Health Research Authority

Report of the Working Group on how we best support research in the NHS – educational research

March 2014

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Introduction

Student research applications have been variable in quality, even acknowledging their educational rather than scientific value. The National Research Ethics Service (NRES) has identified that approximately 40% of studies submitted to Research Ethics Committees (RECs) are stated to have educational value as a named objective. The NRES has been keen to support research with educational objectives[1]. Initiatives such as the proportionate review service are not specifically for educational projects, but capture a great deal of such research. These have helped to address concerns that the ethics review process prevented educational research. There may be similar issues for 'own account' studies and researchers pursuing these may find it more difficult to navigate the review and approval processes.

Recent conversations with NHS Research and Development (R&D) have made the Health Research Authority (HRA) aware that there are similar concerns at a Trust level in England. The HRA has received reports of a high volume of poor quality applications taking a disproportionate amount of resource locally, and thereby distracting from support for good quality applications.

This project sought to review educational research across the research approval process to consider how we can better improve our support to research in the NHS.

Initially the remit of the group also included 'own account' research, that is research conducted by NHS staff without explicit funding (excluding educational research). It was thought possible that 'own account' research could also be of low quality and create problems in research governance. It quickly became apparent at an early stage that it is no longer the case. Reassurances have been given that current ' own account' research is usually peer reviewed and of a good quality. Furthermore 'own account' research is often conducted as a pilot or precursor to something more substantial and funded. Consequently 'own account' research was dropped from the review.

Aims

The aims of this review were to:

- Scope the extent of the volume of studies where purpose is limited to an individual educational benefit
- Determine the extent to which educational research applications is poor quality or poorly presented, and are taking more resources to obtain required approvals.
- Consider if there are issues for specific disciplines.
- Consider the extent to which the HRA, and other, improvement agendas may address issues, i.e. scope in new world as well as current
- Determine and set out proposals to define good quality ethical research

[1] For convenience we will term this 'educational research' in this paper, that is, research with an educational objective for its investigators, regardless of whether the student or the supervisor is the named Chief Investigator.

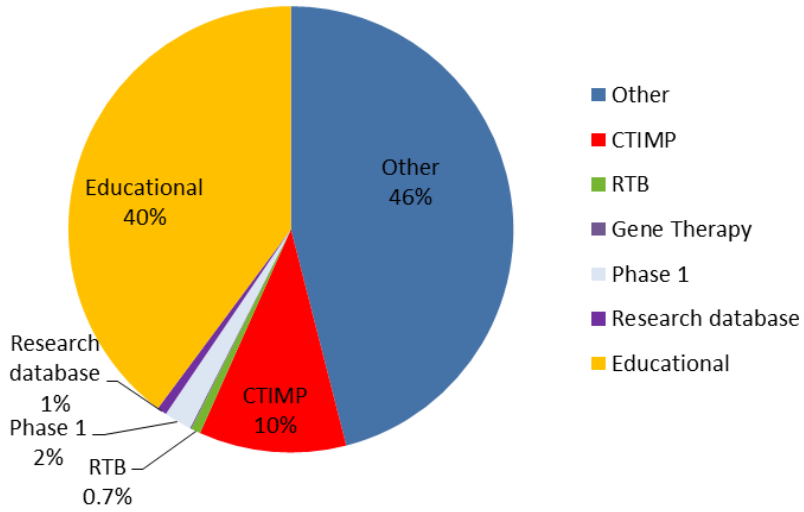
Background information

Management information derived from valid applications submitted via the Integrated Research Application System (IRAS) has been analysed over a five year period from 1st April 2008 to 31st March 2013 and shows the type of studies reviewed by NRES. Applications for ethical review with a declared educational value[2] (including undergraduates, Masters, PhDs and doctoral applications) make up roughly 40% of the workload although this has dropped more recently. This definition of student research has been used throughout this report regardless of whether the student or the supervisor is the named Chief Investigator.

Table 1 – Type of Application received by NRES (2008 – 2013)

	No.	%
Educational (student) studies	14,214	39.8%
CTIMP	3,835	10.7%
Phase 1	732	2.0%
Research database	233	0.7%
Research Tissue Bank (RTB)	262	0.7%
Gene Therapy	22	0.1%
Other	16,455	46%
Total	35,753	100

Figure 1– Type of Application received by NRES (2008 -2013)



The other category shown in the pie chart above contains a wide range of different methodologies including qualitative research and quantitative research such as surveys and excludes clinical trials of investigational medicinal products [CTIMPS]).

[2] As defined in the IRAS form

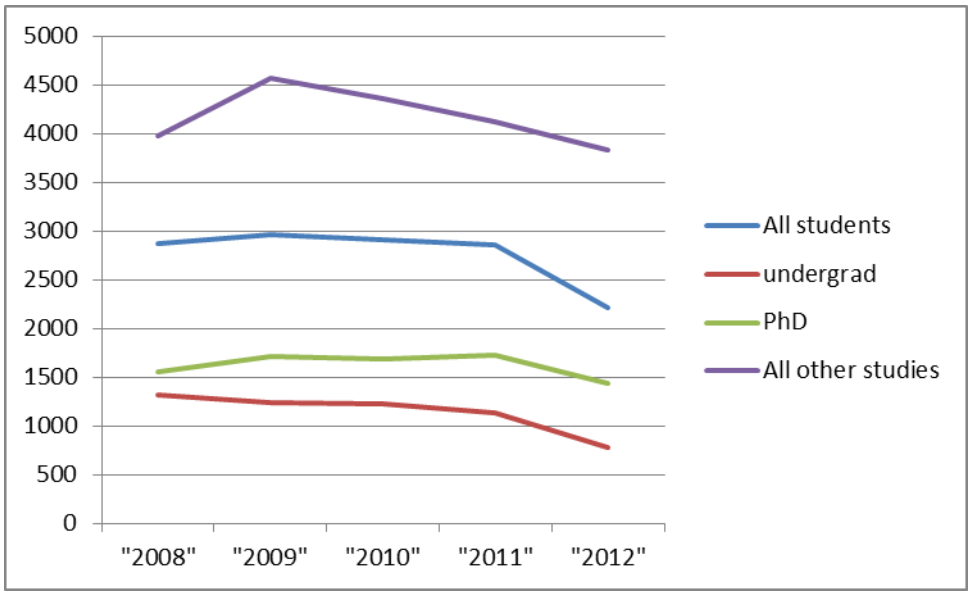
Student studies over time

The table below shows how the volume of student studies has changed over time (only full years have been shown here).

Table 2 - Volume of applications by type from 2009 to 2012

	2008	2009	2010	2011	2012
Student applications	2865	2957	2907	2858	2213
Undergraduate/Masters	1314	1241	1223	1136	782
PhD applications	1551	1716	1684	1722	1431
All other studies	3975	4573	4357	4116	3834
Total	100%	100%	100%	100%	100%

Figure 2 - Volume of applications by type over time (2008 – 2012)



Student studies (i.e. studies with a declared educational value regardless of the CI) have been consistently around 40% of all applications for ethical review; the percentage fell by over 3% between 2011 and 2012. This drop is mainly due to a decrease in the percentage of undergraduate and Masters applications, probably related to the revised guidance in 2011 that excluded research on staff from ethical review. In addition many student applicants may have deliberately switched from studies involving patients to those involving NHS staff as participants once they realised that this would save them time and effort.

Table 3– Students applications as a percentage of all applications over time

	2008	2009	2010	2011	2012
Student applications	41.9%	39.3%	40%	41%	36.6%
Undergraduate/Masters	19.2%	16.5	16.8%	16.3%	12.9%
PhD applications	22.7%	22.8%	23.2%	24.7%	23.7%
All other studies	58.1%	60.7	60%	59%	63.4%
Total	100%	100%	100%	100%	100%

Proportionate Review

Researchers have the option of submitting their application for proportionate review as opposed to full review by all the members of a Research Ethics Committee[3]. Proportionate review takes the form of a sub-committee review with an additional option to refer for full committee review if the sub-committee determines there are material ethical issues to consider. Studies falling into the categories below are reviewed through proportionate review:

1. Research using data or tissue that is anonymous TO THE RESEARCHER

2. Research using existing tissue samples already taken with consent for research

3. Research using "extra tissue" (e.g. further blood taken at time of routine sampling or tissue taken at "clinically directed" operation)

4. Questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences

5. Research interview / focus group that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences

6. Research surveying the safety or efficacy of established non drug treatments, involving limited intervention and NO change to the patients' treatment

7. Minimally invasive basic science studies involving healthy volunteers

8. Other study which does not have any material ethical issues.

As one might expect, student studies were more likely to pass through the proportionate review process than non-student studies; 8.6% of student studies are approved under proportionate review compared with 5.4% of non-student studies. Under-graduate and Masters applications are more likely to pass through proportionate review than PhD and doctoral applications. Just over 5% of non-student studies are submitted for proportionate review compared with 6.5 of PhD/doctoral applications and 11.6% of under-graduate and Masters applications. This difference is statistically significant at p=0.001.

Table 4 - Type of Review

	Undergrad/ Masters	**PhD/ Doctoral**	**All other studies**
Review by Full REC	88%	93%	94%
Proportionate review	12%	7%	6%
Total	100%	100%	100%

[3] Further information on proportionate review can be found at http://www.hra.nhs.uk/documents/2013/08/standard-operating-procedures-for-research-ethics-committees-sops.pdf

Decision made at First Review for all studies

27% of all studies that are validated obtain a favourable opinion; this includes both those going to full review and those going through proportionate review. Student studies are slightly more likely to obtain a favourable opinion than non-student studies. Conversely student studies are also slightly more likely to obtain an unfavourable opinion than non-student studies.

Table 5– Decision made at first review by type of study (2008 – 2013)for both full and proportionate review

	Student study	All other studies
Favourable	28.3%	26.4%
Provisional	63.9%	66.2
Unfavourable	7.1%	6.9%
No opinion	0.7	0.6%
Total	100%	100%

Breaking down this information further by type of student, we can see that the biggest difference is attributable to undergraduate and Masters levels applications rather than PHD and doctoral applications. Undergraduates and masters level students have both higher levels of both favourable and unfavourable opinions and lower levels of provisional opinions. The difference is statistically significant at p=0.001.

Table 6– Decision made at first review by type of student (2008 – 2013) for both full and proportionate review

	Undergrad/ Masters	PhD/ Doctoral	All other studies
Favourable	31.3%	26.3%	26.4%
Provisional	60.1	66.5	66.2
Unfavourable	8.0%	6.5%	6.9%
No opinion	0.7%	0.7%	0.6%
Total	100%	100%	100%

Decision made at First Review (at full ethical review only)

Looking at applications passing through full ethical review only, we can see that these have lower levels of favourable opinion at the first review with broadly similar outcomes for both student and other types of studies.

Table 7– Decision made at first review by type of study (2008 – 2013) for full review only

	Student study	All other studies
Favourable	25.0%	24.0%
Provisional	67.5%	68.8%
Unfavourable	7.5%	7.1%
No opinion	0.1%	0.2%
Total	100%	100%

Decision made at First Review (proportionate review only)

Not surprisingly the profile of applications going through proportionate review is significantly different as by design these are much lower risk studies with a far higher percentage of all types of studies receiving a favourable opinion the first time round. As the table below shows student studies as a whole that have been submitted for proportionate review are less likely to receive a favourable opinion than other types of studies.

Table 8– Decision made at first review by type of study (2008 – 2013) proportionate review only

	Student study	**All other studies**
Favourable	59.7%	63.5%
Provisional	30.2%	25.8%
Unfavourable	3.5%	4.0%
No opinion - refer to full committee	6.6%	6.6%
Total	100%	100%

Favourable decisions following proportionate review are much higher with 61.6% of all studies undergoing proportionate review obtaining a favourable opinion; this ranges from 63% for undergraduate and Masters applications versus 55.7% for PhD and doctoral studies and 63.6% for all other types of studies.

Time to review

RECs have a legal obligation to review Clinical Trials of Investigational Medicinal Products (CTIMPs) within 60 days. In addition the HRA sets a stretch target for all studies of 95% to be given a final opinion within 40 days. The mean average number of days from submission to the application to ethical review for all types of studies is 33.3 working days (this includes both full ethical review and proportionate review). The mode is 28 days and the median is 31 days. An analysis by type of review indicates that the mean average number of days taken until full ethical review is 34 days and the corresponding figure for proportionate review is just 11 days.

The mean number of days taken to review all other studies excluding those with an educational purpose is 33.6. The corresponding figure for students is 32.7. Although the variation is small, the difference is statistically significant (p=0.001).

If we break down the student figure, it can see that the mean number of days to review is 31.3 days for undergraduate/masters studies and is 33.6 days for PHD/doctoral studies. An analysis of variance shows that the difference is statistically significant (p=0.001), even if operationally small.

Table 9 - Time to review by type of study (2008 – 2013) for both full and proportionate review

Number of days from submission to review	**Undergrad/ Masters**	**PhD/ Doctoral**	**All other studies**
Mean	31.3	33.6	33.6
Median	29	32	31
Mode	28	28	28

It should be noted that the number of days from submission to final decision does not necessarily reflect the amount of effort and time spent on the application by REC managers and committee members.

Validity

On receipt of an application for ethical review, Research Ethics Committee (REC) Managers work through a validation process. Applications found to be invalid are not submitted to the REC and are sent back to the investigator either for any corrections or inclusions which can be made in time for the cut-off date for the planned meeting, or, because the issues making the application invalid are so significant , with a letter detailing the reasons for invalidating the application and inviting a new application when these can be addressed. Just over 5% of non-student studies are classified as invalid and the researchers are informed by letter. Undergraduate and Masters studies are more likely to be invalidated than non-student studies (See the table below)). PhD or doctoral studies are slightly less likely to be invalidated at 3%. The difference between these groups is statistically significant at p= 0.001.

It should however be noted that the studies which are valid, have often been subject to additional intervention by the REC Manager to make them valid in time for the allocated REC review. Management information indicates that roughly one in six applications pending validation are not actually rejected as invalid.

Table 10 – Validation status by Type of study (12 months data ending 31st May 2013)

	Undergrad/ Masters	PhD/ Doctoral	All other studies
Invalid	7%	3%	5%
Valid	93%	97%	95%
Total	100%	100%	100%

Further Analysis

The information above has been derived from standard management information which does not allow us to differentiate between undergraduates and Masters level students. A separate analysis of individual IRAS forms has enabled us to drill down to undergraduate level and this information is shown in Appendix 3. In addition we measured the amount of time taken by REC staff and members to both validate and review student research versus other types of research. This is shown in Appendix 4.

The student experience

We believed that it was important to understand the students' experiences from their perspective and so we ran an online survey for 12 weeks. Students who had sought ethical review of their studies were invited to complete the survey at the end of the research approval process. Only 29 responses were received, although more than 400 student applications must have passed through the system in that timeframe. Summary findings are given in Appendix 2; the most notable point being that 20 out of 24 said that they found it difficult to fill in the IRAS form, with only three people saying that they found it easy. Nevertheless, building on their experience, 19 out of 21 said they would feel confident in completing the form on a future occasion.

Key Themes

In addition to management information, we also sought opinions from a range of stakeholders. Over 35 interviews were undertaken with a selection of people working in health research across the National Research Ethics Service, R&D in Trusts and Universities, R&D leads and Champions, University REC managers, National Institute of Health Research (NIHR), Health Education England and the Royal Pharmaceutical Society. In addition a few people who were not available for interview have also sent in their opinions by email.

Quality in student research

There is a general consensus that applications for review submitted by students are of variable quality. Whilst some issues relate to a lack of understanding of the research approval process, more worryingly, many concerns relate to the use of inappropriate methodology. Some students were also considered over ambitious about what they could achieve within their timeframe. Typical quotes include:

'some of it is exceptionally good, about 10% is awful'

'it is not always clear what they are trying to achieve'

'there is a general feeling that research should be better'.

Poor quality research was seen at all levels of research but most respondents thought that PhD students were better supported and prepared. One respondent (REC chair) noted that PhDs are more original and so are inherently more risky. Several respondents commented on the poor quality of 'professional doctorates' as opposed to PhDs, for example, one respondent said *'the quality of doctoral research is in a free fall decline; there is a proliferation of professional doctorates'.*

Whilst there is some random variability in the quality of research according to both students and their supervisors, there seems to be a consistent view that there is also variability according to organisations. Respondents were agreed that student research tended to be of a higher quality at those institutions with a long experience of doing clinical research and that problems with quality often appear in organisations where the academic staff lack clinical research experience. This has implications for how the HRA should target training.

Particular quality issues were described in relation to specific discipline:

- nursing students often struggle with undertaking quantitative methodologies with poor supervision. Some respondents noted problems linked to particular professional groups and their preference for particular methodologies. For example, some professional groups want to do research which is almost entirely qualitative with an emphasis on grounded theory.
- Pharmacists undertake a four year Masters degree with a research project in the fourth year. The students are, however, undergraduates with little research experience and often 'patchy' supervision.
- Over a quarter of all PhDs/doctoral levels studies requiring ethical review were undertaken by psychologists. These commonly involved either vulnerable subjects or very sensitive topics or both. Consequently these proposals can lead to extensive review and debate.

In general, student research suffers from a lack of peer review. Some Trusts and universities do offer a peer review process for student research but in most places, review seems to be conducted by the supervisor alone.

Undergraduate research

Most universities now encourage their undergraduate students not to undertake projects that require ethical review. This is mostly because undergraduates are not thought to have the necessary time or expertise to conduct such projects in their entirety including seeking research approval. In addition, the supervisor to student ratio may not allow for adequate supervision of complex projects. However we know from our analysis of IRAS applications that 9% of student applications are from undergraduates; these are mainly medical students pursuing an intercalated degree before clinical studies.

Very few people thought that undergraduates should be doing the sort of research that requires ethical review. Academics suggested that undergraduates should be doing literature reviews, writing research protocols or conducting laboratory based studies. At undergraduate level it is common for students to undertake audit or evaluation rather than undertaking a research project.

The burden placed on the NHS by undergraduate research impacts not just on Trust R&D staff and REC staff who can oversee many iterations of the same project but also impacts directly on NHS staff who may be asked to complete questionnaires and undertake interviews with little or no prospect of benefit to the NHS. It was suggested that undergraduate students should be learning research skills but not be expected to apply these skills directly with patients. In the main, it was thought that undergraduates should focus on:

- Conducting systematic reviews
- Writing research proposals/protocols (which they are not expected to complete)
- Conducting audits
- Doing research with populations outside of patients in the NHS, such as other students.
- Conducting laboratory based studies where appropriate.

There was considerable support from the stakeholders consulted for the concept of multiple students taking part in a project led by their course leader or supervisor. In this scenario a member of academic staff would develop and seek ethical review of a research project in which a group of students could undertake various roles assisting with different elements of the work. This reduces the time that students spend on the research approval process and encourages a team approach to research as well as enabling the team to tackle bigger research questions than they could undertake on an individually.

Time spent supporting students

As noted above, there was a view that reviewing and working with students takes a disproportionate amount of time compared with other types of research because they frequently need higher levels of support:

'Students do take more of your time – mostly because they are research naïve'. R&D manager large teaching hospital.

'We spend an inordinate amount of time holding the hands of students'. R&D manager large teaching hospital.

One REC Manager said *'Student research tends to be problematic, leads to more questions'*. Some respondents were very keen on placing 'realistic' limitations on the type of research that students can do at different levels.

An analysis of the data collected by our audit of applications coming into RECs shows that student studies take as long to validate and review as other types of studies. We do not have the equivalent data for the time for R&D in Trusts but it would appear that R&D staff spend even longer dealing with student research, particularly where they are the sponsor. They also see a greater volume of research than the ethics service because they are also dealing with staff research which no longer requires ethical review. R&D staff can see many iterations of the same project before it is submitted to NRES.

An analysis of time taken to validate and review student applications by R&D in a large teaching hospital shows that on average R&D see over 4 iterations of the same project before they can sign it off, although this ranges from 2 through to 25 over a three month period. On average it can take almost five days to acquire the valid documents for R&D sign off (up to a maximum of seven months). The actual elapsed time for review by R&D staff of student applications is on average seven working days but varies between 1 and 23 working days.

All Trust R&D staff interviewed for this project stated that they help students to write their proposals/protocols. They also noted the seasonality of applications from students which could have a significant impact on their workload when a lot of applications arrived at the same time.

In many cases it was thought that students needed more support from ethics committees and R&D because they are not getting the support they need from their supervisors. REC members and chairs talked about trying to be supportive to students (some of it in their own time) and trying to avoid an unfavourable decision when really that was what the project deserved.

Apart from supporting students in putting together their applications for research approval, the conduct of student research also has an impact on the NHS. Many studies now focus on NHS staff rather than patients. Staff may be may be interviewed or asked to complete questionnaires which may be of little value to the NHS. We were unable to quantify this aspect, but have noted the concern.

Students from non-health related courses

Both NRES and R&D staff reported seeing many applications from students on non-health related courses such as psychology, sociology, IT, business studies, architecture and sports studies. Some of these have only very tenuous links with the NHS. For example, several IT undergraduate students from universities in Wales wished to do research at Trusts in Manchester. It does seem that students on non-health related courses often present to both R&D and RECs with additional problems over and above other students, as both they and their supervisors are unfamiliar with NHS procedures. In particular, it was reported that students from non-health related research tend to struggle with how data might be accessed, the concept of consent, the concept of statistical power and are often over-ambitious about what they can achieve.

On the other hand, there was an overwhelming sense that these students have a lot to offer the NHS by bringing in fresh ideas and new management tools. Consequently there was no enthusiasm for placing any restriction on non-health degree students, rather respondents noted the need for additional support. There was a strong feeling that partnership working had much to offer, and in some trusts, this has taken the form of clinical supervisors in addition their existing academic supervisors. Nevertheless it was acknowledged that getting a partnership between clinical and academic supervisors can be challenging.

Role of supervisors

REC coordinators and REC members say that students at Masters level frequently attend the ethics committee meeting without their supervisors. There is strong opinion that the supervisor should attend the REC meeting. This is especially true at Masters level, the supervisor is normally also the Chief Investigator. It was also acknowledged that compulsory attendance by supervisors could be difficult to enforce. The amount of notice which could be given to a supervisor to attend a meeting with a REC might only be a few weeks and this might not be long enough, especially if they had several students under their supervision. Some respondents suggested the quality of supervision varies between disciplines. It was suggested that nursing students often have poor quality supervision due to lack of research experience by supervisors.

Some respondents noted that PhD students are sometimes allowed to supervise other undergraduate and Masters students and queried their competence to take on this role. We consider this practice to be inappropriate.

Finally there was a common perception that some supervisors did not have a good understanding of what was expected of them and that more could be done by the sponsor to make this clear.

Training of supervisors

There was much discussion of the training needs of supervisors and how these could be met. There was enthusiasm for the current course which is being piloted jointly by the HRA and Association of Research Ethics, but there was some concern that this might be limited in its reach. It was noted that supervisors often had training needs both in relation to their understanding of the current research approval process but also occasionally in their understanding of the methodology to be used by their students.

Some R&D leads talked about how they managed the performance of supervisors including a mandatory training element. Several Trusts have made attendance at a research governance sessions a mandatory requirement for all supervisors.

Establishing an early filter to poor quality research

Currently research applications submitted for ethical review are validated by the REC manager before being passed to the Ethics Committee. However this process of validation is largely process driven. It normally just involves checking that the study has been correctly categorised and that the right documents have been submitted, and are signed and dated. The HRA feasibility pilot work includes an early assessment which considers the content of the submission as well. This would allow for very poor submissions from students and others to be picked up at an earlier stage and to

be sent back to the applicants before review. The individual doing the early assessment would be able to have a conversation with the applicant and direct them to both people and material which might be able to help them and perhaps, in the case of student research, raise issues with the supervisor as well.

Expanding the criteria for Proportionate Review

There was strong support for the concept of a generic or batch submission to an NHS Research Ethics Committee whereby a supervisor or course leader could make a single application on behalf of a group of students. This mechanism is currently used with non-health courses when applying to University Ethics Committees for Masters level courses, some MPhils and taught doctorates. One common model is to encourage a batch mode application from the course leader; the research could fit into either of the scenarios below:

1. The students will do an identical research exercise , for example, all analysing the same dataset, or
2. The students are expected to conduct similar research activity within an agreed set of parameters which can be deemed to be low risk. For example, students might have access to a range of anonymised datasets or anonymised tissue.

In each case the course leader or supervisor would act as the Chief Investigator. This could be part of an extended proportionate review system for low risk research. This approach would seem to lend itself to studies involving either data or tissue. Some universities also use this batch approach to cover interview based studies.

Both NRES staff and Chairs as well as R&D management thought that proportionate review has improved the situation for students who wish to undertake low risk research. However some felt that more could be done to raise awareness of the proportionate review option.

Information for students

Several respondents suggested that more information could be made available for students on the research approval process. Several Trusts have developed their own individual research handbooks for students. It was suggested that information could be put together for students at national level. In particular it is suggested that the HRA website could have a separate section for students covering the following aspects:

- Basic information including consent and patient information sheets
- Frequently Asked Questions that they might be embarrassed to ask
- Deal with staff research
- Set out what is and isn't research
- Flow charts
- Case studies and examples of different scenarios.

Currently the HRA website has a section for the 'research community' but this covers a broad spectrum of researchers. Much of the information students need may already be on the website but is not necessarily easily accessible. A dedicated student section could signpost all the key material.

Using the Integrated Research Application System (IRAS) form as an educational tool

There was a positive reaction to the idea of using the IRAS form as a form of assessment in its own right. This was thought to be a suitable exercise for undergraduates, some Masters students and for preclinical students pursuing intercalated degrees. Students were thought to lack experience at form filling. They require practice at formulating their research plans. It was noted that some laboratory students, in particular, resented the idea of being tied down to a fixed protocol where every option has to be defined in advance. These students would benefit from completing the IRAS form as an assessment in its own right.

Whilst R&D staff provide considerable assistance to students in completing the required forms for approval, this can be more difficult for students who live remotely. A tool which helps people to learn to complete the IRAS form could appeal to students unable to get support in other ways.

Giving better feedback to academic institutions

Currently the letter from the REC giving the student a final decision after ethical review is copied to both the supervisor and the R&D office of the sponsor. However, several respondents noted that this was probably insufficient and called for better feedback at a more senior academic level so that Universities can understand if they have a problem with supervision. It was suggested that annual feedback should be sent to the Vice Chancellors or to the Deans of particular schools. REC Chairs talked about the importance of shaming some Universities into taking action.

REC Managers and Chairs also talked about doing more to share good practice. For example, some REC Managers have shared the validation check list with sponsors but this is not done routinely.

The Role of the Sponsor

NHS Trusts are expected to support both education and research as core functions of the NHS and all NHS Trusts have a duty to support students undertaking research within their organisation. A small number of Trusts appear to be charging students to sponsor studies and some are also charging to act as a host site for students . We regard this practice as inappropriate.

Ultimately problems with the quality of supervision of students undertaking research are the responsibility of the sponsor. It was suggested to us that in some cases the ratio of students to supervisor is too large for adequate supervision. Others noted that a single student may have 3 -4 supervisors in the course of a year and others complained that supervision is sometimes delegated to other students who may not be sufficiently experienced to advise others.

Respondents were also concerned about the lack of sponsor review in some organisations. It was felt that the robustness of sponsor review varied widely between organisations.

It was reported to us that a number of universities and colleges refuse to sponsor their own students and expect NHS organisations to assume this role on their behalf, leaving the student in a difficult position. Conversely some NHS Trusts will only sponsor funded PhD students.

Making student research more relevant to the NHS

There was a call for student research to be more relevant to the NHS. Many local trusts we spoke to had an arrangement with local university departments to identify research questions which could then be addressed as part of a student project. Refocusing student activity, in terms of relevance and possibly scale, could offer direct benefits. It was suggested that CLAHRCS (Collaborating in Leadership in Applied Health Research and Care) would have a role in facilitating this process.

Conclusions

There was a clear consensus that that there are often problems with the quality of student research, even allowing for the fact that it is being undertaken for educational purposes. Some respondents also pointed out the impact which student research has on the NHS in terms of implementation.

Whilst concerns have been expressed about the number of students undertaking non-health related degrees and wishing to carry out research in the NHS, the overall opinion was that these students often have a lot to offer the NHS in terms of bringing a fresh perspective and new techniques in business management and IT. Consequently there is no desire to restrict this type of student from doing research in the NHS. It was suggested that the academic supervisor's lack of awareness of healthcare research could be addressed by the addition of a clinical supervisor.

Data collected by the HRA suggests that, overall, student research takes as long to validate and review as other types of studies such as clinical trials (See Appendix 4). What these data do not reveal is the number of iterations that the applicant submits in order to move the application from a provisional decision to a favourable one. They also do not show the amount of work conducted by R&D offices in Trusts to get the research application into an acceptable format before it is submitted to the ethics committee. Experience suggests that student research goes through multiple iterations before it is considered good enough for ethical review. The R&D management perspective is that they are conscious that the time spent supporting students could be better spent facilitating trials and other funded research.

For the first time we can see the volume of undergraduate applications (see Appendix 3). The numbers of undergraduate applications are significant at almost one in ten of all student applications. Whilst many Universities actively prevent their undergraduate students from undertaking research which would require ethical review, this practice may not be consistently applied across the country. There was agreement that, normally, the ratio of students to supervisors at undergraduate level would not allow students to be adequately supported to undertake research which would require ethical review. In addition, it was thought that most undergraduate students would not have sufficient time to follow the research approval process in addition to undertaking the research itself.

Although the current IRAS form allows for more than one student on the same application, the number of applications on behalf of multiple students is extremely limited. This feature is not widely known. Applications on behalf of multiple students save the students considerable time of effort in working through the research approval process and allow them to concentrate on the research activity itself. Our limited survey of the student experience illustrates the difficulty which students experience when completing the IRAS form. There is considerable support across both the REC and the R&D community for the concept of single applications on behalf of multiple students.

The current feedback from a REC to a University R&D office does not help senior academics see the overall picture and it is possible that more could be done to improve this communication.

Finally supervisors are ultimately held responsible for the poor quality of student applications but the ability of the HRA to influence their behaviour is limited. There are a number of initiatives that the HRA could implement to provide further support to students directly such as developing a student dedicated section of the HRA website.

Recommendations

The Working Group made the following recommendations:

1. **Normally students should not take the role of Chief Investigator (CI) at any level of study.** A permanent academic member of staff, not necessarily the supervisor, should normally take the role of CI in all student applications for research approval and ethical review. This should apply to all students undertaking health research including those at PhD and doctoral level. By making a permanent member of staff the CI, this puts the onus on the University to take responsibility for the study. It is the view of the Working Group that, where the CI is a member of staff, the application for review should be presented in a near finished form and should not require multiple iterations of review by R&D and REC staff/members.

2. **Undergraduate students should normally be directed to do low risk research and discouraged from undertaking research which interfaces directly with patients**
   Most universities now encourage undergraduates not to undertake the type of research which would require ethical review. However an analysis of applications made by students for ethical review indicates that 9% are currently from undergraduates. It is recommended that undergraduates should be steered away from conducting research which require ethical review, not least because undergraduate students are unlikely to have the time to undertake the process of seeking research approval. Furthermore supervisor to student ratios at undergraduate level are unlikely to be sufficient to allow the level of support required to undertake this type of research.
   Undergraduate students might instead be directed towards undertaking research where the participants are NHS staff or other students. Undergraduate students should be encouraged to focus on:
   - Systematic review
   - Writing research proposals
   - Audit
   - Critical appraisal
   - Service evaluation
   - Laboratory based research where applicable.

   There was a consensus that course leaders/supervisors should encourage those students wishing to do research at undergraduate and Masters levels to undertake studies that only require proportionate review and not full ethical review. In addition, undergraduate and Masters students should be made aware that staff research does not require ethical review.

3. **Encourage course leaders/supervisors to develop and lead research projects that individual students at Masters level and below can contribute to at different stages**
   Given the lack of time experienced by both Masters and undergraduate students and the length of time required to work through the research approval process, it is recommended that more students undertake the research element of their course as part of a larger research project developed and led by a member of their faculty, such as the course leader or supervisor. The member of staff would act as the chief investigator and would take the

project through the research approval process. A team of students could then contribute to different elements of the project as required, for example:

- Writing the research proposal
- Developing and piloting questionnaires
- Feasibility testing
- Data collection
- Validity and reliability testing
- Patient and public involvement
- Data analysis
- Report writing.

Some courses already operate in this way but a greater adoption of this approach would be welcomed.

4. **Allow academic staff to make a single 'batch' application for ethical review on behalf of a number of different students for very low risk projects under proportionate review**
It is recommended that course leaders or supervisors could make single applications for research approval on behalf of a group of students undertaking the same course. The projects would have to be low risk and involve an identical or very similar research exercise that could involve the analysis of an anonymised dataset or anonymised tissue. The academic as the chief investigator would be responsible for ensuring that the data/ tissue had been collected appropriately and that the projects are conducted within the agreed parameters. Unlike the previous recommendation, students would not be expected to work as part of a team but would instead conduct their own research project. However all the students would be undertaking an identical or similar exercise within agreed constraints. This approach would require careful piloting to ensure its feasibility but has been used extensively with research projects outside of health at Masters level. As with the recommendation above, the members of academic staff would take the role of chief investigator and could seek approval for the project before the identity of the students is known.
This approach would require careful piloting and if successful, could perhaps be rolled out to other methodologies such as interviews on non-sensitive topics.

5. **Students from non-health related courses wishing to undertake research which involves accessing patients or their data in an NHS setting should be offered a co-supervisor with a health-related background to help them negotiate their way through the research process**
It is the responsibility of the University as sponsor to ensure that students on non-health related courses are given access to a co-sponsor with a health related background. This individual might be based in the NHS organisation where the student wishes to conduct the research.
The role of the co-supervisor would be to:
    - help the student minimise the burden placed on the NHS,
    - make students aware of the issues around patient data access, approaching patients and consent, and
    - help them achieve a feasible research design.

Local CLAHRCs may have a role in facilitating the linking of students with co-supervisor s with a health background.

6. **NHS organisations should provide local universities with research questions/priorities that they want addressing locally.**
   The extent to which students can carry out research which is of benefit to the NHS is questionable. Students can be helped to undertake potentially helpful research if they are given some direction by Trusts and CCGs. Some universities are already working in partnership with local Trusts to identify suitable realistic research questions for students to address, either individually or as part of a team; local CLAHRCs may wish to take a role in facilitating this process. These questions might be addressed by research but equally could take the form of an audit or a service evaluation and could be small scale projects.

7. **Establish an early filter to poor quality research**
   The research approval process should have a mechanism in place to identify and send very poor quality student applications back to chief investigators at an early stage rather than spending any more time on them. If the HRA goes ahead with its plans for early assessment, there will be a process an early filter in the system, to identify very poor quality research. This will use an agreed set of criteria to refer applications back to the student and supervisor at an early stage, saving time for both the REC and R&D.

8. **The HRA should develop a section of its website dedicated to supporting students and their supervisors**
   A dedicated student section of the website could address the specific needs of students including frequently asked questions, definitions, flowcharts of the approval process together with signposting of key issues such as consent and patient information sheets. This section of the website could also provide a range of case studies covering different methodologies and clinical disciplines which could be added to over time. The website could promote proportionate review as well as non-research options.

9. **The HRA should develop the IRAS application form so that it can be used for teaching and assessment purposes.**
   For some students just completing the IRAS application form can be an assessed activity in its own right and some courses currently require their students to complete the form as an educational activity with no intention of actually submitting the application or carrying it out. The HRA could facilitate this approach by developing a version of the form specifically for this purpose with drop down boxes within each section of the form explaining what each question means and giving examples of the type of answers that might be expected, together with some some exemplar applications.

10. **Universities and colleges should accept the role of sponsor for all educational research conducted by their own students unless it is more appropriate for an NHS organisation to do this.**

    Occasionally, where NHS staff are also undertaking educational research within their own workplace, it can sometimes make more sense for their NHS employer to act as the sponsor of their research. However in the first instance, the educational organisation requiring the research component of a course should be prepared to act as sponsor of the research in relation to its own students. NHS organisations should not be obliged to take on the sponsorship role for students simply because the educational organisation is unwilling to do so.

11. **Sponsors of educational research should ensure that their supervisors are competent to fulfil this role.**

    It is apparent that many supervisors do not understand the research approval process and many are not up-to-date with the latest requirements. They often have a lack of awareness of the issues around identifying and approaching potential participants and taking consent. In addition, some supervisors are not fully aware of their own responsibilities towards the students they supervise. Training in the research approval process needs to be made accessible to all supervisors.

    Specifically it is recommended that it is the sponsors' responsibility to ensure that:

    - Supervisors should be able to demonstrate that they are either adequately experienced and/or have received training in the research methodology their students are proposing to use.
    - Supervisors should be able to explain the research approval process including key ethical issues, such as consent, to their students and guide them through it.
    - The ratio of students to supervisors should be small enough to allow supervisors to provide adequate support to their students.

12. **NRES should give feedback to Universities on the quality of the applications that they receive.**

    Whilst individual letters giving the final decision following ethical review are copied to the sponsor, usually the R&D department of the University, the current system does not make Universities aware of specific problems. Feedback to Universities should take two forms:

    - Firstly at individual REC level, where a REC detects a discernible pattern of poor quality applications either from a particular academic department or supervisor, these facts should be fed back to University academic staff at a senior level within the organisation. It might also be useful for RECs to feedback to Universities what is working well and to seek permission from researchers to use good applications which could be used in the training of others.

- Secondly NRES should conduct an annual audit of the decisions made in ethical review for each University; in effect producing a league table of Universities showing the percentage of favourable and unfavourable opinions. It is recommended that information on each university and their ranking together with bench marked data for comparison should be sent to each individual university.

Appendices

Appendix 1 – Membership of the Working Group

Chair	Professor John Saunders	Chair of the Ethics Committee for the Royal College of Physicians
Members	Dr Charles Bruce	Managing Director Health Education North West England
	Professor Peter Furness	Assistant Medical Director & Consultant Histopathologist, Leicester Royal Infirmary. Professor of Renal Pathology , University of Leicester.
	Professor Peter Heasman	Professor of Periodontology University of Newcastle. Member of National Advisors Ethics Advisors Panel
	Professor Sue Mawson	Director of NIHR CLAHRC for South Yorkshire Professor of Health Services Research ScHARR, University of Sheffield
	Professor Paula McGee	Chair of Nursing Birmingham City University
	Mr Gary Roper	Head of Regulatory Compliance, Imperial College London and Imperial College Healthcare NHS Trust
	Professor Nalin Thakker	Associate Vice President for Compliance, Risk and Research, University of Manchester. Consultant Histopathologist, Central Manchester University Hospitals NHS Foundation Trust
	Professor Jon Wass	Professor of Endocrinology, University of Oxford. Academic Vice President of the Royal College of Physicians
	Professor Ken Wilson	Chair of Old Age Psychiatry and Head of Division of Psychiatry, School of Population, Community and Behavioural Sciences, University of Liverpool. Clinical Director of Cheshire and Merseyside NIHR Comprehensive Local Research Network University of Liverpool

Appendix 2 – Student experience survey

We felt it was important to understand the student experience from their perspective and so we ran an online survey for 12 weeks. Students who had sought ethical review of their studies were invited to complete the survey at the end of the research approval process. Only 29 responses were received.

- 21 of the 29 respondents were PhD/doctoral students, 3 were undergraduate and 5 were at Masters level.
- 19 were studying to become or were currently working as a healthcare professional.
- 5 students were in medicine, 5 in nursing and 5 in clinical psychology.
- When asked to state the decision made by the REC, only 7 responded. All seven had received favourable opinions leading to high levels of satisfaction.
- 20/24 said that they found it difficult to complete the IRAS application form (17 fairly difficult and 3 very difficult). Just 3 people said it was easy.
- 20/24 spent more than 20 hours completing the form and 10 spent more than 70 hours.
- Despite their difficulty 19/24 had received support to complete the form.
- 16/18 said they had support or advice from their supervisor, 12/18 from the University research support staff and 12/20 from Trust R&D staff.
- Although 20 students were studying at a doctoral level, only 9 said they were taking the role of chief investigator.
- The supervisor had accompanied the student to the ethics committee meeting in about half of all cases. 6/10 though they might have had a better outcome if their supervisor had accompanied them.
- 20/22 had applied for proportionate review and almost half thought that it was not clear which was the most appropriate type of review for their application.
- 15/22 used the HRA website to find information to help them with their application. Of these 13 found what they were looking for.
- 3/21 said they did not have enough time left to undertake their research.
- Asked how confident they would be in completing the form successfully again, 19/21 said they would be confident (7 very confident).

Appendix 3 - Analysis of student applications for ethical review

This paper looks at all applications made by student researchers over an 8 month period including November 2012 to April 2013 and September to October 2013 across all Research Ethics Committees (RECs) in England. This covers a total of 660 applications for ethical review by student researchers.

The type of students undertaking research in the NHS

The table below shows the level of students making applications for ethical review. Previous management information did not separate undergraduate applications from Masters. We can see here that 9% of student applications are at undergraduate level. The bulk of student applications are doctoral at 66% and Masters account for a quarter

Table 1 - Volume of applications by type over an 8 month period (2012 – 2013)

	No.	%
Undergraduate	55	9
Masters	160	25
Doctoral	415	66
Total (all student applications)	630	100%

Detailed analysis shows a wide range of courses undertaken by the student applicants. Whilst the single largest category of applications is from students on medicine-related courses, 25% of all student applications are made by psychology students, mainly at doctoral level. Psychology students account for over a third (36%) of all doctoral level applications; more than any other discipline. Analysis shows that applications for research made by psychology students have a propensity to include either vulnerable people and/or sensitive topics

Nevertheless the applications made by psychology students have a higher level of favourable opinions compared with studies carried out by other student researchers. 38% of psychology students in the period covered received a favourable opinion compared with 32% of other types of student researchers; however this difference is not statistically significant. Verbal evidence suggests that psychology student applications tend to be well prepared with support from supervisors who are aware of the issues that might arise. Looking just at doctorate level students; 38% of psychology doctorates obtain a favourable opinion at the first review compared with 28% of other doctoral students. The difference however is not statistically significant.

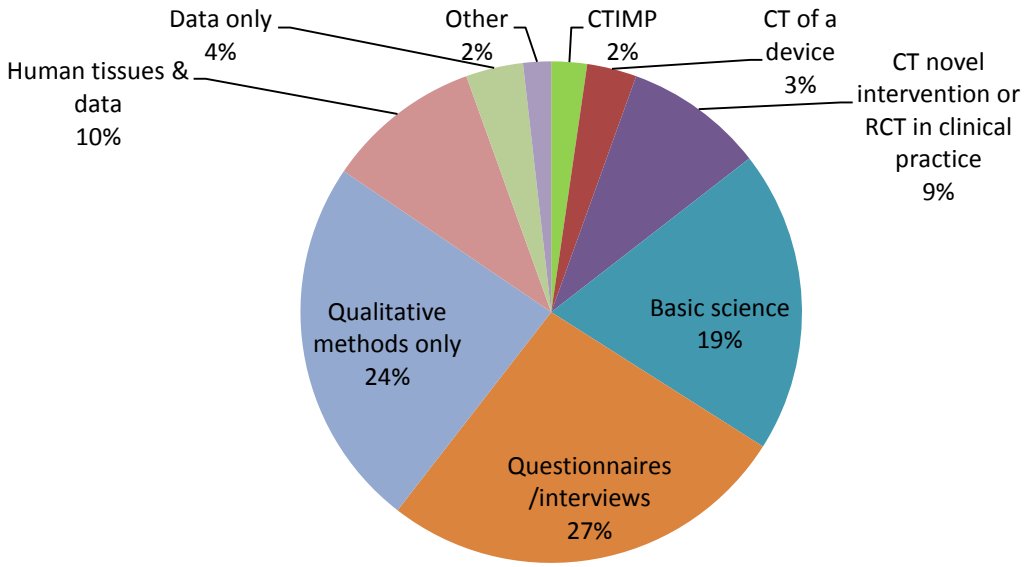
The Types of Research reviewed by NRES

The data below shows the types of research being undertaken by students based on their completion of the IRAS form. The two most popular types of student studies are either studies involving the administration of a questionnaire (26.5%) or qualitative studies (23.9%) which together account for half of all student studies. Use of data only is a surprisingly small category given that this is also covered by the proportionate review category and can be very low risk. 14% of all student studies take the form of a clinical trial.

Table 2 – Type of study conducted by students (8 months data from 2012/13)

	No.	%
Clinical trial of an investigational medicinal product	15	2.3
Clinical investigation of a medical device	21	3.2
Combined trial of medicinal product and a device	-	-
Other clinical trial to study a novel intervention or RCT to compare interventions clinical practice	59	9.0
Basic science involving human participants	127	19.4
Study administering questionnaires/interviews for quantitative analysis or using mixed methods	173	26.5
Qualitative methods only	156	23.9
Human tissues samples and data	65	9.9
Data only	24	3.7
Research Tissue bank	-	-
Research database	-	-
Other study	12	1.8
Total	658	100

Figure 1– Type of study undertaken by all types of student (8 months data 2012/13)



The three pie charts below show the type of studies undertaken by students at each level.

Figure 2– Type of study undertaken by undergraduates (8 months 2012 - 2013)

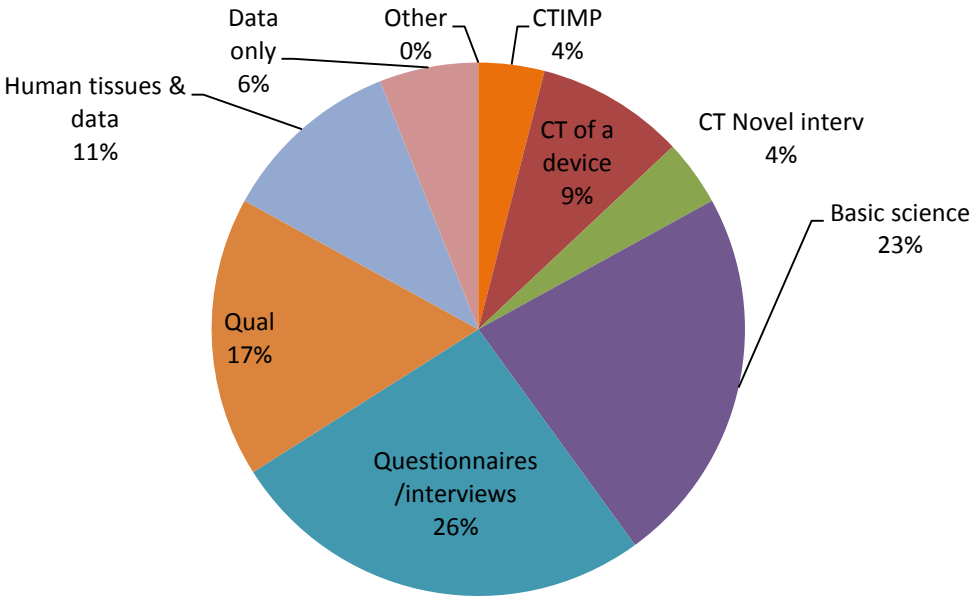


Figure 3– Type of study undertaken by Masters students (8 months 2012 - 2013)

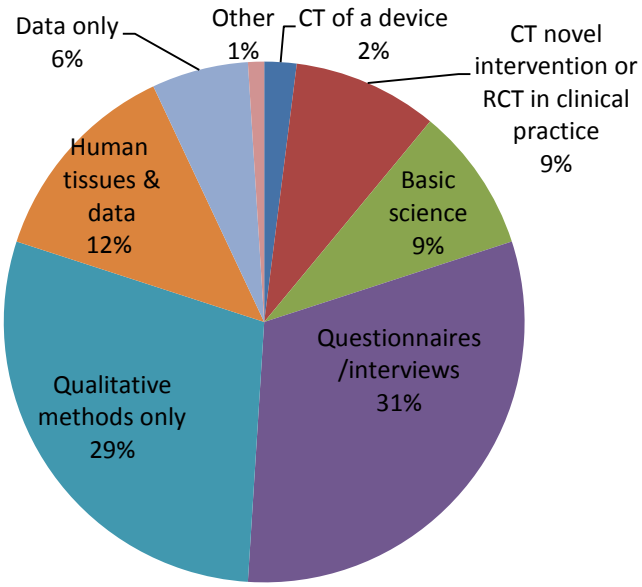
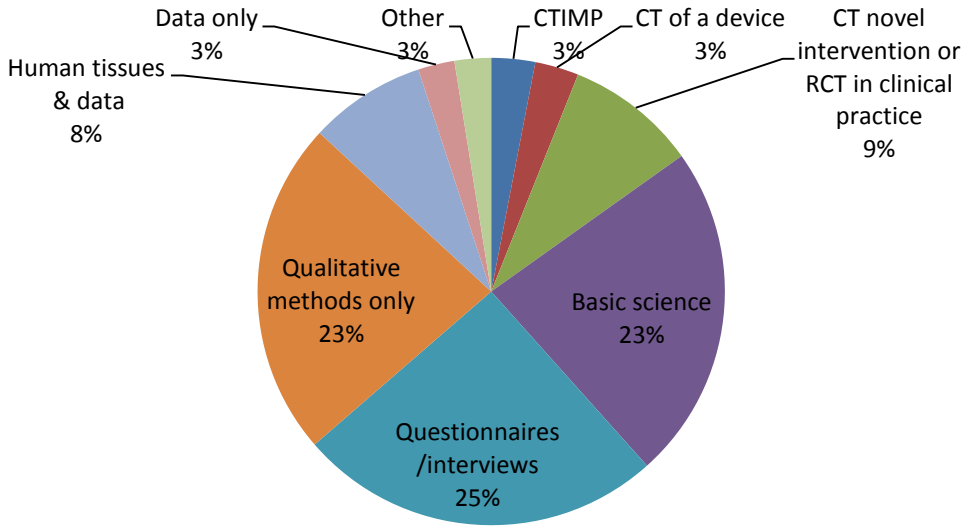


Figure 4 – Type of study undertaken by PhD/doctoral students (8 month 2012 - 2013)



Type of review

Researchers have the option of submitting their application for proportionate review as opposed to full review by all the members of a Research Ethics Committee.

73% of all student applications were made for full review and 27% were for proportionate review, although as the table below indicates this varies significantly by the level of study. PhD and doctoral students were much more likely to go to full review than undergraduates and Masters level students, presumably reflecting the increased complexity of PhD studies. (This difference was significant at 0.000.) Undergraduates were more likely to apply for full ethical review than Masters level students, perhaps reflecting the fact that most undergraduates applying for ethical review are preclinical students pursuing intercalated degrees.

Table 2 - Type of Review

	Undergraduate	**Masters**	**PhD/ Doctoral**
Review by Full REC	65.5%	58%	83%
Proportionate review	34.5%	42%	17%
Total	100%	100%	100%
Base	55	160	415

Decision made at First Review by a REC

We know that overall 27% of all validated studies obtain a favourable opinion. Management information shows that 28% of student studies get a favourable opinion at the first review and 64% get a provisional opinion. 7.1% of student applications are given an unfavourable opinion. 1% of all student applications are given no opinion at proportionate review and are referred for full review by

a REC. What we can't see from any of the data is the number of iterations that researchers need to go through in order to move from a provisional opinion to a favourable one.

Applications from undergraduate students achieved higher levels of favourable opinion and Masters students achieved the highest level of unfavourable opinions. However the differences are not statistically significant.

The decision made by the REC also varies according to the level of the student, with Masters students receiving the highest proportion of favourable opinions. The difference is not statistically significant.

Table 3 – Decision made at first review by level of the student (8 months 2012 - 2013)

	Undergrad	**Masters**	**PhD/ Doctoral**
Favourable	36%	38%	32%
Provisional	60%	56%	62%
Unfavourable	4%	6%	4%
No opinion	-	-	1.5%
Total	100%	100%	100%
Base	55	158	412

Student researchers seeking proportionate review were more than twice as likely to be given a favourable opinion at the first review than those student researchers seeking a full review. As the table below shows the percentage of provisional opinions is also greatly reduced for those seeking proportionate review. The chance of getting an unfavourable opinion is halved under proportionate review for students. This difference in opinion by type of review is statistically significant at 0.001)

Table 4 – Decision made at first review by type of review – student applications (8 months 2012 - 2013)

	Full Review	**Proportionate Review**	**Promoted to full review**
Favourable	24.5%	65.4%	13.3%
Provisional	69.9%	30.8%	33.3%
Unfavourable	5.6%	2.5%	0
No opinion	-	1.3%	33.3
Total	100%	100%	100%
Base	481	159	15

The table below shows the percentage of favourable opinions given by type of study conducted by students. So, for example, three quarters of students doing a study which involves only data obtain a favourable opinion first time round. Not surprisingly those employing what are generally regarded as low risk methods under proportionate review are receiving the highest levels of favourable opinion, whereas those seeking full review are likely to be conducting more complex, interventional studies. The variation in opinion by type of study is statistically significant at 0.001.

Table 5 – Type of study conducted by students by % with a favourable first opinion (8 months 2012 - 2013)

Type of study	Favourable %	Base	
		No.	%
Data only	75%	24	100
Human tissues samples and data	50%	64	100
Qualitative methods only	47%	155	100
Study administering questionnaires/interviews for quantitative analysis or using mixed methods	29%	172	100
Other clinical trial to study a novel intervention or RCT to compare interventions clinical practice	21%	58	100
Basic science involving human participants	21%	127	100
Clinical trial of an investigational medicinal product	0	2114	100
Clinical investigation of a medical device	19%	21	100
Other study	33.3%	12	100
Total Base:	649	649	100

Multiple student applications

The current IRAS form allows for more than one student to make the same application but only eight applications out of 660 were for multiple students. Of these eight, six were 2 students and two were 5. In all cases the students appeared to be undertaking different elements of the same project with the course supervisor acting as a Chief Investigator.

Appendix 4 - Analysis of time taken to validate and review student research in comparison with other types of research

Background

This data collection exercise was developed around triangulated observations made by Research Ethics Committee (REC) chairs, members and coordinators. REC staff and members have reported that they try to take a constructive approach to student research which can sometimes be of a poor quality and suggest that it may, as a consequence, take longer to process and review. This exercise seeks to quantify that assumption.

An adhoc data collection activity has been conducted to measure the time taken to validate and review applications for ethical review. Two REC centres (Bristol and Jarrow) were asked to collect data on the time taken to:

1. Validate applications for proportionate review
2. Validate applications for full review
3. Review applications in full review.

This report covers the data collected by RECs across two centres. RECs in Bristol Centre were asked to collect data from June to September 2013 inclusive. RECs in Jarrow are collected data from October to December 2013.

This covers a total of 542 applications made for ethical review (including 420 applications for full review and 122 applications for proportionate review) and the table below shows the breakdown of student studies in each of the three categories.

Table 1 – Data collection: June to Dec 2013

	Total No. of applications	**No. of student applications**	**No. of undergrad/ Masters applications**	**No. of PhD applications**	**No. of other applications excluding students**
Validation for full review by REC coordinator	420	126	104	316	294
Validation for PR by Rec coordinator	122	58	94	28	64
Review by full committee	420	126	104	316	294

Validation of applications for full review

Before a study application can be submitted for ethical review it has to be validated by the REC coordinator. Overall, across all types of studies, the mean average time spent by REC coordinators in validating applications for full review is 48 minutes, but the mode is 40 minutes. The maximum time spent on validation on a single study was two hours and 40 minutes. Invalid studies take a similar time to process to valid ones; a mean average of 50 minutes as opposed to 47 minutes.

Student studies take roughly the same time to validate as other types of studies. The average time taken to review non-educational application is 48 minutes and 49 minutes for student applications. Applications from PhD students take the same amount of time at 49 minutes.

Time spent in full review

The mean average amount of time taken to review a study in general in a full ethical review is just 31 minutes (mode= 30 mins, median=30 mins). The minimum amount of time is 5 minutes and longest recorded time is one hour and 30 minutes. Student studies taken an equivalent length of time as other types of studies at 32 minutes. PhD applications also take 32 minutes.

Validation of applications for proportionate review

As with a full review, REC coordinators also have to validate applications for proportionate review and ensure that they are actually suitable for proportionate and fit within the criteria. Applications which are found to not be suitable for proportionate review are referred to the REC for full review.

The mean average amount of time spent validating applications prior to proportionate review is 42 minutes, although the median is 35 minutes. The minimum time spent validating proportionate review applications is just 15 minutes; the maximum time is 3 hours. The mean validation times for student applications was 44 minutes for proportionate review compared with 40 minutes for other types of studies. The mean average validation times for PhD applications is also 44 minutes.

Summary

The table below shows the average times recorded at different stages of the process.

Table 2 – Mean time for validation and review of student and non-student studies by type of review

	Time spent in full review pathway (minutes – mean)	
	Student applications	**All other applications**
Validation time	49	48
Time spent in full review	32	31
Total time	81	79
	Time spent in proportionate review – validation only (minutes – mean)	
	Student applications	**All other applications**
Validation time	44	40

The data collected in the validation process prior to proportionate review indicate that the time taken for both student and other types of studies is similar, with student studies taking slightly longer on average. Applications undergoing proportionate review should, in the main, be low risk studies and we could expect proportionate review to take less time than validation of full review and this is borne out by the data.