCT's policies, or because their case is exceptional.

1.4 This panel will not consider an appeal purely on the basis of new clinical or social information and in those circumstances a request will be resubmitted to the Individual Patient Funding Panel or Restricted Treatments Funding Panel.

2. Procedure

Appeals should be made in the following manner:

2.1 Appeals should be made in writing by the patient's General Practitioner to the Chair of the Treatment Decision Appeals Panel, Devon Primary Care Trust, Crown Yealm House, Pathfields Business Park, South Molton, Devon, EX36 3LH.

2.2 The General Practitioner should produce a covering letter with supporting information, including on what grounds s/he supports the patient's appeal, or otherwise. This may include clinical and social details, the patient's medical records, as well as written correspondence from the patient to the General Practitioner.

2.3 Patients who write direct to the Primary Care Trust but without the support of their General Practitioner will have their appeal request acknowledged but will be advised

that no further action will be taken without a written appeal and support from the relevant General Practitioner.

2.4 Prior to making the appeal, the General Practitioner must obtain the patient's written consent to appeal on his/her behalf to the Primary Care Trust.

2.5 The General Practitioner must also obtain the patient's written consent for the Primary Care Trust to obtain and view copies of the patient's medical records and any other relevant correspondence relating to the case. [NOTE: without written consent the appeal will be automatically rejected.]

2.6 The Primary Care Trust will acknowledge all written appeals in writing within 2 working days.

2.7 The Primary Care Trust will write to the General Practitioner within 5 working days to confirm whether or not a Treatment Decision Appeal Panel will be established, or whether further written information is required. Alternatively, where the appeal is due to new clinical / relevant social information, the PCT will write explaining that the new information will be reviewed at the Individual Patient Funding Panel. The General Practitioner will be expected to inform the patient of any developments.

2.8 The Primary Care Trust will confirm in writing the date and time of the Appeal Panel established to review the case. The Appeals panel will normally meet monthly and will review the case at the next scheduled meeting.

2.9 The Appeal Panel will to review the case. Neither General Practitioner nor patient will be present at the Appeal Panel**.** However, the General Practitioner will receive a copy of all papers that the Appeal Panel has with the exception of any legal advice that the Trust has requested. Minutes of the meeting will be recorded.

2.10 The Chair of the Appeal Panel will write to the General Practitioner within 2 working days of the panel having met and set out the panel's decision (in some sensitive or clinically urgent cases the decision will need to be relayed to the GP by telephone on the day of the panel). The letter will be signed by the Chair of the Appeal Panel.

2.11 There is no right of further appeal (unless there are new clinical / relevant social circumstances) although the patient will be informed of the right to complain to the PCT if s/he disagrees with the panel's decision.

2.12 The General Practitioner will be responsible for informing the patient of the decision of the Appeal Panel, together with the patient's right to formally complain if s/he disagrees with the panel's decision.

2.13 If requested, the Primary Care Trust will provide the General Practitioner with a copy of the minutes of the relevant part of the appeal panel meeting.

2.14 The work of the Appeal Panel will be reported to Board via the quarterly complaints report.

TREATMENT DECISION APPEALS PANEL

Terms of Reference

1. Purpose

To consider requests from patients, via their GP, who consider that a refusal of the Primary Care Trust to fund care or a course of treatment has been wrong in terms of process, adherence to the PCT's policies, or because their case is exceptional and cannot be fairly considered within the existing policies.

In this context, the care or course of treatment will be one which:

- is a non standard treatment for a medical condition, for example use of a drug which is undergoing clinical trials, or is outside NICE guidance
- is a specific exclusion from existing contracts or is specified as requiring PCT approval
- is excluded under the Peninsula Fertility Treatments Policy
- is identified in the PCT Low Priority Treatments policy
- or any other requests for medical treatment or care which the PCT's current contracts do not cover.

2. Membership

One Non-Executive Primary Care Trust Board Member (who will act as Chair of the Committee), one Professional Executive Committee GP and the Director of Public Health (or deputy) make up the panel.

3. In attendance

The patient, or/and patient's representative, may attend the relevant hearing to present their case . This arrangement will be reviewed after six months (January 2008).

4. Meetings and Conduct of Business

- The quorum of the Panel will comprise three members (or deputies).
- The Panel will be convened on an "ad hoc" basis to review individual appeals normally within three working weeks of their receipt and within a maximum of 1 calendar month.
- Meetings of the Panel will be minuted.
- Secretarial and administrative support will be provided through the Director of Communications and Corporate Affairs.

Board approved 27.06.07

- Decisions of the Panel will be final but will not affect the patient's rights under the NHS Complaints Procedure.

- Decisions of the Panel will be sent in writing to the complainant's GP.

- It is expected that the Panel will reach decisions without having recourse to voting, but voting will be used if necessary with all members having an equal vote.

5. Reporting Arrangements to the Primary Care Trust

- A summary of cases reviewed will be reported to the Primary Care Trust's Board via the quarterly Complaints Report.

- Ad hoc matters considered by the Panel to be of significant importance or public interest may be referred to the full Primary Care Trust Board for consideration.

- The Panel will prepare an annual report for the consideration of the Primary Care Trust Board.

PENINSULA FERTILITY REVIEW PANEL

Terms of Reference

1. Background

1.1 Since the NICE Guidance on Infertility was issued, PCTs have worked together in the Peninsula to develop a Peninsula Policy which PCTs have adopted and are using to decide whether to fund treatment or not. However, given the unusual nature of some of these cases and the risks of a 'postcode lottery' within the Peninsula, it was agreed that a Peninsula Review Panel should be established.

2. Membership

2.1 Membership will comprise:

- Four commissioners (one from each Health Community)
- Four other members:
  - Fertility Consultant
  - Fertility Nurse
  - PEC GP/clinician
  - PCT Non-Executive Director

2.2 This membership gives a balance of commissioners and non-commissioners. The meeting is quorate as long as there are at least 4 people present and they are not all commissioners.

2.3 Deputies can be sent in place of the panel member, but it will be helpful if there is a consistent membership.

2.4 The Chair will be elected at the first meeting.

3 Frequency of Meetings

3.1 The meetings will be timetabled to take place quarterly in the first instance. If the number of cases is greater or less than anticipated this frequency may change.

4 Panel Process

4.1 The Panel will consider appeals within the framework of the Peninsula Fertility Policy criteria. However, by **considering each case on an individual basis**, the Panel will also refine the policy over time.

4.2 The Peninsula Fertility Group recently reviewed the Peninsula criteria. The criterion causing most discussion was that couples are only eligible for NHS-funded IVF if

there are no existing children of either couple from the current or previous relationships. The group could not agree where to 'draw a line' that would allow a few exceptional cases to be funded without opening the criteria so widely that it would become unaffordable and would consume disproportionate resources compared to all our other priorities.

4.3 Given the failure of the Peninsula Fertility Group to adequately specify of the characteristics of these exceptional cases in advance, the Panel will develop a 'case law' type approach. This will hopefully lead to the development of clear revised criteria.

4.4 Cases will be discussed in the context of the Policy and previous Panel cases. A consensus will be agreed if possible. If not, members (or deputies) will vote (abstentions are permitted) and a majority decision will be taken. In the case of a balanced vote, the Chair will have the casting vote.

5 Process for Submitting Cases

5.1 PCTs should respond to requests for funding within the framework of the existing Peninsula Policy. If patients wish to appeal, authorisation for the sharing of their information with the Peninsula Panel should be obtained and they should be given the opportunity to submit any additional information to the PCT. PCTs should then forward all correspondence to the Peninsula panel. This correspondence for each patient should be anonymised, stapled together and on the front page PCTs should use the following identification system:

PCT (followed by) *case number*
e.g. *Teign 001*

5.2 When requested, the cases should be sent to,

Warwick Heale
Assistant Director of Provider Development
Devon PCT
Bridge House
Collett Way
Brunel Industrial Estate
Newton Abbot
TQ12 4PH

5.3 Cases should not be sent before they are requested in order to keep better control of the correspondence.

6 Panel Outcomes

6.1 The Panel will make recommendations to PCTs. As independent accountable organisations, PCTs can choose to follow or ignore the recommendations of the Panel, but they are advised to follow these recommendations. PCTs should write to patients with their decision following receipt of the notes of the Panel meetings.