The Bullen Healthcare Group Ltd

Consent Policy & Consent

Document Control

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1.0	13/01/2016	iQ Medical	iQ Medical	Reviewed & unchanged
2.0	May 2018	FPM	FPM	Updated – included GDPR Consent changes and new Rights of data subjects for consent (p3-5)
	May 2019	FPM	FPM	Reviewed and Unchanged
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2.1	May 2021	FPM	FPM	Added 'Consent to proxy access to GP online services for 13-16 year old' form (p 13)
3.0	Mar 2024	Bullen Healthcare	Bullen Healthcare	Adopted and Amended

Contents:

Introduction

The purpose of this policy is to set out the organisations approach to consent and the way in which the principles of consent will be put into practice.

Where possible, a clinician must be satisfied that a patient understands and consents to a proposed treatment or investigation.

The clinician must also ensure that other possible treatment options, including the risks and benefits of each, have been explained to the patient before the patient makes their decision to consent.

Where a patient is accompanied by a carer, advocate or other support person, the clinician will ensure that:

- they understand the care, treatment and support choices available to the patient;
- involve them appropriately in making decisions about the patient's care;
- give opportunities for them to represent the views of the patient;

Whether explaining to a patient, carer, advocate or other support person; information given will include the nature, purpose, and risks of the procedure. If necessary, the use of drawings, interpreters, videos or other means will also be used to ensure that they understand, and have enough information to give 'Informed Consent'.

Bullen will ensure that where consent is necessary, the forms contained within this document will be completed and the action noted on the patient record.

Bullen will undertake an audit, annually, to determine that consent is always sought and recorded in-line with this policy.

Consent under Revised Data Protection regulations.

The Data Protection Act will be revised to incorporate the General Data Protection Regulations (GDPR) from May 2018, which has built new emphasis on the protection of data of individuals, or 'data subjects'.

This new set of regulations has redefined the ability and requirements for consent to use personal data, and as such means that Bullen will be more stringent on the requirements, ensuring that;

- Consent must be asked explicitly for a clear purpose
- Consent must be freely given
- Consent is not linked to provisioning of services that are agreed upon in the contract, or that the data subject is already entitled to
- Consent must not be requested in ambiguous or uncertain language, it must be clear and easily understandable
- Consent must be recorded for future evidence – a form that is signed or a clear digital action (e.g. ticking a box)

- Requires a clear and affirmative action from the user.
- Pre-ticked checkboxes and opt-outs are not acceptable
- Consent should not be bundled – if asking for consent for multiple purposes, the consent for each purpose should be separated
- The data subject has the option to withdraw consent at any time
- No Processing should be carried out before receiving written or recorded consent from the data subject

How and when to ask for consent

- The responsibility for seeking consent before the start of processing lies with the Controller
- The Controller must prove with evidence (written forms, online actions etc.) that consent was obtained in line with the rules of data protection
- All data subjects (patients, employees, supplier's employees) should be asked to provide consent if their personal data is being processed outside of a legitimate purpose that the data subject has already been informed of and agreed to.
- Consent from a parent should be requested when processing the personal data of children.
- The age criterion for being considered children is 16 years.

Rights of a Data Subject

Data subjects can make a specific request that their personal data is not being misused for anything other than their legitimate purpose (See also "Obtaining Consent")

- **Right to Information**:
  The ability to ask for information about what personal data is being processed, and the reasons for such processing.

- **Right to Access**
  Get access to their personal data that is being processed – they can see their own personal data as well as request copies

- **Right to Rectification**
  Data subject can ask for modifications to their personal data if it is not up to date or accurate.

- **Right to withdraw consent**
  Data subject can withdraw previously given consent for the processing of their personal data for a purpose.

- **Right to object**
  Object to the processing of their personal data. Normally this is the same as the right to withdraw consent (and no processing other than for legitimate purposes is being conducted). E.g. customer may ask that personal data should not be processed while a legal dispute is ongoing in court.

- **The Right to object to automated processing**
  Can object to a decision based on automated processing.

- **The Right to be forgotten (Right to Erasure)**
  Request deletion of their data. Generally applies to situations where the practice/patient relationship has ended. It is important to know that this is **not** an absolute right, and that it depends on your retention schedule and retention period in line with other applicable laws. E.g. laws require medical records to be retained for a certain period. In such cases, the patient cannot invoke the right to deletion of medical files.

- **Right for data portability** – data subject can ask for a transfer of their personal data, and ask for it to be provided back to them, or transferred to another controller. When doing so, the data must be transferable in a machine-readable electronic format.

Implied Consent

Implied consent will be assumed for many routine physical contacts with patients.

Where implied consent is to be assumed by the clinician, in all cases, the following will apply:

- An explanation will be given to the patient what s/he is about to do, and why.
- The explanation will be sufficient for the patient to understand the procedure.
- In all cases where the patient is under 18 years of age, a verbal confirmation of consent will be obtained and briefly entered into the medical record.
- Where there is a significant risk to the patient, an 'Expressed Consent' will be obtained in all cases.

Expressed Consent

Expressed consent (written or verbal) will be obtained for any procedure which carries a risk that the patient is likely to consider as being substantial.

A note will be made in the medical record detailing the discussion about the consent and the risks. A Consent Form may be used for the patient to express consent.

Obtaining Consent

- Consent (Implied or Expressed) will be obtained prior to the procedure, and prior to any form of sedation.
- The clinician will ensure that the patient is competent to provide a consent (16 years or over) or has "Gillick Competence" if under 16 years.
  Further information about Gillick Competence and obtaining consent for children is set out below.
- Consent will include the provision of all information relevant to the treatment.
- Questions posed by the patient will be answered honestly, and information necessary for the informed decision will not be withheld unless there is a specific reason to withhold. In all cases where information is withheld, then the decision will be recorded in the clinical record.

- The person who obtains the consent will be the person who carries out the procedure (i.e. a nurse carrying out a procedure will not rely on a consent obtained by another unless the nurse was present at the time of the consent being given).
- The person obtaining consent will be fully qualified and will be knowledgeable about the procedure and the associated risks.
- The scope of the authority provided by the patient will not be exceeded unless in an emergency.
- Bullen acknowledges the right of the patient to refuse consent, delay the consent, seek further information, limit the consent, or ask for a chaperone.
- Clinicians will use a Consent Form where procedures carry a degree of risk or where, for other reasons, they consider it appropriate to do so (e.g. malicious patients).
- No alterations will be made to a Consent Form once it has been signed by a patient.
- Clinicians will ensure that consents are freely given and not under duress (e.g. under pressure from other present family members etc.).
- If a patient is mentally competent to give consent but is physically unable to sign the Consent Form, the clinician should complete the Form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

Other aspects which may be explained by the clinician include:

- Details of the diagnosis, prognosis, and implications if the condition is left untreated.
- Options for treatment, including the option not to treat.
- Details of any subsidiary treatments (e.g. pain relief).
- Patient experiences during and after the treatment, including common or potential side effects and the recovery process.
- Probability of success and the possibility of further treatments.
- The option of a second opinion.

Consent for Children under 16 (Gillick Competence)

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated.

If a child under the age of 16 has “sufficient understanding and intelligence to enable him/her to understand fully what is proposed” (known as Gillick Competence), then s/he will be competent to give consent for him/herself.

Young people aged 16 and 17, and legally ‘competent’ younger children, may therefore sign a Consent Form for themselves, but may like a parent to countersign as well.

For children under 16 (except for those who have Gillick Competence as noted above), someone with parental responsibility should give consent on the child’s behalf by signing accordingly on the Consent Form.

Withdrawal of Patient Consent

- Bullen acknowledges the right of the patient to refuse consent, delay consent, seek further information, limit the scope of consent, or ask for a chaperone.
- The patient or parent / guardian has the right to withdraw consent at any time.
- A Withdrawal of Patient Consent Form will be required to be completed and documented on the patient's medical record
- Questions posed by the patient will be answered honestly, and information necessary for them to make an informed decision will not be withheld unless there is a specific reason to withhold it. In all cases where information is withheld, the reasons for this will be recorded in the patient's clinical record.
- The person who would have been carrying out the procedure will make sure that all issues around the withdrawal of consent have been fully explained to the patient or parent / guardian to enable them to fully understand what may happen if the treatment / operation is not carried out. (The person discussing this must be fully qualified and knowledgeable about the procedure itself and the associated risks).
- The scope of the authority provided by the patient will not be exceeded unless in a medical emergency.
- No alterations will be made to the Withdrawal of Consent Form once it has been signed by a patient.
- If a patient is mentally competent to withdraw consent but is physically unable to sign the form, the clinician should complete the form as usual, and ask an independent witness to confirm that the patient has confirmed they wish to withdraw their consent orally or non-verbally.

The Bullen Healthcare Group Ltd
PATIENT CONSENT FORM
(for medical treatment, immunisation, investigation or operation)

This form can also be used for a parent or guardian to give consent for treatment to be given to a young person

Patient's Details

Surname: ……

First Names: ……

Date of Birth: …… Male/Female: ……

This Section to be completed by the Clinician

This consent form has been prepared for the treatment, immunisation, investigation or operation detailed below:

……

……

……

I confirm that I have explained the above treatment, immunisation, investigation or operation to the patient, and such options as are appropriate such as the type of anaesthetic (if any) proposed, in terms that in my judgement are suited to their understanding and/or these have been explained to a parent or guardian of the patient.

Signature of Clinician: …… Date: ……

Name of Clinician completing the procedure: ……

This Section to be completed by the Patient / Parent / Guardian

1. I am the patient / parent / guardian (delete as necessary)
   (See statement at end of form for information on consent for children).
2. I agree to the procedure(s) proposed on this form and the clinician named on this form has explained this to me.
3. I agree to the use of the type of anaesthetic that has been explained to me.
4. I understand that any procedure, in addition to that described on this form, will only be carried out if it proves to be necessary and in my best interests and can be justified for medical reasons.
5. I have explained to the clinician about any procedures listed below which I would not wish to be carried out without the opportunity to consider them first. These include:

   ……

6. I have notified the clinician of the following allergies/medications which I am currently taking and that may be relevant to my treatment:

   ……

Signature of Patient/Parent/Guardian: ……

Full Name of Patient/Parent/Guardian: ……

Address (if not the same as patient):

……

……

If the treatment is for a child and if the child wishes to sign this form, he/she may do so here;
(See statement at end of form for information on consent for children).

I agree to have the treatment that has been explained to me.

Date …… Signature ……

Note to clinician:
A patient has the legal right to grant or withhold consent prior to this procedure.
Patients should be given sufficient information in a way they can understand, about the proposed treatment and the possible alternatives.
The patient's consent to the procedure should be recorded on this form.

Note to Patient:
The clinician should explain the proposed treatment and any alternatives.
You can ask questions and seek further information.
You have the right to refuse this treatment.
You may ask for a relative, friend or nurse to be present.

Statement of interpreter (where appropriate)

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

Signed …… Date ……

Name ……

This form, once completed, must be kept with the patient's medical records.

Consent for children under 16 (Gillick Competence)

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated.

If a child under the age of 16 has "sufficient understanding and intelligence to enable him/her to understand fully what is proposed" (known as Gillick Competence), then s/he will be competent to give consent for him/herself.

Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this Consent Form for themselves, but may wish a parent to countersign as well.

If the child is not able to give consent for him/herself, someone with parental responsibility should do so on his/her behalf by signing this Form.

The Bullen Healthcare Group Ltd
WITHDRAWAL OF PATIENT CONSENT FORM
(for medical treatment, immunisation, investigation or operation)

This form can also be used for a parent or guardian to withdraw consent for treatment to be given to a young person

Patient's Details

Surname: ……

First Names: ……

Date of Birth: …… Male/Female: ……

This Section to be completed by the Clinician

This consent form has been prepared for the clinician to explain the issues that could arise if the patient withdraws consent for the treatment, immunisation, investigation or operation detailed below:

……

……

……

I confirm that I have explained the above issues that could arise because the patient has withdrawn consent for the treatment, immunisation, investigation or operation to the patient. I have explained the above in terms that in my judgement are suited to their understanding and/or these have been explained to a parent or guardian of the patient.

Signature of Clinician: …… Date: ……

Name of Clinician……

The Bullen Healthcare Group Ltd

Patient Consent Form
for another Person to Access their Medical Records

Patient's Details **(The person whose records another individual(s) is to be given access to)**	
Surname	
First Names	
Date of Birth	
Male / Female	
Address	
Tel No.	

Details of person to be given access to this Patient's information	
Full Name	
Address	

(if more than one person is to be given access, please list the above details for each additional person on a separate sheet of paper)

Please detail below if the above access is to be limited in any way (e.g. only for test results, or only for making & cancelling appointments, or for a specified time period only)

I confirm that I give permission for the Practice to communicate with the person identified above in regards to my medical records.	
Signature	
Date	

Consent for children under 16 (Gillick Competence)

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated.

If a child under the age of 16 has "sufficient understanding and intelligence to enable him/her to understand fully what is proposed" (known as Gillick Competence), then s/he will be competent to give consent for him/herself.

Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this Consent Form for themselves, but may wish a parent to countersign as well.

If the child is not able to give consent for him/herself, someone with parental responsibility should do so on his/her behalf by signing this Form below.

I am the Patient / Parent / Guardian (delete as necessary).

Signature: ……..

Full Name: ……..

Address (if not the same as patient):

……..

……

The Bullen Healthcare Group Ltd

Patient Third-Party Enquiry / Complaint Consent Form

Patient Name:	
Telephone No:	
Address:	
Enquirer / Complainant Name:	
Telephone No.	
Address:	

If you are making an enquiry or complaining on behalf of a patient, or your complaint or enquiry involves the medical care of a patient, then the consent of the patient will be required.

Please obtain the patient's signed consent below:

I (Insert Name) ……..
fully consent to Bullen releasing information to, and discussing my care and medical records with the person named above in relation to this enquiry / complaint, and I wish this person to enquire / complain on my behalf.

This authority is for an indefinite period / for a limited period only (delete as appropriate).

Where a limited period applies, this authority is valid until (insert date)……

Signed (Patient): ……

Print Name: ……

Date: ……