

Consent for publication: Best practice for authors

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The purpose of this document

This document provides guidance for authors about how to obtain consent for publication for research and articles involving human participants.

Context

The guidance in this document was informed by [BMJ's roundtable on capacity to consent](#) including contributions from clinicians, ethicists, patient representatives and lawyers with significant expertise on this topic. We also considered relevant legislation. As an international publisher with our head office in London, we refer to legislation for England and Wales i.e. the Mental Capacity Act (MCA), 2005, 2007. We see this legal baseline as the minimum standard.

Above this legal baseline, publishers and authors have ethical responsibilities towards patients and subjects of research such as those outlined in the Declaration of Helsinki and the Singapore Statement on Research Integrity.

Duties and responsibilities

As publishers, BMJ has a duty to make sure that proper consent for publication has been obtained by the authors and that the individual(s) involved is/are aware of the possible consequences of publication.

As authors submitting manuscripts for publication involving human subjects, you have a duty to ensure the individual(s) involved is/are aware of the planned publication and has given their consent as early as possible.

You also have an ethical and legal duty to consider the individual's capacity to consent on their own behalf when obtaining consent for publication.

All four elements of consent are equally important, namely; i) capacity; ii) sufficient information; iii) voluntariness; and iv) the ongoing or continuing nature of permission.

Consent for publication vs. consent for participation

We often find that authors have confused consent for publication with consent for participation in their study. For the purpose of this document, “consent” refers to consent to publish personal information about an individual, and not informed consent for participation in a study.

Some consent forms for participation in research do cover intended publication, however these forms rarely meet BMJ’s requirements which ensure the individual has been fully informed of the benefits and harms of publication.

Consent for participation in research still must be obtained according to appropriate ethical standards.

The best way to ensure you have obtained appropriate consent for publication in one of BMJ’s journals and to prevent delays in the editorial process is to use our [BMJ consent form](#). This includes a comprehensive description of what is involved in publication and sharing of our publications and is a requirement for publication in any BMJ journal. It is available in multiple languages. You should be aware that while we are happy to consider alternative consent forms, they rarely meet our legal requirements for publication.

You should also confirm that the original copy of the signed form is held by the treating institution should any queries be raised in the future.

Assessing if your manuscript requires consent for publication

At BMJ we require a signed BMJ consent form for any manuscript (or other content) that includes identifiable information about an individual.

What is identifiable information?

Identifiable information is any personal information about an individual, patient or participant in research that can be identified as belonging to, or likely to belong to, a particular individual.

Case reports, small case series or referring to individuals in commentary or personal observations are most likely to contain identifiable information and require consent.

Aggregated data is not usually considered to be identifiable, however be wary of small numbers which might effectively make this information identifiable. At BMJ, we consider groups of less than 5 to be identifiable.

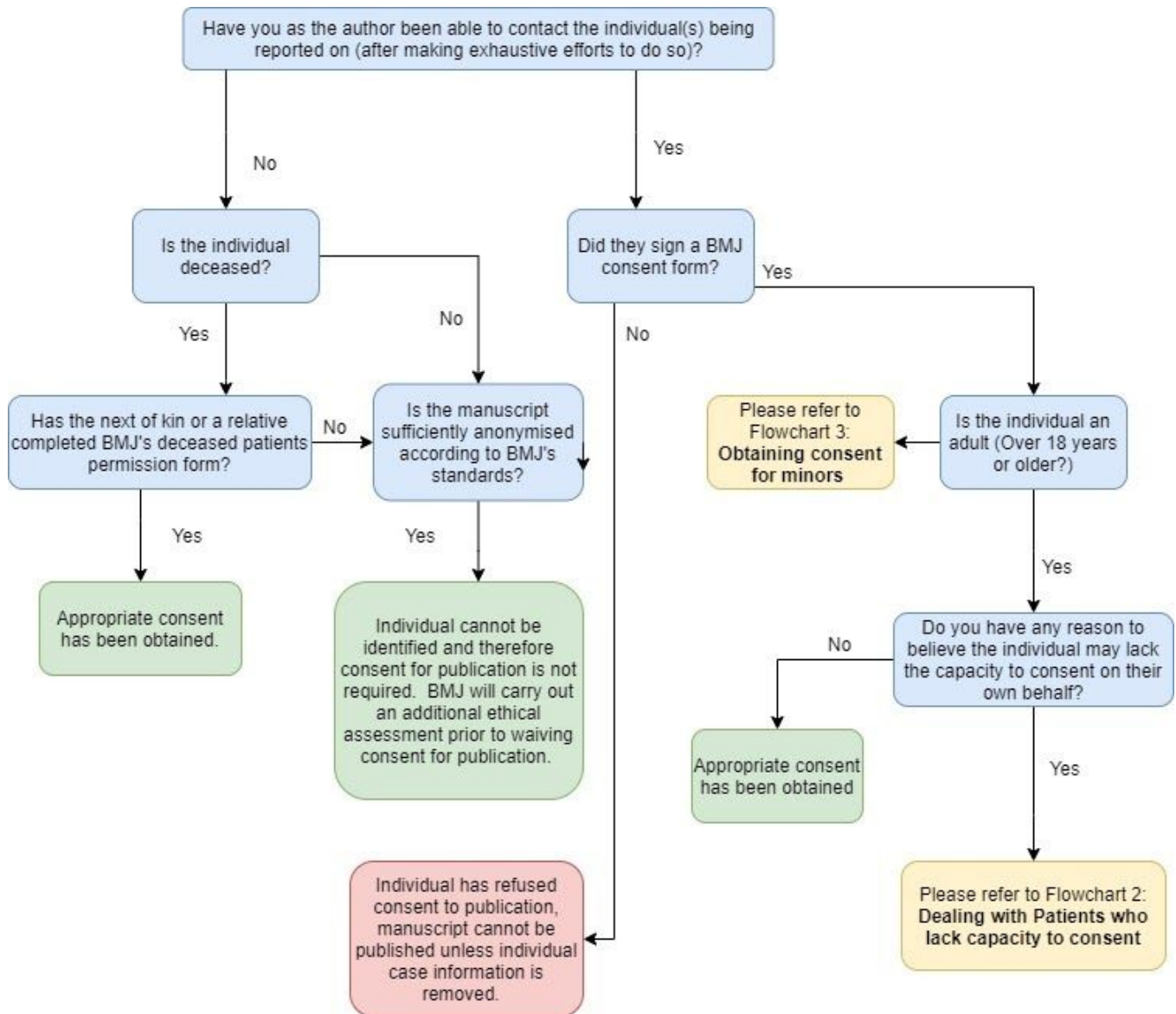


Figure 1: Flowchart depicting standard procedure for consent for publication.

How to proceed if the individual cannot be contacted

It is BMJ’s view that confidentiality and “true anonymisation” can never be 100% guaranteed. This is particularly the case given the increasing general availability of data in the public domain including social media platforms.

If you want to submit your manuscript without a consent form, you must ensure that your manuscript is sufficiently anonymised according to BMJ’s anonymisation policy. See: [How to check if my report is sufficiently anonymised](#). Some journals and article types will not consider articles without a consent form, whether they are anonymised or not.

Obtaining Consent for Publication

i) capacity; ii) sufficient information; iii) voluntariness; and iv) the ongoing or continuing nature of permission

Sufficient Information

When seeking consent, you must ensure you give the individual sufficient information about the content of the material to be published, including providing them a copy and discussing the implications of publication.

This includes explaining that others may reuse and republish the information, it might be made widely available via the internet and that we cannot guarantee anonymity though also should always remove identifiable personal information where possible.

BMJ's consent form requires the individual to confirm they have seen any material about them prior to providing their consent and clearly outlines any important information to give people, before asking them for consent to publication.

Voluntariness

It is important that the individual is able to make a decision freely with regard to their own thoughts and feelings about publication without being overly influenced by others.

This is especially important if an author has a relationship with the individual e.g. is their treating clinician and the individual may feel that his or her care could be influenced by their decision about publication.

Questions for authors to ask themselves and individuals include:

- Is the individual making a free decision about publication?
- What influences might there be on the individual's decision regarding publication?
- Do they understand that agreeing or not agreeing to publication will not affect their care?

Capacity

Assessing capacity

You should keep in mind the following principles when assessing if individuals have capacity to consent:

1. The law in England and Wales presumes that all adults have capacity to consent. Where the behaviour of the individual makes us unsure if they can consent, the law

still requires that we presume the person has capacity and incapacity must be proven (Mental Capacity Act 2005, 2007).

2. The focus should be on exploring the individual's ability to make a specific and informed decision about publication
3. The best outcome is that the individual, where possible, is supported to make their own decision about the proposed publication
4. Capacity to consent for participation in treatment does not necessarily mean that the individual has capacity to consent to publication. Decisions around releasing confidential information often require more complex decision making than decisions related to treatment.
5. Whether an individual may temporarily or permanently lack capacity is an important part of assessing capacity. It is unhelpful to put "individuals who lack capacity" into one broad category; each individual and specific decision should be considered carefully.

Is there reason to doubt the individual's ability to consent?

When assessing whether the individual has capacity to consent on their own behalf, we advise asking the following questions (**see also**: Figure 2: Flowchart for authors on assessing capacity to consent).

- Does their current behaviour or communication suggest they are not able to understand the benefits and harms of publication or the consent process?
- How long is their lack of capacity likely to last?
 - If they can be expected to regain capacity, any decision should wait until then
- Does their capacity change at different times (fluctuate)? If yes, then there is an opportunity to work with them to enable them to consent on their own behalf (**see**: Providing person-centered support to help with decision-making within the UK)
- Have all reasonable steps been taken to help the person make a decision on their own behalf? (**see**: Providing person-centered support to help with decision-making)

Providing person-centered support to help with decision-making

Authors must provide all practicable support as necessary and appropriate to help an individual to make their own decision.

This support must be person centred. It cannot be assumed that all individuals with the same condition should be treated the same: be guided by the individual.

We recommend the following:

- Start by discussing the publication decision with the individual.
- Where possible, ask friends or relatives what support works best for the individual.
- Examples of person-centered support techniques that may improve capacity for decision making can be simple things such as
 - turning off background noise
 - choosing a better time of day for that person
 - providing information in different formats and breaking it down
 - pictures or objects as prompts
 - having someone else present who knows them to support them
 - if the person has good days and bad days be prepared to gain consent another time

Seeking appropriate proxy consent on behalf of an individual who lacks capacity

BMJ's guidance allows proxy consent in certain situations where an individual is not able to consent on their own behalf and is unlikely to ever be able to do so. But it bears repeating that individuals should *a/ways* be supported to make their own decisions, if possible.

If you plan to obtain proxy consent, then consider the following:

- There is no obvious default legal proxy for an adult who lacks capacity in England and Wales.
 - In the law governing adults, being someone's "next of kin" does not provide a legal right or power to (refuse) consent on behalf of another individual.
 - A Lasting Power of Attorney (LPA) for Health & Wellbeing (H&W) can provide consent on behalf of an adult who lacks capacity and this should be the first choice if one is assigned.
 - Court appointed deputies can act as proxies for an individual who lacks capacity
 - There may be legal equivalents outside of England and Wales.

- If a legal proxy is not appointed, then a best interests decision must be made on behalf of the individual.
- Best interests decisions can only be made if the individual is unlikely to ever regain capacity.
- When you make a best interests decision, under section 4(4) of the MCA, you still have an ethical duty to encourage and improve a person's ability to participate in the decision.
- You (as the author) are responsible for doing everything you can to help the individual to participate in making a decision about publication and to determine what is in their best interests

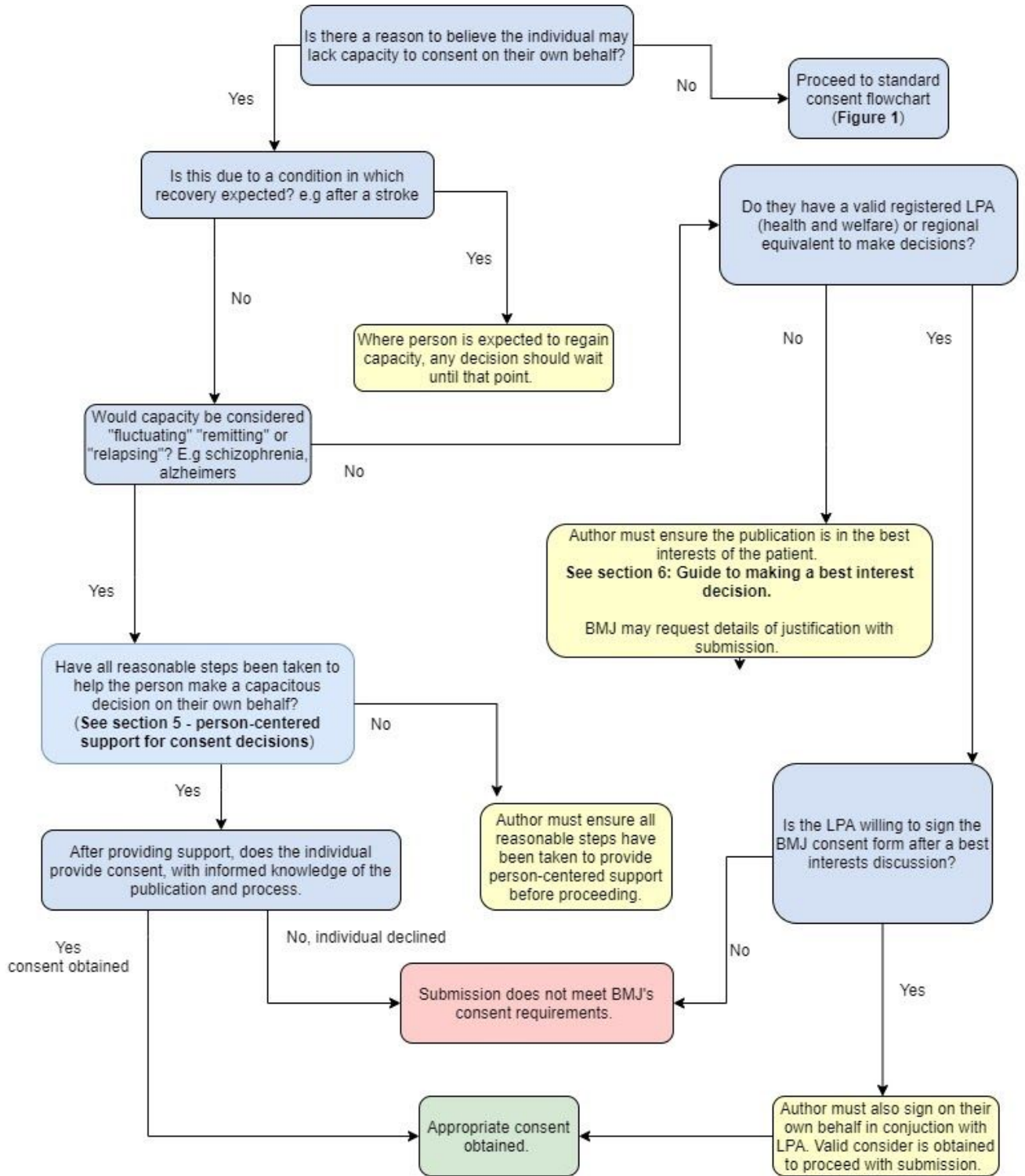


Figure 2: Flowchart for authors on assessing capacity to consent

Ensuring the publication is in the best interest of the individual

When thinking about what is in the best interests of the individual, you should remember the following:

- A best interests decision must consider the wishes and values of the individual before they lost capacity.
 - Talk to the individual themselves, as well as their next of kin, loved ones or relatives to find out what they think of taking part and sharing scientific research, contributing to the public good and their feelings on sharing personal information and privacy.
 - If the individual has no family or friends (the legal term is unbefriended) then in England and Wales an Independent Mental Capacity Advocate (IMCA) can support them. There may be a local equivalent if you are outside of this jurisdiction.
- Find out about past actions: if the individual consented to participating in research when they had capacity, this (along with other evidence) may suggest they would be willing to be involved in scientific publication.
 - Beyond deciding what is in the individual's best interest, you must explain the importance of the publication itself. This is particularly important if the publication contains highly sensitive personal information. To what extent does publication serve public interests?
 - Does it further scientific knowledge?
 - Is there a way to investigate or discuss this topic without describing a specific individual?
 - Can you remove individual cases without losing valuable learning from the paper itself?

Consent for children

Children are a vulnerable group and as such BMJ has strict consent standards for papers that report on children. For publishing purposes, we consider individuals under the age of 18 to be children.

As with adults, you must think about i) their capacity; ii) providing sufficient information; iii) voluntariness; and iv) the ongoing or continuing nature of permission, when you obtain consent for publication.

Children who have the capacity to consent to publication

Individuals of any age may have the capacity to consent to share their confidential information. We advise that you engage the child in making a decision about publication. If they can understand the information provided and are able to voluntarily make a decision, then children can consent to publication.

Where the individual is under the age of 18, we require parents or guardians to provide consent as well.

We recognise that this differs to clinical practice in England and Wales where 16 & 17 year olds can provide consent without their parents and there may be 16 & 17 year olds who want to share their personal information without involving their parents, as the publisher we will consider the decision to publish these on a case by case basis

Principles

If the child has capacity and does not give their consent to publication then it is BMJ policy that we will not publish, even if their parents or guardians consent.

If the child has capacity and consents to publication but the parents or guardians refuse, then we consider these on a case by case basis.

Children who do not have capacity to consent to publication

A child's default proxy is the person who has parental responsibility or their legal guardian. A parent or guardian is able to give consent on behalf of a child who lacks capacity, as long as publication is in the best interests of the child. As an author, you must consider whether publication is in the best interests of the child and whether their parent or guardian has given sufficient consideration to the benefits and harms. It is important to recognise where a child may come to regret the decision of publication in the future and all material should be anonymised where possible to minimise this risk.

If the child's parents or guardians disagree with each other about whether they should consent to publication then BMJ will consider whether to publish on a case by case basis.

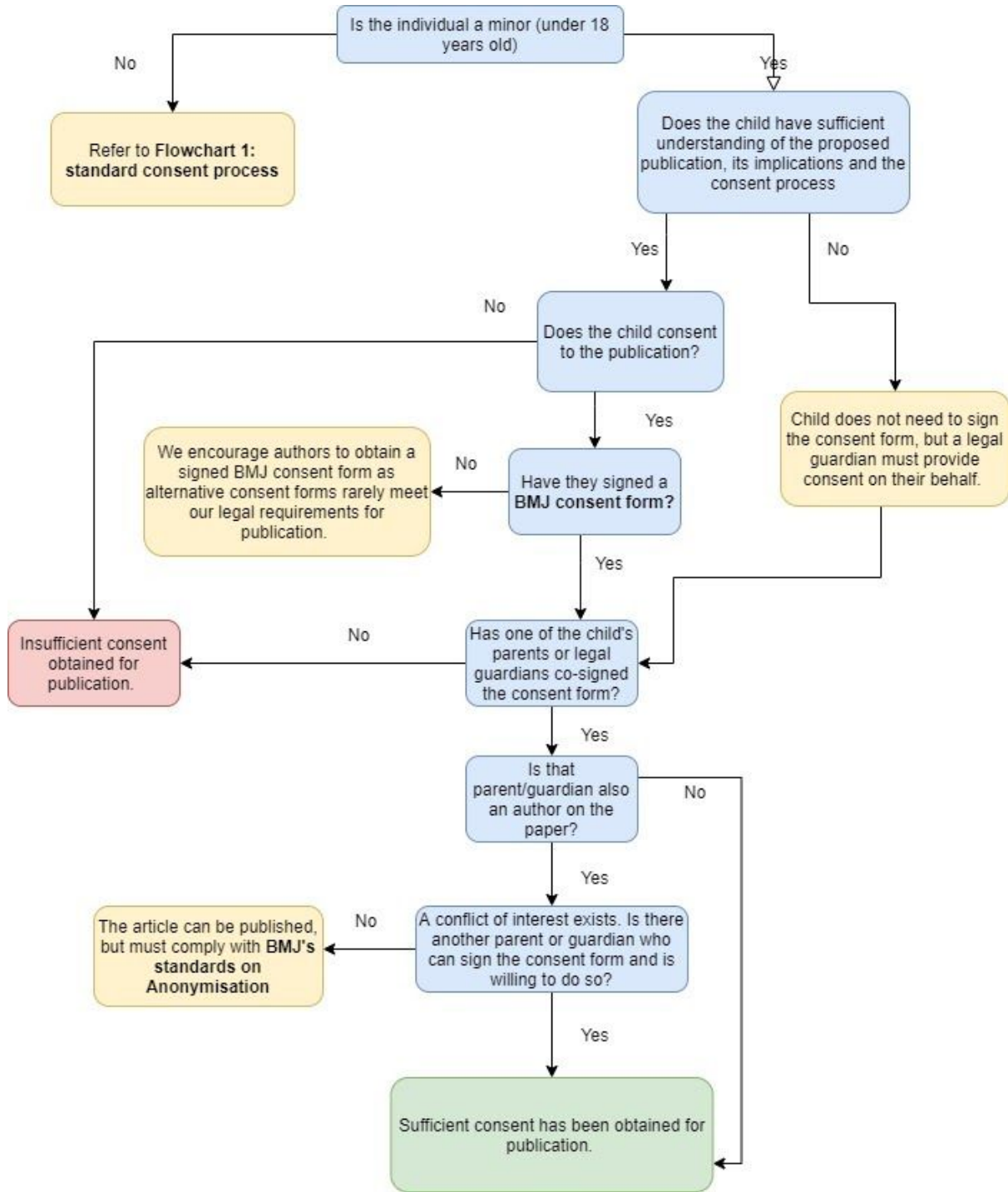


Figure 3: Process for obtaining consent for minors

BMJ policy

[BMJ's consent policies](#) are managed and upheld by BMJ's [research integrity team](#). The objectives of BMJ's consent policies are to protect patient confidentiality while at the same time supporting the communication of important medical and scientific information. We hope to balance these two aims in a way that delivers our mission for a healthier world.

We know that ethics is rarely about absolutes, context matters, and judgment is essential and we often consult [the BMJ ethics committee](#) on individual cases to ensure a high standard of publication ethics.

We assess the scientific value of the submission along with a benefits and harms discussion, to ensure the following:

- Exhaustive efforts have been made to obtain valid and appropriate consent.
- There is a low risk of harm to the individual if they were to be identified
- There is a low risk of identification of the individual reported on (see anonymisation policies)
- The best interests of the individual has been considered to the full extent possible
- The value and necessity of the publication
- That the interests of the author have not been over prioritised.

We may ask authors to provide any necessary information in order to enable us to make that assessment.

Acknowledgements:

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