Major compulsory revisions
a
(1) Although the Background sections of both the abstract and the article are interesting and relevant, I feel that they leave out the most important part, namely, the structure of your argument. I take it that is as follows:
1. For participation to be ethical, the subject must give informed consent. (A conceptual premise). A sub argument for this premise is
   a. For participation to be ethical, the subject must participate autonomously
   b. The subject cannot participate autonomously without first having given informed consent
2. Informed consent requires a sufficient level of understanding. (A conceptual premise)
3. This level is not achieved in the contexts you study. (An empirical premise that your study supports.)
4. Therefore, research is not ethical in these contexts. (Your conclusion.)

Also: some parts of your text suggest that you are making the moral argument above (based on moral principles), which concludes that research is not ethical, whereas other parts suggest that you argue that legal requirements applicable to research are not satisfied. I believe that you are making both the moral and legal argument. However, you should distinguish them. Not everything that is illegal is immoral (parking offenses). Not everything that is immoral is, or should be, illegal (minor lies).

(2) You say â€œa dual figure -- Physician/researcher - prevails in the ethical research field and requires further analysis. Be aware, and tell your readers, that there is a whole literature on whether or not investigators should also be regarded as doctors and whether or not the obligations that apply to doctors apply to investigators as well. Those who say they do include Marquis 1983, and Miller and Weijer 2003, Gifford 1986 and Hellman 2002. Those who think they donâ€™t include Brody and Miller 2003.


Minor essential revisions
(3) Although your conclusion is clear -- informed consent in the contexts you study is not valid -- your practical recommendations about how to ensure that trials are unethical are not and should be clarified.

(4) The data at the bottom of Table 3 is missing. (Do you think the patient understands the wording of the informed consent?)

(5) Some questions are unclear e.g. Table 3 â€œIn what terms does the law address the informed consent?â€ Some answer choices are also unclear e.g. â€œthe terms and conditions required for its elaborationâ€ (also, â€œelaborationâ€ is misspelled)

(6) Be careful of sweeping generalizations. â€œ(1) Internal Review Boards in developed countries are nearly always paternalistic and (2) have a low regard for the quality of IRB reviews in less developed
The first part (1) of the sentence assumes, without argument, that all attempts by IRBs to protect human subjects are paternalistic and thus bad. The presupposition that such attempts are paternalistic is contentious -- one purpose of IRBs is to safeguard patients’ autonomy -- as is the presupposition that all paternalism is bad. Some paternalism is justified, such as when we try to prevent depressed children from committing suicide. The second part of the sentence (2) contradicts my experience; it may be true, but you need to cite evidence.

Although the language is much better, there are still several errors of grammar, spelling and punctuation, particularly in the questionnaires. It is a commendable achievement to write a paper in a foreign tongue, but these mistakes must be corrected before publication.

IRB stands for Institutional (not Internal) Review Board

Optional: you might like to consider the question of whether or not consent forms with simpler language will fulfill the informational requirements of national and international regulations.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No

Declaration of competing interests:

I write on the ethics of compensating human subjects, but have never written on informed consent. Apart from that, I declare that I have no competing interests.