Development and Approval of UHB Local Procedure Specific Patient Information Leaflets Principles and Framework

Introduction and Aim

This guidance aims to set out the principles and framework for the development and approval of Local Procedure Specific Patient Information Leaflets within the UHB, to ensure that they are evidenced based and up to date.

It aims to assist the UHB to comply with its external obligations to meet the standards laid down by Standard 4.2 in the Health and Care Standards for Wales which reinforces the need for people who use health care services to be given information which enables them to make appropriate choices, to make informed decisions about their health and care and which enables them to lead healthier lives.

Objectives

Local Procedure Specific Patient information leaflets where EIDO or nationally recognised alternatives are not available provide particular benefits to enhance the informed consent process and improve patient safety as well as reducing risk for both individual healthcare professionals and the UHB. The particular benefits are;

- Improved communication of the nature of the treatment or procedure as well as risks, benefits and alternatives,
- Standardisation of evidence-based information which is reviewed for readability and meets Welsh Language requirements,
- Clinical teams can agree and develop forms and implement across the Health Board, leading to standardised care delivery across the organisation,
- A standard checklist has been developed at the request of the All Wales Medical Directors Forum to support /inform a local governance framework to develop Local Procedure Specific Patient Information Leaflets for information about procedures, treatments and investigations
- Using Local Procedure Specific Patient Information Leaflets can improve the efficiency of the informed consent process in out-patient clinics or treatment areas so allowing more time for discussion and agreement with patients.

The UHB encourages clinical staff to generate Local Procedure Specific Patient Information Leaflets according to the process set out in this guidance, where this is no EIDO or compliant nationally recognised alternative.

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts who are looking to develop Local Procedure Specific Patient Information Leaflets (LPSPIL)

Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has not been completed, as this procedure has been developed in support of the Consent to Examination or Treatment Policy.

Documents to read alongside this Procedure	Consent to Examination or Treatment Policy, 2023
Approved by	Consent Group

Accountable Executive or Clinical Board Director	Executive Medical Director
Author(s)	Consent Lead
Disclaimer **If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.**	

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	08/10/2024	11/10/2024	New document

Contents

1. ROLES AND RESPONSIBILITIES

Executive responsibility for this procedure lies with the Medical Director.

Clinical Board Directors are responsible for ensuring that staff are aware of this procedure, how to access it and what to do if they have queries about it.

All staff who are involved in the development of Procedure Specific Patient Information leaflets have a responsibility to familiarise themselves with, and follow the content of, this framework and to ensure that they remain up to date with regard to relevant legislation, case law and guidance regarding Consent to Examination or Treatment.

1.1 The Mental Capacity Team/Consent Lead will:

- Ensure that the LPSPIL is compliant with the requirements of this guide namely that the CAVUHB LPSPIL checklist has been adopted
- Keep a register of LPSPIL developed in accordance with this guidance
- Monitor the date that a LPSPIL is due for review
- Archive LPSPIL's that are no longer applicable / in use following a review.

1.2 Specialties

Specialties are responsible for:

- Development and seeking approval and translation of LPSPIL's in accordance with this guidance
- Initiating the review of LPSPIL's
- Conducting the review of LPSPIL' s
- Contacting Medical Illustration in order for them to produce the documentation
- Complying with the framework described in this guidance.

Specialties are responsible for appointing a lead clinician who will identify the necessity for and the development of the LPSPIL

Specialties should at all times endeavour to create a UHB wide LPSPIL in relation to the treatment / procedure. If this is not possible a clear explanation needs to be given when the LPSPIL is submitted to the specialty's relevant Quality and Safety Group for approval.

1.3 Healthcare professionals

Healthcare professionals are responsible for:

- Knowing how to access patient information from the intranet
- Ensuring that their departments keep up to date LPSPILs
- Giving patients LPSPIL's appropriate to their condition and/or treatment and ensuring that the latest version is provided
- Using LPSPIL's to support verbal information given to patients

- Identifying the need to develop LPSPIL's in line with service requirements
- Adhering to this Guidance and to the UHB's Consent to Examination or Treatment Policy.

2. SOURCE OF PATIENT INFORMATION FOR USE WITH ALL WALES CONSENT FORMS AND PROCEDURE SPECIFIC CONSENT FORMS

On 2nd July 2020 the Welsh Risk Pool (WRP) Committee issued a WRP Management Alert, number 2020/01 requiring all Welsh health bodies to use EIDO leaflets, where available, as part of the consent to treatment process. On 3rd December 2020, the Criteria for use of Procedure-specific Patient Information Leaflets following publication of RMA2020-01 was issued.

Therefore, the UHB's first option is the use of EIDO Patient Information documents, which provide detailed information to support and inform consent for specific treatments. They are available on the intranet site to download (EIDO Healthcare (eidosystems.com). These documents will then provide the patient information which is included in the PSCF.

The second option is to use existing nationally produced procedure specific leaflets such as leaflets from the Royal Colleges or Professional Associations, NICE, Cancer Research UK and MacMillan if available

The final option, if there is no EIDO or nationally produced leaflet, is to produce a UHB own patient information leaflet. Such leaflets must be developed in accordance with UHB's guidance for the development of patient information leaflets. The procedure to confirm use of nationally produced patient information leaflets or approval of UHB developed patient information leaflets to the WRP is set out on All Wales Consent to Examination and Treatment Improvement Programme SharePoint page.

3. CHECKLIST FOR WRITING INFORMATION ABOUT PROCEDURES, TREATMENTS AND INVESTIGATIONS

3.1 Local Procedure Specific Patient Information Leaflet Content

The below should be considered and incorporated when developing the local procedure specific patient information leaflet These are not an exhaustive list or designed to provide definitive procedure, and professional judgement within the general scope of this policy must be exercised at all times, as the guidelines may not be appropriate in all contexts. Whilst the procedure refers specifically to patient information leaflets it is also likely to be relevant to other forms of written patient information.

3.1a Checklist for writing information about operations.

- What is the leaflet / document etc about, and who is it for?
- What is the procedure, treatment?
- Why are they having it?
- Do they need a general anaesthetic, sedation or local anaesthetic?
- Include details about intended benefits and significant, unavoidable or frequently occurring risks: during and following the procedure / treatment - Essential
- Indicate that other important (material) risks specific to this patient during and following the procedure / treatment will be discussed with the patient (to be completed at the time that the consent is sought from the patient) - Essential
- Are there any alternatives including no treatment? - Essential
- What preparation do they need or not need?
- Will they be asked to sign a consent form?
- What happens when they arrive at the hospital or the clinic, and who will they meet?
- What does the procedure involve? How long does it last? What does it feel like?
- What happens after the procedure – pain control, nursing checks, stitches etc.
- How long will they stay in hospital?
- Do they need someone with them or any special equipment when they go home?
- What care do they need at home?
- What follow-up care is needed? Do they need to visit their doctor?
- What can go wrong, what signs to look out for and what to do if something goes wrong
- When can they start their normal activities again, for example, driving, sport, sex or work?
- Who can they contact if they have any more questions?
- Tell people where they can find more information, for example, support groups and websites.
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3.1b Checklist for information about conditions and treatments

- What condition is being described?
- What is the leaflet about, and who is it for?
- What causes it? Or, if the cause is not known, say so.
- Does anything increase the risk, for example, age, sex, ethnic origin or a family history of the condition?
- What are the signs and symptoms?
- Are there any tests or examinations needed to confirm the diagnosis?
- What treatments are available? Give brief descriptions.
- What are the side effects and the Significant, Unavoidable or Frequently
- Occurring risks of getting treatment or not getting treatment?
- Indicate that other important (material) risks specific to this patient during and following the procedure / treatment will be discussed with the patient (to be completed at the time that consent is sought from the patient
- What are the next steps?
- What can patients do for themselves?

- Are there other implications, for example, infecting other people?
- Who can they contact if they have any more questions?
- Say where the patient can find more information, for example, support groups and websites.

Checklist for Producing Patient Information

All patient information should be checked against the following questions before it is sent to the MCA Team/Consent Lead.

Does the patient information include?

1. A title

2. Health Board Trust name and logo

3. Identify the Author

4. Date of production

5. Date for review, maximum of 3 years

6. Statement regarding availability of large print, other formats and languages

7. Contact details for further information

8. Statement that the document is also available in Welsh

Is the patient information?

1. Typed in Arial or non-serif font and 12 pitch

2. Written in plain English using everyday words including consistency of terms and tenses

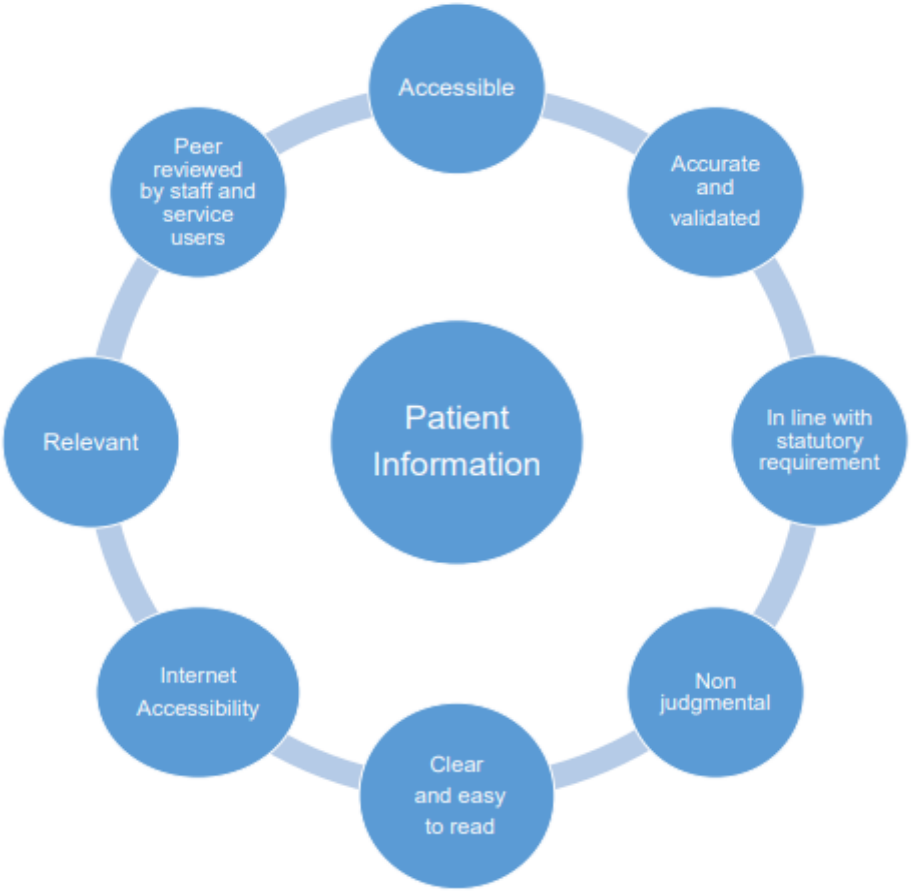
3. Easy to understand (medical terminology explained)

4. Clear - instructions or diagrams easy to understand

Has the patient information been reviewed by a lay-person?

Where possible all information produced for patients, should be shared with a member of that patient population prior to panel, and feedback sought

Figure 1 - Requirements for Service User and Carer Information



Ensure the information is:

- Accessible: The information provided must ensure that our patients, service users and carers are aware of alternative formats of information with the consideration on the Equality Act (2010), Information for People with Sensory Loss (WG, 2013), All Wales Standards for Accessible Communication and the Accessible Information Standards (2017).

- Accurate and Validated: All information must be factual and commensurate with the treatment pathway. If clinical information is included, then this must be approved prior to its inclusion on the panel. The information should provide adequate resources and include further reading in line with the NHS Wales Information Governance Policy (2018).

- Current: All information should be up to date with current policy and legislation in line with GDPR.

- Balanced and Non-judgmental: Allowing our patients, service users and carers to make effective decisions by providing them with relevant and balanced information. The provision of such enables the understanding of the

options and choices associated with their treatment, including their side effects and wider implications

- Internet Accessibility: All public sector websites in the UK must comply with WCAG 2.11 AA standards. These standards recommend that all documents housed on websites meet the necessary accessibility checks before being published online. These include clear and simple instructions and the ability to link alternative pages for additional information.

- Relevant: Produce information, which targets its audience, through clear, concise and easy to read formats. Do not include any unnecessary information.

- Peer Reviewed: Relevant professionals, patients and the public representatives should review the information in order to ensure that the information is fit for the purpose which it is intended and that the views of key stakeholders underpin this process. Any BCUHB developed procedure specific patient information leaflet which involves the consent to treatment processes will be passed back to the author to establish if this material already exists on the EIDO Inform TM Download Centre or whether there is a professionally recognised patient information leaflet , which has been produced using a consistent national approach. This may therefore include procedure-specific leaflets from the Royal Colleges or Professional, Associations, NICE, Cancer Research UK and MacMillan.

3.2 The law on consent to treatment

All clinical staff should have regard to the judgement in the case of:
Montgomery –v- Lanarkshire Health Board Montgomery Update &
Supreme Court Update

Following this case, **clinical staff are reminded of their professional responsibility to take "reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments." The test of whether a clinician acted in accordance with a responsible body of medical practitioners (The Bolam Test) should no longer be applied in relation to consent to treatment and clinical staff should move away from the percentage risk of an occurrence as set out in Chester v Afshar.**

Clinical staff must decide what counts as a "material risk" to the patient in question. The test of materiality is fact and patient sensitive. The law defines it as either a risk to which a reasonable person in the patient's position would be likely to attach significance to or a risk that a doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and consent must be obtained before treatment.

This standard of consent is similar to that required in GMC Guidance – Decision making and Consent – 9th November 2020.

You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action. You should tailor the discussion to each individual patient, guided by what matters to them, and share information in a way they can understand See GMC Guidelines Decision making and Consent - Consent (sharepoint.com)

Doctors must now be satisfied of all of the following:

- The patient knows about the material risks of the treatment proposed
- The patient knows about reasonable alternatives to this treatment
- He / She has taken reasonable care to ensure that the patient actually understands all this
- Whether any of the exceptions to the duty to disclose apply here

The three exceptions to the duty to disclose are.

- The patient tells the doctor that he or she prefers not to know the risks.
- The doctor reasonably considers that telling the patient something would cause serious harm to the patient's health.
- Consent is not required because the patient requires urgent treatment and is unconscious or lacks capacity.

3.3 Process for developing a new locally produced specific patient information leaflet

(please read in conjunction with Appendix 1)

a) Getting started - Authors must use the All Wales LPSPIL checklist to develop their LPSPIL (Appendix 2).
b) Review of the draft by users – by the relevant specialty's reader panel (stakeholder reference group & virtual editorial panel)
c) Specialty approval –The LPSPIL should then be ratified by the specialty's relevant clinical governance group
d) Final approval – All LPSPIL's should be sent to the Consent Lead for review and taken to the Consent Group for final ratification
e) Translation – the author or the specialty identified lead Clinician (if different) should contact CAV Welsh translation team via CAV Welsh translation page Alternatively, go to Cardiff Council - Bilingual Cardiff Translation Request
f) Leaflets should be sent to Medical Illustration for design support (this service is free of charge within the UHB)
g) Publication
   - Links to both English and Welsh versions of the form should be available on the relevant specialty's SharePoint page
   - If it is necessary to have hard copies, request should be made to Medical Illustration for printing to ensure quality and that the most up to date version is provided.

- There may be circumstances when it is necessary to pre-print forms, in bulk, in A4. In this situation, authors should agree this within their specialty. The specialty is responsible for all printing costs.

3.4 Archive

All forms that are out of date and which have been superseded by a newer version will be archived by the Consent Lead A copy of each form will be archived including a copy of any revised forms which may be electronic or paper copies. Copies of revised forms will be retained in line with the Health Board's Record Management Policy.

3.5 Review

The LPSPIL should be reviewed by the relevant specialty every three years following the publication date or earlier in light of new evidence / information. It is the specialty's responsibility to ensure that this is done.

Any errors in the LPSPIL should be recorded and corrected by the author before being sent for review at the specialty's relevant clinical governance group for ratification.

If significant changes are made to the content of the form, the form should be re-sent to the Consent Lead for review, prior to translation.

3.6 Audit

Audit of LPSPILs is required in order to ensure that the documents developed are appropriate and that their development is compliant with this guidance. Clinical audit of the use and completion of the LPSPIL should be undertaken by the relevant specialty.

4. EQUALITY INCLUDING WELSH LANGUAGE

An Equality Impact Assessment has not been carried out as this procedure has been developed in support of the UHB's Consent to Examination or Treatment Policy. There is no evidence that the Consent Policy adversely affects any of the equalities groups and it is neither directly nor indirectly discriminatory under the equalities legislation.

When producing a LPSPIL, authors will need to consider the needs of different groups of people. These groups will include people whose first language is not English or Welsh and people with sight or learning difficulties. People with learning difficulties may need a healthcare professional to go through the leaflet with them, especially if the leaflet has not been specifically designed for people

with learning difficulties. The Mental Capacity Act 2005 requires clinicians to optimise every patient's ability to make decisions.

The UHB is committed to providing information to patients in a range of formats i.e. other languages, easy read and other formats (including audio).

The guidance advises on use of the Welsh Language where appropriate. The PSCF template has been designed to be bilingual, thus supporting the taking of consent in the Welsh language.

5. TRAINING

All Staff developing LPSPIL's and seeking consent from patients should undertake Consent training. This is available through ESR via the NHS Wales Consent to Examination and Treatment E-learning Programme and classroom sessions provided by the Mental Capacity Team/ Consent Lead.
It is recommended that relevant staff undertake Consent training once within each revalidation cycle.

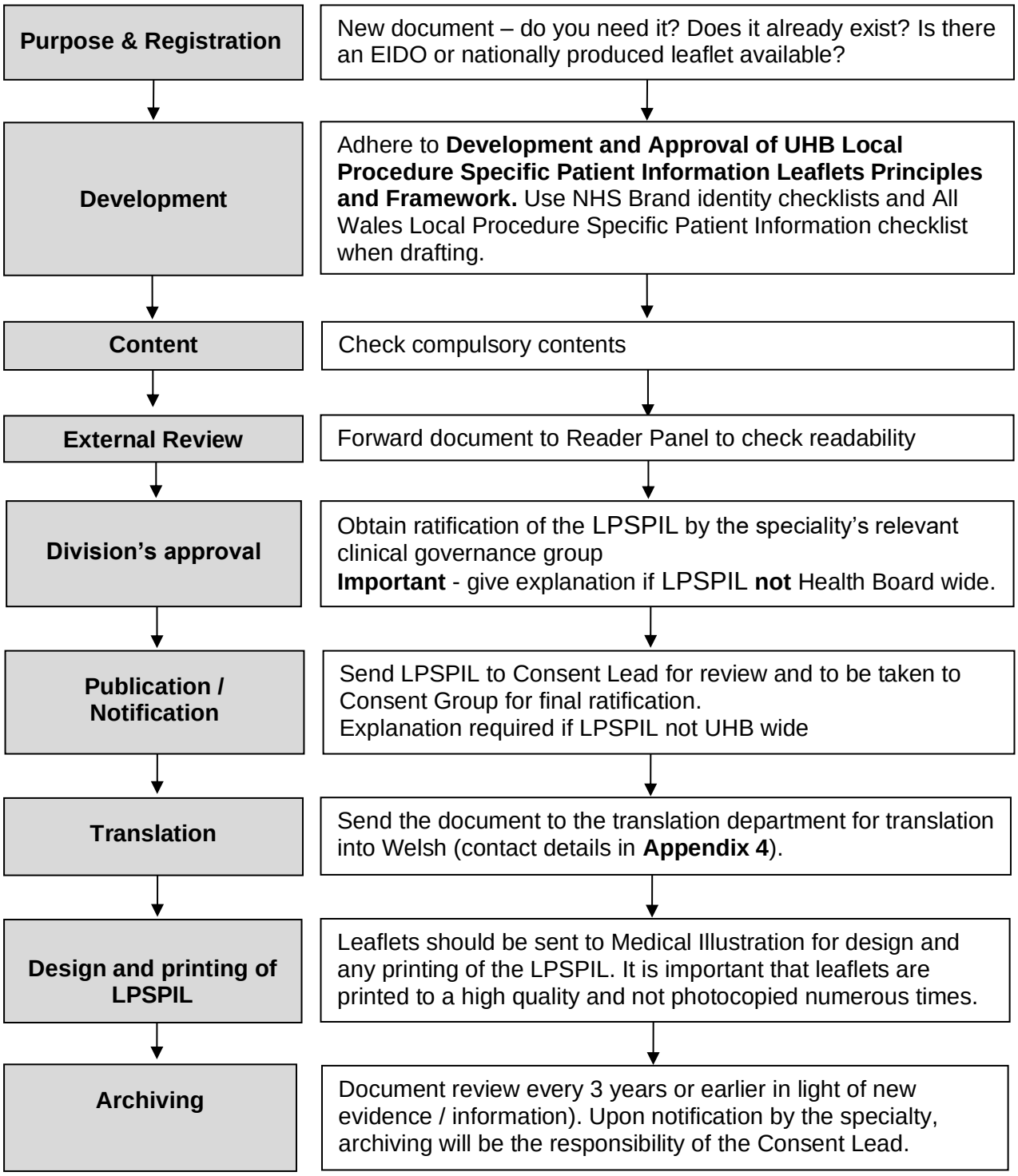
6. DISTRIBUTION

This procedure will be made available on the UHB's SharePoint site.

7. REVIEW OF THIS GUIDANCE

This procedure will be reviewed every three years or sooner if appropriate.

Example Appendix 1 – Locally produced specific patient information leaflet: Summary of Process



Appendix 2

Rhaglen Cydsynio i Driniaeth Cymru Gyfan

All Wales Consent to Treatment Programme

Example checklist - Local Procedure Specific Patient Information to be used in the consent to examination and treatment process

This checklist has been developed at the request of the All Wales Medical Directors Forum to support / inform a local governance framework to develop local procedure specific patient information where there is no appropriate EIDO leaflet or compliant nationally recognised alternative.

The following checklist provides a list of possible subheadings that you should consider when developing written patient information. This is not an exhaustive list and professional judgement within the general scope of this guidance must be exercised at all times, as the information may not be appropriate in all contexts.

Checklist for writing information about procedures, treatments and investigations

- What is the leaflet / document etc about, and who is it for?
- What is the procedure, treatment or investigation?
- Why are they having it?
- Do they need a general anaesthetic, sedation or local anaesthetic?
- Include details about intended benefits and significant, unavoidable or frequently occurring risks: during and following the procedure / treatment - **Essential**
- Indicate that other important (material) risks specific to this patient during and following the procedure / treatment will be discussed with the patient (to be completed at the time that the consent is sought from the patient) - **Essential**
- Are there any alternatives including no treatment? - **Essential**
- What preparation do they need or not need?
- Will they be asked to sign a consent form?
- What happens when they arrive at the hospital or the clinic, and who will they meet?
- What does the procedure involve? How long does it last? What does it feel like?
- What happens after the procedure – pain control, nursing checks, stitches etc.
- How long will they stay in hospital?
- Do they need someone with them or any special equipment when they go home?

- What care do they need at home?
- What follow-up care is needed? Do they need to visit their doctor?
- What can go wrong, what signs to look out for and what to do if something goes wrong.
- When can they start their normal activities again, for example, driving, sport, sex or work?
- Who can they contact if they have any more questions?
- Tell people where they can find more information, for example, support groups and websites

Appendix 3

Guidance to health professionals

(to be read in conjunction with the Consent Policy)

The form should act as an *aide-memoire* to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. **In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.**

The law on consent

See the Welsh Government's Reference *guide to consent for examination or treatment* (www.wales.nhs.uk/consent).

Provision of Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds.

The patient should be informed about important (material) risks. Materiality is whether, in the circumstances of the particular case

- **A reasonable person in the patient's position would be likely to attach significance to the risk, or**
- **The doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.**
-

Health professionals should make a record of the information given. Further advice is given in the GMC guidance on consent.

You should always answer questions honestly. If there is insufficient space on the consent form to include all the details discussed, these should be documented in full in the patient's notes.

Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. To give valid consent the patient needs to understand in broad terms the nature and purpose of the procedure. Where information is refused, you should document this on the form or in the patient's notes.

Appendix 4

Canllaw i staff proffesiynol iechyd

(i'w ddarllen ar y cyd â'r Polisi Cydsynio)

Beth yw pwrpas ffurflen gydsynio?

Mae'r ffurflen hon yn dogfennu cytundeb y claf i fynd ymlaen â'r archwiliad neu driniaeth rydych chi wedi'i gynnig/chynnig. Nid yw'n hawlildiad cyfreithiol – os na fydd cleifion, er enghraifft, yn cael digon o wybodaeth i seilio eu penderfyniad arni, mae'n bosibl na fydd y cydsyniad yn ddilys, er bod y ffurflen wedi cael ei llofnodi. Mae gan gleifion hefyd yr hawl i newid eu meddwl ar ôl llofnodi'r ffurflen (cyn belled bod yr unigolyn yn parhau i fod â'r gallu meddyliol i wneud y penderfyniad hwn). Os bydd y claf wedi colli galluedd meddyliol cyn i'r driniaeth ddechrau, dylai gweithwyr iechyd proffesiynol ystyried a yw'r driniaeth er ei fudd neu beidio.

Dylai'r ffurflen fod yn *gymorth cof* i weithwyr iechyd proffesiynol a chleifion, trwy ddarparu rhestr wirio o'r math o wybodaeth dylid ei chynnig i gleifion, a thrwy alluogi'r claf i gael cofnod ysgrifenedig o'r prif bwyntiau a drafodwyd. **Fodd bynnag, ni ddylid ystyried yr wybodaeth ysgrifenedig mewn unrhyw ffordd fel rhywbeth sy'n cymryd lle trafodaethau wyneb-yn-wyneb â'r claf.**

Dim ond dan amgylchiadau clinigol penodol ddylai staff proffesiynol iechyd dderbyn cydsyniad, yn dilyn ymgymryd â hyfforddiant ffurfiol, gan gynnwys cydsynio a gallu meddyliol a'u bod wedi'u hasesu'n alluog. Dylent gyfarwyddo eu hunain gydag unrhyw ganllaw proffesiynol priodol, polisi cydsynio'u sefydliad a chanllaw Llywodraeth Cymru ar gydsynio.

Y gyfraith ar gydsyniad

Gweler canllaw Cyfeirio *Llywodraeth Cymru at gydsyniad ar gyfer archwiliad neu driniaeth*). http://www.wales.nhs.uk/sitesplus/documents/1064/Welsh%20Government%20Guide%20to%20Consent%20for%20Examination%20or%20Treatment%20%28July%202017%29.pdf

Darparu Gwybodaeth

Mae gwybodaeth am yr hyn bydd y driniaeth yn ei chynnwys, ei buddion a'i risgiau (gan gynnwys sgîl-effeithiau a chymhlethdodau) a'r dewisiadau amgen i'r weithdrefn benodol a gynigiwyd, yn hanfodol i gleifion wrth iddyn nhw wneud penderfyniad.

Dylid hysbysu'r claf am risgiau (perthnasol) pwysig. Mae perthnasedd yn golygu, dan amgylchiadau'r achos dan sylw

- **Byddai unigolyn rhesymol yn sefyllfa'r claf yn debygol o allu cysylltu arwyddocâd i'r risg, neu**
- **Dylai/mae'r meddyg yn rhesymol ymwybodol bod y claf penodol yn debygol o allu cysylltu arwyddocâd iddo.**

Dylai staff proffesiynol gofnodi'r wybodaeth a roddwyd. Rhoddir cyngor pellach yng nghanllawiau'r GMC ar gydsyniad.

Dylech bob amser ateb cwestiynau'n onest. Os nad oes digon o le ar y ffurflen gydsynio i gynnwys yr holl fanylion a drafodwyd, dylid eu dogfennu'n llawn yn nodiadau'r claf.

Weithiau, bydd cleifion yn mynegi'n glir nad ydyn nhw eisiau cael unrhyw wybodaeth am yr opsiynau, ond eisiau i chi benderfynu ar eu rhan. Mewn achosion fel hyn, dylech wneud eich gorau i sicrhau bod y claf yn cael gwybodaeth sylfaenol iawn o leiaf am yr hyn a gynigir. Er mwyn rhoi cydsyniad dilys, mae angen i'r claf ddeall natur a phwrpas y weithdrefn yn

gyffredinol. Pan fydd claf yn gwrthod gwybodaeth, dylech ddogfennu hyn ar y ffurflen neu yn nodiadau'r claf.

Appendix 5 - Contact Details

Consent Lead, Safeguarding - Tel: 029 2183 2001

Head of Corporate Governance - Tel: 029 21836691

Appendix 6- Approval of UHB Local Procedure Specific Patient Information Leaflets (Form to be sent with final version of Local Procedure Specific Information Leaflet)

Title of Document	
Name of Lead Clinician (identified by specialty – *responsible for clinical information content*) Base: Phone Number: Email: Signature:	
Name of main author (if different to above): Base: Phone Number: Email:	
Reader Panel Approved	Date
EIDO Healthcare Patient Information Leaflet title and document reference / Nationally recognised Patient Information Leaflet document title / Health Board developed leaflet (If applicable). Please provide link / attach the relevant leaflet here:	
Does the LPSPIL apply Health Board wide? **If no, please explain why**	Yes / No
Attach minutes of the relevant Clinical Governance Group ratifying the LPSPIL here	Date of meeting:
Attach electronic version of the LPSPIL here	
Review Date:	

This form should be forwarded to the Consent Lead at: mca-lps.cav@wales.nhs.uk