Author’s response to reviews

Title: Protocol for a multicenter, real-world study of HIV pre-exposure prophylaxis among men who have sex with men in China (CROPrEP)

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Author’s response to reviews:

Dear Editor,

Thanks very much for your valuable comments, we have amended the manuscript of ”Protocol for a multicenter, real-world study of HIV pre-exposure prophylaxis among men who have sex with men in China (CROPrEP)” (INFD-D-19-00924). The point to point responds to each comment are listed as following.

Best regards

Yours sincerely,
Response to the editor’s comments:

Comments 1:

- According to our submission guidelines, there should be no conclusions section for a study protocol as you cannot draw any conclusions until the study is completed.

Response:

Thank you for your valuable advice. We have delete the part of conclusions from the newly submitted manuscript.

Comments 2:

- I can see that you have obtained ethical approval from the First Affiliated Hospital of China Medical University. As this is a multi-centre study being conducted in 4 different cities in China, we need to see proof of ethics approval from all study sites. Please send the relevant proofs for each individual centre to BMCSeriesEditorial@biomedcentral.com. Please update your "Ethics approval and consent to participate" statement to clarify if ethical approval was obtained for all study sites.

Response:

Thank you for your valuable advice. We have sent an email with the subject line "INFD-D-19-00924-Ethical and Funding Approval Documentation " to BMCSeriesEditorial@biomedcentral.com, which have attached ethical approvals from four centers.

Comment 3:

- Please update your "Ethics approval and consent to participate" statement to explain who will provide consent to participate and confirm that consent will be written.

Response:
Thank you for your kindly comments and we have update information on "Ethics approval and consent to participate" in the newly submitted manuscript as follow:

“Ethics approval and consent to participate

This study was approved by the Institutional Review Board in four research centers - the First Affiliated Hospital of China Medical University, Beijing Youan Hospital Capital Medical University([2018]-037), the Third People’s Hospital of Shenzhen(2018-007) and Chongqing public health medical center(2018-004-02-KY), and research procedures were carried out strictly in accordance with relevant guidelines ([2018]2015-139-5). Written informed consent will be obtained from each participant prior to starting any study procedure. All research procedures will be carried out strictly in accordance with the Declaration of Helsinki, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice, and Guidelines for Ethical Review Work of Drug Clinical Trials in China. To ensure privacy, every participant will be uniquely assigned an identification code, in place of his real name, during the survey to link their questionnaire and laboratory testing results.”

Comments 4:

- After the list of abbreviations, please add the heading "Declarations".

Response:

Thank you very much. We have added the heading "Declarations" after the list of abbreviations in the newly submitted manuscript.