# Clinical Patient Information Standing Operating Procedure

## 1.0 Procedure Statement (Purpose / Objectives of the Procedure)

Patient/ Carer information relating to a patient's clinical treatment is an essential part of the patient's journey and a key element in the overall quality of the patient's experience. It is therefore important that the Trust provides suitable patient/ carer information that meets the needs of the recipient.

The aim of the Standing Operating Procedure (SOP) is to provide guidance on the development of written/ printed or published information given to patients, relatives, or carers about their clinical treatment, in line with the NHS recommendations and equalities legislation.

The SOP:

Provides the processes and guidance for the:

- Creation and ratification of new Trust Internal leaflets
    - App 01 Process for creating a new patient information leaflet
    - App 07 Guidelines for the development of patient information leaflets
    - App 08 Patient Information Leaflet order of content template
    - App 09 Quality Assurance Checklist
    - App 10 Public Patient Review of Patient Information Leaflets
- Review and ratification of Trust internal leaflets requiring review
    - App 02 Reviewing a patient information leaflet
- Review, ratification, and registration of externally produced leaflets
    - App 03 Process for agreeing external leaflets for use in consent
    - App 04 Process for agreeing external leaflets for use in non-consent
- Creation, review, and ratification of new alternative media of published information. For example, presentation, video, audio, animation
    - App 05 Creating patient information in an alternative media
    - App 06 Reviewing patient information in an alternative media
- Identifies the role and responsibilities of the persons/ groups within this process
    - App 12 Directorate internal monitoring and management process
- Confirms that all Patient Information (Internally or Externally produced) relating to a patient's clinical treatment, must be reviewed as a minimum every 3 years. This is the Directorate's responsibility to have an internal process to ensure this happens
    - App 12 Directorate internal monitoring and management process
- Non-clinical Patient Information is not included in this SOP, for example:
    - General information regarding a specific team/department which contains contact details

- Posters advertising a new department process
- Any staff focused leaflets

## 2.0 Definitions

- **Internal**
  - Any patient information document internally produced by Clinical Illustration
- **External**
  - Any patient information document produced outside the Trust
- **Consent**
  - Where written consent must be obtained for a clinical treatment or procedure. To be used in conjunction with the completion of a Consent Form
  - Please refer to CP06 Consent to Treatment and Investigation Policy for specific details relating to obtaining consent
- **Alternative Media**
  - Any media format other than leaflets, for example patient information in a presentation, video, audio or animation format

## 3.0 Accountabilities

### 3.1 Directorate (App 12 Directorate internal monitoring and management process)

- To ensure that there is a robust internal monitoring process to effectively manage all patient information
- To review, feedback and provide directorate approval of all patient information
- To ensure all clinical content is correct
- To ensure when patient information is being used for obtaining consent, it contains separate headed sections for explaining the consent process, benefits, risks, and alternatives
  - App 07 Guidelines for the development of patient information leaflets
- To ensure all Patient Information (Internally or Externally produced) relating to a patient's clinical treatment, must be reviewed as a minimum every 3 years
- To consider and approve whether the patient information is suitable for publication on the Trust's internet page

### 3.2 Patient Information Lead (App 12 Directorate internal monitoring and management process)

- To manage the monitoring process for all patient information within the directorate
- To ensure all new patient information follows the process for ratification set out in the 'Clinical Patient Information SOP'
- To ensure all patient information is reviewed within the specified timeframe to

avoid becoming out of date

- To provide advice and assistance to the author and directorate
- To consider and approve whether the patient information is suitable for publication on the Trust's internet page

### 3.3 Author (App 12 Directorate internal monitoring and management process)

- To ensure all patient information either new or being reviewed, contains only accurate and clinically sound information
- To ensure when patient information is being used for obtaining consent, it contains separate headed sections for explaining the consent process, benefits, risks and alternatives
    - App 07 Guidelines for the development of patient information leaflets
- To ensure all new/reviewed patient information follows the process and guidelines set out in the 'Clinical Patient Information SOP'
- To ensure that all feedback received (from colleagues/patient or public review/directorate/ Trust-wide Clinical Patient Information Group TCPIG) is considered and amended via Clinical Illustration
- To ensure that all relevant documentation is completed and submitted for each patient information
- To review and approve any changes made by Clinical Illustration
- To consider and approve whether specific patient information is suitable for publication on the Trust's internet page

### 3.4 Directorate Governance Meetings/Specialist Group Meeting

The Directorate Governance Meeting/Specialist Group Meeting must include clinical staff who will be responsible for:

- discussion and local approval of the submitted patient information
- ensuring that all feedback received from the patient/public review has been considered
- ensuring appropriate completion of Appendices
- producing Directorate Minutes/ notes evidencing discussion of submitted patient information

### 3.5 Trust-wide Clinical Patient Information Group (TCPIG)

The Trust-wide Clinical Patient Information Group (TCPIG) will be responsible for the final ratification of patient/carer information within the Trust, in accordance with this SOP. Sign off will be in alignment with Appendix 11 and upon receiving assurance that Directorate review and approval has taken place and been minuted.

**TCPIG will ratify:**

- All new internally produced leaflets
- All review, consent-based leaflets
- Any review leaflets, non-consent based, that directorates have made moderate/significant changes to
- All external leaflets that are consent based
- All new patient information in alternative media (other than leaflets, for example presentation, video, audio, animation)
- All review patient information in alternative media (other than leaflets, for example presentation, video, audio, animation)

**TCPIG will also:**

- Acknowledge the changes detailed on the Sign-Off sheet for any review leaflets, non-consent based, that directorates feel have had no changes/minor changes. A full review of these leaflets will not take place
- Ensure the Clinical Illustration database is updated with directorate approval of publications on the Trust's internet website
- Provide formal comments/changes to the author and Clinical Illustration for patient information that are approved subject to amendments
- Identify areas for progression within Patient Information
- Formulate and manage plans and discussions to progress with Patient Information where it is in the remit and control of the group
- Escalate areas of progression, which fall outside of the remit of the group, to appropriate individuals or groups
- Identify areas for risk or non-compliance within Patient Information
- Formulate and manage plans and discussions to manage risks and non-compliance where it is in the remit and control of the group
- Escalate areas of risk or non-compliance, which fall outside of the remit of the group, to appropriate individuals or groups
- Answer queries and engage in discussions with individuals or groups within the wider Trust.

### 3.6 Clinical Illustration

All Patient Information relating to a patient's clinical treatment must go through Clinical Illustration to ensure correct formatting and version control is maintained.

The Clinical Illustration Department will hold and maintain a Trust register/library of all patient/carer information produced by the Trust, and produced by external sources (such as charities and national organisations) (linked to the Publication Scheme with IG Toolkit Standard 603). This includes provisions for archive, review, and audit trail of production in line with the Trust's process. Medical Illustration holds a local protocol which details archiving arrangements (Protocol 27).

Once ratified, for internally produced patient information, Clinical Illustration will:

- Make any necessary amendments. They will liaise with the Author regarding content/wording where necessary
- Format information and return to the author/team/ department for a final accuracy check prior to publishing
- Assign a unique code to the leaflet and maintain a catalogue of codes for current and archived leaflets
- Aim to ensure that patient/carer information meets equalities legislation with the support of the Equality and Diversity Officer, for example by addressing any requests for leaflets in an alternative format
- To gain approval of the final version by the Author or Patient Information Lead
- If approval has been confirmed by the directorate, the finalised patient information will then be automatically sent to Communications for upload onto the Trust's internet

### 3.7 Communications

If approval has been confirmed by the directorate (approval is documented on App 11 Sign Off Sheet), the finalised patient information will be sent to Communications for upload onto the Trust's internet

Communications will:

- Upload new patient information onto the Trust's internet
- Remove any previous version
- Maintain the Patient Information Leaflets internet page

## 4.0 Procedure/Guidelines Detail/Actions

- **App 01 Process for creating a new patient information leaflet**
  Providing details of what is required to create a new internal patient information leaflet
- **App 02 Reviewing a patient information leaflet**
  Providing details of what is required when reviewing an internal patient information leaflet. Review to take place a minimum every 3 years
- **App 03 Process for agreeing external leaflets for use in consent**
  Providing details of what is required to approve the use of an external patient information leaflet which relates to written consent needing to be obtained
- **App 04 Process for agreeing external leaflets for use in non-consent**
  Providing details of what is required to approve the use of an external patient information leaflet which does not require written consent to be obtained
- **App 05 Creating patient information in an alternative media**
  Providing details of what is required to create a new internal patient information in a media format other than leaflet
- **App 06 Reviewing patient information in an alternative media**
  Providing details of what is required to review an internal patient information in a media format other than leaflet
- **App 07 Guidelines for the development of patient information leaflets**
  Providing details of what needs to be included in all patient information leaflets. This includes details of:
  - Information Clinical Illustration automatically include on the leaflet
  - Specific information which must be contained, under separate headings, on all consent related leaflets
  - Useful phrases, sentences and paragraphs that can be used in leaflets
  - Other important information for consideration
- **App 08 Patient Information Leaflet order of content template**
  Provides an order in which the content of the leaflet should follow
- **App 09 Quality Assurance Checklist**
  Provides a checklist for new internal leaflets, to provide assurance that all necessary points have been actioned or considered
- **App 10 Public Patient Review of Patient Information Leaflets**
  Provides a list of questions that can be used to obtain feedback from the public/patients regarding their view of new internal leaflets
- **App 11 Sign Off Sheet**
  - The sign off sheet which must be completed for all patient information requiring ratification from TCPIG
  - The sign off sheet which must be completed for external leaflets for use in non-consent process, to enable direct registration onto the Clinical Illustration's database
- **App 12 Directorate internal monitoring and management process**
  Provides details to aid directorates internal process for managing patient information. This includes details of:
  - Requirements for reviewing patient information – minimum every 3 years
  - Responsibilities of the Directorate, Patient Information Lead and Author

## 5.0 Equipment Required

No specialist equipment required

## 6.0 Training

No specialist training required

## 7.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | No |
| 2 | Does the implementation of this document require additional revenue resources | No |
| 3 | Does the implementation of this document require additional manpower | No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | No |
| | Other comments | |

## 8.0 Equality Impact Assessment

An initial equality analysis has been carried out and it indicates that there is no likely adverse impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.

## 9.0 Maintenance

The Governance Department will ensure this SOP is reviewed and updated as and when it is required.

## 10.0 Communication and Training

No specialist Communication and Training required.

## 11.0 Audit/monitoring Process

There is no requirement to audit this SOP. Assurance as to whether the process of ratification by the directorate and TCPIG has been adhered to, is provided through Clinical Illustration receiving the completed App 11 Sign Off Sheet. Clinical Illustration also ensure that all changes following TCPIG ratification have been amended and approved by the directorate. If this is not done, directorates will not be able to use their patient information, for example print leaflets or have them uploaded to the Trust's internet site.

The monitoring of whether directorates are reviewing their patient information leaflets within the required 3 years, is being undertaken monthly by Governance. Results are reported/escalated monthly to Directorates and Division.

## 12.0 References - Legal, professional, or national guidelines

No external references required for this SOP

## Part A - Document Control

| | | | | |
|---|---|---|---|---|
| Procedure/ Guidelines number and version<br><br>2.0 | **Title of Procedure/Guidelines**<br>Clinical Patient Information SOP | **Status:**<br><br>Final | | **Author:** Governance Support Team Leader<br><br>**For Trust-wide Procedures and Guidelines Chief Officer Sponsor:**<br>Director of Nursing |
| Version / Amendment History | Version | Date | Author | Reason |
| | V1.0 | June 2017 | Healthcare Governance Manager | Request for policy to be reviewed and updated as a SOP |
| | V1.1 | Feb. 2018 | Governance Team Leader | Change from DPIRG Coordinator to rwhtr.patientleaflets@nhs.net throughout SOP and slight change to process regarding update of database versus sending paperwork. |
| | V1.2 | Nov. 2018 | Governance Team Leader | Inclusion of Appendix 6 |
| | V1.3 | June 2020 | Governance Team Leader | Inclusion of Directorates ensuring no description of ligature points, ligatures, or detail of any other means of self-harm are included. |
| | V2.0 | Feb 22 | Governance Support Team Leader | Complete review of SOP as over the required 3-year date |
| **Intended Recipients:** All staff | | | | |
| **Consultation Group / Role Titles and Date:**<br>Selected staff, Trust-wide Clinical Patient Information Group (TCPIG), Trust Policy Group | | | | |

| | |
|---|---|
| **Name and date of group where reviewed** | Trust Policy Group – May 2022 |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust Management Committee – May 2022 |
| **Date of Procedure/Guidelines issue** | June 2022 |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1) | May 2025, every 3 years |
| **Training and Dissemination:** SOP will be available on Trust intranet and advice as required will be provided by the Governance team. | |
| **Publishing Requirements: Can this document be published on the Trust's public page:**<br><br>Yes | |
| **To be read in conjunction with:** N/A | |
| **Initial Equality Impact Assessment:** **Completed** Yes<br>**Full Equality Impact assessment (as required):** **Completed** No<br>If you require this document in an alternative format e.g., larger print please contact Policy Management Officer 85887 for Trust-wide documents or your line manager or Divisional Management office for Local documents. | |
| **Contact for Review** | Governance Support Team Leader |
| **Monitoring arrangements** | Trust-wide Clinical Patient Information Group (TCPIG) |
| **Document summary/key issues covered.** The development, review and ratification process of patient information relating to their clinical treatment. | |
| **Key words for intranet searching purposes** | Patient information leaflets |

**(Part B)** **Ratification Assurance Statement**

**Name of document: Clinical Patient Information SOP**

**Name of author: Rebecca Jones** **Job Title: Governance Support Team Leader**

I, Rebecca Jones the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Management Officer for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: Rebecca Jones

Date: 25/02/2022

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to:
The Policy Management Officer

**IMPLEMENTATION PLAN**

**To be completed when submitted to the appropriate committee for consideration/approval**

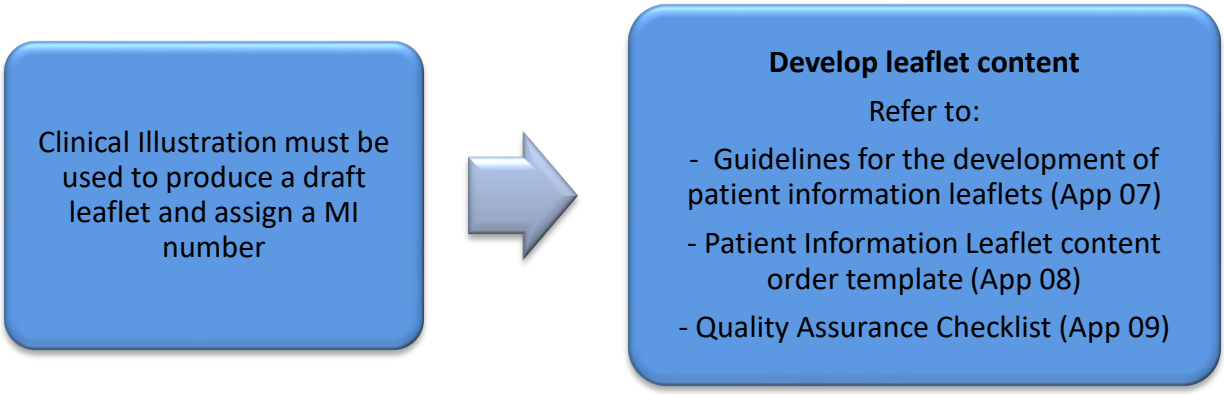
| | | |
|---|---|---|
| **Procedure/Guidelines number and version** V2.0 | **Title of Procedure/Guidelines** Clinical Patient Information SOP | |
| **Reviewing Group** Trust Policy Group | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** Rebecca Jones, Governance Support Team Leader, Bec.jones@nhs.net | | |
| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | N/A | N/A |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | N/A | N/A |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | N/A | N/A |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | N/A | N/A |
| Financial cost implementation<br>Consider Business case development | N/A | N/A |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | Trust Risk (5785) relating to delayed review and ratification of patient leaflets<br><br>Governance Directorate Risk (5421) relating to lack of local and Trust wide capacity to manage all aspects of Patient Information | Actions are monitored on the Risk Register |

Patient Information

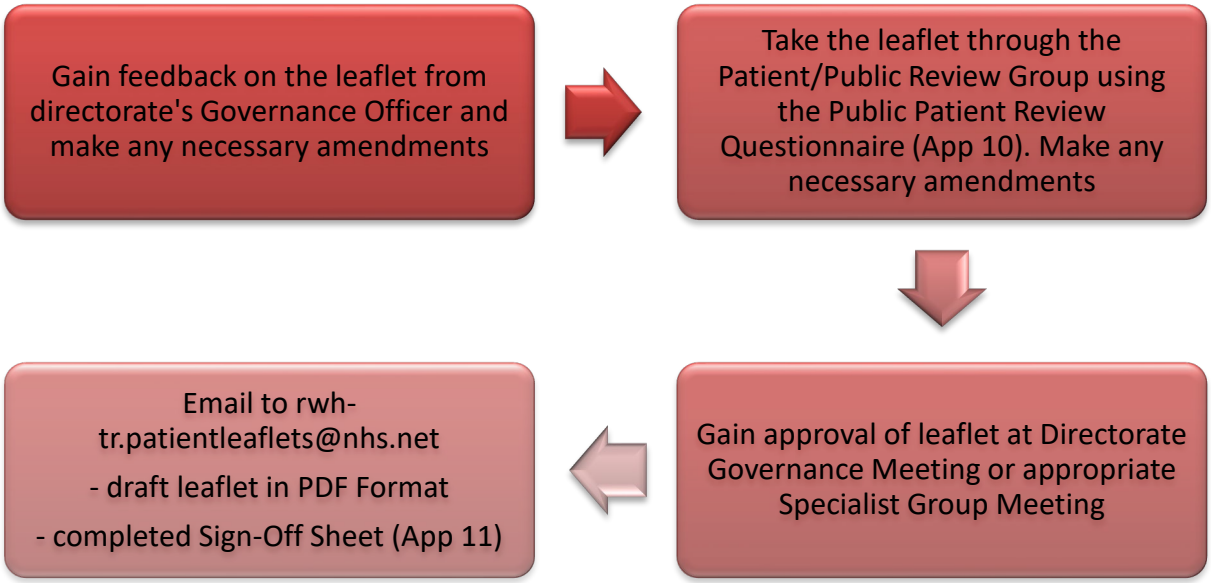
**App 01**

# Process for creating a new patient information leaflet

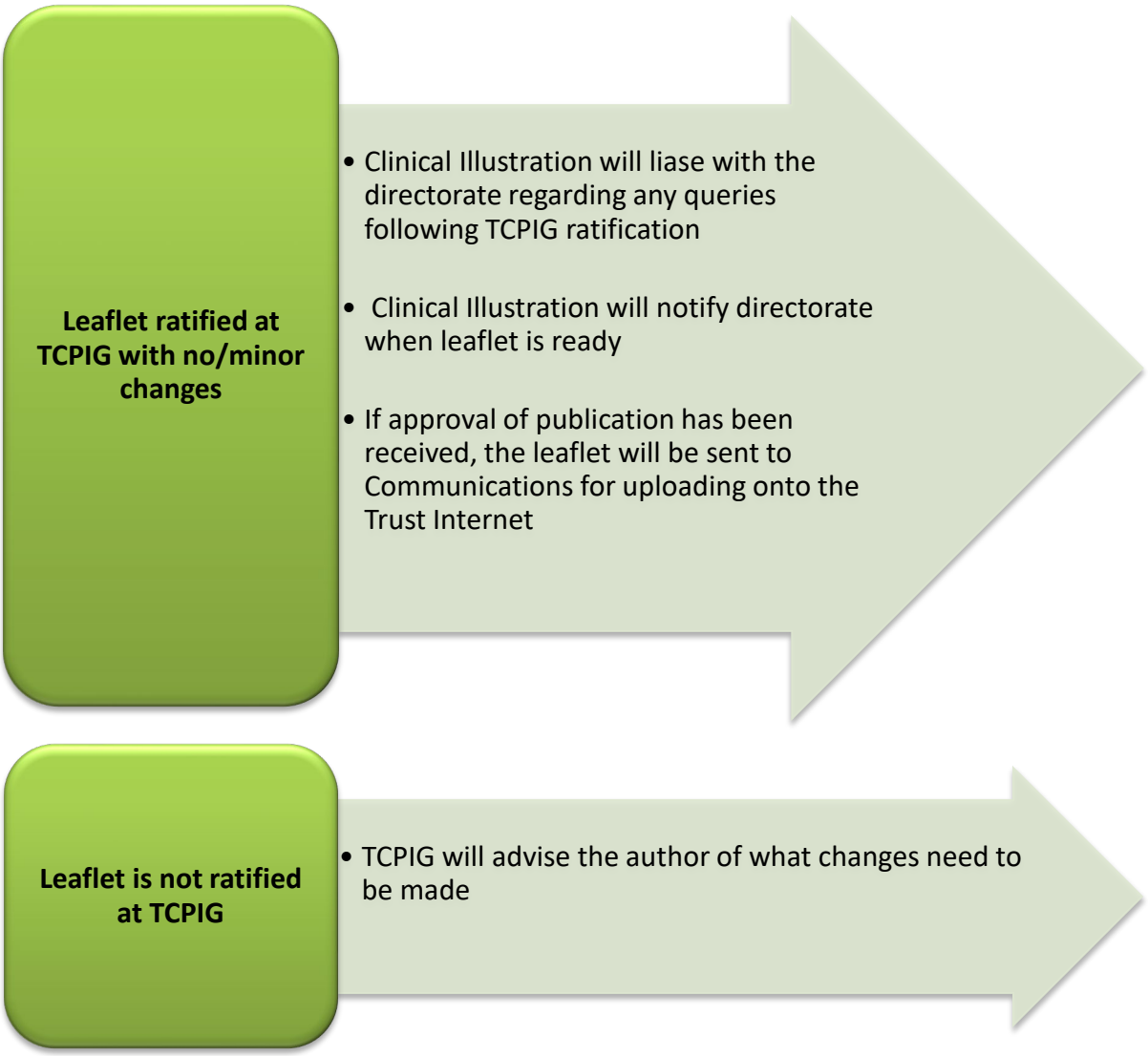
## Creating the leaflet:




## Directorate review and approval process:



## Ratification at TCPIG:

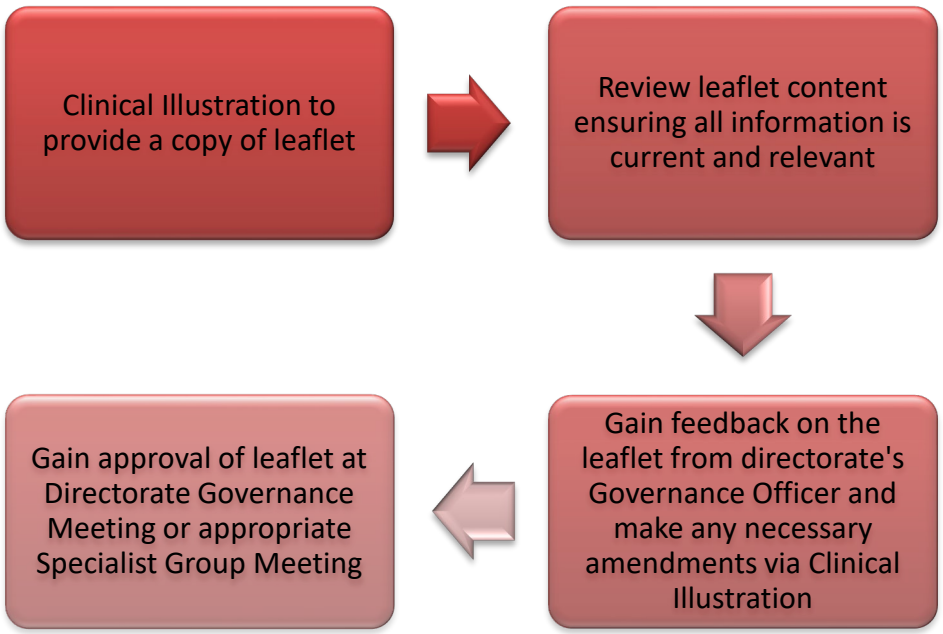


Patient Information

**App 02**

# Reviewing a Patient Information leaflet (minimum every 3 years)

## Directorate review and approval process:




## Send to TCPIG:

**No changes or minor clinical or format changes**

Examples: changes to references, statistics, contact details and grammatical changes

- Email completed Sign-Off Sheet (App 11) to rwh-tr.patientleaflets@nhs.net
- **Please note:** If it is a CONSENT based leaflet, a copy of the updated draft leaflet will also need to be sent

**Any moderate/significant clinical or format changes**

Examples: amendments or additions to clinical element or removal or restructuring of paragraphs.

- Email completed Sign-Off Sheet (App 11) and the updated draft leaflet to rwh-tr.patientleaflets@nhs.net

## Ratification at TCPIG:

**no/minor changes ratified at TCPIG**

Consent - full review will be undertaken

Non-based consent - will automatically be approved without review

- Sign-Off Sheet (App 11) detailing any amendments will be added to Clinical Illustration's database
- Clinical Illustration will notify directorate when leaflet is ready
- If approval of publication has been received, the leaflet will be sent to Communications for uploading onto the Trust Internet

**Moderate / significant changes ratified at TCPIG**

- Sign-Off Sheet (App 11) detailing any amendments will be added to Clinical Illustration's database
- Clinical Illustration will notify directorate when leaflet is ready
- If approval of publication has been received, the leaflet will be sent to Communications for uploading onto the Trust Internet

**Leaflet not ratified by TCPIG**

- TCPIG will advise the author of what changes need to be made

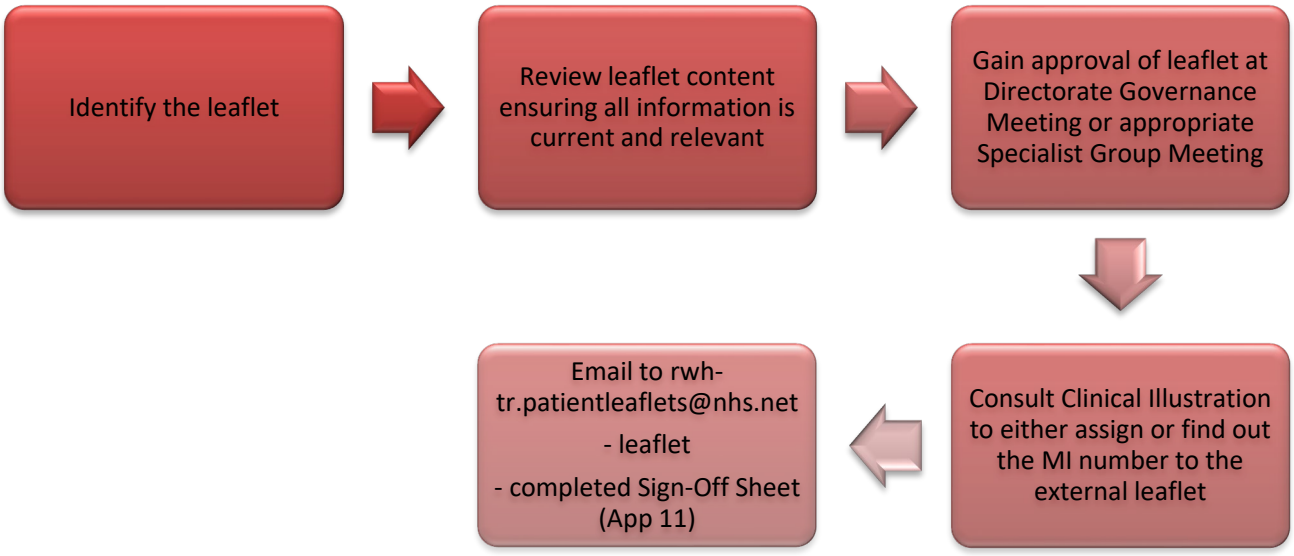
Patient Information

**App 03**

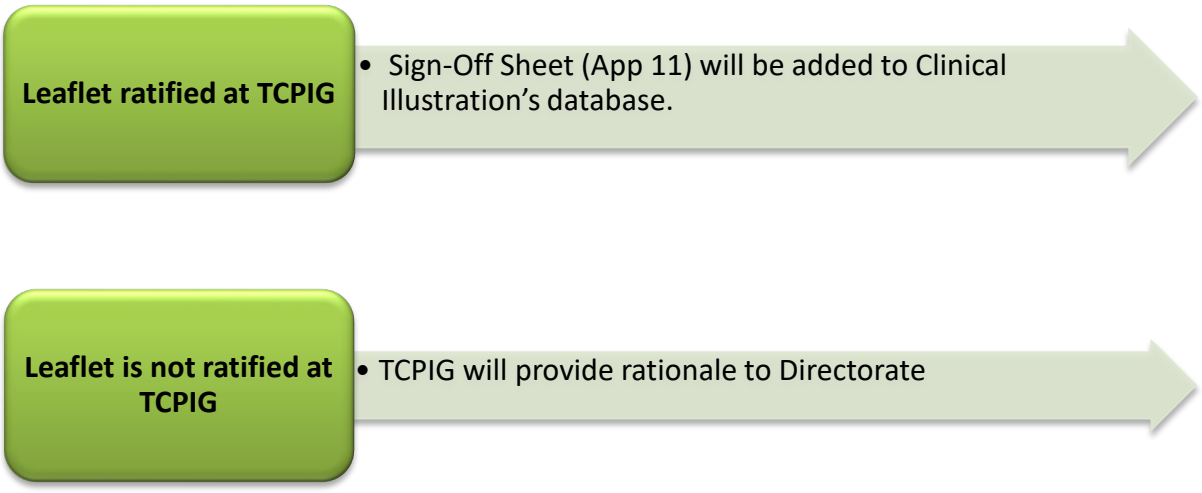
# Process for agreeing external leaflets for use in formal consent process

## Registering of new leaflets or minimum 3 years review of existing leaflets

## Directorate review and approval process:




## Ratification at TCPIG:



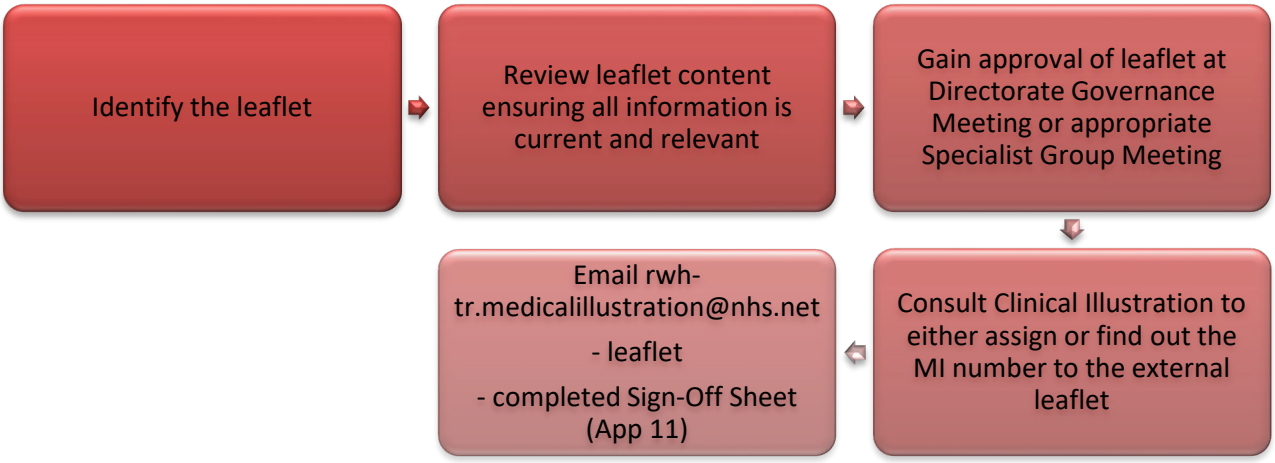
Patient Information

**App 04**

# Process for agreeing external leaflets for use in non-consent process

## Registering of new leaflets or minimum 3 years review of existing leaflets

## Directorate review and approval process:




## No Ratification at TCPIG required

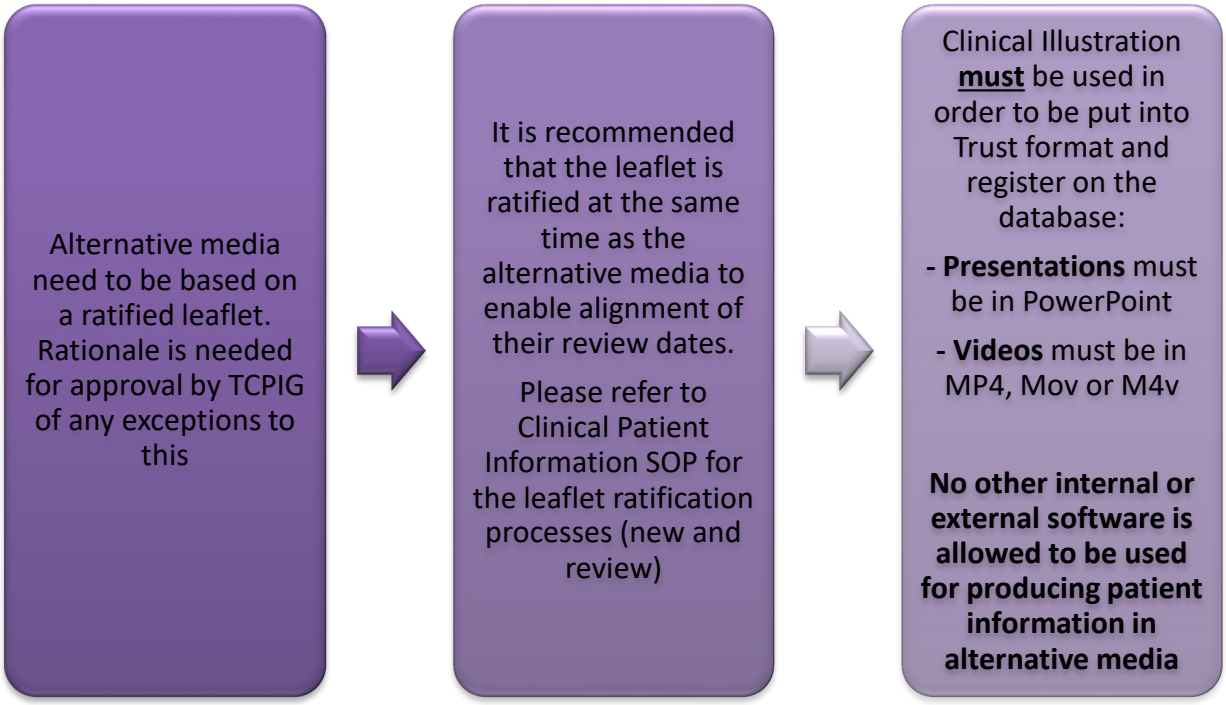
Patient Information

**App 05**

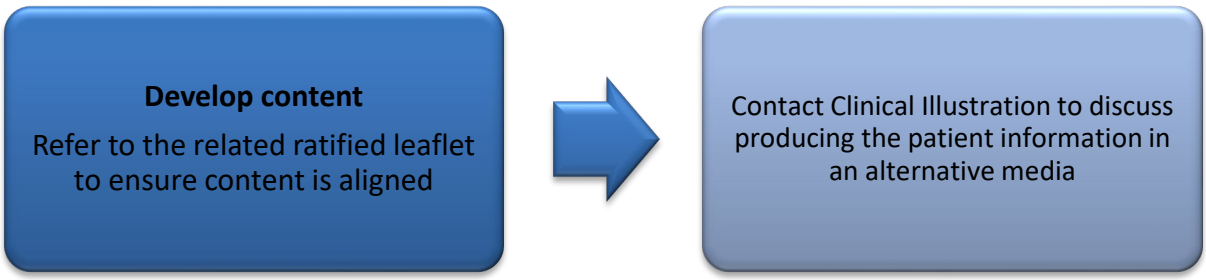
# Creating a new Patient Information in an alternative media

**(For example, presentation, video, audio, animation)**

## Important information:



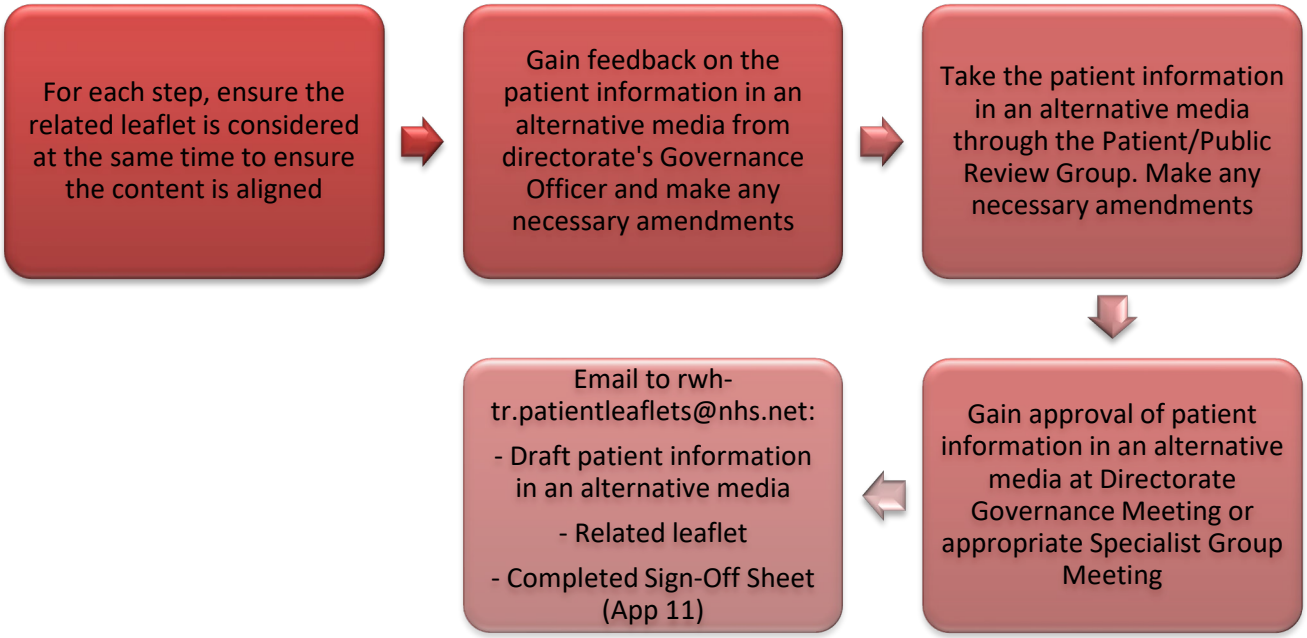

## Creating an alternative media:



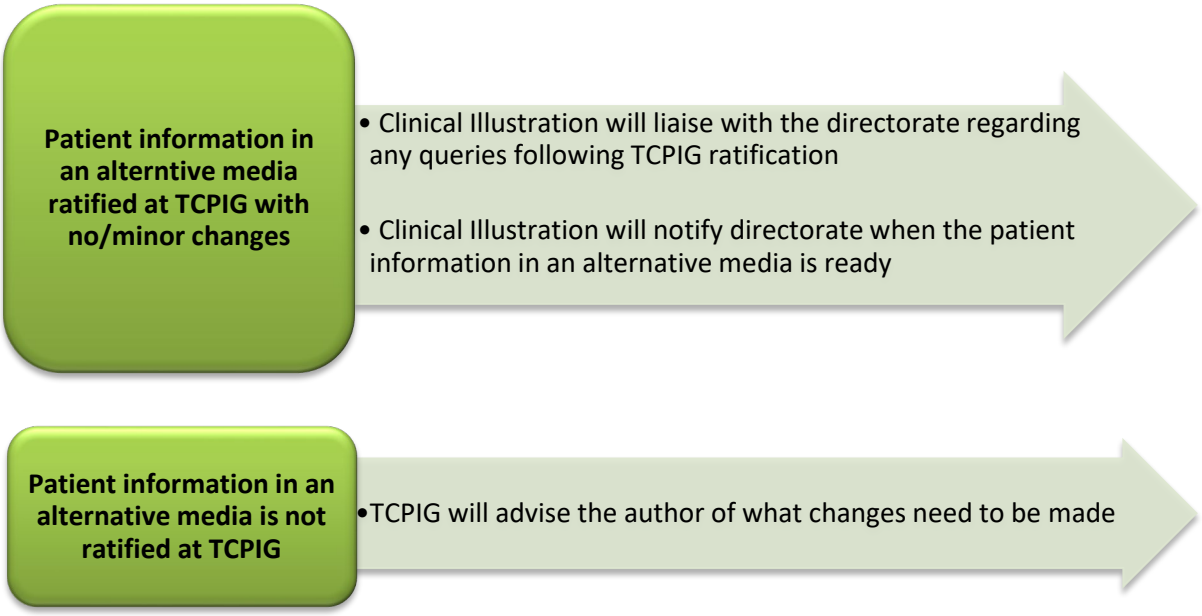
Patient Information

# App 05

## Directorate review and approval process:




## Ratification at TCPIG:



Patient Information

**App 06**

# Reviewing patient information in an alternative media

**(For example, presentation, video, audio, animation)**

**(Minimum every 3 years)**

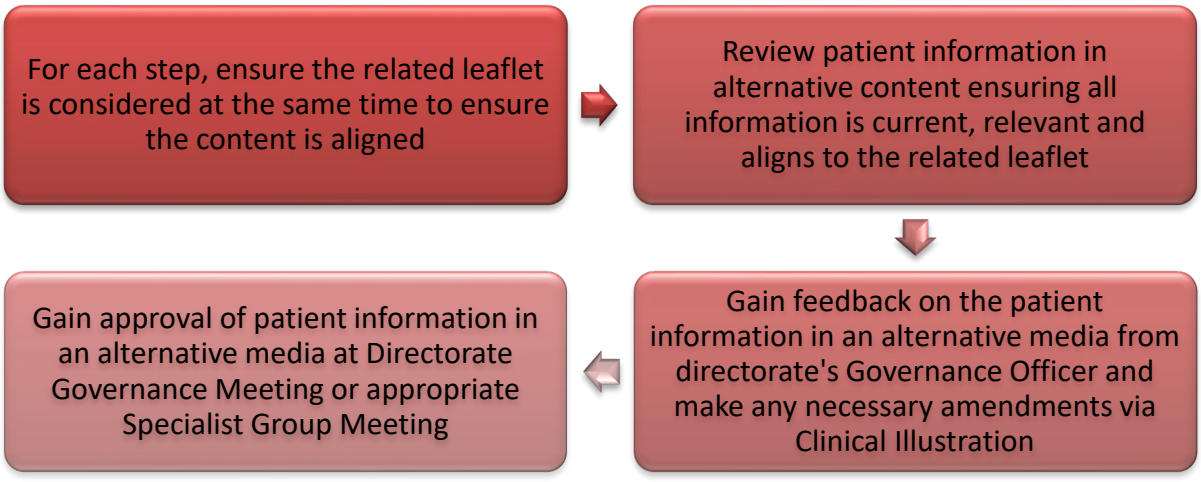
## Important information:

Alternative media needs to be based on a ratified leaflet. Rationale is needed for approval by TCPIG of any exceptions to this

It is recommended that the leaflet is ratified at the same time as the alternative media to enable alignment of their review dates.

Please refer to Clinical Patient Information SOP for the leaflet ratification processes (new and review)

## Directorate review and approval process:



## Send to TCPIG:

**No changes or minor clinical or format changes**

Examples: changes to references, statistics, contact details and grammatical changes

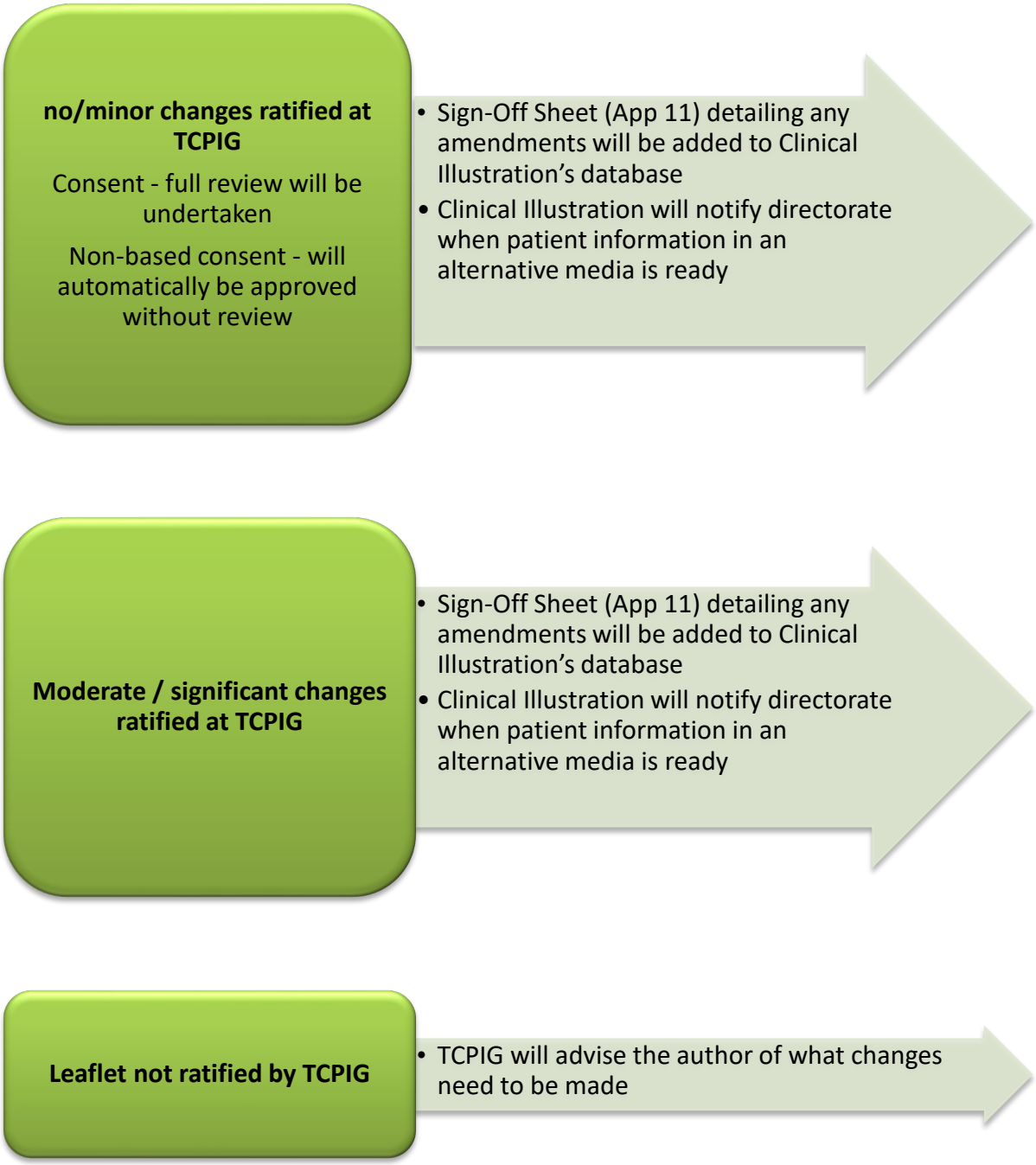
- Email to rwh-tr.patientleaflets@nhs.net
- Completed Sign-Off Sheet (App 11)
- **Please note:** If it is CONSENT based, a copy of the updated alternative media as well as the updated related draft leaflet (which should be going through the review leaflet process at the same time) will also need to be sent. This will ensure content is aligned.

**Any moderate/significant clinical or format changes**

Examples: amendments or additions to clinical element or removal or restructuring of paragraphs or slides

- Email to rwh-tr.patientleaflets@nhs.net
- Completed Sign-Off Sheet (App 11)
- Updated patient information in an alternative media
- Draft related leaflet (which should be going through the review leaflet process at the same time). This will ensure content is aligned.

## Ratification at TCPIG:



Patient Information

**App 07**

# Guidelines for the development of patient / carer information leaflets

It is essential that patients/ relatives/ carers have confidence in the information they receive and that it enables them to make choices about their care.

The information produced must be:

- Clear
- Concise
- Relevant
- Accurate
- Easily understood

**All patient/ carer information leaflets should include:**

- Contact details for further information
- Any external sources of information (e.g. local self-help groups, national bodies and internet addresses)

## Clinical Illustration automatically include the following:

The date the leaflet was produced/approved

The date the leaflet will become out of date and require reviewing (maximum of three years)

**Infection Prevention statement:** *Clinical Illustration will ensure that the current Trust Infection Prevention statement is included.*

**Equality and Diversity format statement:** *"If you require this document in an alternative format e.g. larger print, different language etc. please inform one of the healthcare staff"*

**Process for requesting an alternative format**

If patients/carers request an alternative format staff should contact Equality and Diversity Officer on rwh-tr.EqualityandDiversity@nhs.net or x 84479 for support.

For further information refer to the Equality and Diversity page on the Trust intranet.

## Leaflets that form part of the formal consent process:

| Patient/ carer information leaflets linked to the formal consent process must contain the following information<br>- under separate headings<br>- applies to internally produced and externally sourced leaflets |
| --- |
| • Obtaining Consent<br>• Benefits<br>• Risks - defined as significant risks as well as significant but remote risks<br>• Alternatives to treatment<br>• It is considered best practice to include a statement about shared decision making |

## Useful Phrases, Sentences or Paragraphs

You may find some of the following phrases useful when writing patient/ carer information:

**What is shared decision making?**

- *The choice about which treatment is best for you will be made together with your doctor. This will be based on the risks and benefits of the treatment and your individual circumstances'.*

**Consent**

- *We must seek your consent for any procedure or treatment beforehand. Your doctor will explain the risks, benefits and alternatives where relevant before they ask for your consent. If you are unsure about any aspect of the procedure or treatment proposed please do not hesitate to ask for more information.*

**Are there any risks involved in having the treatment?**

- *There are nearly always risks to any treatment. Here are the risks that may arise when having [insert name of treatment];*

**Side effect**

- *You may experience____Your doctor may suggest that you take [insert name of treatment] to help relieve the symptoms.*

**Are there any alternatives to [insert name of treatment] and what would happen if I decided not to have this treatment?**

- *The choice about which treatment is best for you will be made together with your doctor. This will be based on the risks and benefits of the treatment and your individual circumstances. The doctor will have explained the different treatment options to you and what will happen if you decide not to have any treatment at all.*

## Other Important information

| | |
|---|---|
| **All patient information** | • Directorates must ensure that the content of the leaflet does not risk the safety of patient or public by describing the detail of ligature points, ligatures, or detail of any other means of self-harm |
| **Specific direction for the production of information leaflets for children** | • Must be developed with the target age range and likely recipients for specific leaflets in mind. For example, clip-art diagrams and pictures may be appropriate for certain childhood conditions and operative procedures<br>• Consideration must also be given to the fact that parents may require their own carer information leaflet, particularly if they are being asked to consent to a procedure on their child's behalf |
| **Exemption of Research & Development individual trial information sheets** | • The external and ethical review processes which the HRA use, ensures patients are given clear information, allowing patients to make informed consent decisions<br>• Research & Development will therefore be exempt from following the Clinical Patient Information SOP in these instances |

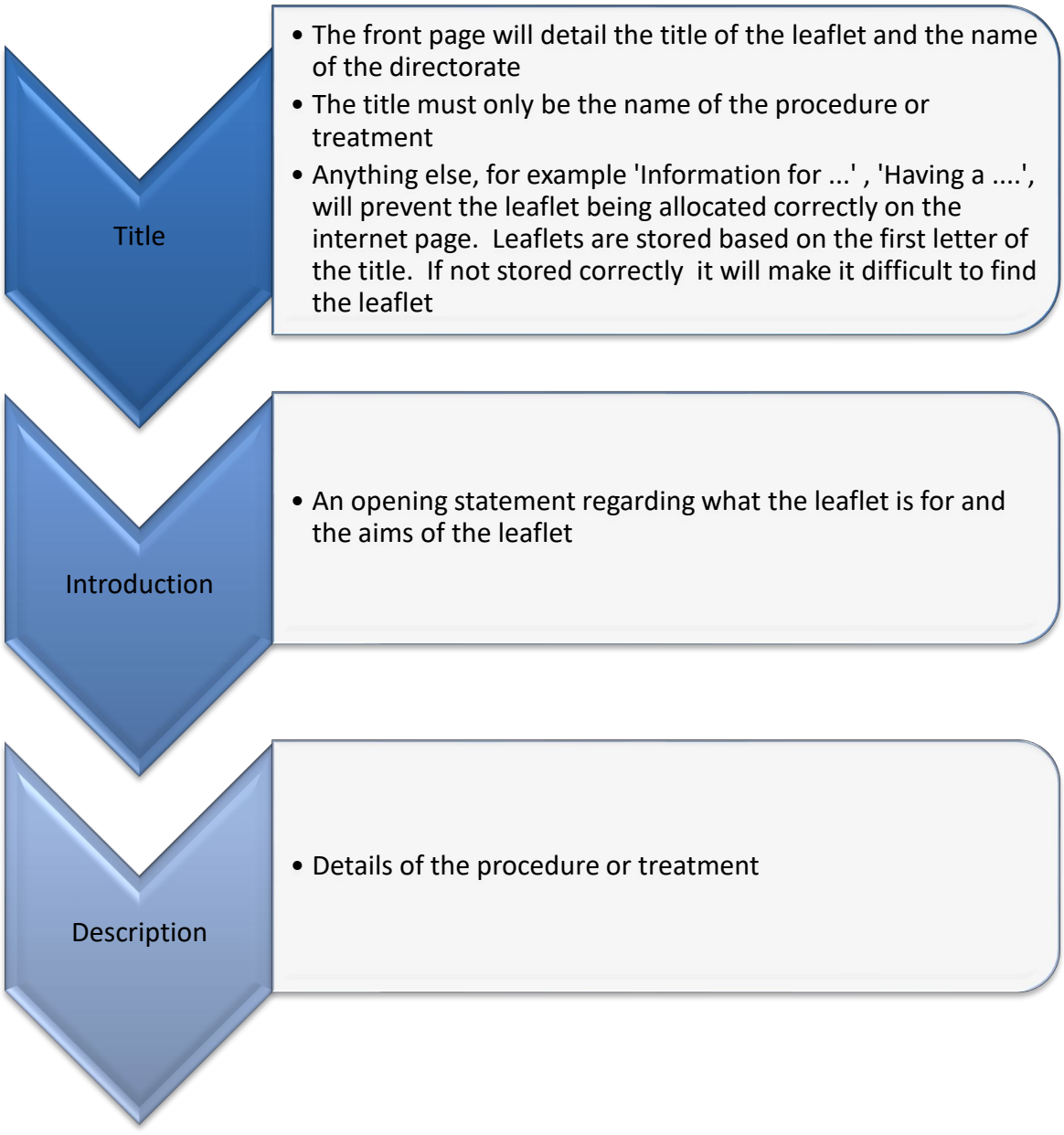
Patient Information

App 08

# Patient information leaflets order of content template

**This is a guide to the order a new Internal leaflet should follow - not all sections will be relevant for all leaflets.**

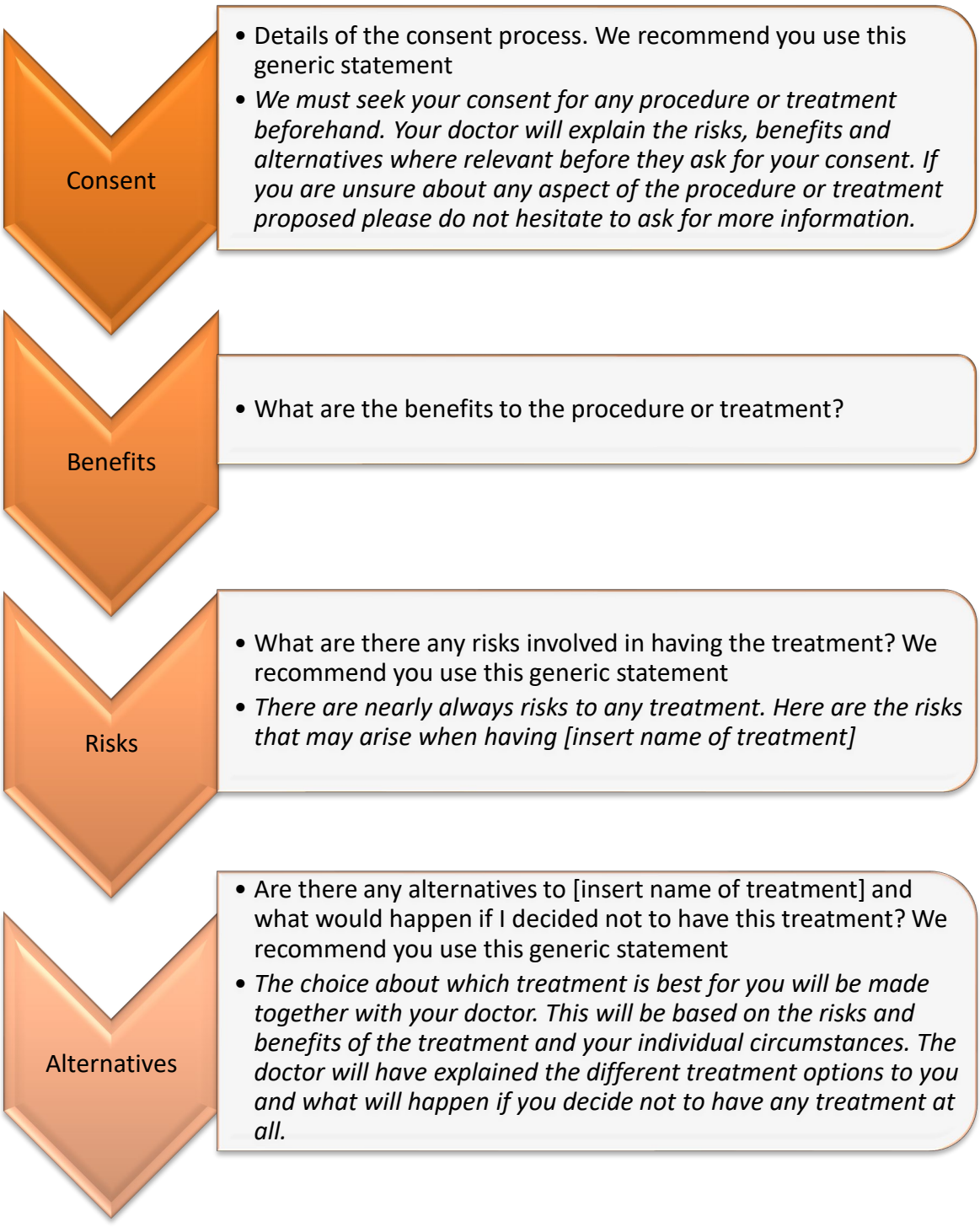
**All patient information leaflets must have the following in this order**



Patient Information

# App 08

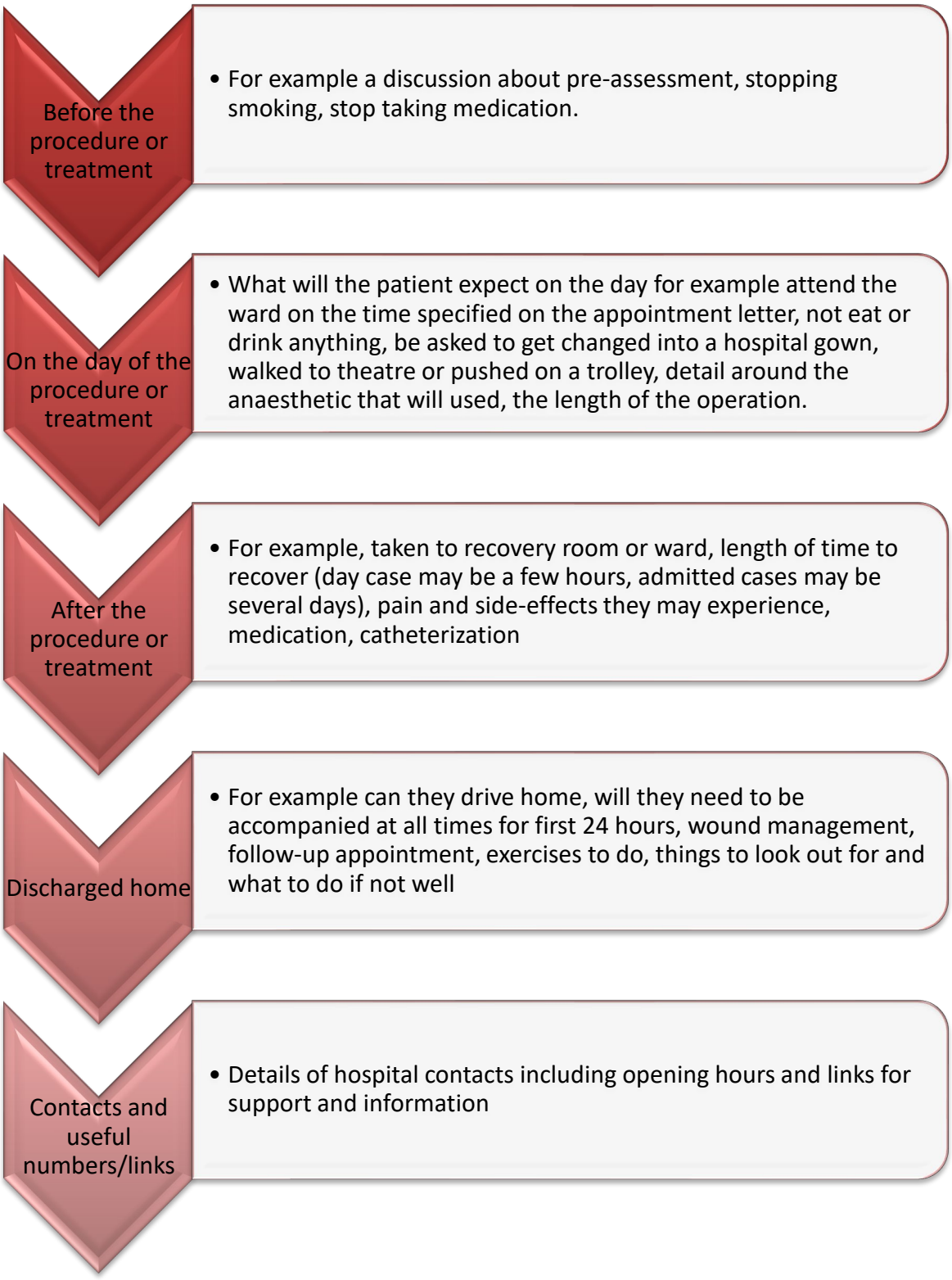
**<u>All Consent</u> leaflets must have the following content in this order. These need to be in separate headed sections. The Benefits, Risk and Alternatives can also be included in non-consent leaflets if applicable.**



Patient Information

# App 08

**All patient information leaflets must have the following content in this order**



**FOR DIRECTORATE USE ONLY - NOT REQUIRED TO BE RETURNED TO THE GOVERNANCE DEPARTMENT**

# Quality Assurance Checklist for internally and externally produced Patient / Carer information leaflets

| | |
|---|---|
| **Title of leaflet:** | |
| **Author/ Originator:** | |
| **Directorate/ Dept:** | |

| | Criterion | Applies to Trust produced leaflets | Applies to externally produced leaflets | Yes | No | Comments |
|---|---|---|---|---|---|---|
| **Content** | Has Clinical Illustration been consulted on the existence of the same or similar leaflets elsewhere in the Trust? | √ | x | | | |
| | Have you considered who your readers are and what their specific needs may be, and produced your information in the most appropriate format? Refer to Equality & Diversity Impact within Guidelines | √ | x | | | |
| | Does the title of the leaflet clearly indicate what it is about? | √ | √ | | | |
| | Does the opening text clearly state who the target audience is? | √ | √ | | | |
| | Does the opening text clearly state what the aims of the resource are? | √ | √ | | | |
| | Is the information presented in a question and answer format? | √ | x | | | |
| | Is the information up to date and evidence based? | √ | √ | | | |
| | Is the information understandable, relevant and concise? | √ | √ | | | |
| | Is the leaflet required for consent to treatment? | √ | √ | | | |
| | If **consent** to treatment is involved, is there under separate headings, an explanation of the benefits, risks and alternatives, to treatment and outcomes of not accepting the proposed treatment? | √ | √ | | | |
| | Has the statement about shared decision making been inserted into leaflets involved in the **consent** process? | √ | x | | | |
| | If any patient information is to be shared with other organisations has this been explicitly stated in the leaflet? | √ | x | | | |

| | Criterion | Applies to Trust produced leaflets | Applies to externally produced leaflets | Yes | No | Comments |
|---|---|---|---|---|---|---|
| | Have patients been advised to discuss questions or concerns with a health professional? | √ | √ | | | |
| | Have specialist terms been explained in the text or in a glossary? | √ | √ | | | |
| | Are all contact details up to date (for Trust leaflets general job titles should be used rather than individual names)? | √ | √ | | | |
| | Have all relevant methods of communication been included? | √ | √ | | | |
| | Has patient/public review been conducted and outcomes incorporated into the leaflet? (you may wish to consider asking whether participants wish to receive feedback on how their comments have been incorporated into the leaflet and/or a copy of the ratified leaflet) | √ | √ | | | |
| | Does the **external leaflet** meet the Trust's clinical advice and standards? | x | √ | | | |
| | Does the **external leaflet** have a sticker added, detailing where in the Trust the leaflet has been supplied from and staff/department contact details? | x | √ | | | |
| | Does the **external leaflet** meet your readers' specific needs and is it presented in the most appropriate format as per Equality & Diversity Guidelines? | x | √ | | | |
| | Does the leaflet include any detail of ligature points, ligatures, or detail of any other means of self-harm, if yes, remove this detail. | √ | √ | | | |

| | Criterion | Applies to Trust produced leaflets | Applies to externally produced leaflets | Yes | No | Comments |
|---|---|---|---|---|---|---|
| **Equality Analysis** | Could patients with 'Personal Protected Characteristics' have difficulty in performing any of the processes/procedures described in the leaflet (for example expecting a patient with visual impairment or manual dexterity problems to write on a urine bottle)? | √ | x | | | |
| | Does the leaflet inform patients with access difficulties how to contact the department? | √ | x | | | |
| **Design & Layout** | Have the blocks of text been kept small? | √ | x | | | |
| | Have lower case letters been used throughout? | √ | x | | | |
| | Have numbers been formatted appropriately throughout (i.e. numbers up to ten written as words; numbers over ten written as numerals)? | √ | x | | | |
| | Is the text free of spelling mistakes? | √ | √ | | | |
| | Does the leaflet display a planned review date? | √ | √ | | | |

Patient Information

**App 10**

# Public / Patient Review of Patient Information Leaflets

| | |
|---|---|
| **Title of leaflet** | |
| **Name of Patient/ User Group** | |
| **Date of Review** | |

This template may be used for individual questionnaires or to summarise a group response.

**1. Did you find the leaflet easy to understand?** Yes No Not sure

If no or not sure, which parts of the leaflet were unclear?

**2. Did the leaflet answer all your questions on the subject?** Yes No Not sure

If no or not sure, what questions would you have liked answered?

**3. Did the leaflet cover the right amount of information?** Yes No Not sure

If no or not sure, did it cover too little or too much information?

**4. Could you explain the content of the leaflet to another person easily?** Yes No Not sure

If no or not sure, which parts would you find difficult to explain?

**5. Did you understand all the words and phrases in the leaflet?** Yes No Not sure

If no or not sure, which words need further explanation?

**6. Did the leaflet present the information well?** Yes No Not sure

If no or not sure, what did you dislike about the way the way the information was presented?

**7. Overall, was this a good example of a leaflet?** Yes No Not sure

If no or not sure, what would improve it?

**Thank you for completing this form**

Patient Information

# Patient Information Sign-Off Sheet

NHS
The Royal Wolverhampton
NHS Trust

## 1. DIRECTORATE APPROVAL (all Patient Information)

| | |
|---|---|
| Title of Patient Information | |
| MI number (if applicable) | |
| Directorate/ Dept. | |
| Name of current Author/Co-ordinator (Trust staff or External Body) | |

**Please select the appropriate option/s by clicking on the box on the right. Any unselected boxes indicate a No**

| SECTION 1 – Complete for Trust INTERNAL Patient Information | |
|---|---|
| Required for **formal consent** to treatment | ☐ |
| **New** Patient Information | ☐ |
| Review of **existing** Patient Information:<br>• **No changes or minor clinical or format changes**<br>Please detail amendments you have made: | ☐ |
| Review of **existing** Patient Information:<br>• **Moderate/significant clinical or format changes**<br>Please detail amendments you have made: | ☐ |

## SECTION 2 - Patient Information on the Trust's website
**This must be completed for ALL internal leaflets**

**Publishing Requirements:** Can this Patient Information be published on the Trust's website? Yes ☐ No ☐

If No, please provide a rationale for your decision. This will go to the Trustwide Clinical Patient Information Group (TCPIG) for discussion.

Key words – Words that can be used to search for the Patient Information on the internet. Please note the title of the leaflet and Directorate will automatically be selected as key words and do not need to be detailed in this section

## SECTION 3 – Complete for EXTERNAL Patient Information (not produced by Trust)

| | |
|---|---|
| External patient information required for **formal consent** to treatment | ☐ |
| **New** external Patient Information (not required for consent) | ☐ |
| **Update to / review** of existing external Patient Information | ☐ |

| SECTION 4 - Patient/Public Review (only complete if applicable) | |
|---|---|
| Name of patient/ public group | |
| Date of review | |
| Outcome of review, e.g. what (if any) issues arose and have they been addressed in the leaflet? | |

**SECTION 5 - Directorate sign off**

**This must be completed for ALL internal and external leaflets – new and existing ones that have been reviewed, even if there are no changes**

Date of Directorate Governance Meeting or Specialist Group Meeting where approval is minuted

Name of Author/Co-ordinator:

Date:

*(NB email from Author/Co-ordinator's email address suffices as electronic signature)*

## 2. TCPIG APPROVAL: Internal use only

| Following review by the Trustwide Clinical Patient Information Group (TCPIG), this Patient Information has been: (select one) | |
|---|---|
| ☐ | Ratified with no changes |
| ☐ | Ratified subject to minor changes |
| ☐ | Ratified subject to moderate or significant changes (to be made by author) |
| ☐ | Noted for registration (external leaflets) |

Name:

(Divisional Healthcare Governance Manager)

Date of ratification:

*(NB email from Governance staff email address suffices as electronic signature)*

Patient Information

**App 12**

# Directorate internal monitoring and management process of patient information

## Why is patient information relating to clinical treatment important?

Patient/ Carer information is an essential part of the patient's journey and a key element in the overall quality of the patient's experience

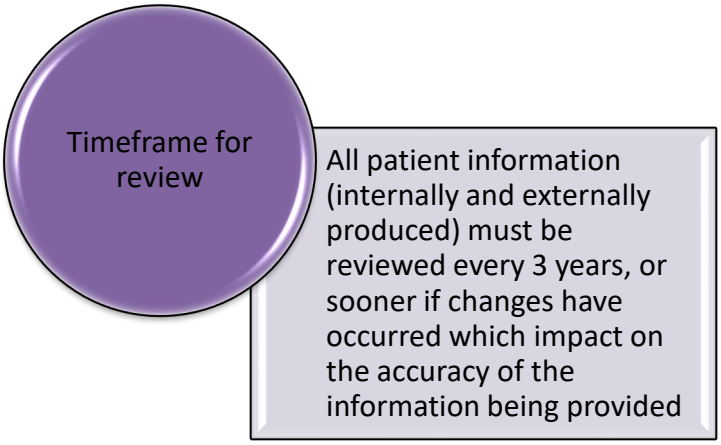
It is important the Trust provides suitable patient/ carer information that meets the needs of the recipient

## The aim of the Clinical patient information SOP:

To provide guidance on the development of written/ printed or published information given to patients, relatives or carers about their clinical treatment, in line with the NHS recommendations and equalities legislation

To provide a process for the ratification and publication of new/ reviewed Trust leaflets, externally produced leaflets and other formats of published information

## Requirements for reviewing patient information:




## The consequence of not reviewing patient information within the 3 year timeframe:

- No assurance as to the quality and accuracy of patient information being given to patients
- Risk of inconsistent poor-quality information being given to patients
- Risk of possible litigation claims
- Out of date leaflets being present on the Trust's internet website which is accessible to all patients, staff and external bodies
- Unable to print patient information via Clinical Illustration

## Responsibility:

### Directorate responsibility

- To ensure that there is a robust internal monitoring process to effectively manage all patient information
- To review, feedback and provide directorate approval of all patient information
- To ensure all clinical content is correct
- To ensure when patient information is being used for obtaining consent, it contains separate headed sections for explaining the consent process, benefits, risks and alternatives

### Patient Information Lead responsibility

- To manage the monitoring process for all patient information within the directorate
- To ensure all new patient information follows the process for ratifaction set out in the 'Clinical Patient Information SOP'
- To ensure all patient information is reviewed within the specified timeframe to avoid becoming out of date
- To provide advice and assistance to the Author and directorate

### Author(s) responsibility

- To ensure all patient information either new or being reviewed, contains only accurate and clinically sound information
- To ensure when patient information is being used for obtaining consent, it contains separate headed sections for explaining the consent process, benefits, risks and alternatives
- To ensure all new/reviewed patient information follows the process and guidelines set out in the 'Clinical Patient Information SOP'
- To ensure that all feedback received (from colleagues/patient or public review/directorate/TCPIG) is considered and amended via Clinical Illustration
- To ensure that all relevant documentation is completed and submitted for each patient information