Department of Health & Human Services

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

iRIS Reference Number ***331411***

Type of Action: Submission Response for Initial Review Submission Form
Project Number: P131352

01/07/2014

TO: Sarah Kobrin
NCI - Division of Cancer Control and Population Sciences

FROM: Chairperson, Special Studies Institutional Review Board, NCI

SUBJECT: Action on Clinical Research Protocol

The Initial Review of your protocol and consent document, "Awareness and Beliefs about Cancer Survey ," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by full board review on 11/04/2013.

The IRB has taken the following action:

	Approved as written. Forwarded to the CC OPS for administrative processing.
	Approved with stipulations pending re-review by SSIRB Chair. See review.
X	Approved with recommendations. See below. Forwarded to the CC OPS for administrative processing.
	Deferred pending response to stipulations and re-review by the full SSIRB. See review.
	Disapproved. See review.

Recommendations:

1) On page 4 of the revised protocol, in the new language regarding random digit dialing, the first sentence is incomplete and should be corrected.
2) Forward a copy of the amended survey instrument when available from the Contractor

UCL RESEARCH ETHICS COMMITTEE
GRADUATE SCHOOL OFFICE

Professor Jane Wardle
Health Behaviour Research Centre
UCL Department of Epidemiology & Public Health
1-19 Torrington Place
London
WC1E 6BT

26 November 2010

Dear Professor Wardle

Notification of Ethical Approval:
Ethics Application: 1122/003: International comparisons of cancer awareness and beliefs – international cancer benchmarking project module 2

I am pleased to confirm that in my capacity as Chair of the UCL Research Ethics Committee I have approved your project for the duration of the study (i.e. until December 2011).

However, approval is subject to the following conditions:

1. You must seek Chair's approval for proposed amendments to the research for which this approval has been given. Ethical approval is specific to this project and must not be treated as applicable to research of a similar nature. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing the 'Amendment Approval Request Form'.

The form identified above can be accessed by logging on to the ethics website homepage: http://www.grad.ucl.ac.uk/ethics/ and clicking on the button marked 'Key Responsibilities of the Researcher Following Approval'.

2. It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. Both non-serious and serious adverse events must be reported.

Reporting Non-Serious Adverse Events
For non-serious adverse events you will need to inform Dr Angela Poulter, Ethics Committee Administrator (ethics@ucl.ac.uk), within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Chair or Vice-Chair of the Ethics Committee will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Reporting Serious Adverse Events
The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Vice-Chair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.

On completion of the research you must submit a brief report (a maximum of two sides of A4) of your findings/concluding comments to the Committee, which includes in particular issues relating to the ethical implications of the research.

Yours sincerely

p.p. Angela Packel

Sir John Birch
Chair of the UCL Research Ethics Committee

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