SOP05
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.

Leaflets are accessible via the home page of the internet Patient Information page

Patient information leaflets - The Royal Wolverhampton NHS Trust. Version control and routine updates are managed via Clinical Illustration. Staff must download the latest versions of patient information leaflets via the link and refrain from printing copies of previous leaflet downloads to preserve the currency and integrity of the information to be provided to patients.

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 an existing internal 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 new, or reviewing existing patient information in an alternative media
- Internal Directorate responsibilities for local Patient Information leaflets management process
    - App 12 Directorate internal monitoring and management process

Overview

Scope

The external and ethical review processes which the Health Research Authority (HRA) use, ensure patients are given clear information, allowing patients to make informed consent decisions. Research & Development will therefore be exempt from following the Clinical Patient Information SOP in these instances.

Detail

This SOP requires that all Patient Information (Internally or Externally produced) relating to a patient's clinical treatment, must be reviewed as a minimum every three years.

This SOP describes the Directorate and other stakeholder responsibilities to implement internal processes for patient information leaflet management. The patient information lead role must be assigned within the Directorate and will default to the respective Directorate management team where it is not delegated. Accountability remains with the Directorate management team to ensure the integrity, accuracy and accessibility of all patient leaflet information is appropriate for care provision.

Non-clinical Patient Information (as stated below) is not expressly included in this SOP, however the principles for development, review, consultation and approval should be applied. This could include:

- General information regarding a specific team/department which contains contact details
- Posters advertising a new department process
- Any staff focused leaflets
-

Guidance for developing easy read material is outlined in section 6 training below.

Where patients require alternative formats eg larger print, different language etc staff are to make such requests via Equality and Diversity Officer on rwh-tr.EqualityandDiversity@nhs.net or x 84479 for support.

Co-production of patient information material is valuable because it considers lived experience and the insights of people who use or will be impacted by the information being produced, allowing for more effective and relevant leaflet design. The co-production approach to creating information involves early engagement with patients, carers, families, and service users, and leads to more inclusive, person-centered, and equitable communication. By actively involving patients in the development process, you can create a patient information leaflet that is not only informative but also empowering and patient-centered. (refer also appendix 10).

Nationally authorised health information such as from NHS Choices Health conditions A-Z Conditions A to Z - NHS can be used to direct patients to supplementary health information unrelated to consent. However, where external information is used within the informed consent process, the patient information/leaflet must be approved according to the proves in Appendix 3 Process for agreeing external leaflets for use in consent.

2.0 Definitions

- **Internal**
  - Any clinical-based patient information document internally produced by Clinical Illustration
- **External**
  - Any clinical-based 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 local monitoring process to effectively manage all patient information
- To review and ratify all Directorate patient information including new and revised internally produced leaflets (including consent-based leaflets), external leaflets that are to be adopted for internal Trust use (including consent-based leaflets), new and revised patient information in alternative media (for example presentation, video, audio, animation)
- To ensure that patient information used for obtaining consent contains separate headed sections for explaining the consent process, benefits, risks, and alternatives. The Directorate management team are responsible for the implementation of the patient leaflet SOP and ultimately accountable for ensuring the integrity, accuracy and accessibility of all patient leaflet information appropriate for care provision.
  - 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 three years. If moderate or significant changes are made within the three-year period, the leaflet will need to be reviewed by the Directorate. Formal comments/changes are to be provided to the author and Clinical Illustration as appropriate before orders can be placed
- To ensure there is appropriate compliance with Easy Read formats available (see section 6).
- On publication of a revised leaflet, it is the responsibility of the Directorate, leaflet author and patient information leaflet lead to remove all previous version and replace with the latest version of the leaflet

- To ensure the Patient Leaflet register/spreadsheet/database is updated with leaflets in existence and their review status
- To oversee accountability for compliance with this SOP and engagement with the Patient Information governance process
- To identify and escalate areas for risk or non-compliance with the Patient Information leaflet governance process
- To consider and approve as to 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 ensure there is appropriate compliance with Easy Read formats available (see section 6)
- To consider and approve whether the patient information is suitable for publication on the Trust's internet page
- On publication of a revised leaflet, it is the responsibility of the Directorate, leaflet author and patient information leaflet lead to remove all previous leaflet versions and replace with the latest version of leaflet

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

- To ensure all new or reviewed patient information contains only accurate and clinically sound and evidence-based information
- To ensure that internal patient information leaflets used for obtaining consent, contains 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 this 'Clinical Patient Information SOP'
- To ensure that all patient information has appropriate consultation and feedback (from colleagues/patient or public review/Directorates/wider stakeholders) incorporated in the final draft issued to Clinical Illustration
- To ensure that all relevant documentation is completed and submitted for each patient information leaflet (ie. The final updated leaflet, App 11 Sign off sheet and App 9 Quality Assurance checklist from the approval group)
- To review and approve the final leaflet proof issued by Clinical Illustration before publication

- On publication of a revised leaflet, it is the responsibility of the Directorate, leaflet author and patient information lead to remove all previous leaflet versions and replace with the latest version leaflet
- 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 with consideration of App 9 Quality Assurance checklist
- ensuring that all feedback received from appropriate consultation, including the patient/public review has been considered
- ensuring appropriate completion of ratification documents
- producing Directorate Minutes/ notes evidencing discussion of submitted patient information

3.5 Divisional

To have an oversight of compliance via reviewing monthly status reports of patient information leaflets to identify any risks posed by beyond review and out of review leaflets.

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 those produced by external sources that are adapted for Trust use (such as charities and national organisations)

Clinical Illustration will provide a patient information leaflet archive and audit trail of leaflet production. Clinical Illustration will provide data from the central leaflets register to inform leaflet reports to Divisions/Directorates via the InPhase system. Directorates are required to quality check the contents of the register, provide updates/corrections to Clinical Illustration and address the review of any out-of-date leaflets.

Clinical Illustration holds a local protocol which details archiving arrangements (Protocol 27)

Clinical Illustration will:

- Format information and return to the Author/Lead 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 and a final version is published and held on central file for reordering.

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 an existing internal patient information leaflet**
  Providing details of what is required when reviewing an internal patient information leaflet. Review to take place a minimum every three 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 and reviewing 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 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. Publix/patient involvement should be sought in partnership with the Patient Experience team, either through the Patient Experience Group or by contacting the Patient Experience Team directly
- **App 11 Sign Off Sheet**
  - The sign off sheet must be completed for all patient information leaflets requiring Directorate/specialist meeting approval
- **App 12 Directorate internal monitoring and management process**
  Provides details of the local process for Directorate management of patient information leaflets.
  This includes details of:
  - Requirements for reviewing patient information – minimum every three 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 although guidance is provided in the attached appendices.

Wherever possible and particularly where patient leaflets relate to consent, are foundational or used in large volumes; services are to ensure an adequate resource of patient information is available in Easy Read formats. Easy read resources can be adopted from external bodies (see appendix 3 and 4).

For developing Easy read material authors can obtain specialist advise from the Trust Learning disability lead and by consulting the following guidance (Refer also the Accessible Information Standard Policy):

To create easily readable health materials, focus on using clear, concise language, short sentences and paragraphs, and a logical structure. Avoid jargon and technical terms, and opt for visuals to enhance understanding. Prioritize the reader's perspective and design for accessibility, considering factors like font size and layout.

Here's a more detailed breakdown:

10. Know Your Audience and Purpose:

- **Identify the target audience:**

Consider their reading level, health literacy, and any specific needs or concerns.

- **Determine the purpose:**

What do you want the reader to understand or do after reading the material?

- **Use plain language:**

  Avoid jargon, technical terms, and abbreviations. Explain complex concepts in simple, everyday language.

- **Write from the patient's perspective:**
  Use language that resonates with the reader and addresses their specific concerns or questions.

2. Structure for Clarity:

- **Use short sentences and paragraphs:** Aim for sentences with 10-15 words and paragraphs with 2-3 sentences.
- **Organize logically:** Use headings, subheadings, and bullet points to break up text and guide the reader.
- **Use active voice:** Active voice is more direct and easier to understand than passive voice (e.g., "The doctor will see you" instead of "You will be seen by the doctor").

3. Design for Readability:

- **Choose easy-to-read fonts:** Use sans-serif fonts like Arial, Helvetica, or Times New Roman.
- **Use a large enough font size:** For most adults, 12-point font is a good starting point, and seniors may benefit from 14-point.
- **Ensure sufficient contrast:** Use black ink on white or light-coloured paper for optimal readability.
- **Avoid all caps:** All caps are harder to read than upper and lower case letters.
- **Use white space:** Adequate white space around text and between lines helps to reduce visual clutter.
- **Incorporate visuals:** Use clear, simple illustrations, photos, or diagrams to support the text.
- **Consider colour blindness:** Be mindful of colour choices and avoid using red and green together if colour blindness is a concern.

4. Enhance Comprehension:

- **Provide context:** Explain the "why" behind the information.
- **Use examples:** Illustrate concepts with relatable examples.
- **Break down complex information:** Use the "chunk and check" method, breaking information into smaller pieces and checking for understanding after each piece.
- **Use the "teach-back" method:** Ask the reader to explain the information back to you in their own words.
- **Offer a glossary:** Define any unfamiliar terms or jargon.
- **Be consistent:** Maintain a consistent style and tone throughout the document.

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: Current finance authorization allows for limited SOP implementation within existing resources only; this is delegated across Directorates and Clinical Illustration	

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. All leaflets include the statement “If you require this document in an alternative format e.g. larger print, different language etc. please inform one of the healthcare staff”.

9.0 Maintenance

The Assurance 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. SOP guidance, instruction and templates are provided for leaflet production.

Communication of the SOP will be via Trust processes and all user communications as well as governance and management communication cascade.

11.0 Audit/monitoring Process

There is no requirement to audit this SOP. Monitoring of the process of ratification by the Care Group will be achieved through the provision of completed App 11 Sign Off Sheet to Clinical Illustration. Clinical Illustration also ensure that all new and revised leaflets for production have been submitted with evidence of approval by the Care Group.

The monitoring of patient information leaflet within the required 3 years will be ongoing and status reports via Clinical illustration records. Results are reported/escalated quarterly to Care Groups and Division.

The Trust will review the results of annual patient survey and a local assurance survey to monitor patient feedback and the effectiveness of leaflets provided to patient.

12.0 References - Legal, professional, or national guidelines

Accessible Information Standard (AIS) HYPERLINK https://www.england.nhs.uk/about/equality/equality-hub/patient-equalities-programme/equality-frameworks-and-information-standards/accessibleinfo No external references are required for the internal approval arrangements outlined in this SOP, however the Trust works towards compliance with the AIS and patient leaflet authors are required to consult National guidance, Research and best practice in composing and reviewing new patient information leaflets before approval.

NHS Choices Conditions A to Z - NHS

CQC Regulation 9 - Person Centred Care and Regulation 17 - Good Governance.

Part A - Document Control

Procedure/ Guidelines number and version 3.0	**Title of Procedure/Guidelines** Clinical Patient Information SOP	**Status:** Final		**Author: Group Deputy Director of Assurance** **For Trust-wide Procedures and Guidelines Chief Officer Sponsor:** **Chief Medical Officer**
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
	V3.0	Sept. 2025	Group Deputy Director of Assurance	Full review
Intended Recipients: All staff				
Consultation Group / Role Titles and Date: Selected staff, Stakeholder group, Trust Policy Group				

Name and date of group where reviewed	Trust Policy Group – September 2025
Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Policy Group – September 2025
Date of Procedure/Guidelines issue	September 2025
Review Date and Frequency (standard review frequency is three yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	September 2028, every three years
Training and Dissemination: SOP will be available on the Trust intranet, instructive flowcharts are appended and advice as required will be provided by the Assurance and Clinical Illustration teams.	
Publishing Requirements: Can this document be published on the Trust's public page: Yes	
To be read in conjunction with: N/A	
Initial Equality Impact Assessment: **Completed** Yes **Full Equality Impact assessment (as required):** **Completed** No 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	
Monitoring arrangements	
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

Patient Information

App 01

Process for creating a new patient information leaflet

Creating the leaflet:

Consult with Clinical Illustration on the existence of the same or similar leaflet before creating a new one. Clinical Illustration must produce the draft leaflet and assign a MI number

Develop leaflet content

Refer to:

- Guidelines for the development of patient information leaflets (App 07)
- Patient Information Leaflet content order template (App 08)
- Quality Assurance Checklist (App 09)

Directorate review and approval process:

Gain feedback on the leaflet from directorate's Governance Officer and make any necessary amendments **

Take the leaflet through the Patient/Public Review Group using the Public Patient Review Questionnaire (App 10). Make any necessary amendments

Gain approval of leaflet at Directorate Governance Meeting or appropriate Specialist Group Meeting

Email to rwh-tr.medicalillustration@nhs.net

- draft leaflet in Word Format
- copy of minutes of approval
- completed Sign-Off Sheet (App 11)

**** For patient leaflets relating to care or to clinical conditions, a literature/evidence search must be completed by the author and references included in the leaflet.**

Patient Information

App 01

Ratification at Directorate Governance meeting:

Directorate Group Ratification of Patient Leaflets

- The leaflet author or patient information lead will provide a final draft (with all consultation comments) to the Directorate Governance meeting for approval.
- The Directorate will minute any required changes and their approval of the leaflet
- The leaflet author or patient information lead will produce and send a final draft in word format to Clinical Illustration with a copy of the approving minute heir approval of the leaflet

Clinical Illustration publication of Patient Leaflets

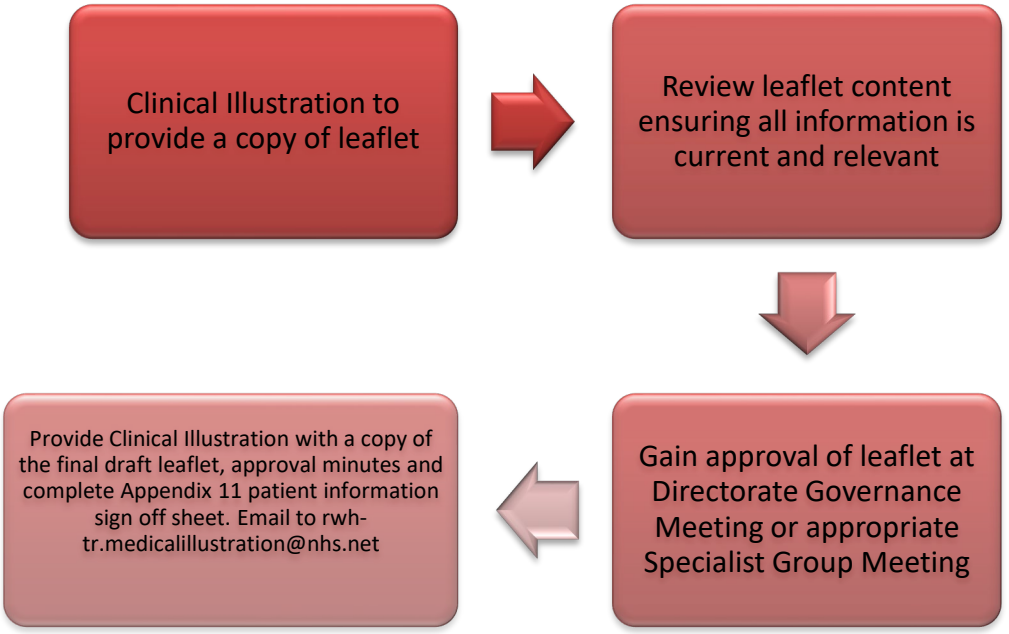
- Clinical Illustration will liaise with the author/lead regarding any queries following submission of final version for publication.
- Clinical Illustration will provide a proof for confirmation by the author before publication.
- If approval of publication has been received, the final leaflet will be produced (with MI number) and sent to the author. A master version held by Clinical Illustration.

Patient Information

App 02

Reviewing an existing internal Patient Information leaflet (minimum every 3 years)

Directorate review and approval process:



On receipt by Clinical Illustration:

NB. Clinical Illustration will maintain a Trust register of patient information leaflets approved for use by Trust Services. Reports from this register will be provided to Services for their update and redress to out of date patient information leaflets.

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.medicalillustration@nhs.net
- **Please note:** If it is an internal 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.medicalillustration@nhs.net

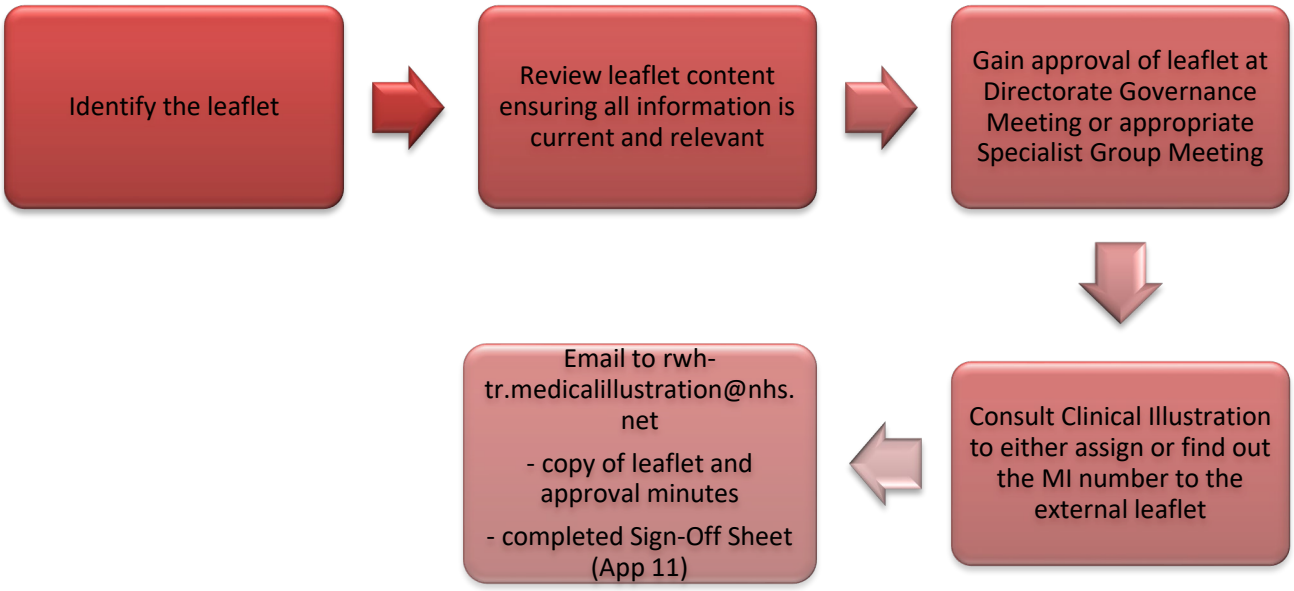
Patient Information

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:



NB. Where nationally approved Health Information or externally produced patient information leaflets are used to support the formal consent process, such leaflets or nationally approved health information eg BAUS or websites must be approved by the Directorate and recorded with Clinical Illustration as per above process.

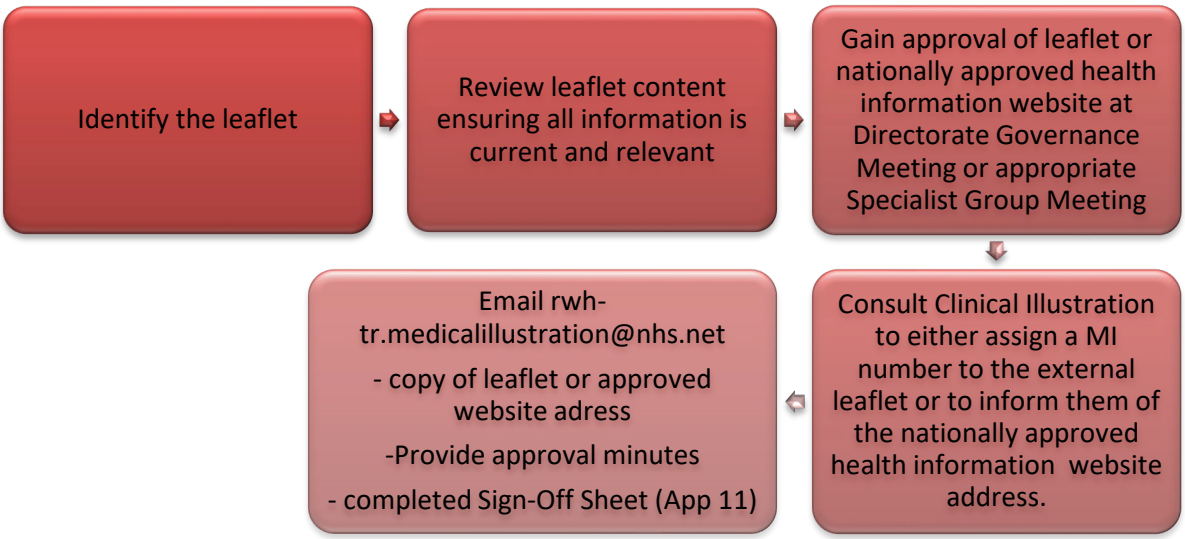
Patient Information

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:



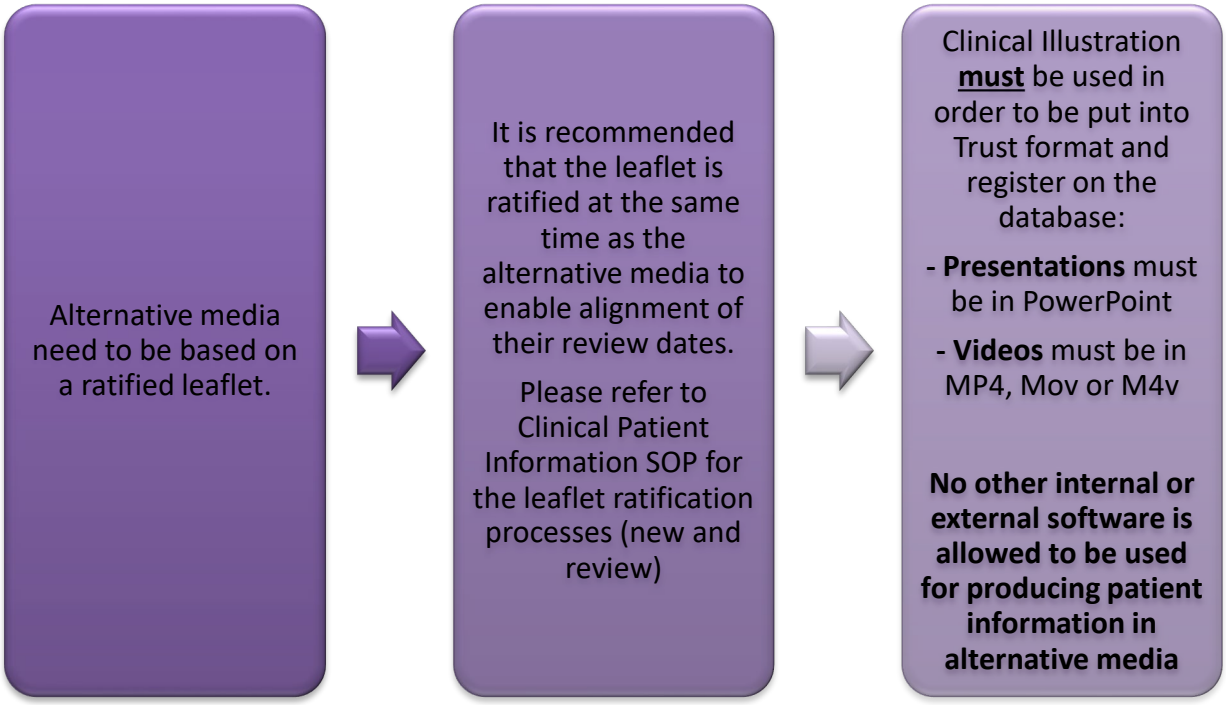
NB. Patients may be signposted to additional information about health conditions via nationally authorised sites such as NHS Choices here Conditions A to Z - NHS. Externally produced information that is provided for informed consent must follow the Trust approval process within appendix 3 (Process for agreeing external leaflets for use in consent).

Patient Information

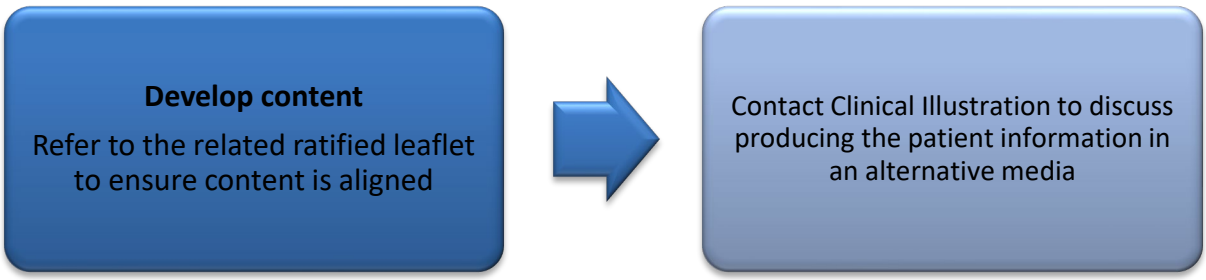
App 05

Creating new or reviewing Patient Information in an alternative media (For example, presentation, video, audio, animation)

Important information:



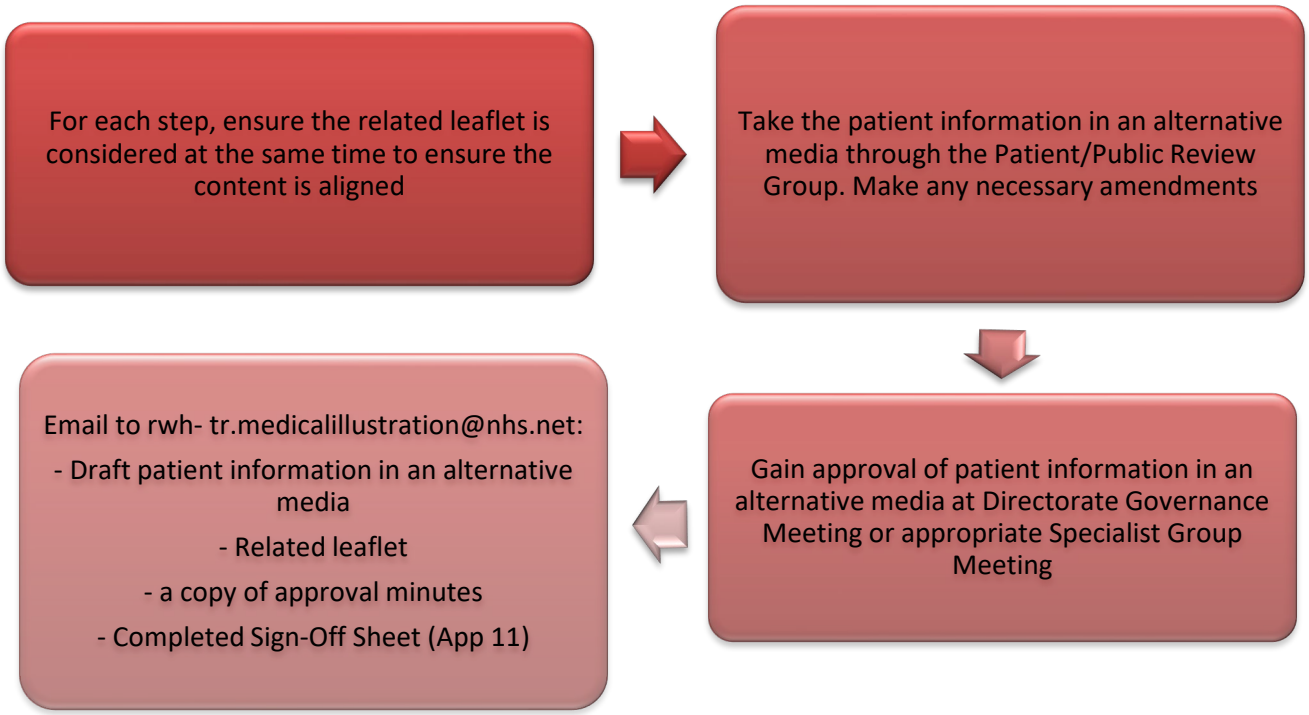
Creating an alternative media:



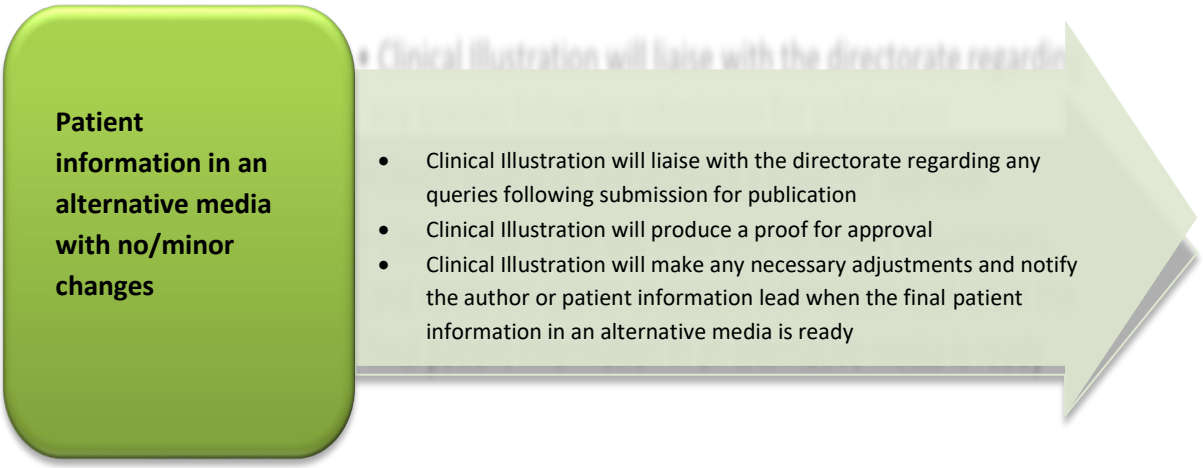
Patient Information

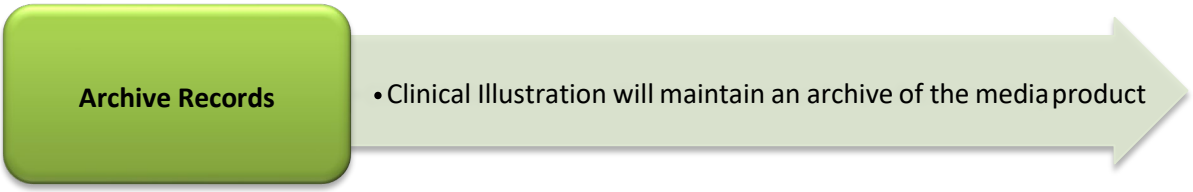
App 05

Directorate review and approval process:



Publication by Clinical Illustration:





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

- under separate headings

- applies to internally produced and externally sourced leaflets

- Obtaining Consent
- Benefits
- Risks - defined as significant risks as well as significant but remote risks
- Alternatives to treatment
- 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 • 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 • Research & Development will therefore be exempt from following the Clinical Patient Information SOP in these instances

Patient Information

App 07

CHECK LIST

PATIENT LEAFLET (New & Review)

Key points to remember when developing a new leaflet or reviewing an existing leaflet:

1. **TITLE OF LEAFLET –** Be mindful of how it will be searched on the internet – so, for example, *'Information about your Laparoscopic Sterilisation Operation'***,** will need to be changed to: **'Laparoscopic Sterilisation'.**

2. **DIRECTORATE –** Ensure this is cited below the title.
   for example, **Gastroenterology – Endoscopy –** Be Mindful again of where to search for the leaflet on internet (by Directorate followed by Department (if applicable)
   For older leaflets please ensure that the Directorate reflects the current Directorate title e.g. '*Obstetrics'* now **Perinatal Services - Maternity**

3. **GRAMMAR** - Correct any Grammar, spelling mistakes, make appropriate paragraphs – ensure good flow. Correct any short forms: 'don't' – change to 'do not', ' ie' change to 'for example', write out numbers up to 9

4. **TERMINOLOGY** - Make sure the terminology and any procedural explanations can be understood by 'lay people' – If you cannot understand, or would want more information before making an informed choice, then this needs to be identified (state what information you would require)

5. **CONSISTENCY** - Ensure consistency throughout the leaflet, with upper and lower case for Professional Titles or reference to Departments. Again, consistency around initials, for example, Computed Tomography (CT) – to then follow on with CT.

6. **ORDER OF CONTENT (Patient Information (Leaflets)** – this must be followed to keep the format of all leaflets consistent:
   - **Introduction**
   - **Description**
   - **CONSENT (if necessary)** – see paragraph, below, to insert – Glean this info. from the sign-off sheet but be aware that the Directorates do not always tick the correct box or may tick two! If you think it is incorrect, challenge the Directorate.

   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.

   - **Benefits**
   - **Risks**
   - **Alternatives**
   - **Before the procedure or treatment**
   - **On the day of the Procedure or treatment**
   - **After the procedure**

- **Discharged home.**
- **Contacts & useful numbers and links**

See Appendices,7, 8, and 9 of the SOP (for Directorates), for further help with order, content, and Quality Assurance.

Link to Internet page: https://www.royalwolverhampton.nhs.uk/patients-and-visitors/patient-information-leaflets/

NHS
The Royal Wolverhampton
NHS Trust

Title

Department

The prevention of infection is a major priority in all healthcare and everyone has a part to play.

- **Please decontaminate your hands frequently for 20 seconds using soap and water or alcohol gel if available**
- **If you have symptoms of diarrhoea and/or vomiting, cough or other respiratory symptoms, a temperature or any loss of taste or smell please do not visit the hospital or any other care facility and seek advice from 111**
- **Keep the environment clean and tidy**
- **Let's work together to keep infections out of our hospitals and care homes.**

English

If you need information in another way like easy read or a different language please let us know.

If you need an interpreter or assistance please let us know.

Lithuanian

Jeigu norėtumėte, kad informacija jums būtų pateikta kitu būdu, pavyzdžiui, supaprastinta forma ar kita kalba, prašome mums apie tai pranešti.

Jeigu jums reikia vertėjo ar kitos pagalbos, prašome mums apie tai pranešti.

Polish

Jeżeli chcieliby Państwo otrzymać te informacje w innej postaci, na przykład w wersji łatwej do czytania lub w innym języku, prosimy powiedzieć nam o tym.

Prosimy poinformować nas również, jeżeli potrzebowaliby Państwo usługi tłumaczenia ustnego lub innej pomocy.

Punjabi

ਜੇ ਤੁਹਾਨੂੰ ਇਹ ਜਾਣਕਾਰੀ ਕਿਸੇ ਹੋਰ ਰੂਪ ਵਿਚ, ਜਿਵੇਂ ਪੜ੍ਹਨ ਵਿਚ ਆਸਾਨ ਰੂਪ ਜਾਂ ਕਿਸੇ ਦੂਜੀ ਭਾਸ਼ਾ ਵਿਚ, ਚਾਹੀਦੀ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

ਜੇ ਤੁਹਾਨੂੰ ਦੁਭਾਸ਼ੀਏ ਦੀ ਜਾਂ ਸਹਾਇਤਾ ਦੀ ਲੋੜ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

Romanian

Dacă aveți nevoie de informații în alt format, ca de exemplu caractere ușor de citit sau altă limbă, vă rugăm să ne informați.

Dacă aveți nevoie de un interpret sau de asistență, vă rugăm să ne informați.

Traditional Chinese

如果您需要以其他方式了解信息，如易读或其他语种，请告诉我们。

如果您需要口译人员或帮助，请告诉我们。

Designed & Produced by the Department of Clinical Illustration,
New Cross Hospital, Wolverhampton, WV10 0QP Tel: 01902 695377.

Patient Information

App 09

FOR DIRECTORATE USE ONLY - NOT REQUIRED TO BE RETURNED TO CLINICAL ILLUSTRATION 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 (has approval been granted where used for consent)?	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

The Royal Wolverhampton NHS Trust

1. DIRECTORATE APPROVAL (all Patient Information)

Title of Patient Information	
MI number (if applicable)	
Care Group / 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: • **No changes or minor clinical or format changes** Please detail amendments you have made:	☐
Review of **existing** Patient Information: • **Moderate / significant clinical or format changes** Please detail amendments you have made:	☐

SECTION 2 – 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 3 - Patient / Public Review (must be completed for internally produced leaflets)	
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 4 - Directorate / Care Group approval

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 Care Group Governance Meeting or Specialist Group Meeting where approval is minuted.

Send copy of minutes to rwh-tr.medicalillustration@nhs.net the email titled with the WHC code number.

Name of Author / Co-ordinator:

Date:

(NB email from Directorate / Care Group Authoriser's email address suffices as electronic signature)

Directorate / Care Group Sign-off: Internal use only

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

Name: _____

(Directorate / Care Group Authoriser)

Date of ratification: _____

(NB email from Directorate / Care Group Authoriser's 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

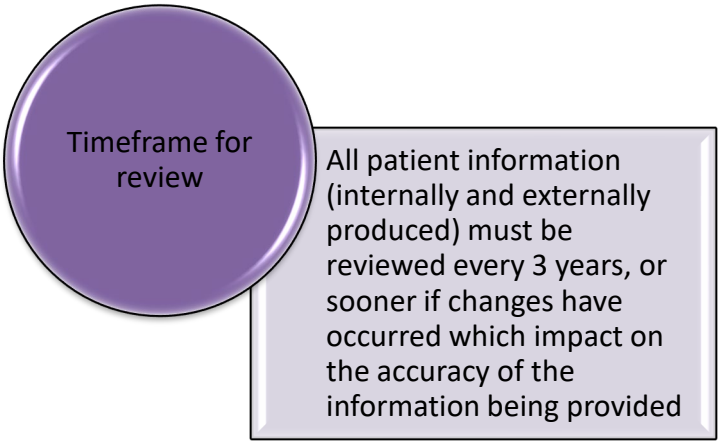
It is important the Trust provides suitable patient/ carer information that meets the needs of the recipient

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) is considered and amended via Clinical Illustration
- To ensure that all relevant documentation is completed and submitted for each patient information