

Hewitt Martin (Children's Services) to me, Maxwell-Armstrong, Game

10/07/2014

Damian

Thank you for your enquiry. I returned today from AL.

I have now stepped down as chair of Nottingham 2 research ethics committee (as of 2 weeks ago) but will offer advice. I have included Dr Game in the circulation as she has taken on the role of chair – just to be sure she agrees with my opinion.

I am unable to read all the details you have provided but I would agree that this work does not need ethical approval. You are assessing an aspect of technology which allows you to improve your current communication with your patients. You will therefore assess whether it helps the development of your service. I would call this Service Evaluation.

The Research Ethics website provides a section on 'Is this research?' which you might find helpful – particularly if you plan to publish your findings.

<http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf>

You will need to be mindful of confidentiality with this system but that would come under your professional standards and does not need an ethical committee to guide you on this.

Best wishes

Martin

Martin Hewitt

Consultant in Paediatric Medicine and Paediatric Oncology

Assistant Professor University of Nottingham

**From:** Damian Bragg [mailto:[damianbragg@gmail.com](mailto:damianbragg@gmail.com)]

**Sent:** 27 June 2014 14:13

**To:** Hewitt Martin (Children's Services)

**Cc:** Maxwell-Armstrong Charles (Endoscopy)

...

**Subject:** Fwd: Service development query

Dear Dr Hewitt,

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I understand you are chair for the local ethics committee.

Please could we ask your opinion as to whether a service development project which involves communicating with patients via text message, requires formal ethics committee approval?

I enclose a letter we have pre-drafted, with appendixes referred to in a zip file, and also forward the opinion of Dr Dumbleton I sought earlier today.

Mr Charles Maxwell-Armstrong is the consultant lead for this project.

Kind Regards,

Damian Bragg

Surgical Registrar

[07947-615898](tel:07947-615898)

E Floor West Block

[damian.bragg@nuh.nhs.uk](mailto:damian.bragg@nuh.nhs.uk)

----- Forwarded message -----

From: **Dumbleton Tim (Research & Development)** <[Tim.Dumbleton@nuh.nhs.uk](mailto:Tim.Dumbleton@nuh.nhs.uk)>

Date: 27 June 2014 12:44

Subject: RE: Service development query

To: Damian Bragg <[damianbragg@gmail.com](mailto:damianbragg@gmail.com)>

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Dumbleton Tim (Research & Development) to me

27/06/2014

Hi Damian

Thanks for your email, and the information about the project.

This information confirms my original conclusion, that this piece of work does not constitute a research study, and as such is not subject to ethical approval. I would consider this to be a service evaluation or service development project.

To compliment my decision about the type of project this is I have attached a leaflet produced by the ethics service (now the HRA) that outlines the differences between research, evaluation and audit. There are also two algorithms which the HRA have produced that can help when deciding if a study is research, and if it is, does it need ethical approval.

Is my study research? <http://www.hra-decisiontools.org.uk/research/>

Do I need ethical approval? <http://www.hra-decisiontools.org.uk/Ethics/>

You can by all means contact the HRA for a second opinion, and there are details of how to do this once you have completed the above algorithm.

Regardless of how the study is defined, the main thing to consider is the safety, and rights of the patient. You have addressed these by providing the patient with information about the project, and obtaining their consent to use their mobile phone number. As with other patient data, you need to ensure that the information provided by the patient for this project s only used for the intended purpose that consent with given, and that all data is handled and stored following the correct procedures as defined by the trust.

I hope this information is of use to you, please don't hesitate to contact me should you wish to discuss this further.

Kind regards

Tim

Dr Tim Dumbleton  
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Research & Innovation  
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**From:** Damian Bragg [mailto:[damianbragg@gmail.com](mailto:damianbragg@gmail.com)]

**Sent:** 27 June 2014 11:47

**To:** Dumbleton Tim (Research & Development)

**Subject:** Service development query

...

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Guyler Tim (Trust HQ) to me, Maxwell-Armstrong, Perumpalath, Sian, Bernard, Dewdney-York

27/06/2014

Thanks Damian et al.

I think this is quite clear that the trial doesn't need ethics approval – it isn't a research study.

So please do continue with the trial.

The key question I think will be if any consultants are unhappy with the current proposal being undertaken for their patients. If so I'd suggest at this point the trial doesn't stop for everyone else and in parallel there is a discussion with that colleague to understand their concerns.

The purpose of all trials is to gain learning and see what needs changing to improve the approach. What is clearly key here is to ensure that there is a very clear comms process so colleagues involved from all disciplines are aware what is going on, know how they can feed back views in as real time as possible, and be kept up to date of where changes have been made in response to feedback.

From what I understand that is exactly what has happened in this instance. The FLO protocol and information to patients has been tightened up and so the trial should now be even better for patients. Hopefully Prof Lobo and other colleagues being aware of these actions on the back of their feedback will reassure them that their views are important and that we are learning and improving accordingly.

Keep up the great work!

Best wishes

Tim

**Tim Guyler**

Programme Director

Better for you – Whole Hospitals Change Programme

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[0115 969 1169 ext 76025](tel:01159691169) (City campus)



**From:** Damian Bragg [mailto:[damianbragg@gmail.com](mailto:damianbragg@gmail.com)]

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**Sent:** 27 June 2014 12:51

**To:** Maxwell-Armstrong Charles (Endoscopy); Perumpalath Binoy (Corporate); Sian Clark; Bernard Helena (Digestive Diseases & Thoracics); Dewdney-York Becky (Community); Guyler Tim (Trust HQ)

**Subject:** Fwd: Service development query

Please see below. I don't feel we need to take this any further but I will await your opinions.

My original email attached and appendixes.

Damian

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**From:** Dumbleton Tim (Research & Development) <[Tim.Dumbleton@nuh.nhs.uk](mailto:Tim.Dumbleton@nuh.nhs.uk)>

**Date:** 27 June 2014 12:44

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