Reviewer’s report

Title: Opt-out as an acceptable method of obtaining consent in medical research.

Version: 1 Date: 6 December 2010

Reviewer: Melvyn Jones

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Background. The authors give a clear summary of the background to the study and include all relevant material including a systematic review which covers this area.

Methods. The methods are clear and succinct I am little unclear about why high users of the pathology facility were used- it may be worth saying something about the generalisability of these practices compared to other Irish general practices (Discretionary Revisions) - are these study practices more deprived, do they have more students etc? Minor Essential Revisions

Results. The results are generally clear although I wonder if a flow chart may help the reader grasp the mechanics of the study recruitment. (Discretionary Revisions/Minor Essential Revisions)

The results imply a 100% response rate which is always a bit surprising- I don’t have clear grasp of the Irish GP system but could the participant ask for their urine to go to another lab or a private lab if they didn’t want to participate? (Minor Essential Revisions)

I think importantly the authors need to be explicit about the bulk of their data has no proof of participant’s actively “opting in”- conceivably they may be analysing results for participants who never got the study invitation letters or never quite made the active decision to make contact to opt out. I think is acceptable, but I think we need to be clearer that silence is not the same as passive consent. I think comments such as “well received by patients” in the 1st line of the conclusion is therefore a bit more misleading. (Major Compulsory Revisions)

I have some concerns about the numbers approached to provide samples? Which is an issue as there are huge variations in numbers of samples submitted (nearly ten fold). I suspect this is more than would be expected by practice size alone? Is there data on how many patients were approached and declined to participate directly to the GP? (Major Compulsory Revisions)

Two potential participants objected, which I think is valuable data for a study empirically testing an ethical issue. What were the concerns raised by objectors and can they be described? (Discretionary Revisions/Minor Essential Revisions)

I think the discussion with the ethics committee might be conceived as part of the
data for this study and might also warrant inclusion as a brief narrative. (Discretionary Revisions/ Minor Essential Revisions)

General issues
“Argumentation” is not a word I have come across before. (Minor Essential Revisions)
Sent / send (Minor Essential Revisions)

I think some of the sentences could do with reworking as their meaning is little cryptic e.g. p2 para 1 “in this interpretation… “ (Minor Essential Revisions)

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

non-financial competing interest
I have published in this field (see citations)