



## Key ethical considerations for patient groups collecting and reporting information for HTA submissions

Short guide

### Purpose

To complete submissions for health technology assessments (HTAs), patient groups may gather information about patients' and caregivers' experiences of living with a condition, preferences and unmet needs for treatment. This may involve (but is not limited to) conducting interviews, focus groups and surveys and collecting input using social media. As a result, patient groups need to think about the ethical and legal issues involved when engaging with people and using their personal information. This document aims to help your patient group identify and respond to those issues. It is not mandatory guidance and can be adapted to meet your needs.

Issue	Consider
<b>1. Need for activity</b>	<ul style="list-style-type: none"><li>Do you already have information that can answer the HTA submission questions?</li><li>Have you found a gap in the available information? Does this gap mean you need to collect new information?</li><li>Have you planned and tested the way you will collect the information to make sure it meets your needs?</li></ul>
<b>2. Inclusivity</b>	Have you taken steps to reach out to as broad a population (including vulnerable groups) as feasible?
<b>3. Informed consent</b>	<p>Is each person who is asked to take part competent to consent?</p> <p>If yes, have they been told:</p> <ul style="list-style-type: none"><li>how the information being collected will be used and shared?</li><li>who is collecting the information?</li><li>that they can refuse to take part, stop taking part at any time, or choose not to answer all the questions without this being held against them?</li><li>any perceived or potential conflicts of interest of the person(s) or group collecting the information?</li><li>what is involved in taking part (how much time, what will be discussed, possible use of their actual words or stories in the submission)?</li><li>the realistic potential benefits?</li><li>the risks or potential harm of taking part (such as distressing thoughts, sense of stigma)?</li><li>That they will not be able to be identified from the submission?</li></ul>

	<p>Have the people taking part:</p> <ul style="list-style-type: none"> <li>○ knowingly given consent for the collection and use of their information for this submission?</li> <li>○ been asked if they consider themselves to belong to a vulnerable population (which will be noted)?</li> <li>○ declared their own conflicts of interest?</li> <li>○ knowingly given consent for the information collected for the submission to be used again for other submissions?</li> </ul> <p>Does your patient group have:</p> <ul style="list-style-type: none"> <li>○ a process in place to destroy information given by people who choose to no longer take part (if permitted by law)?</li> <li>○ steps in place to reduce any potential risks to the people taking part?</li> </ul>
<p><b>4. Ensuring anonymity and confidentiality</b></p>	<p>Have you put in place a process that makes sure that people taking part:</p> <ul style="list-style-type: none"> <li>○ cannot be identified in the submission, such as: <ul style="list-style-type: none"> <li>○ not using the real names of those taking part</li> <li>○ using initials, letters or numbers</li> <li>○ not collecting any identifying information?</li> </ul> </li> <li>○ are told the outcome of the HTA in a way that does not reveal to others that they took part?</li> </ul> <p>Do the people taking part understand:</p> <ul style="list-style-type: none"> <li>○ the guarantees given about concealing their identity?</li> <li>○ how their information will be stored and kept safe?</li> </ul>
<p><b>5. Data protection and privacy</b></p>	<ul style="list-style-type: none"> <li>○ Does your patient group have a data protection policy you need to follow?</li> <li>○ Does your region/country have a data protection or privacy policy you need to follow?</li> <li>○ Have you informed the people collecting the information that: <ul style="list-style-type: none"> <li>○ responses must be stored securely</li> <li>○ they must not discuss or report responses in a way that would allow someone to be identified?</li> </ul> </li> <li>○ Have you locked the data you collected and reported in a drawer or password protected it?</li> <li>○ Have you backed up the data you collected and reported?</li> </ul>

**Need more information?**

- See: *Key Ethical considerations for patient groups collecting and reporting information for HTA submissions: Long Guide*
- Links to further information and useful examples can be found at HTAi.org under the Patient and Citizen Interest Group
- Contact the HTAi Patient Involvement and Education Interest Group at [info@htai.org](mailto:info@htai.org)