MANCHESTER 1824

The University of Manchester

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Application form for ethical approval of a research project by a University Research Ethics Committee

The University Research Ethics Committees meet on a weekly basis between September and July each year. All applications must be submitted to your School/Institute Signatory by the end of June or it will not be considered until September. Please see here for the calendar of UREC meetings. The normal expectation is that your application will be reviewed in the third week after submission by the School/Institute Signatory. Please note that the School/Institute signatory process aims to take an average of 10 working days.

Guidance on completing the form

This form should be completed by the Principal Investigator(s). For student research, the Supervisor must provide guidance to the student on the application and sign off the form.

Guidance can be found by clicking on the links provided with some sections. Additionally, guidance can be found here.

The form must be completed **succinctly** and in **plain, jargon-free English** so that committee members, who may not be familiar with your academic discipline, are able to understand it.

Applicants are asked to forward all supporting papers in **one document**, preferably in a PDF format. Experience indicates that it is easy for separate documents to get misplaced as they are transferred from one office to another during the review process.

Submitting the form

Your form must be submitted to the UREC via your assigned School/Institute Signatory. Please see here for a list of current Signatories:

Checklist of documentation to include

Please DO NOT include CVs

- ☒ **Participant Information Sheet**
- ☒ **Consent form [Two – one for jurors and one for substitute jurors]**
- ☐ **Letters to gatekeepers (i.e. those from whom permission is required such as employer or data custodian) if applicable**
- ☒ **Questionnaire (if using) [Two – one for recruitment and one end-of--jury questionnaire]**
- ☐ **Interview/focus group schedule (if using)**
- ☐ **Any advertisements/flyers/posters to be used**
- ☐ **Research Protocol (if applicable)***

Please note:** a research protocol is **NOT** a substitute for information provided on the UREC form. The committee will only read it when the UREC form **refers to specific sections** which explain, illustrate or expand on the information contained in the form. **PLEASE DO NOT ATTACH GRANT PROPOSALS

Insurance Questions

Please answer the following questions. If in doubt, err on the side of caution and answer yes. If you answer yes to any of the questions below then your application, Participant Information Sheet and Consent form will be forwarded to the Insurance Office by the Research Governance, Ethics and Integrity team. For additional guidance for completing the Insurance Questions, please see here.

Title of Research: To what extent should patients control access to patient records? Two citizens' juries.

Principal investigator: Dr Mary Tully

School/Institute: School of Pharmacy, Medical and Human Sciences

Question		**Yes/No**
Is any part of the research, or use of the protocol, to be carried out outside the UK (including internet-based research that could include respondents from abroad)?		No
If yes, does the research also involve medical content?		
Does the research involve "first into man" use of a medicinal product?		No
Do the research subjects deliberately include:	• pregnant women?	No
	• children aged five or under?	No
	• adults who lack the capacity to give informed consent?	No
Does the research include medical intervention involving:	• investigating a medical device?	No
	• contraception?	No
Is the research to be carried out by other organisations where the University is required by contract to provide insurance cover for the research if it proceeds?**		No

Signed (PI): Date:

****If you are unclear of the responsibilities please provide any contract conditions/agreements for review.**

Insurance Office approval (not required if all answers above are 'No')

Signed: Date:

SECTION A – Administrative information

**** Do you also need to obtain NHS R&D approval?**

No

****If yes, have you already contacted your University sponsor regarding NHS R&D approval?**

☐ **Yes** ☐ **No**

IMPORTANT: You MUST contact your University sponsor regarding NHS R&D approval PRIOR to submitting a UREC application. Any UREC applications submitted prior to contacting your University sponsor will be returned.

1. **Title of the research:**

To what extent should patients control access to patient records? Two citizens' juries.

2. **Investigator(s)** *(nb. In the case of postgraduate student applications the supervisor is always the joint investigator):*

		Supervisor/Staff
Title	Dr.	Dr.
Surname	Oswald	Tully
First name	Malcolm	Mary
Post	Honorary Research Fellow in Law	Reader in Pharmacy Practice and Engagement and Involvement Academic Lead for Faculty of Medical and Human Sciences
Qualifications	PhD	PhD, FFRPS, MRPharmS
School/Unit/Institute	School of Law (Centre for Social Ethics and Policy)	Manchester Pharmacy School
Contact Address	22 Hawthorn Grove, Stockport SK4 4HZ	Stopford Building. Oxford Rd. Manchester
Email address	Malcolm.oswald@manchester.ac.uk	mary.tully@manchester.ac.uk
Telephone	0161 431 0322	0161 275 4242

3. **School contact (if applicable): The School/Institute Signatory will receive a copy of the outcome of the ethical review,** *If the School wishes anyone else to receive a copy, the relevant details should be entered here.*

   Name: Dr Sarah Willis

   Post: Lecturer in Pharmacy

   Email address: sarah.willis@manchester.ac.uk

4. **Is this study, or any part of this study a student project?** No

   If Yes what degree is it for?

5. **Please provide the names and email addresses of any academic staff or students involved, other than those named at 2 above:**

Lamiece Hassan, PPI Research Officer, Health e-Research Centre, lamiece.hassan@manchester.ac.uk

Ruth Norris, Programme Manager, Health e-Research Centre, ruth.norris@manchester.ac.uk

Niels Peek, Reader in Health Informatics, Health e-Research Centre, Niels.Peek@manchester.ac.uk

SECTION B – Details of Project

6. **When will the data collection take place?** (*If your research will be conducted outside the UK borders, please specify the duration for each country)*

   Start date: 14/01/2016

   End date: 23/01/2016

7. **What is the principal research question?**

To what extent should patients control access to patient records?

8. **What is the academic justification for the research?** *(Must be in language comprehensible to a lay person)*

Researchers, commissioners, pharmaceutical companies, even the Prime Minister, want "big data" within heath records used for public and private good. However, the law tells us to draw a line between anonymised data which can be used for "secondary purposes" like research and commissioning, and identifiable health data, which is confidential and to be protected. Anonymised data does carry a small risk of re-identification; there is a chance they could reveal confidential information about a person. So given this residual risk, and given that health records contain confidential information, what rights should patients have to control access to patient records?

Do patients "own" their health records and thus can reasonably expect that their permission is sought explicitly before their records are used for secondary purposes? Is an opt-out system justifiable? Is ownership a meaningful concept to apply to health records? What ethical responsibilities do patients have to accept access to health records and to enable research and the provision of effective health care to others? Is it fair and practicable to provide patients with choices about the purposes, and the types of organisations, allowed to use health records?

The law provides some guidance on these big questions but ultimately public officials must determine what health data can be disclosed to whom under what circumstances, and what choices to offer patients. Where officials misjudge the public mood, it can lead to a public outcry and parliamentary scrutiny, as witnessed in 2014 over care. data and the use of hospital records by private companies. Their decisions are informed by surveys of public opinion. However, few surveys have asked fundamental questions such as those raised above. Furthermore, as in many areas of public policy, these are complex questions, and ill-suited to opinion polling where participants must choose quickly between multiple choice answers. Citizens are liable to change their minds about a complex policy question after participating in a process where they are more fully informed, and where they deliberate with their peers. For example, in one process,

24 citizens were polled before and after a 3-day citizens' jury about whether NHS funding should be ring-fenced. Before the jury, 79% said "yes", but afterwards 91% of jurors said "no".

Therefore, there is an important gap in our knowledge about what control informed citizens would seek over health records. This project aims to plug this gap and inform policymaking.

9. Give a brief summary of the design and methodology of the planned research. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, participant groups or communities in the design of the research. *(This section must be completed in language comprehensible to the lay person and should be no longer than half a page. A research protocol is **NOT** a substitute for information provided on the UREC form. The committee will only read it when the UREC form **refers to specific sections** which explain, illustrate or expand on the information contained in the form. **PLEASE DO NOT ATTACH GRANT PROPOSALS**)*

Two citizens' juries, each of 18 different jurors, will be held in Central Manchester to investigate public views into the extent to which patients should control access to patient records. The first jury will meet on 14, 15, and 16 January 2016, and the second jury will meet on 21, 22 and 23 January 2016. Jurors will be over 18, fluent in English, and have the capacity to give consent to participate in the jury. The citizens' jury method is chosen for this research because it provides a framework for jurors to:

- Become informed about this complex problem by expert witnesses (chosen either to inform the jury, or to air arguments from a particular position e.g. a privacy lobbyist);
- Ask questions of experts;
- Deliberate amongst themselves;
- Have the freedom to explore different aspects of the research question; and
- Reach a consensus where possible, and for polling of individual juror views.

The methodology is set out in the Citizen Jury Handbook produced by the Jefferson Center, the founders of the citizens' juries method. Kyle Bozentko, Executive Director of the Jefferson Center, will be the lead facilitator of the two juries. The other facilitator will be Amanda Hunn, Engagement and Policy Manager at the Health Research Authority. They are also involved in planning the juries.

As recommended in the Citizens' Jury Handbook, a random sample of jurors will be recruited to represent the age, educational attainment, gender, and ethnic group profile of residents of England. However, to minimise travel and accommodation costs, all jurors recruited will be Greater Manchester residents. Potential jurors will also be asked a question about their attitude to health record privacy as part of the recruitment process. Jurors will be selected so as to broadly reflect UK attitudes to privacy (based on previous surveys) in order to avoid potential bias from choosing jurors from Manchester.

The jurors will be paid £375 including expenses for their time at the end of the 3-day jury. They will also be paid £25 in cash on the first morning. This helps jurors who might need the cash for travel to and from the venue.

In addition, five reserve jurors will be paid £50 cash for saving the 3 diary dates and turning up on day 1 (cash paid on day 1). If one or more of the jurors send their apologies or do not arrive on day 1, substitute jurors will be asked to take their place as jurors for the 3 days.

The juries will be filmed. This will capture not only what is said by participants but also enable more to be learnt about the body language and non-verbal communication which occurs during a jury session. The jurors will be asked for their

consent to be filmed, and for the resulting videos to made available for further research into the citizen's jury method and into the topic of the jury discussions.

Jury recruitment will be face-to-face and by inviting (e.g. by email) members of existing groups of people (membership organisations such as choirs and sports clubs, and groups of people who have expressed an interest in being involved in such consultations) whether they wish to take part. There will be no cold phone calling. The recruitment method is described in more detail at Q19.

10. How has the scientific quality of the research been assessed? *(Tick all that apply)*

Yes Internal review (e.g. involving colleagues, academic supervisor)

Yes Review within a multi−centre research group

☐ Independent external review

☐ Review within a commercial company

☐ None external to the investigator

☐ Other, e.g. in relation to methodological guidelines *(give details below)*

If relevant, describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

11.1 Does the research involve the administration of any physically invasive procedures, physical testing or psychological intervention (apart from the administration of standard psychological tests)?

No

If No, proceed to 11.2 If Yes, please ensure you complete Section F

11.2 Does the research involve human blood or tissue samples? If you are unsure, please see here for guidance relating to HTA.

No

If No, proceed to 11.3

11.3 Does the research involve interviewing participants or focus groups?

Yes

If No, proceed to 11.4

If Yes, please describe briefly how they will be conducted

Some participants may be interviewed informally as part of the recruitment process, as described in Q19, but the interviews will *not* be audio-recorded.

11.4 Does the research involve the administration of questionnaires?

Yes

If No, proceed to 11.5

If Yes, please describe the process of delivery and collection

A recruitment questionnaire will be completed by people interested in participating in the research. End-of-jury questionnaires will be given out by jury facilitators to the jurors at the end of the jury process. The jurors will complete the questionnaires before leaving. The questionnaire results will be summarised by the research team and disseminated.

11.5 Is statistical sampling relevant to this research?

No

If No, proceed to 11.6

If Yes, please answer the following questions:

11.5.1 Has the protocol submitted with this application been the subject of review by a statistician independent of the research team? Select one of the following:

11.5.2 If relevant, specify the statistical experimental design and why it was chosen.

Not applicable.

11.6 If you are not using statistical sampling how was the number of participants decided upon?

The number of 18 jurors is within the range recommended in the Jefferson's Center's methodology.

A sample of jurors will be purposively selected so that they broadly reflect the resident population of England in terms of age, sex, educational attainment, ethnic group and views on privacy. Publicly-available 2011 UK Census data for England has been used to derive the average number of jurors that could be expected in an 18-person jury:

Target sample - Sex	Females: 51%, 8 - 10 jurors Males: 49%, 8 - 10 jurors
Target sample - Age	Aged 18-29: 21%, 2 - 5 jurors Aged 30-44: 26%, 3 - 6 jurors Aged 45-59: 25%, 3 - 6 jurors Aged 60+: 28%, 4 - 7 jurors
Target sample – Ethnic group	White: 85%, 14 - 17 jurors Groups other than White: 15%, 1 - 4 jurors
Target sample - Educational attainment	Level 1 or no qualifications: 36%, 5 - 8 jurors Level 2, level 3, apprenticeship & other qualifications: 37%, 5 - 8 jurors Level 4 qualifications and above: 27%, 4 - 6 jurors

In order to avoid the risk of recruiting a group of jurors whose initial views on privacy of health records are not broadly representative of people in England, each potential juror will also be asked the following question that was posed in a previous survey ("Perceptions of Data Sharing" survey of 506 GB adults aged 16-75) carried out by

IPSOS MORI in 2014. This survey question (see Jury Recruitment Questionnaire) will also be used to select the 18-person jury:

Target sample – Privacy views	"As you may know, different government departments and services collect data about individuals, for example your tax records and health records. People have different views on how much this information should be shared within government. Data sharing can bring benefits, such as finding more effective medical treatments, using information about local communities to plan local schools or roads etc. But some people worry that data sharing will be a risk to their privacy and security, by linking different types of data together and potentially allowing them to be identified. Overall, which of the following statements is closest to your view?" Agree more with a than b: 52%, 7 - 11 jurors Agree more with b than with a: 34%, 5-7 jurors Agree equally with both / don't agree with either/don't know: 14%, 1 - 4 jurors

The classification groupings (e.g. age groups) and the target range of jurors in each group (e.g. 2-5 jurors aged 18-29) have been chosen to strike a balance between precise representation and what is practicable in terms of recruitment. The greater the number of classification groupings, and the narrower the range of jurors in each band, the more accurately the jury can be said to reflect the chosen characteristics of the population of England, but the more difficult it is to recruit jurors. An expert statistician could not advise on where that balance should be struck. This is unlike statistical sampling, and no claims will be made in relation to statistical significance. The actual sample achieved (and the target samples above) will be published so that people can judge for themselves the extent to which the jury reflects the population of England.

11.7 Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The main output from the juries will be short statements from the juries responding to the topic that the jury are asked to discuss (i.e. the "jury charge"). The other significant output will be the summary of results of the bias questionnaire completed by jurors. These outputs will be published.

The videos of the jury discussions will be analysed at a later date, when funding is available, using appropriate qualitative methods. As there will only be this sole opportunity to collect this data during the time that the jury is running, we are asking consent to record the proceedings now and store the recordings securely for later analysis.

12.1 What do you consider to be the main ethical issues which may arise with the proposed study?

A. The validity of juror consent

Jurors should be made aware in advance of what to expect, and what will be expected of them, so that they may take this into account when deciding whether to participate (although exactly what may happen during a jury cannot be anticipated to the same extent as, say, a clinical trial, it being dependent in part on how jurors respond to the proceedings).

B. The protection of jurors from harm

Jurors should be treated with respect, both by those running the jury, and by other jurors, to protect their dignity and privacy.

C. The filming of jury proceedings

The plan to film the jury proceedings would provide a potentially valuable resource for future research on citizens' juries, and a record of events that could be used to check for evidence of bias but some jurors may be concerned that it interferes with their privacy.

D. The risk of making excessive claims about the significance of the juries and their deliberations for policy and practice

The jury design, recruitment process, the jury proceedings and outputs should be as transparent as possible so that those who are interested in the juries' work (e.g. policymakers and practitioners) can judge its significance for themselves. Controls should be put in place to monitor, recognise and minimise bias (although bias cannot be eradicated).

12.2 What steps will be taken to address the issues raised in question 12.1?

A. The validity of juror consent

Jurors will be invited without any coercion to apply to join the jury process. They will be provided with information about the jury process orally to help them decide if they wish to apply to be a jury member. If selected (selection will be determined so as to achieve a suitable sample of jurors based on the characteristics identified in 11.5 above) they will be contacted and asked again if they wish to join the jury. They will be provided with written information about the jury process, and about payment for their time. If they wish to go ahead, they will sign a consent form, which will include a question about jury filming. If jurors wish to participate in the process, but do not wish to be filmed, their wishes will be respected (see C below). Applicants not selected for the jury will be informed.

B. The protection of jurors from harm

Experienced facilitators will manage the jury process and will encourage all members of the jury to contribute appropriately and treat all their contributions with respect. Each juror will be provided with an information sheet asking them to behave respectfully to other jurors, and the facilitators will promote appropriate behaviour, and address any problems that might arise or result in individuals being offended.

C. The filming of jury proceedings

Jurors will be told in advance of the plan to film the jury proceedings, and how the video record will be used, and will be asked whether they consent to being filmed. If they choose not to be filmed, they will be asked whether they object to a voice recording being made. Where consent is given to just voice recording, either just a voice recording will be made, or a video will be made but jurors who dissent will be seated so that they will not be visible in the recording. As the research is specifically designed to include jurors who are privacy conscious , the decision may be made by the research team not to record video or sound footage if a sufficient number of jurors are concerned about a record of proceedings being stored and used that might identify them. If video or sound records are made, they will be stored securely on the university's servers and used solely for the purposes described to the jurors in the consent form.

D. The risk of making excessive claims about the significance of the juries and their deliberations for policy and practice

The jury design, recruitment process, the jury proceedings and outputs will be published, redacting identifying information about any juror who wishes not be identified. As such, it will be open to scrutiny. The jury is open to bias at virtually every stage of the process. Steps will be taken to minimise this, including:

- An Oversight Panel will review the design of the jury (both the selection and jury process);

- The Oversight panel will contain a minimum of three people with no conflict of interest in the jury outcomes (though they may have a special interest in the jury charge);
- The funders of the juries will be able to influence the juries' charge but are independent from the jury process and outcomes;
- Expert witnesses will be briefed to be either impartial information givers (day 1 of the juries) or partial persuaders (day 2) but not both;
- Jurors will work with facilitators on day of the juries to construct the statement that addresses their charge (for publication);
- Jury questionnaires will ask jurors to identify signs of bias, and questionnaire results will be published;
- The jury process will be filmed and made available on request for scrutiny and/or further research (subject to juror consent);
- The jury to be run twice with the same facilitators, witnesses and jury process but with two different sets of jurors in order to validate outputs – significant differences could be a sign of bias.

12.3 What qualifications/experience do the researchers have relevant to the conducting of this research? (*For details about requirements for specific types of research click here*)

Mary Tully is an experienced qualitative researcher, also with an up to date GCP certificate. As Engagement and Involvement Academic Lead for the Faculty of Medical and Human Sciences and as Patient and Public Involvement Lead for the Health e-Research Centre, she has considerable experience in involving members of the public in research.

Malcolm Oswald completed his PhD in Bioethics and Medical Jurisprudence in 2013 which explored how citizens can and should contribute to public policy. He has worked for national agencies over much of the last 15 years, addressing questions concerning access to patient records, and the extent to which patients should make decisions about patient records.

Kyle Bozentko, the lead facilitator, is director of the organisation which developed the citizens' jury methodology.

13. Has this or a similar application been previously considered by a Research Ethics Committee in the UK, the European Union or the European Economic Area?

No

If Yes give details of each application considered, including:

Name of Research Ethics Committee or regulatory authority:
Decision and date taken:
Research ethics committee reference number:

SECTION C – Details of participants

14. How many participants will be recruited? *(If there is more than one group, state how many participants will be recruited in each group. For international studies, say how many participants will be recruited in **each country** and in total. Please ensure you clearly state the total number of participants)*

2 x 18 jurors, and 2 x 5 substitute jurors.

15. Age range of participants:

Participants to be aged 18 and over. There is no upper age limit.

16. What are the principal inclusion criteria for participants? *(Please justify)*

- Resident in Greater Manchester for 1 year minimum
- Over 18 years of age

  Questions of consent validity may arise if younger people were recruited. There is no reason why there should be an upper age bar.

- Has mental capacity to consent to participation in jury

  Valid consent is necessary.

- Fluent in English

  Jurors must be able to understand, be understood, and contribute to, proceedings. Translators would significantly reduce what could be achieved in three days and would increase costs significantly. In addition, the privacy concerns regarding health data may be very different for migrants, and so a proper exploration of this would need to be the subject of its own research study.

17. What are the principal exclusion criteria for participants? *(Please justify)*

- NHS healthcare professional

  The facilitators have advised that having NHS healthcare professionals in such public engagement events can interfere with deliberation, and that there is a tendency to look to NHS professionals as experts rather than as equal participants in the process.

- Special interest or conflict of interest in jury charge

  Again this could lead other jurors to look to these individuals for expert knowledge. A juror with a clear conflict of interest (e.g. from a manager in a pharmaceutical company) could introduce avoidable bias.

- Should not know other jurors (other than by coincidence)

  It is important that jurors contribute as individuals and have no prior allegiances to other jurors.

18.1 Will the participants be from any of the following groups? ***(Tick all that apply)***

Yes Adult healthy volunteers (i.e. not under medical care for a condition which is directly relevant to the application)

No Children under 16

No Adults with learning difficulties

☐ Adults who have a terminal illness

☐ Adults with mental illness (particularly if detained under mental health legislation)

No Adults with dementia

No Adults in care homes

No Adults or children in emergency situations

No Prisoners

☐ Young offenders

No Those who could be considered to have a particularly dependent relationship with the researcher, e.g. students taught or examined by the researcher.

☐ Other vulnerable groups

Please note: *If an adult participant is not able to give informed consent (eg through mental capacity or is unconscious) or if a prisoner or young offender is involved in health related research ethical review should be undertaken by an appropriate NHS Research Ethics Committee*.

Several of the boxes above are left unticked deliberately. It is unlikely that many (if any) participants from these groups will be included, and none of these groups will be specifically targeted. However, on their own, the characteristics above are not considered sufficient to exclude a person from becoming a juror and it is considered inappropriate to ask all potential jurors whether they fall into any of the above categories.

18.2 If you will be using participants other than healthy volunteers please justify their inclusion:

N/A

19. How will the potential participants be identified, approached and recruited? *(Where research participants will be recruited via advertisement, please append a copy to this application)*

Jurors will be recruited in two phases.

The first phase of recruitment will be by the research team. In this phase, jurors will be recruited in the street. This is a typical way that market research organisations recruit people for such public engagement exercises. People will be asked if they would be interested in taking part in the research, and if they are interested, they will be told about the nature of the project and the jury process, how much they will be paid, and any questions that they have at that time will be answered. They will be able to take away the information sheet and the recruitment form to complete and submit in their own time. It will be explained that not all candidates will be selected, because a cross-section of Greater Manchester residents is required. Candidates who submit a completed form will be told (by a mutually-agreed method) in October or November whether or not they have been selected. Candidates will have an opportunity at this point to accept or reject this offer.

In addition, the research team will advertise on relevant websites (such as the university's research volunteering website), and approach bodies which maintain lists of people who have agreed to receive emails to ask if they could contact their group members to see if they might be interested in learning more and/or taking part in the research. For example, contact will be made with Salford Citizen Scientist, and with Salford City Council which maintains a list of people who are interested in participating in discussions of local government policies and practice. A few membership organisations such as choirs and sports clubs may also be contacted. The initial enquiry will provide very brief details about the project, such as:

To what extent should patients control access to patient records?

The University of Manchester is inviting applications to take part in an exciting new study to explore what citizens think about sharing health records. Over 3 days in January, a panel of participants will be paid to work together as a "citizens' jury" to find an answer this important question.

Interested in taking part?

Please read the attached information sheet and visit https://www.surveymonkey.com/r/juries to apply.

People who respond and want to learn more about the project and how they can be involved will be sent an information sheet and recruitment form, or will be pointed towards a website where they may apply to be a juror.

There will be no recruitment by phone. Such calls tend to be invasive, and could only be carried out using a purchased phone directory (from which people who strongly valued their privacy would be disproportionately likely to opt out). Some recruitment will be done face-to-face, either by setting up a stand enabling members of the public to approach the recruiters, or by recruiters approaching members of the public. Where recruiters approach people face-to-face, care will be taken to avoid harassing members of the public.

This first phase of recruitment will be carried out in October. Jurors will be selected and gaps that have been difficult to fill in the required quotas of characteristics (e.g. age, gender) will be identified. The second phase of recruitment to select the remaining participants will be subcontracted to a market research company governed by the Code of Conduct of the Market Research Society. This second phase of recruitment to "fill the gaps" will take place during November and early December 2015. Jurors selected in phase two will be provided with the same information, the same payment, and the same participation opportunities as those selected in phase one.

20. Will individual research participants receive *reimbursement of expenses* or any other *incentives* or *benefits* for taking part in this research?

Yes

(If yes, indicate how much and on what basis this has been decided)

£25 + £375 was decided as a sufficient incentive, and recompense for the time of jurors, many of whom will have to take leave from work to participate in the jury (the jury runs from Thursday to Saturday, 09.30 to 17.00). Although jurors may leave the jury proceedings at any time - there is no coercion - they will in general only be paid the £375 for the full three days, and will not receive a portion of that payment for partial attendance. This is because the research relies on 18 jurors throughout the process to ensure the validity of the output that they will produce at the end, and no substitutes jurors will be able to join after lunchtime on day 1. This is made clear to all participants in advance. However, if a juror leaves the jury early with good reason (e.g. an unforeseeable emergency) the research team can exercise discretion to pay the juror on a pro-rata basis for their attendance.

£50 was considered a sufficient incentive and reward for “reserves” who will be paid to save the dates in their diaries, and stay until lunchtime on day 1 of the jury. If they become research participants, they will sign the consent form for jurors and receive a further £375 for completing the jury process.

21. What is the expected total duration of participation in the study for each participant? *For ethnographic research focussing on one or more groups rather than individual participants, indicate the approximate period of time over which research will focus on particular groups*

Three days.

22. What is the potential benefit to research participants?

The Jefferson Center has many accounts of people being positively engaged by the process, and going on to campaign on the issues discussed. People can gain satisfaction from the process of working constructively with their peers towards a common goal, and from contributing to an important policy debate.

23. Will any benefit or assistance, which the participant would normally have access to, be withheld as part of the research?

No

(If yes, give details and justification)

SECTION D – Consent

24.1 Will informed consent be obtained from the research participants?

Yes

If Yes, give details of how consent will be obtained. Give details of your experience in taking consent and of any particular steps to provide information to participants before the study takes place eg information sheet, videos, interactive material.

If participants are recruited from any of the potentially vulnerable groups listed in Question 19.1, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

If consent is not to be obtained, please explain why not.

Jurors will be invited without any coercion to apply to join the jury process. They will be provided with information about the jury process orally to help them decide if they wish to apply to be a jury member. They will be provided with written information about the jury process, and about payment for their time. If selected (selection will be determined so as to achieve a suitable sample of jurors based on the characteristics identified in 11.6 above) they will be contacted and asked again if they wish to join the jury. If they wish to go ahead, they will sign a consent form, which will include a question about jury filming. If jurors wish to participate in the process, but do not wish to be filmed, their wishes will be respected. Applicants not selected for the jury will be informed.

Mary Tully has considerable experience in designing consent forms, and taking consent in qualitative research projects. Malcolm Oswald has designed consent forms and will be trained in the appropriate methods of taking consent for this study.

24.2 Will a signed record of consent be obtained?

Yes

If not, please explain why not. Please append any consent forms to this application.

25. How long will the participant have to decide whether to take part in the research? (*If less than 24 hours please justify***)**

One week from being offered a place on a jury.

26. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

None – see Q16 above.

SECTION E – RISKS AND SAFEGUARDS

27. Activities to be undertaken (*This should be in the form of a brief list, such as answering a questionnaire, being interviewed***)**

- Listen to, and ask questions of, expert witnesses
- Take part in group discussions
- Develop short statements in response to the jury's charge
- Complete questionnaires to monitor for bias.

28. Where will the research/data collection take place?

In a meeting room in Friends' House, 6 Mount Street, Manchester, M2 5NS

29.1 What are the potential adverse effects, risks or hazards for research participants, including potential for pain, discomfort, distress, inconvenience or changes to lifestyle for research participants? Are they any greater than those that would arise from normal social interaction?

Minimal potential harms; please see "protection of jurors from harm" in Q12.2 above.

29.2 Could individual or group interviews/questionnaires raise any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. in the application of screening tests for drugs)?

No, this is not planned as an expected outcome of the juries, as the discussions are not expected to cover topics or issues of this nature.

If yes, provide your distress policy/give details of procedures in place to deal with these issues:

29.3 What precautions have been taken to minimise or mitigate the risks identified above?

Please see "protection of jurors from harm" in Q12.2 above.

30.1 What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? ***(If any)***

There are no likely harms but the researchers, like the jurors, may be affected by the discussions that take place in the jury sessions. Some of the juror recruitment will be carried out off-site, and will be done in accordance with the University of Manchester's lone worker policy by two researchers working together, partly for reasons of safety.

30.2 What precautions have been taken to minimise or mitigate the risks identified above? (*If the research means working alone in a location which is not public, semi-public or otherwise risk-free, please describe your lone worker policy or append a copy*)

All of those involved will be made aware of the nature of jury proceedings, and to behave respectfully towards others.

31. √ I confirm that any adverse event requiring a radical change of method or design, or even abandonment of the research, will be reported to the Committee.

Yes, confirmed.

SECTION F – MEDICAL INTERVENTION

This section need only be completed by applicants whose project involves any form of medical or other therapeutic intervention or any physically invasive procedures, physical testing or psychological intervention (apart from the administration of standard psychological tests) (i.e. you answered 'Yes' to question 12.1)

32. Drugs and other substances to be administered (if applicable)

Indicate status, eg full product licence, CTC, CTX. Attach: evidence of status of any unlicensed product; and Martindales Phamacopoeia details for licensed products

DRUG STATUS DOSAGE/FREQUENCY/ROUTE

33. Procedures to be undertaken

Details of any invasive procedures, and any samples or measurements to be taken. and/or any psychological tests etc. What is the experience of those administering the procedures?

34. Will any procedures which are normally undertaken be withheld?

35.1 Will the research participants' General Practitioner be informed that they are taking part in the study?

☐ Yes ☐ No

If No, explain why not

35.2 If you answered yes to question 35.1, will permission be sought from the research participants to inform their GP before this is done?

☐ Yes ☐ No

If No, explain why not

36. What are the criteria for electively stopping research prematurely?

SECTION G – Data protection and confidentiality

37.1. Will the research involve any of the following activities at any stage (including identification of potential research participants)? *(Tick all that apply)*

Storage of personal data on any of the following:

Yes	Storage of personal data on manual files
Yes	Storage of personal data on laptops or other personal computers
Yes	Storage of personal data on University computers
No	Storage of personal data on NHS computers
No	Storage of personal data on private company computers
Yes	Use of audio/visual recording devices
Yes	Use of personal addresses, postcodes, faxes, e-mails or telephone numbers
Yes	Electronic transfer by magnetic or optical media, e-mail or computer networks
No	Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access
No	Sharing of data with other organisations
No	Export of data outside the European Union
Perhaps, but only with consent	Publication of direct quotations from respondents
Perhaps, but only with consent	Publication of data that might allow identification of individuals

Note that personal data about jurors and applicant jurors held in both paper and electronic form will be held and processed securely in accordance with principle 7 of the Data Protection Act 1998. Personal data held on non-university issued computers will be in encrypted form on a password-protected laptop. As soon as practicable, the paper forms will be transferred for long-term storage into locked filing cabinets, and the electronic records about jurors and applicants and video recordings of the jury meetings will be transferred to the P drive of university's secure servers.

37.2 Please provide details of how you plan to store and protect the study data as stated in 37.1 above.

Limited personal data that are necessary for recruitment purposes will be collected and stored on paper records, and potentially on a computer:

- Name, address, phone number, email address, age, educational attainment, sex, ethnic group, answer to privacy question
- Completed consent forms

Questionnaires will not directly identify individuals. The questionnaires will contain a numbered pseudonym so that the research team will be able to trace the questionnaire to the participant where necessary.

Video footage of jury proceedings will be stored securely on University computers, and used by ourselves or our collaborators for research as described in the participant information. Participants will consent to the recording and these uses.

Where personal data are stored on a non-university computer, they will be encrypted. Any other personal data will be stored on university servers. Paper records will be handled and stored securely.

38. What measures have been put in place to ensure confidentiality of personal data? Give details of what encryption or other anonymisation procedures will be used and at what stage? *Note: the University requires all personal data stored electronically to be held on wholly managed University servers or to be encrypted.*

Please see answer to Q37 above.

39. Where will the analysis of the data from the study take place and by whom will it be undertaken?

The researchers, and primarily Malcolm Oswald, will carry out the analysis of the data necessary for jury recruitment in Manchester. Care will be taken to process the data securely, and the data will subsequently be stored securely within University of Manchester servers.

40.1 Who will control and act as the custodian for the data? *Note: for a student project this must be a supervisor or a permanent member of staff*

Records will be passed to Mary Tully for secure university storage.

40.2 Who will have access to the data and where are they based?

Temporary recruiters with knowledge of data protection and experience of managing personal data will be hired and will collect and have access only to the data as necessary for recruitment. Other than that, only those directly involved (named in this application) will have access to the personal data (and on a need-to-know basis).

40.3 Will the data be stored for use in future studies? If yes, has this been addressed in the consent process?

Yes the videos of jury proceedings may be used for later research, and yes.

41. For how long will the data from the study be stored?

5 years.

Note: the University requires non-medical data to be held for a minimum of 5 years and medical data to be held for a minimum of 10 years after the completion of the research. Some funding bodies require storage for longer periods.

42. What arrangements are in place to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

As the jurors are involved for only three days, this is unlikely, but jurors will be provided with relevant information about their participation during the course of the jury.

43. What arrangements are in place for monitoring the conduct of the research by parties other than the researcher?

- An Oversight Panel will review the design of the jury (both the selection and jury process);
- The Oversight panel will contain a minimum of three people with no conflict of interest in the jury outcomes (though they may have a special interest in the jury charge);

Will a data monitoring committee be convened?

Not relevant

SECTION H – Conflict of Interest

44.1 Will individual *researchers* receive any personal payment over and above normal salary and reimbursement of expenses for undertaking this research?

No

If Yes, indicate how much and on what basis this has been decided:

44.2 Does the principal researcher or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

No

If Yes, give details:

45. Will the host organisation or the researcher's department(s) or institution(s) receive any payment of benefits in excess of the costs of undertaking the research?

No

If Yes, give details:

SECTION I – Reporting Arrangements

46. How is it intended the results of the study will be reported and disseminated? *(Tick as appropriate)*

Yes Peer reviewed academic journals

☐ Book or contribution to a book

☐ Other published outlets e.g. ESRC or Cochrane Review,

☐ Thesis/dissertation

☐ Conference presentation

☐ Internal report

Yes Other e.g. post-jury workshop with policymakers and practitioners

47. How will the results of research be made available to research participants and communities from which they are drawn?

☐ Presentation to participants or relevant community groups

Yes Written feedback to research participants

☐ Other e.g. videos, interactive website

48.1 Will dissemination allow identification of individual participants?

No, this is not planned.

If No, proceed to 49

If Yes, indicate how these individuals' consent will be obtained:

48.2 Will dissemination involve publication of extended direct quotations from identified participants and/or distribution of audiovisual media in which identified participants play leading roles?

☐Yes ☐ No

If No, proceed to 49

If Yes, indicate how the participants' possible Intellectual Property or Performance Rights in these outputs will be negotiated. Where relevant, attach a model of the release form that will be used.

48.3 Are special arrangements needed to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants on grounds such as libel, breach of confidence and infringement of Intellectual Property or Performance Rights?

SECTION J – Funding

49. Has external funding for the research been secured?

No – this research is funded internally by Health e-Research Centre and the GM Patient Safety Translational Research Centre

If Yes, give details of funding organisation(s) and amount secured and duration:

Organisation:

UK contact:

Amount (£):

Duration: Months

SECTION K – Confirmation of Application

Note: Student applications must also be signed by their supervisor

Signature(s) of applicant(s):

31/07/2015

_____ **_____**

SIGNATURE (Name in italics is sufficient) **DATE**

Dr. Malcolm Oswald, Honorary Research Fellow in Law

NAME AND POST OF APPLICANT (PLEASE PRINT)

Signature of supervisor (if applicable):

 _____ **31/07/2015__**

SIGNATURE (Electronic signature is required) **DATE**

Dr. Mary Tully, Reader in Pharmacy Practice

NAME AND POST OF SUPERVISOR (PLEASE PRINT)

Please note: Once complete, please submit this application form and ALL supporting documentation to your signatory for review. Please DO NOT send directly to Research.Ethics@manchester.ac.uk or your application will be returned to you.

Citizens' Jury Event details [note to research ethics committee: this will be given to jurors just prior to the jury for information, and not in advertising for jurors.]

Location: The Upper Hall, Friends' House, 6 Mount Street, Manchester, M2 5NS

Time: 09.30 – 17.00 for three days: Thursday 14/01/16, Friday 15/01/16 and Saturday 16/01/16 / Thursday 21/01/16, Friday 22/01/16 and Saturday 23/01/16 [delete as applicable]

Meals: Lunch, drinks and snacks will be provided for all participants

Attire: Dress comfortably.

Payment: Each participant will receive £25 cash on day 1, and £375 for attending the 3-day jury at the end of day 3. No additional payments for expenses will be paid.

Other Questions: Please email citizens@manchester.ac.uk with any additional questions.

PARTICIPANT CONDUCT

Respectful body language. Please use respectful body language toward everyone. Match your body language with your intent of listening and learning, and be aware that eye rolling, crossing arms, or turning away from someone while they are speaking may send a message of disrespect.

Respectful verbal language. Do not use language that disrespects anyone's religion, culture, racial group, appearance, etc.

Avoid distracting behaviour. Keep all electronic devices turned off and refrain from talking or text messaging on mobile phones during the sessions. Some things may not seem disrespectful to you, but can be distracting to others. Refrain from wearing clothing with messages or pictures on them that may be distracting or offensive.

Attending all sessions and being attentive. It is very important that participants hear all the information presented. There will be breaks to give panelists time to visit the toilet and/or take care of other needs and we ask that participants remain in the room when the group is in session. To maintain the legitimacy and fairness of the process, anyone who misses a significant amount of time (i.e. 3 hours or more) will likely not be able to stay for the remainder of the jury process, even if their absence is due to a medical emergency.

Emergency Contact. During the Review, you may have emergency calls directed to you through XXX. Phone:

Participation Recruitment Questionnaire

Please return this questionnaire by XX/XX/XX to ensure your eligibility for participation in this University of Manchester research project "To what extent should patients control access to patient records?". You should send it to Citizens' Jury Project, c/o Dr Mary Tully, Manchester Pharmacy School, Stopford Building, Oxford Rd, Manchester M13 9PT. You may use the pre-paid envelope provided.

Participants will receive payment of £25 on day 1, and £375 at the end of day 3 for attending and taking part in the research over three days. No further payments will be made (e.g. for travel). We will let you know before XX/XX/XX if you have been selected to participate.

Your Information: Please complete the form below. Your information will be kept confidential. It is being collected to enable the right mix of people required for the research to be recruited. The information will be destroyed after 5 years.

<table>
<tr><th colspan="3">YOUR INFORMATION</th></tr>
<tr><td>Name:</td><td>Gender:</td><td>Age:</td></tr>
<tr><td colspan="3">Address:

Postcode:</td></tr>
<tr><td>Email:</td><td colspan="2">Phone:</td></tr>
<tr><td colspan="3">Ethnic group (tick only one):
☐ White ☐ Asian
☐ Black ☐ Other</td></tr>
<tr><td colspan="3">Education – Highest Level Attained (tick only one):
☐ 0-4 O Levels/CSE/GCSEs (any grades)
☐ 5+ O Level (Passes)/CSEs (Grade 1)/GCSEs (Grades A*- C), 1 A-Level and/ or Apprenticeship
☐ 2+ A-levels
☐ Graduate Degree</td></tr>
<tr><td colspan="3">Occupation</td></tr>
</table>

Have you…

☐ A special interest in IT security or in health records? ☐ A conflict of interest? ☐ Worked as a health care professional (now or ever)?

If you ticked any of these, please explain briefly below. If you are unsure whether you have a conflict of interest, sa and we will contact you.

As you may know, different government departments and services collect data about individuals, for example your tax records and health records. People have different views on how much this information should be shared within government. Data sharing can bring benefits, such as finding more effective medical treatments, using information about local communities to plan local schools or roads etc. But some people worry that data sharing will be a risk to their privacy and security, by linking different types of data together and potentially allowing them to be identified. Overall, which of the following statements is closest to your view?

a) "We should share all the data we can because it benefits the services and me – as long as I can opt out if I choose"
b) "We should not share data as the risks to people's privacy and security outweigh the benefits"

☐ Agree much more with a) than with b) ☐ Agree a little more with a) than b) ☐ Agree equally/ don't agree / don't know ☐ Agree a little more with b) than with a) ☐ Agree much more with b) than with a)

I am available (select all that apply):

☐ For a 3-day, 09.30 – 17.00, citizens' jury event on Thu 14/01/16, Fri 15/01/16 and Sat 16/01/16 ☐ For a 3-day, 09.30 – 17.00, citizens' jury event on Thu 14/01/16, Fri 15/01/16 and Sat 16/01/16

Your Signature: _____ Date: _____

Thank you for applying to participate in this Manchester University study

We will contact you by **[date]** if you are selected to participate in the research. We may contact you if we would like to ask you to be a substitute in case a selected participant drops out of the research or is unable to attend. Substitutes will be asked to reserve all three days in their diary, and as a minimum will be paid £50 to attend day 1 until 13.30, but will be paid an additional £375 at the end of day 3 if asked on day 1 to act as a participant for all three days.

End-of-jury Questionnaire

Please complete and return before leaving. Any information that you give us here will not be passed on to any of the facilitators or witnesses, other than in a general and anonymous way.

The information will be destroyed after 5 years.

Juror Number:

Questionnaire to complete
As you may know, different government departments and services collect data about individuals, for example your tax records and health records. People have different views on how much this information should be shared within government. Data sharing can bring benefits, such as finding more effective medical treatments, using information about local communities to plan local schools or roads etc. But some people worry that data sharing will be a risk to their privacy and security, by linking different types of data together and potentially allowing them to be identified. Overall, which of the following statements is closest to your view? c) "We should share all the data we can because it benefits the services and me – as long as I can opt out if I choose" d) "We should not share data as the risks to people's privacy and security outweigh the benefits" ☐ Agree much more with a) than with b) ☐ Agree a little more with a) than b) ☐ Agree equally/ don't agree / don't know ☐ Agree a little more with b) than with a) ☐ Agree much more with b) than with a)
Did you ever feel that the jury facilitators tried to influence you towards particular conclusions? ☐ Yes ☐ No If yes, please explain:
Did you feel that the expert witnesses on day 1 tried to influence you towards particular conclusions? ☐ Yes ☐ No If yes, please explain:

Did you feel that anyone else outside the jury tried to influence you towards particular conclusions?

☐ Yes ☐ No

If yes, please explain:

Did you have any other concerns that the process was biased?

☐ Yes ☐ No

If yes, please explain:

Information sheet for potential research participants

Citizens' jury: To what extent should patients control access to patient records?

Our names are Mary Tully and Malcolm Oswald and we are researchers at the University of Manchester. We are inviting you to participate in a research study. Involvement in the study is voluntary, so you may choose to participate or not. This sheet explains the study to you. Please take the time to read this information and feel free to ask questions about the research if you have any.

Why we are doing the research

We are interested in learning more about how citizens think about the privacy of their patient record, and what control they think they should have over records about their health. Organisations like the Information Commissioners' Office and NHS England, who influence how patient records are used for purposes other than individual patient care, are also involved and want to learn from this research.

What will happen

We will choose a cross-section of adults to take part in this research. If you are offered and decide to take part, you will be a participant in a three-day "citizens' jury" which begins on Thursday XX/XX/XX and finishes on Saturday XX/XX/XX. Each day will begin at 9.30am and finish no later than 5pm. It will take place in the Upper Hall, Friends' House, 6 Mount Street, Manchester, M2 5NS. You will be asked to listen to presentations about patient records and how they can be shared, not only for your direct care and treatment, but also for other purposes like research, and health service management. You can ask questions of the presenters. You will also take part in discussions with the 17 other jurors so that together you can reach conclusions about how you will answer the questions you will be posed. For research purposes, you will be asked to complete a questionnaire at the beginning and conclusion of the three-day event. The information gathered through survey will be kept confidential, and only the researchers will know what you wrote in the questionnaire. We will number each questionnaire, and only the research team will have the key to indicate which number belongs to which participant.

The group discussions will involve sharing your questions, thoughts and ideas with other jurors and these discussions will be observed. What you say in this context is not confidential within the group, as clearly everyone will know what you have said. Things that you say may be published later but it would be an anonymous quote, not attributed to you. You will not be asked to disclose sensitive personal information. Nor will you be required to speak at any point and you may always choose to remain silent.

We plan to record these discussions. If you do not wish to be filmed, you may ask to be seated so that your face will not appear on the video recording. Your voice will be recorded. The recordings, and any other information from the research that might identify you, will be stored securely at the University of Manchester and may be used for further research into the citizen's jury method and into the jury's topic of access to patient records, or to demonstrate that the jury was conducted fairly. The recordings and other research records will be destroyed after 5 years.

The project has been reviewed by the University of Manchester Research Ethics Committee 1/2/3/4/5/.

What this research will mean for you

You will receive £25 payment on day 1 for attending the first day. You will receive a further £375 at the end of day 3 for completing the 3-day jury session. No additional payments will be made for expenses. If you withdraw at any point on day 1, day 2, or day 3, you will receive the £25 payment, but you may receive no further payment.

The benefit of this research is that you will be helping us, and public bodies that store and use patient records, know what citizens think about how patient records should be used. This information could help to design better ways to involve patients in decisions about patient records, so that records can be used for the public good whilst patients' wishes are respected. By taking part in the research you may experience the following benefits:

- Greater understanding of how patient records are used;
- Increased skill in discussing and solving problems with others; and
- Satisfaction from contributing to public policy that affects us all.

The risks to you of participating in this study are minimal. You may become weary in extended discussion or feel mild irritation with another participant if you disagree. You may feel discomfort or anxiety if you or someone you care about has been affected by the issue being discussed. These risks will be minimised by professional facilitation to keep discussions interesting and respectful and facilitators will listen to you if you express any discomfort or anxiety.

You have the right to refuse to take part, without penalty. If you decide to take part and then later no longer wish to continue, you have the right to withdraw from the study at any time. Early withdrawal will reduce how much you are paid, as described above. If you withdraw before the jury begins, you may ask for any personal data held about you to be destroyed.

Contact Information

If you have any questions, concerns, or complaints about the research, contact the researchers Dr. Malcolm Oswald on Malcolm.Oswald@manchester.ac.uk or Dr. Mary Tully, Reader in Pharmacy Practice, Manchester Pharmacy School, Stopford Building, Oxford Rd, Manchester at Mary.Tully@manchester.ac.uk or on 0161 275 4242.

If you wish to make a formal complaint about the conduct of the research you can contact a Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 8093.

Citizens' Jury: To what extent should patients control access to patients records?

Consent Form

If you are happy to participate please complete and sign the consent form below.

Please initial box

1. I confirm that I have read the information sheet on the above project and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2. I understand that my participation in the research is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself although I understand that this will affect how much I am paid. I understand that I will be paid £25 for attending the first morning, and that the only other payment is for £375 and this is only paid if I attend all three full days of the citizens' jury.	
3. I understand that my data will remain confidential, and will be stored securely for 5 years and then destroyed. If I withdraw before the jury begins, I understand that I may ask you to destroy any personal data you hold about me.	
4. I understand that the jury proceedings will be audio-recorded. I ***agree / do not agree*** to be part of a video recording used for the purposes described. [delete as applicable]	
5. I agree to the use of anonymous quotes.	
6. I ***agree / do not agree*** to the University of Manchester storing my personal details so that I may be contacted if there is an opportunity to participate in similar future research. [delete as applicable]	
7. I am at least 18 years of age and I agree to be a participant in the 3-day jury starting on XX/XX/XX and to behave respectfully to others throughout the jury process, just as I would reasonably expect them to behave respectfully towards me.	

Name of participant	Date	Signature
Name of researcher	Date	Signature

This Project Has Been Approved by the University of Manchester's Research Ethics Committee [UREC reference number].

This consent form will be stored securely and destroyed after 5 years.

Information Sheet and consent form for substitute jurors

Citizens' Jury: To what extent should patients control access to patient records?

Our names are Mary Tully and Malcolm Oswald and we are researchers at the University of Manchester. We are inviting you to participate in a research study. Involvement in the study is voluntary, so you may choose to participate or not. This sheet explains the study to you and please feel free to ask questions about the research if you have any.

Why we are doing the research

We are interested in learning more about how citizens think about the privacy of their patient record, and what control they think they should have over records about their health. Organisations like the Information Commissioners' Office and NHS England, who influence how patient records are used for purposes other than individual patient care, are also involved and want to learn from this research.

Why we need to recruit substitute participants

At this stage, we are inviting you to be a substitute juror for the citizens' jury to be run on XX/XX/XX through to XX/XX/XX. We have invited 18 people to be jurors, and to save those three dates in January. They are in no way "better" than you, but rather the group of 18 people we have invited are the ones that together best match our requirements for a mix of citizens in terms of age, gender, ethnic group etc. However, there is a chance that one or more of the 18 people selected may not appear on the first day, or may have to leave on day 1 before the afternoon session begins. If that happened, we would not have less than our target of 18 jurors. We would need other people to take their places. Therefore, we are inviting you, and four other substitute jurors, to attend and watch day 1 of the jury proceedings from 09.30 until 13.30. Unless we ask you and you agree to become a juror by 13.30 on day 1, you will be free to leave from 13.30.

What we will pay you

We will pay you £50 for keeping the three dates free in your diary, and for attending from 09.30 to 13.30 on day 1. This will be paid in cash at approximately 13.30 on day 1. If on day 1 we ask you to become a juror, you will be paid another £375 for your participation at the end of the three-day jury event, the same amount as the other jurors. If you would like to go ahead and act as a substitute juror, please fill in the form overleaf to show you understand and consent to being a substitute juror. In case we ask you to become a juror on day 1, please also read and fill in the jurors' consent form which follows on pages 3- 5. You are entirely free to decide whether or not to participate.

Your consent to participate as a substitute juror

All of my questions have been answered, I am 18 years of age or older, and I wish to participate in this research study as a substitute juror in the 3-day jury starting on XX/XX/XX.

I will keep free the 3 dates XX/XX/XX, XX/XX/XX, XX/XX/XX, and will attend the jury on XX/XX/XX between 09.30 and 13.30.

I agree / do not agree to the University of Manchester storing my personal details so that I may be contacted if there is an opportunity to participate in similar future research. [delete as applicable]

_____ _____

Signature of participant Date

_____

Printed name of participant

_____ _____

Signature of researcher Date

_____

Printed name of researcher

Information about what will happen if you become a juror

We will choose a cross-section of adults to take part in this research. If you are offered and decide to take part, you will be a participant in a three-day "citizens' jury" which begins on Thursday XX/XX/XX and finishes on Saturday XX/XX/XX. Each day will begin at 9.30am and finish no later than 5pm. It will take place in the Upper Hall, Friends' House, 6 Mount Street, Manchester, M2 5NS. You will be asked to listen to presentations about patient records and how they can be shared, not only for your direct care and treatment, but also for other purposes like research, and health service management. You can ask questions of the presenters. You will also take part in discussions with the 17 other jurors so that together you can reach conclusions about how you will answer the questions you will be posed. For research purposes, you will be asked to complete a questionnaire at the beginning and conclusion of the three-day event. The information gathered through survey will be kept confidential, and only the researchers will know what you wrote in the questionnaire. We will number each questionnaire, and only the research team will have the key to indicate which number belongs to which participant.

The group discussions will involve sharing your questions, thoughts and ideas with other jurors and these discussions will be observed. What you say in this context is not confidential within the group, as clearly everyone will know what you have said. Things that you say may be published later but it would be an anonymous quote, not attributed to you. You will not be asked to disclose sensitive personal information. Nor will you be required to speak at any point and you may always choose to remain silent.

We plan to record these discussions. If you do not wish to be filmed, you may ask to be seated so that your face will not appear on the video recording. Your voice will be recorded. The recordings, and any other information from the research that might identify you, will be stored securely at the University of Manchester and may be used for further research into the citizen's jury method and into the jury's topic of access to patient records, or to demonstrate that the jury was conducted fairly. The recordings and other research records will be destroyed after 5 years.

What this research will mean for you

In addition to the payment of £50 you receive on day 1 for attending as a substitute juror on the first day, you will receive a further £375 at the end of day 3 for completing the 3-day jury session. No additional payments will be made for expenses. If you withdraw at any point on day 1, day 2, or day 3, you will receive the £50 payment, but you may receive no further payment.

The benefit of this research is that you will be helping us, and public bodies that store and use patient records, know what citizens think about how patient records should be used. This information could help to design better ways to involve patients in decisions about patient records, so that records can be used for the public good whilst patients' wishes are respected. By taking part in the research you may experience the following benefits:

- Greater understanding of how patient records are used;
- Increased skill in discussing and solving problems with others; and
- Satisfaction from contributing to public policy that affects us all.

The risks to you of participating in this study are minimal. You may become weary in extended discussion or feel mild irritation with another participant if you disagree. You may feel discomfort or anxiety if you or someone you care about has been affected by the issue being discussed. These

risks will be minimised by professional facilitation to keep discussions interesting and respectful and facilitators will listen to you if you express any discomfort or anxiety.

You have the right to refuse to take part, without penalty. If you decide to take part and then later no longer wish to continue, you have the right to withdraw from the study at any time. Early withdrawal will reduce how much you are paid, as described above.

The project has been reviewed by the University of Manchester Research Ethics Committee 1/2/3/4/5/.

Contact Information

If you have any questions, concerns, or complaints about the research, contact the researchers Dr. Malcolm Oswald on Malcolm.Oswald@manchester.ac.uk or Dr. Mary Tully, Reader in Pharmacy Practice, Manchester Pharmacy School, Stopford Building, Oxford Rd, Manchester at Mary.Tully@manchester.ac.uk or on 0161 275 4242.

If you wish to make a formal complaint about the conduct of the research you can contact a Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 8093.

Citizens' Jury: To what extent should patients control access to patients records?

CONSENT FORM

If you are happy to participate please complete and sign the consent form below.

Please initial box

1. I confirm that I have read the information sheet on the above project and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2. I understand that my participation in the research is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself although I understand that this will affect how much I am paid. I understand that I will be paid £25 for attending the first morning, and that the only other payment is for £375 and this is only paid if I attend all three full days of the citizens' jury.	
3. I understand that my data will remain confidential, and will be stored securely for 5 years and then destroyed.	
4. I understand that the jury proceedings will be audio-recorded. I ***agree / do not agree*** to be part of a video recording used for the purposes described. [delete as applicable]	
5. I agree to the use of anonymous quotes.	
6. I ***agree / do not agree*** to the University of Manchester storing my personal details so that I may be contacted if there is an opportunity to participate in similar future research. [delete as applicable]	
7. I am at least 18 years of age and I agree to be a participant in the 3-day jury starting on XX/XX/XX and to behave respectfully to others throughout the jury process, just as I would reasonably expect them to behave respectfully towards me.	

Name of participant	Date	Signature
Name of researcher	Date	Signature of

This Project Has Been Approved by the University of Manchester's Research Ethics Committee [UREC reference number].

This consent form will be stored securely and destroyed after 5 years.