Author’s response to reviews


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Author’s response to reviews:

Dear Dr Oerlemans,

Thank you for reviewing our manuscript. Kindly find our responses to the reviewers' comments below.

• Thank you for explaining the SOP for including illiterate individuals in research in Egypt and for ensuring their rights in your rebuttal letter. Please also include this information in the paper itself, for instance under Declarations or under Subjects and Methods. Please also say how the research participants could withdraw from the research project and provide information about how you ensured data protection.
We added a statement about this in the manuscript and paragraphs from some SOPs under declaration section as follows

“A survey conducted among a range of groups in Saudi Arabia reported similar concerns, with most participants voicing the importance of confidentiality in biobanks. Therefore, protection of the rights of participants and security of data is the responsibility of every biobank. Under the declarations section in this paper, we are providing examples for the standard operating procedures (SOP) about informed consent, withdrawal of consent, and data protection from the Egyptian National Cancer Institute (ENCI) biobank."

These paragraphs were added under the declarations section as requested

1. **ENCI biobank SOP about the informed process.** The following paragraph is about presenting the informed consent to a subject who can’t read “If the subject/representative cannot read, obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by the subject/representative, and that consent was freely given. The witness may be a family member or friend. The witness should not be a person involved in the design, conduct or reporting of the research study.”

2. **ENCI biobank SOP about withdrawal of consent.** The following paragraph the first section in the procedure section of the SOP “The participant may withdraw consent at any time. Personnel at the tumor biobank should take appropriate steps to respect the will of the participant and ensure that the participant is able to withdraw without consequence.”

3. **ENCI biobank SOP about information access control.** The following paragraph is in the purpose section of the SOP "ENCI biobank is intended to manage the safekeeping of clinical and sample data in its custody, and it is accountable for limiting disclosure of information, maintaining privacy of the participants and safeguarding the integrity of the information.

- Page 8 line 19: «apparently easily irritable patients» - what do you mean? What is the reason for excluding those that may get irritated?
Some patients may look angry or irritable because they feel worried about their meeting with the doctor. We excluded them because we assumed that the psychological condition of these patients at the moment will affect their answers. This was added in the following paragraph

“Critically ill and apparently easily irritable patients, as well as patients in apparent pain were excluded. We assumed that the psychological condition of these patients at the current moment will affect their answers. “

• Throughout the survey and the article, the terms «donor» and «donating» are used. These are terms that are now increasingly avoided as the terms are loaded and indicate gift-giving or charity. Can this possibly have affected the answers you received, for instance the ones listed in table 4? It would be nice to see a problematization of the terms in the discussion section.

We have searched the websites of some biobanks worldwide, and the term “donors” and “donate” are used in the sections addressing participants. Here are 3 examples from Cardiff biobank, the national institute for health and welfare biobank in Finland, and the Helsinki Biobank.

•  https://www.cardiff.ac.uk/biobank/donors
•  https://www.terveyskyla.fi/helsinginbiopankki/en/sample-donor/sample-donor%C2%B4s-rights

We also added a statement about why we used these terms in the following paragraph

“Although using the terms “donors” and “donating” may indicate gift-giving or charity, we preferred using them since these terms are commonly found in biobank websites in the donor section, and since we thought that using these terms entails and encourages more involvement and sharing rather than the terms “participants” and “participation” for example. ”

•  Page 17: Please explain the difference in knowledge between males and females.
“Difference in knowledge between men and women could be a reflection of the community culture in Egypt where men have more communications and interests than women, especially in lower education and socioeconomic sectors. Consequently, this would give men more general knowledge than women.”

• Page 21: Regarding commercialization: Please elaborate on your proposed solution, explaining what you mean by fair distribution of benefits, and how this may enhance trust and foster commercialization.

We added the following statement

“These benefits may include sharing in authorship in scientific papers, patents and intellectual property rights for researchers participating with their samples in research with commercial entities, as well as providing drugs that may come out of this research at an affordable price for the public.”

• Page 22: Please reference examples of ethical guidelines stating that research participants own their samples after participation.

On a second and deeper look in the literature, we found that the issue of ownership is debatable and there is no consensus about it. We added two references (no 41 and 42) and we modified this statement into

“Ethical guidelines show a considerable debate about who owns research and biobank samples? Some authors proposed that “custodianship” and “stewardship” are the suitable terms to define the role of researchers and the bioabanks with regard to samples. However, these guidelines state that research subjects or participants can withdraw their consent at any time.”