QResearch Application Amendment Form for Scientific Committee

Project Information

1. Project Reference Number: OX39
2. Project Title: Project DELTA - integrated Diagnostic solution for Early detection of Oesophageal cAncer
3. Chief Investigator: Prof Julia Hippisley-Cox

Amendment Information

4. Name of the person requesting the amendment: Winnie Xue Mei
5. Institutional email address of the person requesting the amendment: winnie.mei@phc.ox.ac.uk
6. Date amendment requested: 16/12/2020
7. Amendment number: 1
8. Are there any changes to the hypotheses being tested?: No
9. Are there any changes to the design of the study?: No
10. Are there any changes to the definition of the study population?: No
11. Are there any changes to the exposures, comparators, or outcomes?: No
12. Are there any changes to the analysis strategy including not performing a planned analysis?: No
13. Are there any changes to other methods such as to control for missing data, confounding, or sensitivity analyses?: No
14. Are there any changes to the linkages to other databases, including additional linkages, or not using linked data which were part of the approved protocol?: No
15. Are there any changes to the research team including the Chief Investigator, co-applicants, or researchers?: No
16. Are there any changes to the UK university at which any of the research team including the Chief Investigator, co-applicants, or researchers are based?: No
17. Are there any other changes not listed above?: Yes
   a) We have included a list of exposure variables and risk/confounding factors we’d like to examine in relation to future risk of oesophageal cancer and Barrett's oesophagus
   b) We would like amended application to include the following: - All cancer related treatments and procedures - All investigative or diagnostic procedures/tests related to examination of the upper gastrointestinal or abdomen region including endoscopies, CT or MRI scans, and X-rays - Family history of any cancer (including blood and colorectal cancers) (1,2) - History or current diagnosis of any cancer (1,2) - History or current liver disease (1,2) - History or current

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pancreatic disease (1,2) - History or current abnormality in oesophageal and gastric region (including but not limited to oesophageal stricture and Hiatus Hernia) (1,2) - Anaemia (1,2) - Loss of appetite (1,2) - All diabetes related drugs (to identify pre-diabetics/diabetics or obese individuals) (3)

c) We believe these variables will help us to better identify and differentiate patients at higher risk of oesophageal cancer. Information related to cancer treatments and procedures will allow us to capture cancer cases not otherwise identifiable from the cancer registry.

18. References: