

**A REPORT**  
**TO THE NATIONAL RESEARCH ETHICS SERVICE**  
**ON THE LAY VIEW**  
**OF THE FAST TRACK PILOT INITIATIVE**

**FROM**

**The three volunteer assessors**

**02 June 2008**

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# A LAY VIEW OF THE FAST TRACK PILOT INITIATIVE

## EXECUTIVE SUMMARY

This report is presented by the three independent lay assessors, who come from differing backgrounds, and who therefore have placed different emphases on their work. This is made clear at the outset because whilst we found a great deal of common ground, we also developed a number of differing perceptions that we consider should present individually.

An introduction and background offer our perspective of the origins of the Fast Track Initiative and our task in the pilot. Part of that background comprises our brief *curricula vitae*.

The pilot process comprised two separate yet contiguous parts. We moved from developing a way of deciding whether applications could be fast tracked or not in Phase 1 to making that decision and then deciding whether the application should be approved or not in Phase 2. In practice, we subsumed a Phase 3 (examining whether the rights, dignity safety and well-being of research subjects would be compromised by fast –tracking) into our Phase 2 work. In both phases we achieved rapidly an excellent *modus operandi* and good interpersonal relationships. We were thus able to find our areas of agreement rapidly. Where our perceptions differed, separate contributions are presented within our descriptions of Phases 1 and 2.

An overall conclusion is that, with reservations, a fast track process is feasible. This needs to be qualified.

We believe we have been able to show that a small group (possibly including an expert in qualitative research) can provide a fast track service for applications that present minimal risk and have no material ethical issues. However there are a number of recommendations we would offer in order that a new procedure operates effectively. These are:–

1. As a check on our decision-making process, there should be further analysis of the decisions we reached in Phase 2 and those reached on the same applications by the participant Research Ethics Committees.
2. We regard it as crucial that the operational implications of a fast track service are met in order to ensure confidence in the process. The following are recommended as areas for work:
  - Understanding the new demands on, and providing training for, co-ordinators
  - Clarifying individual and Fast Track Committee accountability
  - Making training available for applicants and their supervisors
  - Dealing with applications that have no material ethical issues but are badly presented
  - Receiving replies to minor queries
  - Making provisional decisions
  - Suggesting improvements to a research project
  - Having contact with the researcher

## **INTRODUCTION**

The lay members of the team offer their perspective of the Pilot Fast Track Approval Process with the hope that their varied experiences may assist in deciding whether such a process merits going into operational use.

Our intention is to present our view of the pilot as we as a team experienced it, to indicate our areas of agreement and disagreement and to offer some conclusions. To do this effectively, we think it desirable to begin with a statement of our understanding of the project background and our working criteria.

## **BACKGROUND**

The project arose out of the Building on Improvement initiative that aimed at implementing the recommendations of the Advisory Group on the Operation of NHS Research Ethics Committees. An NPSA Change Project Team was charged *inter alia* with developing the implementation plan for those recommendations and to co-ordinate the work of the various sub-project teams that emerged. One project was entitled Research Ethics Service – Screening Function - Fast Track Approval for Low Risk Studies. This established a pilot study envisaged as a screening operation by lay persons of applications for low risk studies in parallel with normal reviews being carried out by RECs that had agreed to participate. Early in the pilot project the NRES Operations Director made it clear to the by then assembled team that no decision had been reached about whether or not a Fast Track Process should operate and that the Pilot was intended to guide the final decision making. There were no preconceived ideas about the feasibility of such a process.

The team was led by the NRES Ethics Advisor, Dr Hugh Davies and comprised: a co-ordinator, Mrs Valerie Heard paralleling the application distribution of the participating RECs and liaising with their counterpart co-ordinators; together with three lay members.

The terms of reference for the lay persons were broadly set recognising that the lay persons, the pilot application co-ordinator and the Ethics Advisor would need to work in an evolutionary way, examining, reviewing and modifying the whole process with particular reference to the following:

1. The identification of the applications selected for fast track review by the co-ordinator
2. The nature of the recommendations reached by the lay team
3. The decisions made by the participating RECs

The co-ordinator offered applications selected from the full agendas using the following criteria (with broad discretion) to exclude applications in the following categories from fast track consideration.

- Studies re-submitted following an earlier Unfavourable Opinion
- Clinical trials of Investigational Medical Products
- Clinical trials of Medical Devices
- Randomised Studies
- Studies involving prisoners
- Studies involving persons unable to give consent including those in Intensive Care
- Studies where the co-ordinator considered the participants to be especially vulnerable
- Studies where the co-ordinator considered Application Form response A10 to be incomprehensible

## THE LAY TEAM

The team was recruited following interviews. The invitation letter inviting expressions of interest contained two explanatory appendices that gave general information about the fast track project with only the most general indications (as above) about what our task would be. The criteria for selection at interview are not known, but we consider it useful to present brief CVs to demonstrate our different backgrounds which have led to our different approaches to the task.

Vera Hughes BA FRSA

Having worked in the law, in supermarkets and in the Civil Service, Vera was for some 25 years a trainer in business. She now earns her living as a writer and actor. She served for four years on the North & Mid Hants LREC, mainly dealing with qualitative research, and has been a member of South East MREC (now SEREC), of which she is one of the Vice Chairmen, for about four years. She is also Chairman of the Test Valley Borough Council Standards Committee.

John Richardson: BA

John's academic background is in French and Theology. He worked for the Methodist Church in the UK and Korea and also travelled widely with the World Council of Churches. He joined the NHS in 1991 and soon included responsibility for a local research ethics committee among his tasks. He became Administrator of the North Thames (later London) MREC in 1997 then worked for COREC (now NRES) from 2000 to his retirement in 2005. He currently holds part-time ecumenical church posts in South London and is a member of Cambridgeshire 3 REC.

Frank Green: PhD MA

Frank is a Chartered Engineer and historian with a background in manufacturing management and consultancy in Europe and the Americas. In recent times he has focussed on the deployment of research outputs into the community and on the identification of fraudulent research. He was a non-executive director of the then Somerset Health Authority and a Lay Chair in the NHS Patient Regional Complaint Review procedure. Currently he serves on the Somerset REC and the Drugs and Therapeutics Committee at Yeovil District Hospital

## THE PILOT PROCESS

Whilst it is assumed that the main report carries a description of the needs of the two phase project and how those needs were met, our views on the process are better understood by providing a similar context.

Phases 1 and 2 were separate yet contiguous. In Phase 1 we took the rôle of the co-ordinator and in Phase 2 the rôles of the co-ordinator and of the sub-committee. In essence we moved from developing a way of deciding whether applications could be fast tracked or not in Phase 1 to making that decision and then deciding whether the application should be approved or not in Phase 2. In practice, we subsumed Phase 3 (examining whether the rights, dignity safety and well-being of research subjects would be compromised by fast –tracking) into our Phase 2 work.

We were greatly helped in our task by the responsiveness of our chair and co-ordinator. Both were always willing to receive comments and reacted positively throughout the project, enabling a helpful evolution of our working guidelines and *modus operandi*. The co-ordinator established an efficient email traffic system and responded rapidly to all requests and suggestions or procedural modifications. Both helped to create a working atmosphere that enabled a somewhat disparate team to settle down and gel surprisingly rapidly.

## **PHASE 1**

- Our aim was to decide which applications could be fast tracked, and which should not
- Our modus operandi was to work on our own
- Our reporting procedures were essentially through email with the co-ordinator making suggestions for modification and inviting our responses
- Our evaluation procedure revolved around the concept of whether or not an application involved research with no material ethical issues - NMEI. The key question asked was: “Is it feasible to identify research with no material ethical issues that can be reviewed by a central REC or sub-committee?” The criteria and guidelines for this evolved almost continuously during Phase 1.

Each lay member of the working party made her/his determination of filtered applications without reference to the others. The lay members made their determinations using the evolving guidance that consisted essentially of a schedule of Research Types coupled with the categorisation of vulnerable and non-vulnerable research subjects.

There was a good deal of email traffic among us and with our chair and co-ordinator about interpretations of guidance, views on how the process was evolving and the implications thereof for the initiative as a whole. These exchanges were reviewed and often acted upon at the face-to-face meetings we had.

The chair was concerned that we (and by implication the workers in an established Fast Track process), should have a common interpretation of GAfREC 2.2; that newer statutes e.g. the Mental Capacity and Human Tissue Acts were properly taken account of and that some commonality with Fast Track practice in Scotland should be achieved. These factors impinged particularly on the evolution and use of the NMEI schedule and our response forms.

We shared a number of perceptions and concerns. These are presented below together with comment from individual members where no commonality of view existed.

### **Our shared views**

We were clear from the outset that, in essence, our task to decide what should, or should not, be offered as a fast track submission to a sub-committee.

We worked well together; where differences occurred we were able find common ground most of the time, and use those differences to develop working guidance. The categorisation chart we evolved proved extremely useful.

We developed a number of concerns about the operational aspects of any Fast Track process. Issues such as work load, sub-committee size and management began to concern us. In the main, our view was that they were immediately germane. A particular concern was that new principles and strategy risked being compromised by the work load; we wondered whether time would really be saved.

We were concerned about the use of the evolving response form in Phase 1 that continued into Phase 2. At one stage whilst it addressed almost every question in a standard Application Form it omitted A68 which deals specifically with ethical issues

## **Comment by Vera Hughes**

### **Initial understanding of the task**

I tried to put myself in the shoes of the Co-ordinator, whose task it is likely to be to make the initial decision: what should, or should not, be offered as a fast track submission to a sub-committee,

### **Personal approach**

My personal approach was to read, very carefully, paragraphs A8, A9 and A10 of the NRES (then COREC) form. If questionnaires were used, I next turned my attention to them, having skimmed through the rest of the application, and then to the PIS to decide whether a participant would understand it. I did not worry too much if paragraphs A8, A9 and A10 were in language I found it hard to understand, provided all was clear in the PIS, and that the PIS reflected exactly what was to happen. Finally I took account of A68. I found this whole process could be done quite quickly.

### **Evolving issues and team working**

Our occasional meetings were invaluable as we learnt to listen and take account of different points of view, particularly as we had no electronic discussion on the actual applications.

### **Personal conclusions to Phase 1**

Personally, using the Categorisation Grid, I feel I would not find it difficult, having done this exercise, to allocate an application to fast track or not. Co-ordinators, whose task this will presumably be, are not necessarily used to reading the applications themselves, and will need training and practice to get used to the system.

It seems likely that, at first, more will be sent to fast track than is warranted, so the sub-committee must have the option to send an application, quickly, to full committee, whose work load for that month may already be full. This is one example where strategic and operational decisions overlap.

## **Comment by John Richardson**

### **Personal approach**

I was aware that there were misgivings about the possibility of fast-track procedures, not least among members of my own REC, and my initial approach was therefore cautious; if I had the slightest feeling that there was a potential ethical issue, however trivial, I decided that the application should go to full committee.

### **Evolving issues and team working**

From the beginning however, I could see that it was pointless for some applications to go to full committee; they were benign, non-intrusive and in my view came genuinely under the heading of 'no material ethical issues'. I gradually became less cautious as we developed the category guidelines though remained wary of letting 'no material ethical issues' become too wide.

### **Strategy versus operations**

With hindsight, I wonder if we were right to include as many categories as we did of research involving vulnerable patients; I don't want to go as far as saying 'vulnerable patients means full committee' but I think that 'minimal risk' and 'limited burden' have a different connotation for those who are vulnerable in any way.

Though the three of us brought different backgrounds and approaches to the task, the way in which we achieved some coherence was impressive.

I appreciate why three members chosen for the pilot group were lay, but given the nature of most of the applications, it might have been good for one of us to be an expert in qualitative research

## **Comment by Frank Green**

### **Personal Approach**

I am quite structured in my approach to a task and evidence driven. I soon came to the conclusion that it would be important to find clear and unambiguous boundaries for determining whether or not to “Fast Track”. I followed much the same process as Vera in vetting applications. I chose to offer comment frequently.

### **Evolving issues and team working**

I am concerned about applicants’ perceptions of what comprises lay language. When a technical term is not in a recent edition of Black’s Medical Dictionary, what chance does a lay person have?

### **Personal Conclusions on Phase 1.**

I am pleasantly surprised at how rapidly we gelled and found ourselves able to debate through individual cases and issues. By the end of the phase we appreciated well what differences separated us and why. More importantly we understood where our common ground was, thus making the entry to Phase 2 easier.

For a variety of reasons the time I took to read and make a decision on an application could vary from 12 to 38 minutes.

I entered Phase 2 believing that Fast Tracking could work, but that its Terms of Reference would need to be tightly defined.

## **PHASE 2**

Phase 2 succeeded Phase one smoothly. Initially we were only required to offer a Yes/No for fast tracking. This was changed. We soon were required, and agreed, to decide on whether or not to approve an application. Inter-lay email traffic in this phase seemed to be less. Our face-to face meetings became more lively, an indication perhaps of how well the whole group had gelled and felt confidence at working together.

The commonality of views we had by the end of Phase 1 was sustained. However, as the project consolidated and we were able to see what decisions the collaborating RECs had made together with some of their reasoning, our individual perceptions about Phase 2 were less cohesive. For that reason those perceptions and some individual overall conclusions follow.

### **Vera Hughes**

#### **Difficulties in offering an application decision**

Very few applications are totally clear-cut, warranting a straightforward favourable opinion. Most opinions are likely to be provisional (often to do with the PIS). Who, then, will approve the ‘amendments’ and in what timescale?

A potential unfavourable opinion was often due to lack of clarity or lack of information, which a short conversation with the applicant often resolves. If a sub-committee gives an unfavourable opinion, who will review the re-submission or an appeal, and in what timescale?

#### **Feasibility of a fast track system**

I believe a fast track system can work with:

1. Very clear guidelines (the Categorisation Grid) on what can be fast-tracked
2. A cautious approach, so that the system does not fall into disrepute at an early stage

3. The facility to give a provisional opinion
4. Well-trained Co-ordinators and sub-committees
5. Electronic conversations among electronic sub-committee members
6. A strict, but attainable, timetable

**Main disadvantages could be:**

- Lack of opportunity to meet the applicant
- The possibility that the system could become a likely route for all student applications.

**Fast track sub-committees**

From my experience of a similar, recent, pilot with Local Authority Standards Committees, a fast track sub-committee works well with three committee members, at least one of whom should be a lay member. This sub-committee would benefit from having a chairman who could draw together the opinions of the sub-committee and know when a point of decision is reached. This chairman would be in addition to any envisaged central chairman in charge of all sub-committees in a region.

Discussion and decisions can be done electronically (although there can be IT difficulties), but it is important to meet from time to time. Whether sub-committees should always be made up of the same three members is a debate yet to be entered into.

Someone needs to be available centrally who can offer advice, when needed, on what a sub-committee may or may not do.

**Training**

As mentioned above, training of Co-ordinators and sub-committee members is vital. We must remember we were plunged into the pilot without training (not possible at that juncture), but that the applications we considered were never 'live', so that any mistakes we made had no effect on the applicants or, more importantly, on the participants. The training of applicants and supervisors for student studies is problematical. Nevertheless, a concerted effort should be made to improve the preparation of applications, not least that lay language is used where it is called for. The new paragraph 6 should help considerably here.

**Personal conclusions on Phase 2**

I felt the lack of opportunity for discussion of any sort with fellow sub-committee members to be a distinct drawback. Many of our decisions would have been 'more unanimous' if discussion had taken place. In particular, I found it difficult to put myself in the participants' shoes, which is always the main criterion, focusing, perhaps, more on the system and the paperwork than the human beings involved - being process driven rather than customer driven.

The average time taken for a Phase 2 application was about 25 minutes.

**John Richardson**

**Difficulties in offering an application decision and Feasibility of a fast track system**

I totally accepted that it was right to move to Phase 2 and to make decisions about the ethical acceptability or otherwise of an application but I approached it with some trepidation; for me, one of the joys of being on an ethics committee is the discussion, often with the researcher present, leading to a decision and I was worried that this would be lacking.

**Main disadvantages could be:**

I did indeed find it difficult to work on my own and I constantly missed the interplay between committee members themselves and between the members and the researcher; I was aware that on my own I could be failing to see something obvious.

I understand that we used the Scottish check sheet for political reasons but I didn't find it helpful.

## **Personal conclusions on Phase 2**

I appreciated the response sheets prepared by Valerie and the meetings the three of us held with Valerie and Hugh.

I gradually became more confident, though I never found the task easy and, if in doubt, remained cautious.

## **Frank Green**

### **Difficulties in offering an application decision**

Even though we received filtered applications, I sometimes found it difficult to offer a decision because of doubts that a discussion (as at an REC meeting) could have resolved.

### **Feasibility of a fast track system**

Two matters concern me. Our view of what was Fast Track often differed from that of the co-ordinator. Our views on whether applications should or should not be approved were overall noticeably different from the REC decisions. There are training issues here that I will address below. On balance though I believe that Fast Tracking is both feasible and desirable. However I return to my Phase 1 concern. Terms of Reference need tight definition, notably the boundaries of discretion need to be as tightly drawn as possible with the bias towards going to a full REC review at the margins.

### **Fast track sub-committees**

They need a chair and comprise an odd number of members to ensure that decisions are reached. Meetings can be electronic but there should be both a desire and a requirement for them meet face-to-face from time to time, because interpersonal nuances are important yet largely get lost in cyberspace.

An issue to be resolved is that of how to deal with applications that merit provisional approval where doubts could be readily cleared, especially if the applicant were to meet the sub-committee. Given that one objective of the whole initiative is to speed the processing of an application, this is an aspect of the operation that needs to be determined.

### **Training**

I believe the key to an effective Fast Track process is adequate training.

Terms of Reference, categories, definitions any associated guidance all need to be set out as unambiguously as possible. For co-ordinators and sub-committee members the need then is to understand fully the structural framework for the process and how all the above criteria are to be interpreted. The aim should be to minimise regional variations of practice at the sub-committee level.

There are training needs related to making IRAS more effective. Applicants and particularly their academic supervisors need training on clarity of expression and what constitutes lay language. As an example, if acronyms and technical nouns and adjectives are not defined at first usage in A7 to A10, then the application should be rejected.

## **Personal conclusions on Phase 2**

The good working established in Phase 1 was sustained.

I never stopped learning; almost every batch of work presented a new facet to be dealt with. This would imply that thorough training and opportunities to “dummy run” the process beyond this pilot are essential.

Discrepancies between the team’s decisions and those of the paralleled RECs need further investigation. The clue may lie in the absence of face-face dialogue during our applications reviews and decision-making.

## **OVERALL CONCLUSIONS ON THE PROJECT**

We have agreed on many facets of the project.

We believe we have been able to show that a small group (possibly including an expert in qualitative research) can provide a fast track service for applications that present minimal risk and have no material ethical issues.

What follows are statements of individual emphasis. Implicit in what each of has concluded is that the recommendations we have made in our statements on Phases 1 and 2 above should be seen as being aimed at making a viable and efficacious Fast Track Procedure.

### **Vera Hughes**

I believe the system can work, with the stringent safeguards already mentioned. As in every new system, confidence and ability grow with practice.

### **John Richardson**

I think we have been nearly able to show that a small group - with an expert in qualitative research included - could work in this way but I have three major concerns which hold me back from saying that we have proved NRES can go ahead with a fast-track procedure:

- I have found it difficult to agree with the positive interpretations given to the comparative figures on decisions taken by the group and the RECs. Vera's analyses seem to me to show that we are miles apart and, though I appreciate there are some mitigating factors, these differences bother me.
- I had a philosophical dilemma when we got to Phase2. We agreed that an application had no material ethical issues but then often had comments on it relating to its methodology, presentation, patient information etc. These comments could not be ethical, as we had decided there were no material ethical issues, so in what capacity were we working at that point – R&D, friendly advisors? Or were we saying that there were no material ethical issues but that there were some “immaterial” ones i.e. insignificant ethical points to be made?
- I know I should have restricted myself to considering two issues – was the application fast track and could it be approved? - but I couldn't help reflecting on the operational issues as these seemed to be crucial in assessing whether the fast-track system could work responsibly, could give confidence to researchers and the public, and could be efficient alongside the full committee procedures. Concerns include:
  - New demands on the (excellent) co-ordinators
  - Individual and sub-committee accountability
  - Dealing with applications that presented no material ethical issues but were badly presented
  - Sorting out minor queries
  - Making provisional decisions
  - Suggesting improvements
  - Contact with the researcher

## **Frank Green**

The single most important conclusion for me is that a Fast Track procedure is a viable and potentially valuable option. Work load issues need special attention.

To ensure viability I place great emphasis on the need for clear, unambiguous definitions.

I remain concerned about the need for thorough training as I have detailed above.

As a team we learned quickly and worked effectively with a minimum of formality; perhaps a good model and augury for a nascent Fast Track.

## **OVERALL RECOMMENDATIONS ON THE PROJECT**

1. As a check on our decision-making process, there should be further analysis of the decisions we reached in Phase 2 and those reached on the same applications by the participant Research Ethics Committees.
2. We regard it as crucial that the operational implications of a fast track service are met in order to ensure confidence in the process. The following are recommended as areas for work:
  - Understanding the new demands on, and providing training for, co-ordinators
  - Clarifying individual and Fast Track Committee accountability
  - Making training available for applicants and their supervisors
  - Dealing with applications that have no material ethical issues but are badly presented
  - Receiving replies to minor queries
  - Making provisional decisions
  - Suggesting improvements to a research project
  - Having contact with the researcher

**Vera Hughes**  
**John Richardson**  
**Frank Green**

**02 June 2008**