

Dr Sinead Smith,  
Tallaght University Hospital,  
Tallaght,  
Dublin 24

23<sup>rd</sup> March 2020

**REF: Helicobacter Pylori Antibiotic Resistance and Previous Antibiotic Use**

**REC: 2020-03 List 9 – Amendment (18)**

*(Please quote reference on all correspondence)*

**Date of Valid Submission to REC: 31.01.2020**

**Date of Ethical Review: 13.03.2020**

Dear Dr Smith,

The Chairman, Prof Richard Deane, on behalf of the Research Ethics Committee, has reviewed the amendment you submitted to the SJH/TUH JREC for the above named study and has given **FULL** approval for use of the updated PIL and consent form. The Chairman also noted that additional sites have been added. Please ensure Ethics approval is sought from these sites. TUH and SJH are approved sites.

The following documents were reviewed:

- Non-clinical amendment request form, dated 31.01.2020
- Patient information Leaflet and Consent Form

*Please note that ethical approval for this study is only active under the following conditions:*

1. *Applicants must submit an annual report for ongoing projects.*
2. *Applicants must submit an end of study declaration/end of study report upon completion of the study.*
3. *All adverse events must be reported to the JREC.*
4. *All changes (minor and substantial) to documentation/study must be submitted to the JREC using the amendment request form and the changes must be tracked/highlighted clearly. Approval from the JREC is required before implementation of the changes.*

*It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 2018.*

Yours sincerely,



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REC Officer – Dr Sadhbh O’Neill  
SJH/TUH Research Ethics Committee