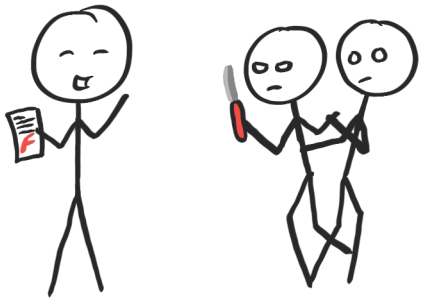
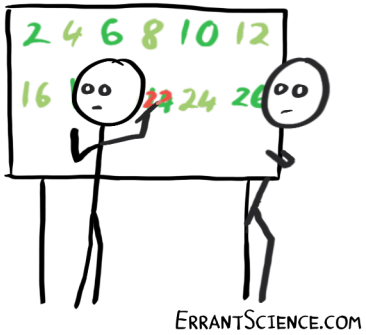
AI 4 Scientific Discovery Network+

PSDS
PHYSICAL SCIENCES DATA-SCIENCE SERVICE



Skills 4 Scientists



Writing an Ethics Application

Dr Samantha Kanza

This series has been co-created by the AI 4 Scientific Discovery Network & The Physical Sciences Data-Science Service

What do you get if you cross an octopus with a cow?

A visit from the ethics committee, and immediate removal of funding!

https://www.deviantart.com/shesewsseashells/art/Octocow-430819080

Why do we need ethics applications/committees?

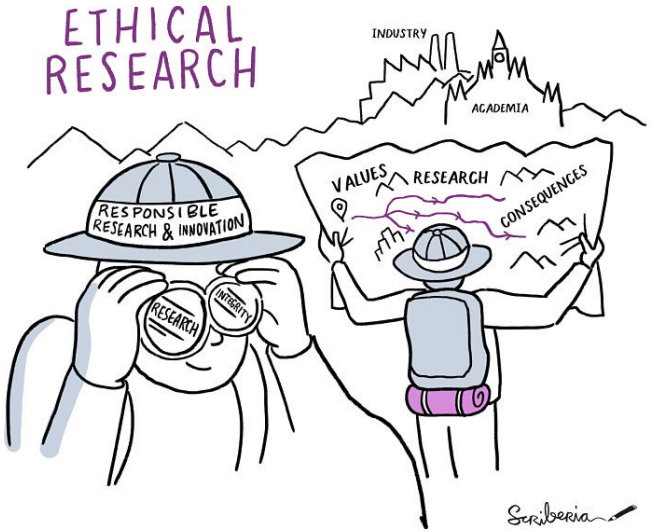
RESEARCH 'FACTS'
ERRANTSCIENCE.COM

THE MOST COMMON CAUSE OF CLINICAL TRIALS FAILING ETHICS APPLICATIONS IS UNEXPLAINED BLOOD STAINS ON THE DOCUMENTATION

...AND THE FREQUENCY OF SUSPICIOUS ABSENCES IN THE ETHICS DEPARTMENT

What is ethical research?

- Research which:
  - Does not *cause harm*
  - Has a positive impact
  - Respects laws - individual's rights/ expectations
  - Is safe



https://www.socialsciencespace.com/2021/06/should-we-mandate-a-course-in-ethics-for-all-research-based-phd-candidates/

Unethical Research Examples

- Tuskegee syphilis experiment
  - US, 1932-1972
  - Progression of syphilis
  - Misinformation
- Facebook 'mood' study
  - Web-based, 2012
  - No consent

"We've got to draw the line on unethical behavior.
But draw it in pencil."

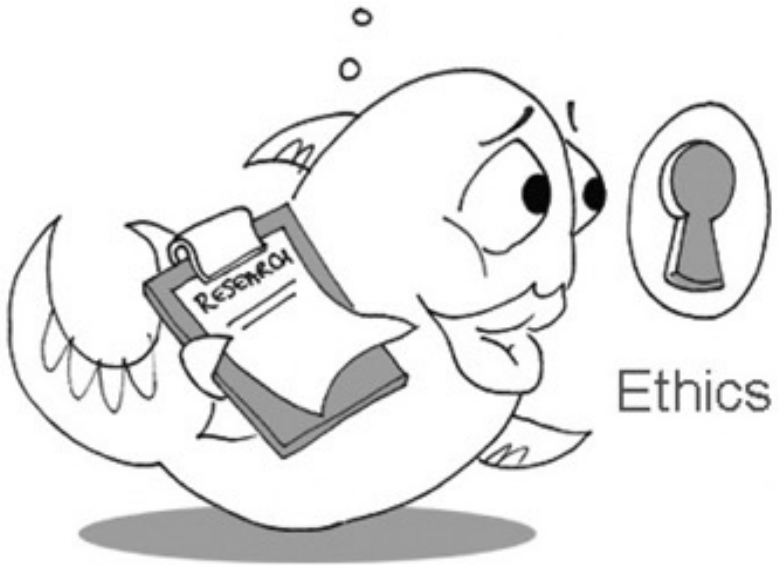
When does ethics apply?

- Will your research involve human participants?
  - Their data, cells/tissue, themselves, their possessions

But its not that simple….

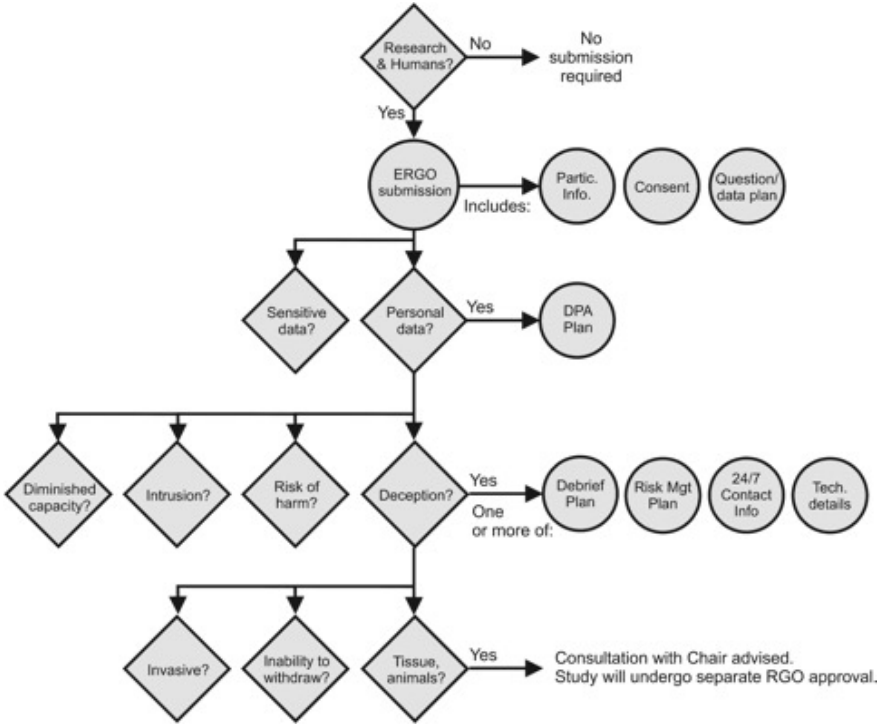
Where/How do I submit?

- Submit to your ethics committee
- Each University will have their own forms/system
- Contact your supervisor / faculty office



https://methods.sagepub.com/book/small-scale-evaluation-in-health/n5.xml

What do I submit?



Submission Questionnaire

Project Information

P1 **Project title**

Test Project

P2 **In what capacity are you submitting this research?**

If you are a student with multiple University accounts you MUST submit through your student account.

- (●) University Staff (research)
- ( ) University Student (undergraduate)
- ( ) University Student (postgraduate taught)
- ( ) University Student (postgraduate research)
- ( ) Research Co-ordinator for staff or students (administrative support)
- ( ) Visitor
- ( ) Other

P3 **Is this research externally funded?**

- (●) No
- ( ) Yes

P4 **Will you (or any other member of the research team) travel outside the UK to conduct this study?**

Please select 'YES' if:

- You or a member of the research team will be physically travelling abroad
- You reside abroad and are conducting the research in your home country
- You are returning to your home country (other than the UK) to conduct your research

N.B. Use of online data collection tools is not classified as travelling.

No

P5 **Does the project involve collaborators from outside the University of Southampton?**

No

P6 **What date do you expect this study to start?**

Please note you are unable to enter a date less than 2 weeks in the future for your first submission. You must ensure you allow enough time for each level of review to take place. University of Southampton reviews take up to 10 working days PER REVISION and per committee. Any external reviews may take longer.

If this is an amendment, this date refers to the start of the amendment only.

31/8/2021

P7 **What date do you expect this study to end?**

This should be the end date of your full study including data analysis.

31/8/2021

P8 **Is this application linked to a previous or another current ERGO submission?**

Please select no if this is only an amendment to a previous submission

No

P9 **Are there any conflicts of interest you need to declare relevant to this research?**

No

P10 **Does this research involve low and/or middle income countries?**

No

Human Participants

H1 **Is your project a survey or questionnaire only?**

This includes online or paper surveys and questionnaires.

No

H2 **Does your project involve only audit or service evaluation within the NHS?**

No

H3 **Please estimate the numbers of participants taking part in the study**

Please enter NUMERIC VALUES only

	Participants (not recruited through the NHS)	NHS patients (if applicable)
Minors (Under 18 years old)	0	0
Adults (18 years old and over)	20	0

H4 **Does this research involve direct contact or interaction with any vulnerable individuals?**

This includes individuals who:

- are under 18 years old;
- are homeless or living in sheltered accommodation;
- are otherwise vulnerable adults such as frail older people or the infirm, those with depression or other mental health issues;
- do NOT have the capacity to give consent in accordance with the Mental Capacity Act 2005;
- do not have (or do not appear to have) the capacity to give free and informed consent for any reason (including under the influence of drugs or alcohol, being coerced, confused etc.)

No

H5 **Does this study involve any of the following?**

- Inducing anxiety, stress or other harmful psychological states on a momentary basis
- Inducing physical discomfort and/or pain beyond which that the participant may routinely encounter in their everyday life;
- Exposing the participants to visual, auditory or other stimuli beyond that which would normally be experienced in everyday life;
- Altering the participant's normal patterns of sleeping, eating or drinking

No

H6 **Does this study involve any of the following?**

- Collecting special category data (under GDPR and Data Protection Act 2018)
  - *These include data regarding: race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation*
- Eliciting information from participants that could render them liable to criminal proceedings (e.g. drug abuse or child abuse)

No

H7 **Does this study involve deception, inducement or covert surveillance?**

No

H8 **Does the study involve invasive techniques?**

No

H9 **Does this research involve ingesting food, drink or other products (including gases, vitamins or nutritional supplements) which exceed normal recommended consumption levels or outside any market authorisations?**

No

H10 **Will your study involve trialling an Investigational Medicinal Product, Medical Device or use a Human Challenge Model?**

If your research involves the development or testing of any component, device or app that has a planned health or medical application please select yes.
This includes research involving existing CE marked devices.

No

Filter Questions

F1 **Will your study involve human participants?**

This is the primary collection of data from human participants.
Human participation includes:

- trials and experiments involving people
- conducting interviews or focus groups
- interaction with users of online environment e.g. Forums
- asking people to complete a questionnaire or survey (both in person or via the Internet, and within the University or on other premises)
- observation of people

Please note, literature reviews and systematic reviews (clinical) do not require an ERGO submission. If your project is either of these please select 'No'.

Yes

F2 **Will your study involve the analysis of secondary data, previously collected from human participants?**

This includes the re-use of any data previously collected for research or clinical data. It also includes any data already available from a public source.

Please note, literature reviews and systematic reviews (clinical) do not require an ERGO submission. If your project is either of these please select 'No'.

No

F3 **Will your study involve human biological material?**

This includes any relevant or non-relevant human tissue or biological material less than 100 years old

No

F4 **Will your study involve any animals (vertebrates and invertebrates) directly or indirectly?**

Animals includes vertebrates and invertebrates. This includes live animals or animal tissues (but not fossils). This also includes insects, nematodes, plankton etc. as well as environmental sampling.

No

F5 **Will your research involve tangible cultural heritage as defined in the University's Ethics Policy on Cultural Heritage?**

According to the University's Policy tangible cultural heritage comprises:

- Movable cultural heritage, including artefacts and other archaeological materials of cultural value, works of art, and artefacts of historic importance such as rare books and manuscripts.
- Immovable cultural heritage including archaeological sites, heritage structures, and cultural landscapes both urban and rural.
- Human remains more than 100 years old.

This includes both land-based and underwater cultural heritage.

No

Skills 4 Scientists

Ethics Form

https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed/ethicalconsiderations/

Risk Assessment

- You need a risk assessment if:
  - Study is intrusive or deceptive
  - Involves risks of harm
  - Involves minors or participants with a diminished capacity to consent
  - Involves less obvious types of risks (food allergies, trip hazards etc)

Reasonably foreseeable hazards	Inherent risk	Controls	Residual risk
I	Low Med High	I	Low Med High
I	Low Med High	I	Low Med High
I	Low Med High	I	Low Med High

Participant Information Sheet

- Study Purpose
- Overview of the study procedures
- Voluntary participation and the right to unconditionally withdraw at any time and for any reason
- The information they will receive (if contact details have been recorded) or may access (through a URL) at the end of the study about the study findings
- The use of their data for research (and if only anonymous data is collected, explaining that once collected it is not possible for a participant to request its removal)

Participant Information Sheet

[Guidance to researchers: Please delete all wording in red italics which is provided for guidance. All wording in black is preferred wording that should remain unchanged wherever possible. (RIG PIS template: effective from 20th Jul 2018)]

Study Title:

Researcher:
ERGO number:

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?
State if this is a student project or if you are working towards an academic qualification. Give a brief summary of who you are and why you are doing the research. What questions are you asking, and why, what is the objective and the expected outcomes of the research? If the research is externally funded (not self-funded) you may wish to state who is funding the study. Studies submitted on IRAS for HRA and/or REC (or MODREC) approval should include details of the research Sponsor.

Why have I been asked to participate?
Potential participants should know the reason why they have been approached and how many participants will be in the study. You should be careful to avoid any wording that could be coercive.

What will happen to me if I take part?

To help you write this section, consider what you would like to know if you were invited to take part in a study.

This section should state who will do what, what activities participants will be expected to do and in what sequence (e.g. lifestyle changes, diet, keeping diaries, completing questionnaires, measurements and biological samples taken). You should make clear the full extent of the involvement (e.g. how long the participant will be involved, how many visits, who they will need to meet with and where and whether there will be a follow up or if they will be contacted again). It is important to use this section to give potential participants an idea of the burden and the amount of time or commitment that will be expected from them. Tell them how long the research project is expected to last if this is different from the length of their involvement. Use diagrams or flow charts if this will make it easier to understand.

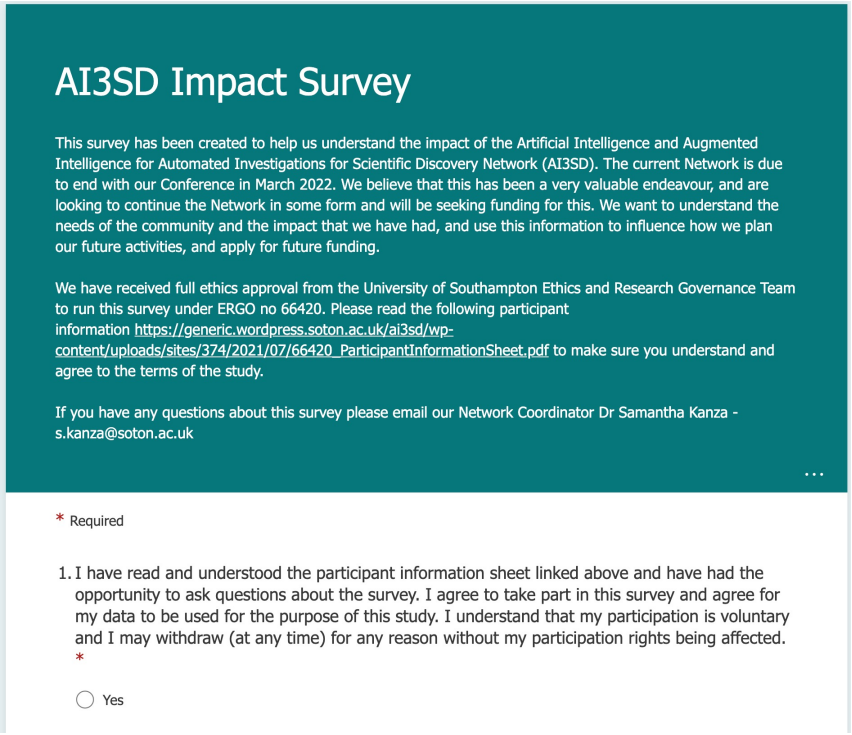
State here if you intend to audio- or video-record any part of the research process. You should state the reason for the recordings and how they will be used. State whether the recordings are optional or required for participation. Your consent form will require specific consent for these recordings.

You should state in simple terms the research methods that will be used.

For healthcare studies, it should be clear if any procedures will be over and above standard care, whether any normal treatment would be withheld during any part of the study and if there will be any long-term monitoring. Explain the reason for taking any biological samples, scans or measurements. Explain how health related information from tests/diagnostics will be used.

Skills 4 Scientists

Consent Form



AI3SD Impact Survey

This survey has been created to help us understand the impact of the Artificial Intelligence and Augmented Intelligence for Automated Investigations for Scientific Discovery Network (AI3SD). The current Network is due to end with our Conference in March 2022. We believe that this has been a very valuable endeavour, and are looking to continue the Network in some form and will be seeking funding for this. We want to understand the needs of the community and the impact that we have had, and use this information to influence how we plan our future activities, and apply for future funding.

We have received full ethics approval from the University of Southampton Ethics and Research Governance Team to run this survey under ERGO no 66420. Please read the following participant information https://generic.wordpress.soton.ac.uk/ai3sd/wp-content/uploads/sites/374/2021/07/66420_ParticipantInformationSheet.pdf to make sure you understand and agree to the terms of the study.

If you have any questions about this survey please email our Network Coordinator Dr Samantha Kanza - s.kanza@soton.ac.uk

...

* Required

1. I have read and understood the participant information sheet linked above and have had the opportunity to ask questions about the survey. I agree to take part in this survey and agree for my data to be used for the purpose of this study. I understand that my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected. *

◯ Yes

CONSENT FORM

[Guidance to researchers: Please delete all wording in red italics which is provided for guidance. All wording in black is preferred wording that should remain unchanged wherever possible. (RIG Consent form template: effective from 20th Jul 2018)]

Study title:

Researcher name:
ERGO number:
Participant Identification Number (if applicable):

Please initial the box(es) if you agree with the statement(s):

I have read and understood the information sheet (*insert date /version no. of participant information sheet*) and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected.	
Add as required	

Name of participant (print name).....

Signature of participant.....

Date.....

Name of researcher (print name).....

Signature of researcher .....

Date.....

***Optional** - please only initial the box(es) you wish to agree to:*

This should be used for any statements that are not mandatory for the participant to be able to take part in the research.	
Add as required	

[Date] [Version Number] [Ethics/IRAS reference *(if applicable)*]

Skills 4 Scientists

Data Protection Act Plan

DPA Plan

Ethics reference number: **ERGO/**FEPS/**xxxx**	Version: X	Date: 201y-mm-dd
Study Title: xxx		
Investigator: xxx		

The following is an exhaustive and complete list of all the data that will be collected (through questionnaires, interviews, extraction from records, etc) ... [list all data including e-mail addresses, telephone numbers, consent forms, notes of telephone conversations, names of contacts, etc, as well as identifying the questionnaire(s) shown in appendix XXX which provides the list of all the data that will be collected by questioning or observing.]

The data is relevant to the study purposes because .... The data is adequate because ..., and the data is not excessive because...

The data will be processed fairly because ... / the participants will have given implicit / explicit consent / the participants deliberately made the data public.

The data's accuracy is ensured because ...

Data will be stored on ... the Investigator's laptop / Investigator's desk-top / University server / [mention where the data is to be stored]. The data will be held in accordance with University policy on data retention.

Data files will be protected by ...; laptops will be protected by ...; desktops will be protected by ...; physical data will be kept in filing cabinets and protected by ...

The data will be destroyed by ...at ... through ....

The data will be processed in accordance with the rights of the participants because they will have the right to access, correct, and/or withdraw their data at any time and for any reason. Participants will be able to exercise their rights by contacting the investigator (e-mail: ...) or the project supervisor (e-mail: ...).

The data will be anonymised by .... Consent forms will be linked to the data by ....

The following data ... will be transferred outside the European Economic Area (EEA). It will be subject to processing by .... The protection controls that will be put in place for this data comprise ..., ..., and ....

If personal or sensitive data is collected or processed, or if personal data may be processed outside the UK, the DPA Plan shows that all personal or sensitive data is:

- Accurate
- Relevant
- Not excessive
- Held securely
- Retained for only as long as necessary
- Used only for the purposes of the study
- Accessible to the participant

Data Gathering

Data Gathering

- Any and all data to be collected and/or derived is explicitly and fully identified
- Where collecting gender information can be justified, participants should be given a list of options such as "Male / Female / Prefer not to say / Other (please specify: _____)."

If there is no questionnaire(s):

- The data gathering plan is adequately described
- It is clear whether personal (and/or sensitive) data will be gathered

If there are questionnaires:

- All are provided (legible screen shots are acceptable for online data gathering)
- They faithfully and specifically reflect what participants will actually be asked

Debrief Plan

- If the study is intrusive, involves risk of harm, or involves deception, a Debrief plan must be provided:
  - Explain outcomes
  - Detail people qualified to deal with any intrusive parts of the study
  - Detail people qualified to deal with any parts of the study where there is a risk of harm
  - Explain reason for deception if the study is deceptive

Top Tips

- Give yourself more time than you need!
- Be consistent!
- Check with your supervisor
- Don’t forget to attach questionnaires!
- Do a pilot study if possible
- Never assume the study is idiot proof!
- Take materials / remind participants
- If in doubt about whether a form is needed, add it in!

Skills4Scientists!