This policy assumes that all organisations subscribing to this policy have a mechanism in place for the approval and management of patient costs associated with approved trial protocols. This is the appropriate route for the funding of experimental and unproven treatments.

Primary research into novel treatments will not be funded through this funding source. The funding of these trials should come through approved medical research routes to ensure patients are protected by the appropriate ethical and other frameworks required for this type of treatment.

The unlicensed use of medication where the particular use is commonplace, particularly in children are excluded from this policy and treated as established therapies for the purposes of this policy if they are part of recognised best or standard practice by a professional group or are part of an agreed local care pathway.

This policy deals with the funding of experimental and unproven treatments only. It does not cover the research governance requirements of the Department of Health.

Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).

Experimental inclusion criteria

Experimental and unproven treatments are not routinely commissioned.

Requests to enter a single patient into a clinical trial will be managed through via the IFR route ONLY if there is a prior agreement in place with the funding organisation that states that the treatment / intervention in question is to be approved in this way. It is expected that requests to support a number of patients entering a clinical trial will be managed as a service development.

IFR applications to support an existing treatment in an experimental context for rare clinical situations will be considered provided that the clinician making the application is able to demonstrate that running a good quality clinical trial for the treatment in the individual clinical situation in question is impossible. In this situation the application should include the following information:

- the biological plausibility of benefit based on other evidence
- the potential benefit and risks of the treatment
- an estimate of the cost of the treatment and the anticipated value for money
- the priority of the patient’s needs compared to other competing needs and unfunded developments
- the clinical markers and clinical outcomes that will be monitored to assess treatment response
- incidence / prevalence of the condition in question

Key references on which this is based must be provided (in full) by the applying physician in support of the application as well as the applying clinician’s summary of support. If indicated a rapid appraisal of the evidence will also be carried out prior to these applications going to local IFR panels.

If funding is agreed, it is a prior condition of that funding that the information from the case is supplied to any relevant clinical database or population registry which is operating.
### Funding Mechanism: Individual funding request (exceptional case) approval

Requests should be submitted with all relevant supporting evidence, which **must** be provided with the request.

<table>
<thead>
<tr>
<th>Clinical Exceptionality:</th>
<th>Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fitness for Surgery:</td>
<td>The clinician making the request <strong>must</strong> confirm that in their opinion the patient is fit for the surgery requested.</td>
</tr>
<tr>
<td>Best Practice Guidelines:</td>
<td>All providers are expected to follow best practice guidelines (where available) in the management of these conditions.</td>
</tr>
<tr>
<td>Funding request form:</td>
<td><a href="#">Experimental and Unproven Treatments</a></td>
</tr>
</tbody>
</table>