Development and Approval of UHB Procedure Specific Consent Forms Principles and Framework

Introduction and Aim

This guidance aims to set out the principles and framework for the development and approval of Procedure Specific Consent Forms (PSCFs) 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

PSCFs 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 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 UHB, leading to standardised care delivery across the organisation,
- The template is standard and compliant with All Wales Consent Form 1,
- Using PSCFs can improve the efficiency of the informed consent process in out-patient clinic or treatment areas so allowing more time for discussion and agreement with patients.

The UHB encourages clinical staff to generate PSCFs according to the process set out in this guidance.

Scope

This framework applies to all our staff in all locations including those with honorary contracts who are looking to develop PSCFs.

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	26/11/2024	28/11/2024	New document

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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 Consent Forms have a responsibility to familiarise themselves with, and follow the content of, this framework and to ensure that they remain up to date regarding relevant legislation, case law and guidance regarding Consent to Examination or Treatment.

1.1 Consent Lead

The Consent Lead will:

- Ensure that the PSCF is compliant with the requirements of this Guide – namely that the CAVUHB (Cardiff and Vale University Health Board) PSCF template has been adopted
- Keep a register of PSCF's developed in accordance with this guidance
- Monitor the date that a PSCF is due for review
- Archive PSCF'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 PSCFs in accordance with this guidance
- Initiating the review of PSCFs
- Conducting the review of PSCFs
- 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 PSCF.

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

1.3 Healthcare professionals

Healthcare professionals are responsible for:

- Knowing how to access patient information from SharePoint
- Ensuring that their departments keep up to date PSCFs
- Giving patients PSCFs appropriate to their condition and/or treatment and ensuring that the latest version is provided
- Using PSCFs to support verbal information given to patients
- Identifying the need to develop PSCFs 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 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 Development and Approval of UHB Local Procedure Specific Patient Information Leaflets Principles and Framework.

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 in All Wales Consent to Examination and Treatment Improvement Programme SharePoint page.

3. PROCEDURE SPECIFIC CONSENT FORM TEMPLATE

3.1 Compulsory content

The **All-Wales Procedure Specific Consent Form template (Appendix 2 (English) and 4 (Welsh))** contains the content / matters for discussion during the consent process which must be included in all PSCFs.

This includes the following sections which require completion:

(a) Title of Procedure Specific Consent Form
(b) In relation to the treatment / procedure the:
- Benefits,
- Risks (any significant, unavoidable, or frequently occurring side effects)
- Other important (material) risks specific to the actual patient being consented
- Alternatives for the treatment or procedure
- What the procedure is likely to involve
- Any particular concerns of the patient

(c) Details of further information and documentation provided to the patient e.g. full title of any patient information leaflet or DVD in relation to the procedure that has been handed to the patient.
(d) Patient's statement and signature
(e) Health professional's confirmation and signature

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 & **McCulloch v Forth Valley 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 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.

Doctors must now be satisfied of all 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.

Further information can be found on this case and Consent to Treatment at Consent (sharepoint.com).

3.3 Process for developing a new Procedure Specific Consent Form (please read in conjunction with Appendix 1)

a) Getting started - Authors must use the All-Wales PSCF template to develop their PSCF (Appendix 2 and 3). Note – Sections / text on this form which are not relevant to the procedure / treatment can be deleted when developing the template form – see guidance on the first page of the template.
b) Review of the draft by users – by the relevant specialty's reader panel (stakeholder reference group & virtual editorial panel)
c) Specialty approval –The PSCF should then be ratified by the specialty's relevant Clinical Governance Group
d) Final approval – All PSCFs should be sent to the Consent Lead for review before being taken to the Health Board's Consent Group for final ratification.
e) Translation – the author or the specialty identified Lead Clinician (if different) shall send the English PSCF to CAV's Welsh Translation Service Welsh Translation Services
f) Publication
   - Links to both English and Welsh versions of the form should be available on the relevant specialty's SharePoint page
   - Once completed, the PCSF should be sent to Medical Illustration for printing. This will ensure management of version control and quality of the forms. 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 PSCF 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 PSCF should be recorded and corrected by the author before being sent for review at the specialty's relevant clinical governance group.

If significant changes are made to the content of the form, the form should be re-sent to the Consent Lead for initial review and will be taken to the Consent Group for final ratification.

3.6 Audit

Audit of all PSCFs 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 PSCF 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 PSCF, 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 PSCFs 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.

It is recommended that relevant staff undertake Consent training once within each revalidation cycle.

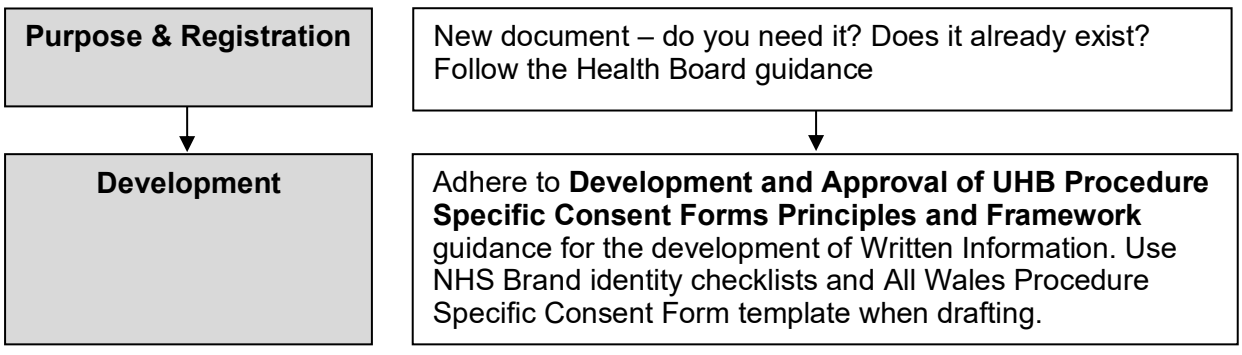
6. DISTRIBUTION

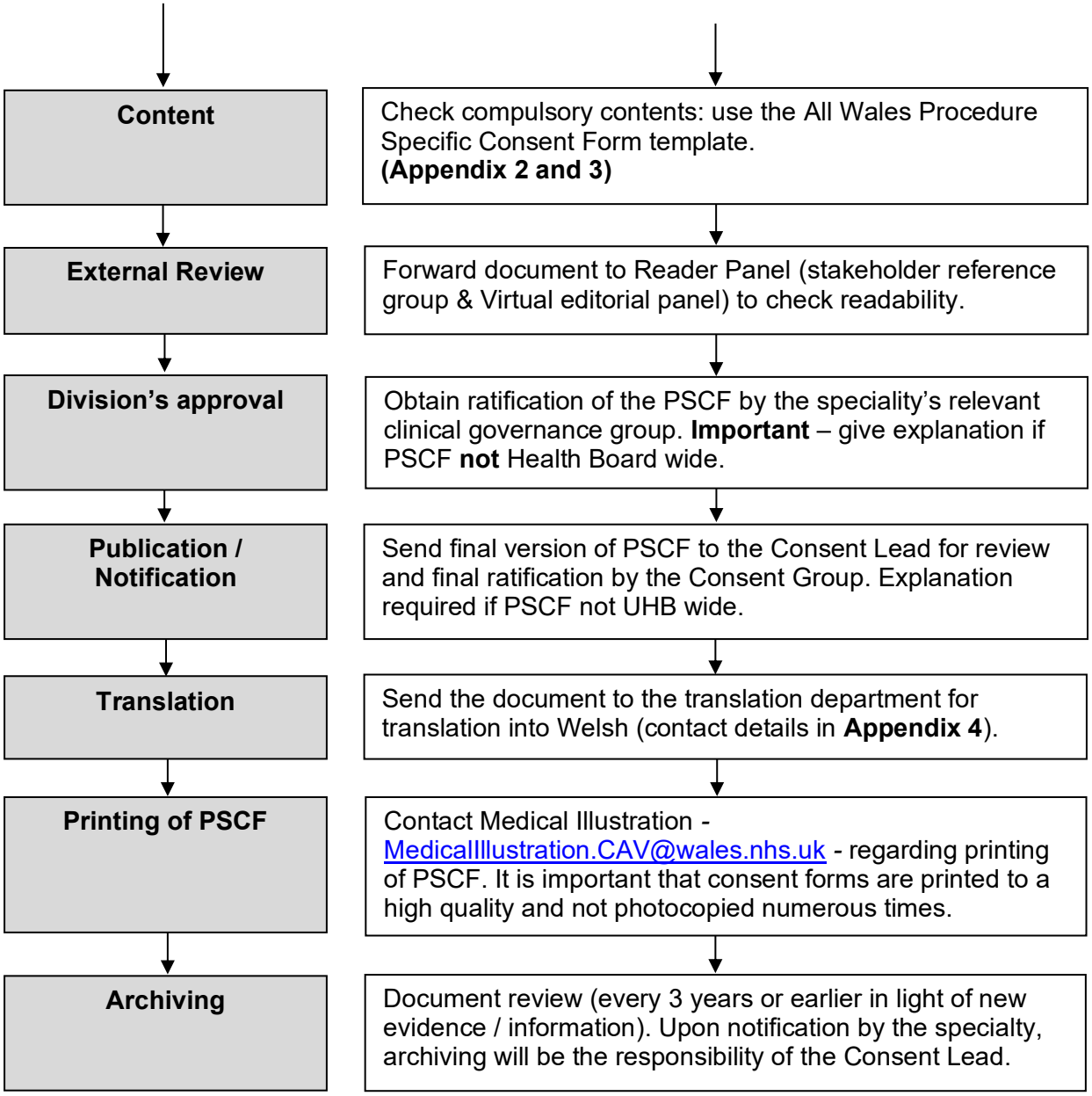
This procedure will be made available on the UHB's SharePoint site.

7. REVIEW OF THIS GUIDANCE

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

Example Appendix 1 - Procedure Specific Consent Forms - Summary of Process




Content
Check compulsory contents: use the All Wales Procedure Specific Consent Form template. (Appendix 2 and 3)
External Review
Forward document to Reader Panel (stakeholder reference group & Virtual editorial panel) to check readability.
Division's approval
Obtain ratification of the PSCF by the speciality's relevant clinical governance group. Important – give explanation if PSCF not Health Board wide.
Publication / Notification
Send final version of PSCF to the Consent Lead for review and final ratification by the Consent Group. Explanation required if PSCF not UHB wide.
Translation
Send the document to the translation department for translation into Welsh (contact details in Appendix 4).
Printing of PSCF
Contact Medical Illustration - MedicalIllustration.CAV@wales.nhs.uk - regarding printing of PSCF. It is important that consent forms are printed to a high quality and not photocopied numerous times.
Archiving
Document review (every 3 years or earlier in light of new evidence / information). Upon notification by the specialty, archiving will be the responsibility of the Consent Lead.

Appendix 2- Template Procedure Specific

Consent Form

Rhaglen Cydsynio i Driniaeth Cymru Gyfan

All Wales Consent to Treatment Programme

All Wales Model Procedure Specific Consent Form Template

Important – please read all paragraphs

- This procedure specific consent form (PSCF) template is based upon the content of All Wales Consent Form 1 and is compliant with the legal framework for consent to examination and treatment. Health Boards / Trusts can prepopulate this template with information relating to a procedure / treatment and use it during the consent process.

- Wording highlighted in grey requires the author to delete or insert text when developing the PSCF.

- Sections / text highlighted in yellow on this template which are not relevant to the procedure / treatment in question may be deleted when developing the PSCF form.

- Sections / text highlighted in red wich are not relevant to young people aged 16 years and over with mental capacity or children under 16 years of age who are Gillick competent may be deleted when developing the PSCF form.

- All other text / sections are essential.

- There is a Welsh version of this template. The form once developed must be translated into Welsh and must be offered to all Welsh speaking patients.

- The PSCF is supported by the Guidance for professionals attached to All Wales Consent Form 1.

- Important - This page does not form part of the PSCF and should be deleted once the form has been drafted.

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Procedure Specific Consent Form

Based on Consent Form 1: Patient agreement to examination or treatment

Patient details (or pre-printed label)

Patient's surname/family name .....
Patient's first names .....
Date of birth .....
☐ Male ☐ Female
NHS Number (or other identifier) .....

This form is to be used for people aged 16 years and over with mental capacity and people under 16 years of age who are Gillick competent. **Please press hard and ensure all three copies are legible.**

Special requirements (e.g. other language/other communication method)

.....

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)

.....

.....

Anaesthetic: This procedure will involve:

☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation ☐ None

Any extra procedures which may become necessary during the procedure:

☐ None expected ☐ Blood transfusion .....

☐ Other procedure (specify) .....

Statement of health professional

(health professional must have appropriate knowledge of proposed procedure)

People aged 16 years and over (are presumed to have capacity to consent to treatment). Please tick ONE box:

☐ *In my opinion there are no reasons to doubt the patient's capacity to make this decision;* ***OR***

☐ *The patient's mental capacity to consent to/refuse this treatment has been assessed and the patient has the mental capacity to make this decision. A note of the assessment has been placed on the patient's record.*

People under 16 years of age

☐ After a full explanation of the procedure and its risks and benefits, I believe that the child has sufficient maturity and intelligence to be capable of understanding fully the treatment proposed and making a decision based on the information provided. I therefore believe that the patient **is Gillick competent** to make this decision.

The child has ☐ ***agreed*** */* ☐ ***declined*** *to involve someone with parental responsibility in this decision.*

Advance decisions (for patients aged 18 years and over only)

☐ *The patient has made a valid and applicable advance decision refusing this treatment/procedure or a treatment or procedure which may become necessary during the treatment/procedure in question.*
(Ensure the patient completes full details in the Advance decisions section on the opposite page.)

Information about the procedure/treatment

I have explained the procedure to the patient. In particular, I have explained:

Intended benefits: .....

.....

Significant, unavoidable or frequently occurring risks, including any risks of particular significance to this patient:

During the procedure/treatment: .....

Following the procedure/treatment: .....

Other important (material) risks specific to this patient during and followingthe procedure / treatment (to be completed at the time that consent is sought from the patient):

.....

.....

I have also discussed:

☐ what the procedure is likely to involve
☐ any particular concerns of this patient
☐ the benefits and risks of any available alternative treatments (including no treatment)

Please include details: .....

☐ I have provided the following leaflet/CD/DVD/weblink: *[specify title of the leaflet and date of issue; title of CD/DVD and "version" if it's been amended]*

.....

☐ Check leaflet/CD/DVD/weblink title/date/version identical to the above. If different note below:

.....

Signed ..... **Date** .....

Name *(PRINT)* ..... **Job Title** .....

Professional registration number *(e.g GMC, NMC, GDC, HCPC, etc)* .....

Contact details *(if patient wishes to discuss options later)* .....

Statement of interpreter

(where appropriate). I have interpreted the above information to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ..... **Date** .....

Name *(PRINT)* ..... **Contact details** .....

Statement and signature of patient

You will be offered a copy of this form. If you have any further questions, do ask – we are here to help you. **You have the right to change your mind at any time**, including after you have signed this form.

I understand:

- the information that I have been given about the examination or treatment described on this form.
- that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)
- that any procedures *in addition* to those described on this form and which are not the subject of an advance decision (see below) will only be carried out if it is necessary to save my life or prevent serious harm to my health.

I agree to the procedure or course of treatment described on this form.

I do / do not agree* that students may be present during the procedure (*please delete as appropriate).

Advance decisions (for patients aged 18 years and over only)

☐ I have previously made an advance decision refusing this treatment or procedure, but have now changed my mind and am happy to have the treatment/procedure described on this form.

☐ I have an existing advance decision refusing a treatment/procedure which may become necessary during the treatment/procedure described on this form. This includes:

.....

(if this advance decision is in writing, file a copy in the medical record. If it is verbal, make detailed notes. If it refuses life sustaining treatment it must be in writing, signed, dated, witnessed and clearly state that the decision applies even if the patient's life is at risk).

☐ I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion, even if not performing such procedures immediately could or would lead to serious permanent injury or death.

.....

.....

Patient's signature ..... **Date** .....

Name *(PRINT)* .....

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signature ..... **Date** .....

Name *(PRINT)* ..... **Relationship to patient** .....

Confirmation of consent

(to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed ..... **Date** .....

Name *(PRINT)* ..... **Job title** .....

Professional registration number *(e.g. GMC, NMC, GDC, HCPC, etc)* .....

I confirm that I still want the procedure/treatment to go ahead.

Patient's signature ..... **Date** .....

Name *(PRINT)* .....

Patient has withdrawn consent

Ask patient to sign/date here and write **"VOID"** across all pages of the form.

Patient's signature ..... **Date** .....

Name *(PRINT)* .....

Top copy of form must be retained in the patient's notes.
Copy offered to patient: Welsh copy / English copy / Declined by patient (please circle)

Appendix 3

Guidance to health professionals
(to be read in conjunction with the Consent Policy)

What a consent form is for

This form documents the patient's agreement to go ahead with the examination or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, (provided the person retains mental capacity for making this decision). If the patient has lost mental capacity before the treatment starts health professionals should consider whether or not the treatment is in their best interests.

The form should act as an *aide-memoire* to health professionals and patients, by providing a checklist 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.**

Health professionals should only take consent in specific clinical situations where they have undertaken formal training including on consent and mental capacity and have been competency assessed. They should familiarise themselves with any appropriate professional guidance, their organisation's consent policy and Welsh Government's guidance on consent.

The law on consent

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

Who can give consent

Everyone aged **16 or more** is presumed to have the mental capacity to give or refuse consent for themselves unless the opposite is demonstrated. However, this does not apply to interventions that do not confer a direct health benefit on the young person such as the donation of blood and tissue (other than for diagnostic purposes). For young persons (aged 16-17) who wish to undergo such "interventions" an assessment of their capacity to give consent will be required.

If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed and make a decision based on the information provided" (*Gillick* competence), then he or she will be competent to give consent for himself or herself (NB. Consent and refusal by competent minors are not seen by the law as entirely symmetrical in that a *Gillick* competent child can lawfully consent but a refusal may be over-ridden). Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so.

Young people aged 16 and 17, and *Gillick* competent younger children, may therefore sign this form for themselves, but may like a parent to countersign as well.

If the child under the age of 16 is not able to give consent for himself or herself, someone with parental responsibility may do so on their behalf and a separate form (Consent Form 2) is available for this purpose.

If a patient has the mental capacity to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient is **16 or over** and lacks the mental capacity to give consent, you should use *Form 4 - Treatment in best interests* instead of this form. A patient lacks mental capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot do one or more of the following:

- understand information about the decision to be made;
- retain that information;
- use or weigh that information as part of the decision-making process; or
- communicate their decision (by talking, using sign language or any other means).

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so.

Relatives **cannot** be asked to sign a form on behalf of an adult who lacks mental capacity to consent for themselves, unless they have been given the authority to do so under a Personal Welfare Lasting Power of Attorney or they are a Court appointed Deputy with the relevant authority.

Consent Form 2 should be used in respect of children aged under 16 who are not Gillick competent.

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 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.

Pre-registration students

The Welsh Government Reference Guide for Consent to Examination or Treatment requires a patient's written consent if pre-registration students are to be present during examination or treatment using sedation or anaesthetic. Patients are, therefore, asked if they agree or disagree with students being present.

Welsh Language
Health professionals should ask the patient whether they speak Welsh and tick the relevant box on the form. If the patient does speak Welsh, a Welsh medium copy of this form should be offered to the patient. The health professional should initial to say that this has been done.

Patients who wish to give consent in Welsh should be given the opportunity to read the Welsh version of the form before signing the English copy of the form. It is essential, for patient safety, that the English version of the form is the one filed in the patient's case notes.

Other All Wales Consent Forms

FORM 2
Agreement of person with parental responsibility to examination or treatment for a child under 16 years of age who is not *Gillick* competent.

FORM 4
Treatment in best interests: Form for patients aged 16 years and over who may lack the capacity to consent to examination or treatment.

(FORM 3 has been discontinued)

Appendix 4 – Templed Ffurflen Cydsynio

I Driniaeth Benodol

Rhaglen Cydsynio i Driniaeth Cymru Gyfan

All Wales Consent to Treatment Programme

Templed Ffurflen Cydsynio i Driniaeth Benodol Enghreifftiol Cymru Gyfan

Pwysig - darllenwch bob paragraff

- Mae'r templed ffurflen cydsynio i driniaeth benodol (PSCF) hwn yn seiliedig ar gynnwys Ffurflen Gydsynio 1 ar gyfer Cymru Gyfan ac mae'n cydymffurfio â'r fframwaith cyfreithiol ar gyfer cydsynio i archwiliad a thriniaeth. Gall Byrddau Iechyd / Ymddiriedolaethau lenwi'r templed hwn ymlaen llaw gyda gwybodaeth sy'n ymwneud â thriniaeth a'i defnyddio yn ystod y broses gydsynio.

- Mae'r geiriad sydd wedi'i uwcholeuo'n llwyd yn ei gwneud yn ofynnol i'r awdur ddileu neu fewnosod testun wrth ddatblygu'r PSCF.

- Gellir dileu adrannau / testun sydd wedi'i uwcholeuo'n felyn ar y templed hwn nad ydynt yn berthnasol i'r driniaeth dan sylw wrth ddatblygu'r ffurflen PSCF.

- Gellir dileu adrannau / testun sydd wedi'i uwcholeuo'n goch nad ydynt yn berthnasol i bobl ifanc 16 oed a throsodd sydd â galluedd meddyliol neu blant o dan 16 oed sy'n gymwys yn ôl safon Gillick wrth ddatblygu'r ffurflen PSCF.

- Mae pob testun / adran arall yn hanfodol.

- Unwaith y caiff ei datblygu, rhaid cyfieithu'r ffurflen i'r Gymraeg a rhaid ei chynnig i bob claf sy'n siarad Cymraeg.

- Cefnogir y PSCF gan y canllawiau ar gyfer gweithwyr proffesiynol sydd ynghlwm wrth Ffurflen Gydsynio 1 ar gyfer Cymru Gyfan.

- Pwysig - Nid yw'r dudalen hon yn rhan o'r PSCF a dylid ei dileu unwaith y bydd y ffurflen wedi'i drafftio.

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Manylion y claf
(neu label wedi'i argraffu ymlaen llaw)

Cyfenw/enw teulu'r claf .....
Enwau cyntaf y claf .....
Dyddiad geni .....
☐ Gwryw ☐ Benyw
Rhif GIG *(neu fanylion adnabod eraill)* .....

Ffurflen Caniatâd ar gyfer Llawdriniaeth Benodol

Yn seiliedig ar Ffurflen Ganiatâd 1: Cytundeb claf i archwiliad neu driniaeth

Mae'r ffurflen hon i'w defnyddio ar gyfer pobl 16 oed ac yn hŷn sydd â galluedd meddyliol a phobl o dan 16 oed sy'n gymwys yn ôl safon Gillick. **Pwyswch yn galed a sicrhewch fod y tri chopi yn ddarllenadwy.**

Gofynion arbennig (e.e. iaith arall/dull cyfarthrebu arall)

.....

Enw'r driniaeth arfaethedig (dylid rhoi esboniad cryno os nad yw'r term meddygol yn glir)

.....

.....

Anesthetig: Bydd y driniaeth hon yn cynnwys:

☐ Anesthesia cyffredinol ac/neu anesthesia rhanbarthol ☐ Anesthesia lleol ☐ Tawelydd ☐ Dim

Unrhyw driniaethau ychwanegol a allai ddod yn angenrheidiol yn ystod y driniaeth:

☐ Dim disgwyl y bydd angen unrhyw driniaeth ychwanegol ☐ Trallwysiad gwaed .....

☐ Triniaeth arall (nodwch) .....

Datganiad y gweithiwr iechyd proffesiynol

(rhaid i'r gweithiwr iechyd proffesiyol fod â gwybodaeth briodol am y driniaeth arfaethedig)

Pobl 16 oed a hyn (y tybir bod ganddynt y galluedd i gydsynio i'r driniaeth). Ticiwch UN blwch:

☐ *Yn fy marn i nid oes unrhyw reswm i amau galluedd y claf i wneud y penderfyniad hwn;* ***NEU***

☐ *Aseswyd gaauedd meddyliol y claf i gydsynio/i wrthod y driniaeth hon ac mae gan y claf y galluedd meddyliol i wneud y penderfyniad hwn. Cofnodwyd yr asesiad ar gofnod y claf.*

Pobl dan 16 oed

☐ Ar ôl esbonio'r driniaeth yn llawn, ei buddion ac unrhyw risgiau cysylltiedig, credaf fod y plentyn yn ddigon aeddfed a deallus i ddeall y driniaeth arfaethedig yn llawn ac i wneud penderfyniad sydd wedi'i seilio ar yr wybodaeth a ddarparwyd. Felly, credaf fod y claf **yn gymwys yn ôl safon Gillick** i wneud y penderfyniad hwn.

Mae'r plentyn wedi ☐ ***cytuno*** */* ☐ ***gwrthod*** *cynnwys rhywun â chyfrifoldeb rhiant yn y penderfyniad hwn.*

Penderfyniadau a wnaed ymlaen llaw (ar gyfer cleifion 18 oed a hyn yn unig)

☐ *Mae'r claf wedi gwneud penderfyniad dilys a chymwys ymlaen llaw i wrthod y driniaeth hon neu driniaeth a all ddod yn angenrheidiol yn ystod y driniaeth dan sylw.* (Gwnewch yn siwr fod y claf yn nodi'r manylion llawn yn yr adran penderfyniadau a wnaed ymlaen llaw ar y dudalen nesaf).

Gwybodaeth am y driniaeth

Rwyf wedi esbonio'r driniaeth i'r claf. Yn arbennig, rwyf wedi esbonio:

Buddion y bwriedir eu cael: .....

.....

Risgiau sylweddol, risgiau na ellir eu hosgoi neu risgiau sy'n digwydd yn aml:

Yn ystod y driniaeth: .....

Yn dilyn y driniaeth: .....

Risgiau pwysig (perthnasol) eraill sy'n benodol i'r claf hwn yn ystod ac yn dilyn y driniaeth (i'w cwblhau ar yr adeg y ceisir cydsyniad gan y claf):

.....

.....

Rwyf hefyd wedi trafod:

☐ yr hyn y mae'r driniaeth hon yn debygol o'i olygu
☐ unrhyw bryderon penodol sydd gan y claf
☐ buddion a risgiau unrhyw driniaethau eraill sydd ar gael (gan gynnwys dim triniaeth)

Rhowch fanylion: .....

☐ Rwyf wedi darparu'r daflen / CD / DVD / dolen we: *[nodwch deitl y daflen a dyddiad ei chyhoeddi, teitl y CD/DVD a'r fersiwn wrth ddatblygu'r PSCF]*

.....

☐ Gwiriwch fod y daflen CD / DVD / teitl dolen we / dyddiad / fersiwn yn union yr un fath âr uchod. Os yw'n wahanol, nodwch hynny isod:

.....

Llofnod ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* ..... **Teitl Swydd** .....

Rhif cofrestru proffesiynol *(e.e GMC, NMC, GDC, HCPC, ac ati)* .....

Manylion cyswllt *(os bydd y claf am drafod opsiynau yn ddiweddarach)* .....

Datganiad y cyfieithydd/dehonglydd

(pan fo'n briodol). Rwyf wedi cyfleu'r wybodaeth uchod i'r claf hyd eithaf fy ngallu ac mewn ffordd y gall ei deall yn fy marn i.

Llofnod ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* ..... **Manylion cyswllt** .....

Datganiad a llofnod y claf

Byddwn yn cynnig copi o'r ffurflen hon i chi. Os oes gennych unrhyw gwestiynau eraill, cofiwch ofyn - rydym yma i'ch helpu. **Cewch newid eich meddwl unrhyw bryd**, gan gynnwys ar ôl i chi lofnodi'r ffurflen hon.

Rwy'n deall:

- yr wybodaeth rwyf wedi'i chael am yr archwiliad neu'r driniaeth a ddisgrifir yn y ffurflen hon.
- na allwch sicrhau y bydd rhywun penodol yn cyflawni'r driniaeth. Fodd bynnag, bydd gan yr unigolyn brofiad priodol.
- y caf y cyfle i drafod manylion yr anesthesia gydag anesthetydd cyn y driniaeth, oni fydd natur frys fy sefyllfa yn atal hyn rhag digwydd. (Dim ond i gleifion sy'n cael anesthesia cyffredinol neu anesthesia rhanbarthol y mae hyn yn berthnasol).
- mai dim ond os yw'n angenrheidiol i achub fy mywyd neu i atal niwed difrifol i'm hiechyd y darperir unrhyw driniaeth *yn ychwanegol* at y rhai a ddisgrifir yn y ffurflen hon ac nad ydynt yn destun penderfyniad a wnaed ymlaen llaw (gweler isod).

Rwy'n cytuno i'r driniaeth a ddisgrifir yn y ffurflen hon.

Rwy'n cytuno / nid wyf yn cytuno* y gall myfyrwyr fod yn bresennol yn ystod y driniaeth. (*dilëwch fel sy'n briodol).

Penderfyniadau a wnaed ymlaen llaw (ar gyfer cleifion 18 oed a hyn yn unig)

☐ Rwyf wedi gwneud penderfyniad ymlaen llaw i wrthod y driniaeth hon, ond rwyf wedi newid fy meddwl yn awr, ac rwy'n fodlon cael y driniaeth a ddisgrifir yn y ffurflen hon.

☐ Rwyf eisoes wedi gwneud penderfyniad ymlaen llaw i wrthod unrhyw driniaeth a allai fod yn angenrheidiol yn ystod y driniaeth a ddisgrifir yn y ffurflen hon. Mae hyn yn cynnwys:

.....

(os gwnaed y penderfyniad hwn mewn ysgrifen, ffeilwch gopi yn y cofnod meddygol. Os yw'n benderfyniad llafar, gwnewch nodiadau manwl. Os yw'n gwrthod triniaeth i gynnal bywyd, rhaid iddo fod mewn ysgrifen ac wedi'i lofnodi a'i ddyddio, a'i lofnodi gan dyst, gan ddatgan yn glir fod y penderfyniad yn sefyll hyd yn oed os yw bywyd y claf mewn perygl).

☐ Rwyf wedi cael gwybod am driniaethau ychwanegol a allai fod yn angenrheidiol yn ystod fy nhriniaeth. Isod, rwyf wedi rhestru unrhyw driniaethau **nad wyf am iddynt gael eu cyflawni** heb drafodaeth bellach, hyd yn oed os byddai peidio â rhoi triniaethau o'r fath ar unwaith yn golygu, o bosibl, anaf parhaol difrifol neu farwolaeth.

.....

.....

Llofnod y claf ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* .....

Dylai tyst lofnodi isod os na all y claf wneud hynny ond bod y claf wedi dangos s ei fod yn rhoi caniatâd. Efallai yr hoffai pobl ifanc/plant i riant lofnodi yma (gweler nodiadau).

Llofnod ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* ..... **Perthynas â'r claf** .....

Cadarnhau caniatâd

(i'w gwblhau gan weithiwr iechyd proffesiynol pan dderbynnir claf i'r ysbyty ar gyfer y driniaeth, os yw'r claf wedi llofnodi'r ffurflen ymlaen llaw).

Ar ran y tîm sy'n trinn y claf, rwyf wedi cadarnhau gyda'r claf nad oes ganddo unrhyw gwestiynau eraill a'i fod am fwrw ati â'r driniaeth.

Llofnod ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* ..... **Teitl swydd** .....

Rhif cofrestru proffesiynol *(e.e. GMC, NMC, GDC, HCPC ac ati)* .....

Rwyf yn cadarnhau fy mod am barhau â'r driniaeth.

Llofnod y claf ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* .....

Y claf wedi tynnu ei ganiatâd yn ôl

Gofynnwch i'r claf lofnodi a rhoi'r dyddiad yma ac ysgrifennu **"DI-RYM"** ar holl dudalennau'r ffurflen.

Llofnod y claf ..... **Dyddiad** .....

Enw *(LLYTHRENNAU BRAS)* .....

Rhiad cadw'r copi uchaf o'r ffurflen hon gyda nodiadau'r claf.
Wedi cynnig copi i'r claf: copi Cymraeg / copi Saesneg / wedi'i wrthod gan y claf (rhowch gylch)

Appendix 5

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

Pwy all gydsynio

Tybir bod gan unrhyw un sydd yn **16 neu hŷn** y gallu meddyliol i roi neu wrthod cydsynio eu hunain, oni bai yr arddangosir i'r gwrthwyneb. Fodd bynnag, nid yw hyn yn berthnasol i ymyriadau nad ydynt yn cyflwyno buddion iechyd uniongyrchol ar yr unigolyn ifanc, megis rhoi gwaed a meinwe (heblaw ar gyfer pwrpasau diagnostig). I bobl ifanc (16-17 oed) sy'n dymuno derbyn "ymyriadau" fel hyn, bydd angen asesiad o'u gallu i roi cydsyniad.

Os yw plentyn o dan 16 â "digon o ddealltwriaeth a gallu i'w alluogi ef neu hi i ddeall yn llawn yr hyn a gynigir a gwneud penderfyniad yn seiliedig ar yr wybodaeth a ddarparwyd" (Gallu *Gillick*), yna bydd ef neu hi'n alluog i roi cydsyniad ei hunan (DS Ni ystyrir cydsyniad a gwrthodiad gan blentyn dan oed galluog yn ôl y gyfraith yn hollol gymesurol, o ran mae plentyn galluog *Gillick* yn gallu cydsynio'n gyfreithlon, ond gellir gwrthwneud gwrthodiad). Hyd yn oed pan fydd plentyn yn gallu rhoi cydsyniad ei hun, dylech bob amser gynnwys y rheini sydd â chyfrifoldeb rhieniol yng ngofal y plentyn, oni bai bod y plentyn yn gofyn yn benodol i chi beidio â gwneud hyn.

Felly gall pobl ifanc 16 a 17 oed, a phlant iau â Gallu *Gillick*, lofnodi'r ffurflen hon eu hunain, ond efallai y byddan nhw'n dymuno i riant gydlofnodi hefyd.

Os na fydd y plentyn o dan 16 oed yn gallu rhoi cydsyniad ei hun, gall rhywun â chyfrifoldeb rhiant wneud hyn ar ei r(h)an ac mae ffurflen ar wahân (Ffurflen Gydsynio 2) ar gael at y diben hwn.

Os oes gan glaf y galluedd meddyliol i roi cydsyniad ond nid yw'n gallu llofnodi ffurflen yn gorfforol, dylech lenwi'r ffurflen hon fel arfer, a gofyn i dyst annibynnol gadarnhau bod y claf wedi rhoi cydsyniad ar lafar neu heb fod ar lafar.

Pryd i BEIDIO â defnyddio'r ffurflen hon
Os yw claf yn **16 oed neu hŷn** a heb y gallu meddyliol i roi cydsyniad, dylech ddefnyddio *Ffurflen 4 Triniaeth er lles* yn lle'r ffurflen hon. Nid oes gan gleifion alluedd meddyliol os oes ganddyn nhw nam ar y meddwl neu'r ymennydd neu gynnwrf sy'n effeithio ar y ffordd mae eu meddwl neu ymennydd yn gweithio ac ni allent wneud un neu fwy o'r canlynol:

- deall gwybodaeth am y penderfyniad y mae angen ei wneud;
- dal gafael ar y wybodaeth;
- defnyddio neu bwyso a mesur yr wybodaeth honno fel rhan o'r broses benderfynu; neu
- ni all gyfathrebu ei benderfyniad (trwy siarad, defnyddio iaith arwyddion neu unrhyw fodd arall).

Dylech bob amser gymryd pob cam rhesymol (er enghraifft cynnwys cydweithwyr mwy arbenigol) i gefnogi claf i wneud ei benderfyniad ei hun, cyn dod i gasgliad na all wneud hynny.

Ni ellir gofyn i berthnasau arwyddo ffurflen ar ran oedolyn sydd â diffyg gallu meddyliol i gydsynio dros ei hun, oni bai rhoddwyd awdurdod i wneud dan Bŵer Atwrnai Parhaus Lles Personol neu eu bod yn Ddirprwy a benodwyd gan lys gyda'r awdurdod perthnasol.

Dylid defnyddio Ffurflen Gydsynio 2 ar gyfer plant dan 16 oed heb fod â Gallu Gillick.

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.

Myfyriwr cyn-gofrestru
Mae Canllaw Cyfeirio Llywodraeth Cymru ar gyfer Cydsynio i Archwiliadau neu Driniaethau angen cydsyniad ysgrifenedig claf os bydd myfyrwyr cyn-cofrestru yn mynd i fod yn bresennol yn ystod archwiliad neu driniaeth sy'n defnyddio llonyddiad neu anesthetig. Felly, gofynnir i gleifion a ydynt yn cytuno neu anghytuno i fyfyrwyr fod yn bresennol.

Y Gymraeg
Dylai staff proffesiynol iechyd ofyn i'r claf a yw'n siarad Cymraeg ac yna'n rhoi tic yn y blwch perthnasol ar y ffurflen. Os yw'r claf yn siarad Cymraeg, dylid cynnig copi cyfrwng Cymraeg o'r ffurflen hon i'r claf. Dylai'r staff proffesiynol nodi eu blaenlythrennau i ddweud bod hyn wedi'i wneud.

Dylai cleifion sy'n dymuno cydsynio yn Gymraeg gael y cyfle i ddarllen y fersiwn Gymraeg o'r ffurflen hon cyn llofnodi copi Saesneg y ffurflen. Mae'n hanfodol er diogelwch y claf, mai'r fersiwn Saesneg o'r ffurflen yw'r un a gwblheir yn nodiadau achos y claf.

Ffurflenni Cydsynio Cymru Gyfan eraill.

FFURFLEN 2
Cytundeb unigolyn gyda chyfrifoldeb rhieniol i archwilio neu driniaeth ar gyfer plentyn 16 oed neu iau heb allu *Gillick*

FFURFLEN 4
Triniaeth er budd: Ffurflen i gleifion 16 oed a hŷn a all fod heb y gallu i gydsynio i archwiliadau neu driniaethau.

(FFURFLEN 3 - wedi'i therfynu)

Appendix 6- Contact Details

Consent Lead, Safeguarding - Tel: 029 2183 2001

Head of Corporate Governance - Tel: 029 2183 6691

Appendix 7 - Approval of Procedure Specific Consent Form (Form to be sent with final version of consent form)

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 [Trust] developed leaflet (If applicable). Please provide link / attach the relevant leaflet here:	
Does the PSCF apply Health Board wide? If no, please explain why	Yes / No
Attach minutes of the relevant Clinical Governance Group (equivalent Group / Committee) ratifying the PSCF here	Date of meeting:
Attach electronic versions of the PSCF here	
Review Date:	

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