In a previous paper I argued that research might be better guided by virtue ethics rather than principlism and other well established theories of practical ethics, such as deontology and consequentialism (Carpenter 2013). There, I drew on the work of Bruce Macfarlane (2009, 2010) in making a case for the virtuous researcher and virtuous research. The ensuing discussion indicated reasonably substantial support for this approach but, perhaps more interestingly, attention was also drawn to the role and conduct of ethics committees in reviewing research. The discussion indicated that, whilst there is an abundance of codes and similar documents aimed at guiding research conduct, there was little to guide ethics committees and their members. A virtue ethics approach to research might help committees identify virtuous research and researchers but it could be equally useful in guiding the reviewing work of committees. In this paper I attempt to relocate and develop Macfarlane’s work in considering its application to the work of ethics committees. In particular I will consider the virtues that reviewers should exhibit or demonstrate when reviewing research and what we might take as the telos of ethics committees.

Introduction

The main aim of this paper is to present some sort of practical guidance to members of research ethics committees; it does not purport to engage in scholarly discourse. A secondary aim, in keeping with the structure and ethos of this symposium, is to inspire discussion.

It is fair to observe that research ethics committees receive a fair amount of criticism; they are often seen as obstructive and a block to academic freedom. Typical concerns include inappropriately focusing on matters of science and research design whilst, paradoxically, rarely understanding the key scientific issues. One of the biggest challenges is lack of consistency both within and between committees; decisions are sometimes seen as arbitrary and idiosyncratic. Many committees are accused of hiding behind matters of law and policy rather than fully engaging with ethical review. Attempts to tackle these problems have included the use of:

- Various codes, declarations and similar documents setting out the ethical boundaries of research; although variable, these documents tend to focus on specific examples of misconduct or, at least, allude to them.
• A particular normative theoretical position – most commonly principlism but consequentialism and deontology might equally have a place.
• Various checklists aimed at alerting reviewers to key domains, for example that produced by the Health Research Authority (Appendix 1)

Key questions relate to the roles of ethics committees; the following are all defensible and not necessarily mutually exclusive:

1. Should ethics committees undertake a skilful analysis of a research protocol by considering its conformity to an agreed code, declaration, treaty or similar document?
2. Should ethics committees analyse research protocols by adopting an agreed normative ethical position or theory?
3. Should ethics committees be guided by checklists in systematically reviewing a research proposal?
4. Should ethics committees endeavour to reflect upon members’ emotional reactions to proposed research, in pursuit of a ‘middle ground’, being mindful of the disposition of the committee and the underlying virtues revealed in that pursuit?

The first question was alluded to, though probably not addressed, in the symposium which took place in 2013. An endeavour to find some common principles, which might be shared by the learned societies in the Academy of Social Sciences, was partly successful. Not surprisingly, there was no obvious prospect of replacing all the individual codes with a single document. The question regarding the usefulness of codes as guides to ethical review was not really addressed. In many years of experience as a member and chair of several ethics committees I have never witnessed the systematic application of a code in the course of review. Reasons for this are numerous and include the simple observation that most codes are written from the perspective of the researcher or the specific discipline with which they identify. It might also be argued that conformity to a code is a matter for the researcher and in itself is no guarantee that the proposed research is, indeed, ethical. Members of ethics committees might agree that a particular proposal, whilst not in breach of a code, raises significant ethical concerns; those concerns cannot always be articulated by reference to the code. It is a moot point whether members of ethics committees should have expertise in the relevant discipline but there is broad agreement on the value of lay members, presumably because they are seen as able to make independent judgements, free from any sort of professional code and the discipline it reflects.

Turning to the second question, it is useful to briefly summarise the main theories which might be used to guide ethical review. Principlism as a theory and a tool for ethical analysis was developed by Tom Beauchamp and James Childress and used to structure their text Principles of Biomedical Ethics, now in its sixth edition (2009). Principlism is based on the idea that there are foundational ethical principles which, in themselves, do not stand in need of any further ethical defence or analysis. Putting matters fairly crudely, they are seen as goods-in-themselves. The principles are broadly used as ‘headings’ which collectively comprise a framework for ethical analysis. The four principles are Beneficence, Non-Maleficence, Respect for Autonomy and Justice (distributive). Reference to the four principles is relatively commonplace, particularly in biomedical contexts.
Beauchamp and Childress have many critics but the most outspoken is Bernard Gert (1997) and, more recently Stephen Hanson (2009, p77) who highlights the limitations of the principles in a secular, pluralistic society. The main objections are summarised by Gert:

The dominant view in question we have labelled "principilism." It is characterized by its citing of four principles which constitute the core of its account of biomedical ethics: beneficence, autonomy, nonmaleficence, and justice. So entrenched is this "theory," that clinical moral problems are often grouped (for conferences, papers, and books) according to which principle is deemed most relevant and necessary for solving them. It has become fashionable and customary to cite one or another of these principles as the key for resolving a particular biomedical ethical problem. Throughout much of the biomedical ethical literature, authors seem to believe that they have brought theory to bear on the problem before them insofar as they have mentioned one or more of the principles. Thus, not only do the principles presumably lead to acceptable solutions, but they are also treated by many as the ultimate grounds of appeal.

Reference to these principles in the course of ethical review is relatively commonplace but I have never witnessed any systematic application of them in structuring an ethical review and providing clear feedback to applicants. Arguably they are often applied in justifying the intuitions of members of a committee rather than being used to identify specific ethical concerns. A committee might, for example, conclude that deception used in the course of research is a violation of autonomy. The label is simply applied *post ante* – adding nothing of substance to the original intuitions of the committee. In brief, members of the committee might see deception as wrong for a range of fundamental moral reasons but feel obliged to use a label raising the matter of appeal.

Less contentious theories include consequentialism and deontology. In the case of the former, morality is measured by the outcomes of actions; contemporary accounts of utilitarianism (a form of consequentialism) posit preference satisfactions (Peter Singer (2011) is probably the best known exponent) as an objective measure of morality. An action (we could substitute 'study') is moral insofar as it brings about the greatest number of preference satisfactions (or the least number of expressions of dissatisfaction) from those affected by it. Again, I have never witnessed any systematic application of consequentialism in the course of ethical review though there is often evidence of it coming into play when considering matters such as risk: benefit and cost: benefit ratios. It has to be observed however that it would be a very unusual ethics committee that readily accepted any situation resulting in significant disadvantage to the few no matter how great the benefit to the many.

Deontology is frequently contrasted with consequentialism in that it relates the morality of an action to the duties of the moral agent rather than the consequences of the act. Consequentialism is easily criticised on the ground that it could be used to support significant degrees of harm to minorities as long as an action results in the maximisation of benefit for a majority. Deontology is equally criticised on the ground that unwavering adherence to duty could nevertheless lead to significant harm to many as a result; for example it is not difficult to envisage circumstances when a refusal to lie could have devastating consequences. Notwithstanding the differences in the approach that each take, there is no necessary conflict in the outcomes of moral analyses drawing on the respective theories. For example, in most situations telling lies leads to harmful consequences so
should be avoided; similarly a duty to not lie generally results in the best consequences. Kantianism
in the form of the categorical imperative, is probably the best example of deontology. The
categorical imperative demands that we

\[ \text{act only on that maxim that we can, at the same time, will to be a universal law} \]

In simple terms, it is the golden rule – do as you would be done by. An underlying imperative of
universalisability strictly implies that an action is right insofar as the moral agent would be content
with others behaving similarly in relevantly similar circumstances. The demands of universalisability
and the derived duty to treat people as ends in themselves rather than means to ends, result in a
shift from a focus on the moral agent to the social context in which he acts. Kantian deontology
would be difficult to apply in the context of ethical review; much research necessarily requires some
departure from a duty to treat people as ends in themselves. Again, whilst there is no evidence of
systematic application of deontology as a guide to ethical review, it is reflected in some typical
preoccupations of ethics committees, for example duties to respect privacy.

Turning to the matter of checklists: Checklists in various forms have been developed largely in the
pursuit of consistency in ethical review. Checklists are useful in identifying key aspects (sometimes
referred to as ‘domains’) of research which might give rise to ethical concerns; there are however
limitations to their use. Checklist items often inspire discussion but they rarely help in guiding
ethically defensible decisions. There are further concerns about the relative weightings of checklist
items such that the goal of consistency is readily lost.

To restate my last question:

Should ethics committees endeavour to reflect upon members’ emotional reactions to
proposed research, in pursuit of a ‘middle ground’, being mindful of the disposition of the
committee and the underlying virtues revealed in that pursuit?

The question invites an answer drawing upon Aristotelian virtue ethics. Virtue ethics raises the
importance of the development of wisdom and, relatedly virtue. Aristotle’s starting question related
to what might comprise the ‘good life’; the answer was derived from the identification of the
purpose of life – its telos, which he concluded to be eudaimonia. Eudaimonia is not easily translated
but it reflects the contentment associated with a life of contemplation, growing wisdom and the
development of virtue.

The virtues are identified through a mechanism known as the doctrine of the mean. Spheres of
action or feelings are established and then the vices of excess and deficiency described; the requisite
virtue is seen as a midpoint between the vices. A fairly typical example is reproduced on the
following page:
# ARISTOTLE'S ETHICS
## TABLE OF VIRTUES AND VICES

<table>
<thead>
<tr>
<th>SPHERE OF ACTION OR FEELING</th>
<th>EXCESS</th>
<th>MEAN</th>
<th>DEFICIENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fear and Confidence Pleasure and Pain</td>
<td>Rashness</td>
<td>Courage</td>
<td>Cowardice</td>
</tr>
<tr>
<td>Getting and Spending (minor)</td>
<td>Licentiousness/Self-indulgence</td>
<td>Temperance</td>
<td>Insensibility</td>
</tr>
<tr>
<td>Getting and Spending (major)</td>
<td>Prodigality</td>
<td>Liberality</td>
<td>Illiberality/Meanness</td>
</tr>
<tr>
<td>Honour and Dishonour (major)</td>
<td>Vulgarity/Tastelessness</td>
<td>Magnificence</td>
<td>Pettiness/Stinginess</td>
</tr>
<tr>
<td>Honour and Dishonour (minor)</td>
<td>Vanity</td>
<td>Magnanimity</td>
<td>Pusillanimity</td>
</tr>
<tr>
<td>Anger</td>
<td>Ambition/empty vanity</td>
<td>Proper ambition/pride</td>
<td>Unambitiousness/undue humility</td>
</tr>
<tr>
<td>Self-expression</td>
<td>Irascibility</td>
<td>Patience/Good temper</td>
<td>Lack of spirit/unirascibility</td>
</tr>
<tr>
<td>Conversation</td>
<td>Boastfulness</td>
<td>Truthfulness</td>
<td>Understatement/mock modesty</td>
</tr>
<tr>
<td>Social Conduct</td>
<td>Buffoonery</td>
<td>Wittiness</td>
<td>Boorishness</td>
</tr>
<tr>
<td>Shame</td>
<td>Obsequiousness</td>
<td>Friendliness</td>
<td>Cantankerousness</td>
</tr>
<tr>
<td>Indignation</td>
<td>Shyness</td>
<td>Modesty</td>
<td>Shamelessness</td>
</tr>
<tr>
<td></td>
<td>Envy</td>
<td>Righteous indignation</td>
<td>Malicious enjoyment/Spitefulness</td>
</tr>
</tbody>
</table>


Retrieved from: [http://www.cwu.edu/~warren/Unit1/aristotles_virtues_and_vices.htm](http://www.cwu.edu/~warren/Unit1/aristotles_virtues_and_vices.htm)
Virtues might be seen as certain dispositions or characteristics. It is not difficult to consider the dispositions of ethics committee members and how they collectively contribute to the general disposition of the committee as a whole. The idea of the virtuous committee, insofar as virtue is evidenced by its reactions to researchers and their research, is relatively straightforward; clearly some committees more readily display the virtues, identified above, than others. It is equally straightforward to consider the possibility of these virtues being acquired over time, through processes of contemplation and wise reflection – assuming reasonable continuity of membership. Ethics committees certainly have reputations – good and bad – and this is apparent when considering national networks such as that provided by the Health Research Authority. It might be posited that reputation is at least partly established with some reference to virtues and vices – though this is rarely explicit.

The matter of the actual review is quite distinct from that of the general disposition of a committee, as outlined above. The essential elements of a virtuous review might be identified through a consideration of Bruce Macfarlane’s (2009) work which focuses on researchers and the nature of research. He constructs a framework identifying phases of research enquiry:

**RESEARCH PHASES**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framing</td>
<td>questions, problems, hypotheses, issues, projects, proposals</td>
</tr>
<tr>
<td>Negotiating</td>
<td>access, consent, permission, time, support</td>
</tr>
<tr>
<td>Generating</td>
<td>data, materials, ideas, inspiration</td>
</tr>
<tr>
<td>Creating</td>
<td>results, interpretations, models, concepts, theories, critiques, designs, artefacts</td>
</tr>
<tr>
<td>Disseminating</td>
<td>through publication, exhibition, performance</td>
</tr>
<tr>
<td>Reflecting</td>
<td>on epistemological and personal learning</td>
</tr>
</tbody>
</table>

An ethics committee could adopt a similar approach in considering research in terms of its prospective phases and the meanings of each of those phases. It is noteworthy that Macfarlane’s ‘meanings’ resonate with the domains identified in typical checklists, for example that included in Appendix 1. In this respect it might be argued that the table, above, is little more than a checklist framework. Alternatively an ethics committee might consider phases of ethical review, seeking associated meanings. A very tentative suggestion follows (this is very much open to discussion):
REVIEWING PHASES

<table>
<thead>
<tr>
<th>Phase</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding</td>
<td>research rationale, primary and secondary objectives, methods, design</td>
</tr>
<tr>
<td>Empathising</td>
<td>with.... researcher, participants, sponsors, funders, peers, supervisors</td>
</tr>
<tr>
<td>Focusing</td>
<td>on ... worthwhileness, benefits and burdens, risks, researcher consideration of participants, impact / wider benefits</td>
</tr>
<tr>
<td>Clarifying</td>
<td>key ethical issues, researcher intentions, researcher ability</td>
</tr>
<tr>
<td>Deliberating</td>
<td>to... find committee consensus, identify significant ethical issues</td>
</tr>
<tr>
<td>Concluding</td>
<td>by arriving at an opinion, establishing clear reasons to support opinion</td>
</tr>
<tr>
<td>Reflecting</td>
<td>on the decision and process, consistency with other decisions</td>
</tr>
</tbody>
</table>

Macfarlane undertakes an Aristotelian analysis to determine the virtues demanded in each phase of the research:

THE VIRTUES AND VICES OF RESEARCH

<table>
<thead>
<tr>
<th>Phase</th>
<th>Vice (deficit)</th>
<th>Virtue</th>
<th>Vice (excess)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framing</td>
<td>Cowardice</td>
<td>Courage</td>
<td>Recklessness</td>
</tr>
<tr>
<td>Negotiating</td>
<td>Manipulativeness</td>
<td>Respectfulness</td>
<td>Partiality</td>
</tr>
<tr>
<td>Generating</td>
<td>Laziness</td>
<td>Resoluteness</td>
<td>Inflexibility</td>
</tr>
<tr>
<td>Creating</td>
<td>Concealment</td>
<td>Sincerity</td>
<td>Exaggeration</td>
</tr>
<tr>
<td>Disseminating</td>
<td>Boastfulness</td>
<td>Humility</td>
<td>Timidity</td>
</tr>
<tr>
<td>Reflecting</td>
<td>Dogmatism</td>
<td>Reflexivity</td>
<td>Indecisiveness</td>
</tr>
</tbody>
</table>

This further analysis adds an important dimension to what would otherwise be a checklist based on typical phases of research, from conception to dissemination. It is not unusual for ethics committees to use the language of virtues in its deliberations and conclusions but I have never witnessed any formally structured review, starting from the perspective of the researcher’s virtues or vices. It would be interesting to consider an ethics committee starting a discussion from the perspective of, for example, the respectfulness of the researcher; this might be more fruitful than the common practice of focusing on content of documents themselves rather than what it reflects in terms of the disposition of the researcher. Alternatively, or perhaps additionally, an ethics committee might identify virtues in relation to the phases of review (again, this is a very tentative suggestion and wider discussion would be welcomed):

**THE VIRTUES AND VICES OF ETHICAL REVIEW**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Vice (deficit)</th>
<th>Virtue</th>
<th>Vice (excess)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding</td>
<td>Ignorance</td>
<td><em>Intelligence</em></td>
<td>Ostentatiousness</td>
</tr>
<tr>
<td>Empathising</td>
<td>Inconsiderateness</td>
<td><em>Mindfulness</em></td>
<td>Emotionality</td>
</tr>
<tr>
<td>Focusing</td>
<td>Distractibility</td>
<td><em>Discernment</em></td>
<td>Narrow-mindedness</td>
</tr>
<tr>
<td>Clarifying</td>
<td>Vagueness</td>
<td><em>Perspicacity</em></td>
<td>Punctiliousness</td>
</tr>
<tr>
<td>Deliberating</td>
<td>Self-absorption</td>
<td><em>Cooperation</em></td>
<td>Collusion</td>
</tr>
<tr>
<td>Concluding</td>
<td>Aberrance</td>
<td><em>Reasonableness</em></td>
<td>Pedantry</td>
</tr>
<tr>
<td>Reflecting</td>
<td>Inconsistency</td>
<td><em>Reflexivity</em></td>
<td>Rigidness</td>
</tr>
</tbody>
</table>

Macfarlane takes each of the virtues sought in researchers and elaborates further in describing how they might be lived out:

**Living out research virtues**

**Courage**

- seeking to challenge one’s own presuppositions or conventional wisdom
- developing a project that might not necessarily attract funding or represent a ‘fashionable’ topic
- pursuing a line of research without undue regard to career and other financial imperatives
- freely admitting when research does not go to plan or when you feel your previous research was factually or conceptually mistaken
Respectfulness

- being respectful to others including vulnerable individuals and communities
- being aware of the temptation to take advantage of organisational, social or intellectual power over others
- taking care not to cede too much power to others who may wish to distort the research process for their own ends

Resoluteness

- being transparent about circumstances when the extent of data collection or creative endeavour has been compromised from original intentions
- being aware of the temptation to start analysing data or other results before a representative sample or case study has been completed

Sincerity

- ensuring that the results of research are based on an accurate representation of all the relevant information collected
- resisting overt or covert pressure from a powerful sponsor or stakeholder to skew results to meet their needs or expectations
- being aware of the temptation to conceal or exaggerate results in order to gain some advantage, either materially and/or to reputation

Humility

- fully acknowledging one’s intellectual debt to others
- ensuring all research partners are fairly represented in being accorded publication credit corresponding with their relative contribution
- inviting others to challenge your own thinking and/or results

Reflexivity

- being self-critical about one’s own research findings or personal performance as a researcher


In similar vein, the virtues required of ethics committees can be elaborated upon in demonstrating how they might be evidenced in its reviewing activities:
Living out research ethical review virtues

**Intelligence**
- trying to understand chosen research designs and methodologies
- seeking advice from within the committee and beyond in endeavouring to improve understanding
- cultivating wisdom through experience
- admitting limitations of knowledge

**Mindfulness**
- being respectful to researchers, their peers, mentors, supervisors and supporters
- trying to understand the researcher’s motivations and goals
- endeavouring to share the researcher’s enthusiasm
- being aware of personal prejudice
- trying to empathise with research participants

**Discernment**
- careful analysis of the impact of the research – its general worthwhileness
- balancing of risks against benefits
- putting research into perspective by focusing on key aspects of context
- focusing on key ethical issues
- avoidance of paternalism
- endeavouring to not be distracted by trivial issues

**Perspicacity**
- seeking clarity
- keeping a sharp focus on key issues
- staying sharp-witted
- avoiding being ‘bogged down’ by detail
- staying flexible and open to new ideas

**Cooperation**
- constant listening
- searching for common ground
- being willing to challenge

**Reasonableness**
- avoiding dogmatism
- endeavouring to give consistent reasons for decisions of a similar nature
Summary and Key Discussion Points

- Ethics committees vary in their dispositions towards researchers and research. Arguably much could be gained by striving to develop virtues resulting in committees being, for example, liberal, patient, and courageous. What might be gained by being more mindful of Aristotelian vices and virtues when considering the general disposition of an ethics committee towards researchers and research?
- Using Macfarlane’s idea of phases of research, I have proposed phases with tentative ‘meanings’ which might be used to characterise the process of ethical review – see p7. How useful is this structure? Might there be some value in elaborating the ‘meanings’ in greater depth?
- I have focused on the phases in an endeavour to capture key virtues and vices – see p8. There are obviously alternative possible candidates for virtues and vices – what might they be?
- In an endeavour to illustrate the virtues and vices I have used Macfarlane’s idea of ‘living them out’ – see p10. There is clearly room to build upon this model – what additional examples might be included?

Bibliography


**Ethical Review Form (Lead Reviewer/REC Member)**

The HRA has an established role to promote transparency, largely through RECs and the publication of research summaries; this will now be extended to include the publication of the summary of REC opinion.

The lead reviewer(s) should complete this form in preparation for the REC meeting. The form may also be used by other REC members. The REC Chair should use the headings as an aide memoire to structure the discussion at the meeting. Completed forms should be given to the REC Manager who will arrange for them to be destroyed once the minutes of the meeting have been ratified.

Meeting Date:

Reviewer Name:

REC Reference Number:

Study Title:

<table>
<thead>
<tr>
<th><strong>Brief overview of study</strong> (optional depending on REC practice)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>1. Social or scientific value; scientific design and conduct of the study</strong> <em>(IRAS A6, A7-14, A 57-62, A75)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge. RECs should take into account the public interest in reliable evidence affecting health and social care. Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data. Is the research question important and necessary? Is the research design and proposed statistical analysis able to answer the question? Is there equipoise; are all treatment arms viable options for the research participants? Is there involvement of patients, service users, the public, in the design, management, and undertaking the research?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Comments/issues for discussion</strong></th>
</tr>
</thead>
</table>
2. Recruitment arrangements and access to health information, and fair research participant selection (IRAS A16, A 17-1, A17-2, A 27-29, A46, A47). Inclusion and exclusion of potential research participants. Selection of research participants so that vulnerable individuals are not targeted for risky research and the rich and socially powerful not favoured for potentially beneficial research. The benefits and risks of research should be distributed fairly among all social groups and classes, taking particular account of age, disability, gender, race, religion or belief and sexual orientation, as well as economic status and culture. How are research participants recruited? How does participation impact on their clinical care? Are compensation arrangements in place? Insurance (negligent/ non-negligent harm).

Comments/issues for discussion:

3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future) (IRAS A 18-25 & part B3 if radiation, and part B 5 if samples). Minimization of risks. Is there evidence of the consideration of any benefits/risk for individual research participants, past/future research participants, including whether the risk/intervention is sufficiently minimal to require no SSA. Are benefits/risk clearly identified for the research participant? Have steps been taken to minimise or eliminate the risk, hazards, discomfort, and distress and enhancement of potential benefits; risks to the research participant are proportionate to the benefits to the research participant and society? Is the balance between risk and benefit equitable?

Comments/issues for discussion:
4 Care and protection of research participants; respect for potential and enrolled research participants’ welfare & dignity (IRAS A25, A50-53, A 76, A 77).

* permitting withdrawal from the research  
* informing participants of newly discovered risks or benefits  
* maintaining welfare of participants  
* provision of appropriate indemnity and insurance  
* trial registration arrangements in place? (note, this is a condition of the favourable opinion, mandatory for clinical trials).

Data protection & research participant’s confidentiality (IRAS A 36 - 43) Where and how (anonymised/coded) and for how long will data be stored? What purpose will be served by the data? Who will access? Are research participants informed that access to their medical notes may be required? Arrangements made to deal with incidental disclosure?

Comments/issues for discussion:

5 Informed consent process and the adequacy and completeness of research participant information (A30 -34, A46, A49 & PIS). Provision of information to research participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate. Is the language used clear and understandable to the research participant it is aimed at? Does it include all the procedures as describe in the protocol? Have uncertainty and randomisation been explained to the research participant? Is consent taken as part of a process with research participants having adequate time to consider the information, and opportunity to ask questions? Is it clear to what the research participant consents or assents? Is there any inducement or coercion? Are vulnerable research participants involved? Is consent obtained to allow GP’s to be informed? (Is the Welsh version an accurate translation of the given English version? Wales only)

Comments/issues for discussion:
6. **Suitability of the applicant and supporting staff** (investigator CV & IRAS question A47, A48)

Applicant and supporting staff are suitably qualified and have experience relevant to the proposed research. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. Are the local facilities and arrangements suitable? Have community issues been considered? Have any conflicts of interest been considered?

**Comments/issues for discussion:**

---

7. **Independent review** (IRAS A 54-56)

Review of the design of the research trial, its proposed research participant population, and risk-benefit ratio by individuals unaffiliated with the research. The REC may be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.

**Comments/issues for discussion:**

---

8. **Suitability of supporting information**

E.g. GP letter, interview schedules, questionnaires, lone working policies etc.

**Comments/issues for discussion:**
9. **Other general comments.**
E.g. missing information / typographical errors / application errors.

---

10. **Consider and confirm the suitability of the summary of the study (IRAS A6-1).**
This summary will be published on the HRA website in this format together with the summary of the REC’s ethical opinion.

**Confirmed satisfactory**

**Changes requested**

---

**DECISION**

*Please highlight or mark/ring:*

Favourable  Favourable with conditions  Provisional  Unfavourable