

## Assessing the decision-making capacity of the addicted population to take part in research: myths, barriers, and benefits

### *Valoración de la capacidad para participar en investigación en población adicta: mitos, barreras y beneficios*

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**O**btaining informed consent in biomedical research is a fundamental ethical requirement in all national and international legal frameworks. To be valid, consent requires the researcher to ensure that his/her work is voluntary and that the patient is competent to make the decision to participate (Navío & Ventura, 2014). Spanish legislation on informed consent in research focuses on decision-making capacity and outlines those situations in which it is limited without, however, defining how this should be assessed. Emphasis is placed on the need to justify the inclusion of “vulnerable populations” in research, without specifying which (Real Decreto (Royal Decree) 1090/2015, 2015). There are no specific regulations governing the participation of patients with substance use disorders (SUDs).

As defined in international classifications, addiction is a disorder in which the person’s control over their drug use deteriorates (American Psychiatric Association, 2014). Addicted people continue to use drugs despite the enormous negative consequences and even though they often voice the desire to stop. Some have interpreted the DSM-5 criteria that describe loss of control and compulsive behaviour in absolute terms (Charland, 2002). They argue that people with SUDs do not meet the standards required for giving voluntary consent, and that we should thus consider addicts unfit for participation in clinical trials unless proven otherwise.

In addition to the above considerations, there are other factors that may affect the ability of addicted persons as a result of the direct effects of drug use, as well as a wide range of comorbidities that may reduce their concentration, thus limiting their understanding of informed consent.

Given the enormous burden on health and the economic and social costs generated by SUDs, there is great public interest in drug prevention and treatment (Carter & Hall, 2012). Research in this field will lead to more effective treatments to reduce the harm done to the individual and society. Addicted persons have the same rights to participate in and benefit from scientific research into their condition as any other person with any other disorder (Morán-Sánchez, Luna, Sánchez, Aguilera & Pérez-Cárceles, 2016). The potential benefits of addiction research, however, do not provide sufficient justification if a vulnerable population is exploited. We must demonstrate that those who participate are able to consent freely, that this consent is obtained while respecting their autonomy, and that the risk/benefit balance is acceptable (Morera, 2000).

For all these reasons, assessing decision-making ability in addicts is vitally important. Available data are scarce. A study of what addiction research focuses on and the area it covers (Nogué & Miro, 2015) reveals that very little work has been done on how consent forms are understood (Morán-Sánchez et al., 2016). Studies with standardized instruments are required. Although there is no gold standard,

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the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) is the most widely used tool for formal assessment of the ability to consent to research (Appelbaum & Grisso, 2001). This semi-structured interview comprising 21 questions combines the description of information relating to a specific research project with an assessment of the subjects' abilities to understand and evaluate the information, their reasoning and decision making with regard to their participation in the research.

It should be paramount that the subjects grasp the basic ideas behind the project rather than merely repeating the information word for word. This includes understanding the degree to which they appreciate that their participation is voluntary, that withdrawal is possible without penalization, and that the objective of the research is not their own personal benefit but a generalizable one in the shape of knowledge. The threshold for considering a person capable of taking a decision should vary depending on its characteristics. Assessing this should involve a specific task and level of risk: an understanding of consent to participate in a simple study does not need to be as thorough than that required for a complex study involving greater risk. The literature recommends that decision-making be routinely evaluated in those studies with greater than minimum risk (Morán-Sánchez et al, 2016).

In 2013, a Spanish version of the MacCAT-CR was prepared by Baón, and a manual was subsequently published (Navío & Ventura, 2014) which takes into account the key points highlighted above and provides clinicians and researchers with a structured method to assist them in the informed consent process. However, it has not yet been widely used and assessments of decision-making capacity are still based on intuitive judgements. These tools could help reduce the vulnerability of addicted people participating in research, respecting their autonomy to decide when their capacity is preserved and establishing protective measures when it is not. Since we will occasionally come across people with wavering decision-making capacity, such measures may be very valuable.

### Conflict of interests

The authors of this article declare no conflicts of interest.

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