Question-Specific Advice for Stage 1 Research Ethics Application Form

If you require this document in an alternative format (Braille, large print, audio, electronic) please contact Julie Scott, Research Ethics and Integrity Manager, on email address research.ethics@aru.ac.uk

Please note that ARU asks that any research with human participants is generally carried out remotely rather than face to face in view of Covid-19. For further information please refer to the research ethics website at: www.aru.ac.uk/researchethics

The main objective of this document is to help you understand how the questions in the ethics checklist in the Stage 1 Research Ethics Application Form may apply to your research. If you have any doubt about how to respond to any question in the checklist, further guidance can be obtained from:

- Your supervisor.
- The Research Ethics Policy and Code of Practice for Applying for Ethical Approval at ARU (hereafter referred to as the Code of Practice) available on the research ethics website.
- The Chair of your School Research Ethics Panel (SREP) or your Faculty Research Ethics Panel (FREP).

Undergraduate and Masters students and their supervisors must also complete the online ethics training and quiz, available at:
For Science and Engineering, Health Education Medicine and Social Care, and Social Sciences: https://anglia-ruskin-university.learnworlds.com/course?courseid=researchethics
For Business and Law, Arts and Humanities: https://anglia-ruskin-university.learnworlds.com/course?courseid=researchprofethics

Undergraduate and Master students must complete the confirmation of completion of passing the quiz with their ethics applications.

Research students and First Supervisors for research degree students must complete mandatory Research Ethics training. Please refer to the Research Degrees Regulations, for more information.

Guidance documents and ethics application forms are on the research ethics website.

Guidance on UK General Data Protection Regulation (GDPR) and Data Protection Act.

If you have any queries about data protection and your research, please contact ARU's Data Protection Officer on dpa@aru.ac.uk

Our processing of personal data must comply with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act (2018). This is equivalent to laws in the European Economic Area (EEA) countries, although you must be aware of any supplementary local laws when sharing personal data to or from participants or organisations in the EEA.

If you are carrying out research outside the EEA, you must ensure that you comply with the data protection legislation of that country in addition to UK law.

If you are carrying out a survey using an online tool, it is highly recommended that you use Online Surveys, given that this is based in the UK. Please contact Emma.Marrow@aru.ac.uk who can set up an account for you. Our Data Protection Officer has also approved the use of Qualtrics. Please refer to the guidance on Online Surveys on the research ethics website for further information. You must not use any other types of online survey platform without permission from ARU's Data Protection Officer.

Personal data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person**.**

You must take the below into account.
1) You should only collect anonymised data if possible.
2) If this is not possible within the framework of your research, you must anonymise it at the earliest opportunity.
3) Should this not be workable, you must pseudonymise it.
4) There may be a small number of cases in which you need to work with personal data. If this is the case, you must only work with the minimum amount required.

If data is ***anonymised,*** it no longer falls under the data protection legislation. *Anonymisation* is the process of permanently removing personal identifiers (which may be direct or indirect) that may lead to an individual being identified from that information or combined with other information. It is often difficult to make a judgement about whether data is truly anonymised and context is key. The data protection legislation still applies to weakly anonymised data. If there is any doubt, you must treat the data as falling under the data protection legislation. Also, please note that if data is only anonymised after collection, this itself counts as processing personal data.

Directly identifiable
You can often directly identify an individual from their name, address, postcode, telephone number, photograph or image or some other unquiet characteristics.

Indirectly identifiable
An individual may be indirectly identifiable when certain information is linked together with other sources of information. This may include, for example, place of work, job title, salary, age, postcode or a diagnosis or condition.

Pseudonymisation means that you have replaced identifiable data (such as a name) with a code or reference number. This means that you can re-identify the individuals from a key or code, but to anyone else the data does not allow them to identify anyone. This means that the 'key' list must be kept secure and only made available on a strict need-to-know basis. As individuals can be re-identified, pseudonymised data still counts as personal data under the data protection legislation. By pseudonymising the data, however, you are reducing risks associated with using it.

You need to ensure that your research complies with the UK GDPR and Data Protection Act (2018), and take into account any additional data protection legislation that may be in place if obtaining personal data and analysis takes place outside the UK. Guidance for this (hereafter known as Data Protection Guidance) and all other ethics documents are available on our research ethics website.

It is mandatory for you to use the standard Data Protection text in your Participant Information Sheet, choosing the appropriate options(s) where required.

Undergraduates and Masters students are strongly advised to use the Participant Information Sheet Guidance, which includes the compulsory data protection sections within it.

Under the GDPR, you need to have a legal basis for processing data for research purposes. In the majority of cases, this will be the '*performance of a task carried out in the public interest'*. This is covered in our corporate privacy notice, available at:

https://www.aru.ac.uk/privacy-and-cookies/research-participants

Please refer to this; it is your responsibility to ensure that you research is consistent with it. If you have any queries, please contact our Data Protection Officer on email address dpa@aru.ac.uk

If you will be collecting personal data, you need complete the Research Checklist for Data Protection as part of completing the Stage 1 Research Ethics Application Form.

https://myaru.sharepoint.com/sites/student-office-for/SitePages/data-protection-in-research.aspx#research-checklist-for-data-protection

If you will be collecting special category data, you must complete the Further Data Protection Questions:
https://myaru.sharepoint.com/sites/student-office-for/SitePages/data-protection-in-research.aspx#further-data-protection-questions

Should your research not comply with any of the statements in either of the above forms, you must contact ARU's Data Protection Officer before you can proceed further with your ethics application. Please include your ethics application and all other correspondence and clarify which statement or statements your research does not comply with in your email to the Data Protection Officer. You cannot proceed with your application until he approves your research.

Safeguarding training

If you are carrying out research with children or vulnerable adults, you may need to complete the online Safeguarding course, available at:

https://angliaruskin2.learnupon.com/

At the end of the course you must take the quiz, achieving at least 70%, confirmation of which must be submitted with your ethics application. If you have any problems accessing the course, please email research.ethics@aru.ac.uk

If you have significant experience of working with children or vulnerable adults, you can request course exemption from your FREP Chair.

Ethical approval and other permissions

It is your responsibility to ensure that you obtain appropriate permission or ethical approvals from organisations involved in your research and also that you adhere to any other requirements (e.g. Risk Assessment, Travel Insurance, Disclosure and Barring Service Check). Please refer to the Code of Practice for further information.

Research falling under the red or purple category

Please note that any research that falls under the red or purple categories (Questions 12 – 27 on the Stage 1 Research Ethics Application Form) may not be suitable for Undergraduate or Masters' student research. If you are an Undergraduate or Masters student thinking of doing any research that might fall under the red or purple category, please speak to your supervisor or FREP Chair in the first instance.

Questions on checklist of Stage 1 Research Ethics Application Form

Will your research:

1. Involve human participants?

This question includes both direct and indirect contact with human participants. Examples of direct contact with human participants include interviewing people or taking measures from them. Indirect contact includes sending questionnaires to people in the post, obtaining data about people on-line including through social media forums, or accessing personal records or data. Ethical issues can arise even when there is no direct human contact. For example, questionnaires might contain questions that respondents could find upsetting. You cannot just use personal data or records relating to participants if they have been collected for another purpose and participants have not given consent for their records to be used for research or the organisation which holds the records have not given permission for their use.

You also need to consider whether you are working with groups of people where particular care may be needed e.g. pregnant women, women with mental health problems and any additional measures you need to put into place.

You must also take the Data Protection Guidance into account.

2. Utilise data that is not publicly available?

Please note that ethical approval may be required for the re-use of secondary data. Research involving the analysis of pre-existing data may require ethical approval if the data is not available in the public domain. If the pre-existing data is not in the public domain and is identifiable, you will require ethical approval before you access the data. You cannot automatically use personal data or records relating to participants if they have been collected for another purpose and participants have not given consent for their records to be used for research. You also need to consider whether participants are potentially identifiable from the linkage of datasets. Another consideration is whether data is commercially sensitive and whether you have the appropriate permissions in place to use and disseminate it.

You must also take the Data Protection Guidance into account.

3. Create a risk that individuals and/or organisations could be identified in the outputs?

Information provided to researchers by individuals or organisations they are representing is normally given either anonymously (i.e. their identities are not made known to the researchers) or in confidence (i.e. their identities are known to the researcher(s) but are not disclosed to others and anonymised in any research outputs).

If research outputs contains photographs, video-clips, personal quotes or case-studies, or if there are not many potential participants or organisations that could be used in the area of your research, the risk of individuals or organisations being identified is increased. In such cases, you will need to explain how the potential for them being identified will be minimised and ensure that participants are aware of the

risk of identification, or gain their explicit consent for the use of personally-identifiable information.

You need to ensure that you do not make false assurances about individuals or organisations being anonymous and take into account that participants may be identifiable by their peers or colleagues, if not by the general public, even though their names are not used. Organisations may also be identifiable and you must make this clear when obtaining written permission to conduct your research. If you wish to use the name of the organisation in dissemination, you must obtain written permission from them for this and consider whether this makes participants more easily identifiable.

In a small number of cases, you may need to use further measures to anonymise participants' identities, for example, when the risk of people being able to tell who they are is high and/or it would place them in a difficult situation should they be identifiable e.g. if they have spoken negatively about an organisation they work for.

You may decide that you need to change certain information relating to participants in order that they could no longer be recognised. You need to think through whether identities could be worked out, who will have access to the intermediate and final (report) data, and whether sufficient warning has been given in the Participant Information Sheet.

Please refer to the Letter from Organisations for Research Permission on the research ethics website. If an organisation would like to see a summary of findings prior to dissemination, you must inform participants of this in the Participant Information Sheet.

You must also take the Data Protection Guidance into account.

4. Involve participants whose responses could be influenced by your relationship with them or by any perceived, or real, conflicts of interest?

If you have a personal or professional relationship with any potential participants, other than that of researcher-participant, special care must be taken to ensure that they do not feel obliged to take part in your research. This is particularly important in situations where the researcher may, in their other relationships, be more senior than, or in a position of power over the participant. In such cases, the potential participants may feel that their relationship with the researcher in those external contexts may be detrimentally affected if they elect not to participate.

You also need to consider whether there are any conflicts of interest. This could relate to the organisation funding the research or any dual role you have as researcher/employee, for example. Conflicts of interest do not usually prevent you from doing the research, but they should be declared in your ethics application and on the Participant Information Sheet.

5. Involve the co-operation of a 'gatekeeper' to gain access to participants?

A gatekeeper could be a Company Director or head teacher, for example. You must ensure that you have written permission to conduct and produce research outputs from any organisations where you will be carrying out research. This must be from someone appropriately senior in the organisation. You must ensure that you have written permission for the use and ownership of data and the right to publish findings. If you wish to name the organisation in dissemination, you must also obtain written permission for this. Please note that written permission is not the same as consent. Consent to take part in the research can only be obtained from individual participants. In addition to this, you may need further permission from gatekeepers or managers at less senior levels. You need to provide details about how you will negotiate this.

Guidance for the permission letter is available on our research ethics website.

6. Offer financial or other forms of incentives to human participants?

Careful consideration must be given if you are planning to pay participants, or provide other types of reward (e.g. vouchers) for participation, as this could lead an individual to participate in an activity they would normally be reluctant to engage with. You must provide detailed information in your ethics application about payments or other rewards offered to participants. You should not pay participants at a level which is likely to invalidate consent and must take into account your participant group when considering this (e.g. lower income groups may be more likely to be influenced by monetary rewards). You should also consider whether you could pay participants at the end of the study and not make them aware of the payment before they participate, as this may help ensure that consent is not influenced.

Reimbursing participants for any travel expenses incurred as a result of taking part in your study is not regarded as an incentive and is good practice. If you are unable to pay participants for travel expenses, you must state this on the Participant Information Sheet, in order that people know this prior to agreeing to participate.

7. Involve the possibility that any incidental health issues relating to participants be identified?

If you are collecting data that could be used as an indicator of the physical or mental health of a participant, you could be placed in a position where you become aware of potential medical problems that the participant is not aware of. The researcher may have a duty of care to pass this information on to a third party (e.g. the person's doctor/GP), but this conflicts with participant confidentiality. Although it may seem that participants should always be informed about such issues, this needs to be balanced against

- whether the data is robust enough to be used in a clinical context
- if you are qualified to interpret the results in a clinical context
- whether the participant would want to be informed and
- if the information has implications for the health of family members or partners. As a researcher you should consider how you will deal with such eventualities at the planning stages of the research and in your ethics application.

8. Involve the discussion of topics that participants may find distressing?

Some research covers areas that are regarded as sensitive. You also need to take into account cultural norms when considering what could be regarded as sensitive. In addition, you need to consider the group of participants. For example, a study looking at memory may not be sensitive for the general population, but would be likely to be so for people with dementia.

You need to consider carefully how you will deal with topics that participants may regard as sensitive. It may not be appropriate to cover these in a questionnaire for example (as you will not know if participants become upset); an interview may be the best approach. You should make it explicit in the Participant Information Sheet that these topics will be covered and always begin an interview with general questions, only proceeding to sensitive questions when you have had a chance to build up a rapport with participants, but making it clear they do not have to answer any questions they do not wish to. You also need to consider what you will do should participants become upset and whether you need to offer information about follow-up support services they can access. Having said this, some research in sensitive areas is very valuable and participants may find it helpful to talk about their experiences. The risk of participants becoming upset does not mean you should not carry out research in these areas, but the risks need to be carefully considered and you need to keep your role as a researcher, rather than a Counsellor, clearly defined.

9. Take place outside of the country where you work and/or are enrolled to study?

Researchers conducting any part of their data collection outside of the country where they work or are enrolled to study need to consider whether there are additional criteria that need to be considered in planning their research beyond those already indicated in the Stage 1 Research Ethics Application Form. These may include how consent is obtained, adapting the manner in which the research is conducted to account for the language, cultural norms and political sensitivities present in that country or region, confirming that relevant local legislation is followed, ensuring that any local ethical approvals or permissions to conduct the research are obtained, and obtaining appropriate insurance cover, research visas and permits (if applicable).

You also need to refer to the research ethics website and the Code of Practice regarding travel insurance.

UK Data Protection Law applies as ARU is the Data Controller for our research activity. It is important that where participants are based outside of the UK, data sharing takes places with organisations outside the UK or analysis takes places outside the UK that local Data Protection laws are taken into account.

- For EEA countries, UK law is viewed as equivalent law, however each EU member state can supplement GDPR with additional measures and researchers will need to be aware of these
- For countries outside the EEA, the researcher will need to understand whether any local national law impacts the use of personal data in research and inform participants and handle personal data accordingly.

10. Cause a negative impact on the environment (over and above that of normal daily activity)?

When designing your research, you should consider the potential impact of the work on the environment and ecosystems. Such impact may be direct (e.g. from working in specific ecosystems that may be damaged as a consequence) or indirect (e.g. produce pollutants, large quantities of waste or toxic waste). Researchers should minimise the environmental impact of their work as much as possible, and be able to justify that the potential benefits of the research offset the potential environmental impact caused.

If your work involves work in protected sites, such as work in Sites of Special Scientific Interest (SSSI's), you may need to hold licences to undertake the work.

11. and 12. Involve genetic modification of human tissue or use of genetically modified organisms classified as Class one activities or above Class One activities?

Prior to obtaining ethical approval for this type of study, a risk assessment needs to be completed and approved before any GM work can begin. Please contact FST-Biologicalsafety.GMO@aru.ac.uk for advice.

The creation and use of Genetically Modified Organisms (GMOs) is a topic of public concern. Researchers planning to develop or use GMO's need to demonstrate that they are aware of these sensitivities. The benefit of the proposed work and a description of how risks will be controlled must be clearly presented in your ethics application.

Work with Genetically Modified animals is subject to appropriate licences being held under the Animals (Scientific Procedures) Act 1986. ARU does not hold a site licence for such work.

Work with micro-organisms, including genetically modified organisms, on University premises should comply with relevant regulations, and should only be carried out in laboratories with appropriate containment measures. Researchers should ensure that their practices and work areas are fully compliant with the Genetically Modified Organisms (Contained Use) Regulations 2000 and subsequent amendments.

More information can be found at: http://www.hse.gov.uk/biosafety/gmo/about.htm

13. Collect, use or store any human tissue or DNA (including but not limited to, serum, plasma, organs, saliva, urine, hair and nails)?

Research using the above material conducted in England, Wales or Northern Ireland may fall under the Human Tissue Act (2004). Such research can be reviewed by an ethics committee at ARU (either the Health, Education, Medicine and Social Care or the Science and Engineering Faculty Research Ethics Panel) if it falls under the conditions of ARU's licence from the Human Tissue Authority, otherwise it can only be legally reviewed by an NHS research ethics committee. You must contact the Human Biological Material Committee at ARU-HBMC@aru.ac.uk if you plan to do research involving human tissue to check whether it falls under the legislation and also because all research involving human tissue, including that approved by the NHS, must be approved by this committee. You must contact ARU HBMC **before** applying for ethical

approval. Once you have obtained ethical approval for your research, you must check your project again with HBMC, for final sign off.

There is also a Human Tissue (Scotland) Act, 2006 which you need to comply with if carrying out your research there.

Further information on this topic can be found on the Human Tissue Authority's website (www.hta.gov.uk) and in the Code of Practice.

Please also refer to the Health Research Authority's website at:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/

14. Involve medical research with humans, including clinical trials or medical devices?

Studies that obtain medical information about human participants can take different forms, including a clinical trial, observational study or any intrusive technique such as hypnotism. Prior to submitting an ethics application the researcher must check that the research:

i) does not fall under the Medical Device Regulations (2002) or the Medicines for Human Use (Clinical Trials) Regulations (2004) as amended, because ARU does not have the infrastructure to support studies falling under this legislation. For the latest information about this legislation post-Brexit, please refer to the Medicines and Healthcare products Regulatory Agency's (MHRA's) website at:

https://www.gov.uk/government/collections/new-guidance-and-information-for-industry-from-the-mhra

ii) falls under the University's insurance policies. This can be done by: checking the clinical trial questionnaire (Research involving human participants) available on the research ethics website.

If your research does fall under any of the questions on this questionnaire, please complete it and send it to ARU's Risk and Insurance Manager at insurance@aru.ac.uk

You must wait for a response and approval to proceed from the Risk and Insurance Manager and email correspondence must be included in your ethics application.

15. Involve the administration of drugs, placebos or other substances (e.g. food, vitamins) to humans?

The administration of substances to research participants may pose a risk to their health. You need to ensure that your study does not fall under the Medicines for Human Use (Clinical Trials) Regulations (2004), as amended. You should also ensure that the proposed research falls under the University's insurance policies. Please refer to the previous section for further information. For studies involving food, dosage, hygiene and allergies should all be addressed. A Risk Assessment (Health and Safety) must

be completed and updates as required. Please refer to Section 3 of the Code of Practice for Applying for Ethical Approval at ARU.

16. Cause (or have the potential to cause) pain, physical or psychological harm or negative consequences to humans?

Researchers should always aim to protect their participants from harm. Any potentially adverse consequences for participants need to be strongly justified and participants need to be fully informed of any potential negative effects that may arise as a consequence of participation. When developing your research proposal, you need to consider these issues very carefully as factors that may cause negative consequences may not always be obvious. For example, you need to consider whether personal questions have the potential to cause emotional or psychological harm. If you are working with groups of people who could be classified as vulnerable (for example, people who have mental health problems), the risk of causing emotional harm may be higher.

17. Involve the collection of data without the consent of participants, or other forms of deception?

Covert data collection means collecting data without the participants or stakeholders being made aware that you are doing this. Consent (agreement to participate) must always be obtained where possible and this must be fully informed, freely given and valid. Obtaining consent from participants must be your default position. If you feel that you have a good reason why this is not possible, then you will need to justify this and explain the steps you will take to manage any harm or distress that may occur through deception. You must also check that this complies with the UK GDPR and/or Data Protection Act (2018) and, for other countries, any other data protection legislation. If you are unsure, you must contact our Data Protection Officer for advice on dpa@aru.ac.uk

18. Involve interventions with people aged 16 years of age and under?

An 'intervention' is where you require the participant to undertake an activity they would not otherwise be doing for the purpose of your research.

Children are regarded as a potentially vulnerable group. They may be less likely to understand what is involved in the research and this will influence whether they are able to give informed consent. Legislation exists to protect children in a variety of settings and, in the UK, you are likely to need to obtain additional consents from parents / carers and those responsible for the child within the social setting that you are using. You are also likely to be subject to a Disclosure and Barring Service (DBS) Check to ascertain that you are a suitable person to be working with children. Please see the research ethics website for guidance on how to apply for a DBS check. In some instances it will be possible for ARU to validate an existing DBS Check and there is also guidance for this. You may also need to complete our online Safeguarding course. For further information regarding this, refer to the Code of Practice.

You must respect the views of children and young people, as at any age, but in general you should involve parents too as a legal safeguard. In such situations, you must ensure that you have consent from the child or young person. In some cases, the child or young person may prefer to given oral rather than written consent.

You must ensure as far as possible that the child or young person wants to take part in the study and has not been coerced by parents/the school he/she attends or any other stakeholder/gatekeeper to get involved.

You may consider asking for a child's direct consent if they are 16 to 18 years provided that

- their parent/guardian is made aware
- an organisation (such as a school) who provides the data or provides access to the children is aware
- the data being collected is not 'special category data'
- for children aged between 16 years and over and 18 years of age.

An age-appropriate Participant Information Sheet should be provided to the child as well as the parent(s). You must ensure that you provide age-appropriate information regarding the UK GDPR and/or Data Protection Act (2018) and, for other countries, any other data protection legislation.

19. Relate to military sites, personnel, equipment, or the defence industry?

Research using human participants undertaken, funded or sponsored by the Ministry of Defence must be scrutinised by the Ministry of Defence Research Ethics Committees (MoDREC). Where participants are to be recruited through the Armed Forces for health and social care research, applications may need to make a submission to a MoDREC. For further information see:

https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees

Please also note that the Ministry of Defence Research Ethics Committee (MoDREC) is also recognised as an Appropriate Body under the Mental Capacity Act 2005 for review of research involving UK Armed Forces personnel who are unable to consent for themselves.

MoDREC ethical approval is regarded as equivalent to ethical approval by ARU. However, you still need to submit the Stage 1 Research Ethics Application Form and confirmation of the ethical approval received from the MoDREC prior to starting your research. For queries, please contact Toni Mawoyo, Project Manager, Veterans and Families Institute, on email address antoinette.mawoyo@aru.ac.uk.

Please note that if your research involves **former** members of the Armed Forces (i.e., veterans, ex-services personnel) and is not conducted on MoD premises there is no need to seek ethical approval from MoDREC, although you must still submit Stage 1 and 2 ethical approval forms.

If your research does not require submission to a MoDREC you must complete both Research Ethics Application Forms (Stages 1 and 2) and associated documents to your FREP.

20. Risk damage/disturbance to culturally, spiritually or historically significant artefacts/ places, or human remains?

Cultural or spiritual objects (including documents) and places are important to individuals and groups within human populations. These persons will have an interest in what happens to these objects or places, even if they do not have control over what happens to them. Research involving these objects or places can potentially cause distress if it is conducted without due consideration to their sensitivities. If your research falls into this category, you will need to ensure that appropriate permissions to conduct the research are obtained, that cultural and religious sensitivities are observed, that objects are appropriately handled, and consider the storage and fate of the objects following the research if you have primary responsibility for them. The *Museums Association* includes wide ranging advice on many of these issues at: http://www.museumsassociation.org/ethics

The conditions under which human remains are kept, used and the procedures for de-accession of material, whether for reburial, repatriation, or disposal, are of particular public concern. Human material over 100 years old is not subject to the Human Tissue Act (2004). The Burial Act (1857) makes it an offence to remove buried human remains without a licence from the Secretary of State or, in relation to ground consecrated according to the rites of the Church of England, a faculty. Researchers should act in line with the document 'Guidance for the Care of Human Remains in Museums' issued by the Department of Culture, Media and Sport (DCMS) in October 2005, 'Guidance for best practice for treatment of human remains excavated from Christian burial grounds in England, 2005' from English Heritage and the code of ethics set out by the British Association for Biological Anthropology and Osteoarchaeology.

Where such research is undertaken outside of the UK, appropriate permissions should be sought and the laws within that country must be followed.

21. Contain research methodologies you, or members of your team, require training to carry out?

Any research study must be designed and conducted in a manner that produces valid results whilst minimising risk to participants, stakeholders and the researchers themselves. In order to achieve this, the research team should be adequately trained in the methods and/or methodology to be utilised in the study.

If you are not trained or qualified to carry out parts of the research, the ethics committee will need to be informed how you will address this before they approve your research, for example by attendance at training courses.

22. Involve access to, or use of, material (including internet use) covered by the Counter Terrorism and Security Act (2015) or Terrorism Act (2006), or which could be classified as security sensitive?

Research that is regarded as security-sensitive includes that relating to terrorism or for example, Ministry of Defence-commissioned work on military equipment, IT encryption design for public bodies or businesses. This is not an exhaustive list. If you have any doubts about whether your research could be classified as security-sensitive, please speak to your FREP Chair.

The Terrorism Act 2006 outlaws the dissemination of terrorist publications, including by electronic means. There is a very wide definition of 'terrorist publication' and 'statements' that could be construed as endorsing or promoting terrorism. The Act includes reference to materials which are indirect encouragement to the commission or preparation of acts of terrorism or Convention offences including anything which is likely to be understood as the glorification of the commission or preparation (whether in the past, in the future or generally) of such acts or such offences.

Sections of the Act also create a risk of prosecution for people who transmit material of this nature, including electronically, and the storage of such material on a computer can, if discovered, prompt a police investigation. However, a publication disseminated for the purposes of a clearly defined research project should not in theory therefore amount to an offence, because the requisite intention is unlikely to be present.

You are required to complete the Stage 1 & 2 Research Ethics Application Forms if your research is security-sensitive and keep all information relating to the project in a central secure document store if your research relates to terrorism. You should also consider whether your research falls within the risk identified in Question 23 (risk being construed as encouraging terrorism or inviting support for proscribed organisations and/or contain extremist views that risk drawing people into terrorism or are shared by extremist groups).

Please also see *Oversight of security-sensitive research material in UK universities:* guidance, available at:

https://www.universitiesuk.ac.uk/what-we-do/policy-and-research/publications/oversight-security-sensitive-research

23. Risk being construed as encouraging terrorism or inviting support for proscribed organisations. Contain extremist views that risk drawing people into terrorism or are shared by extremist groups

Research which risks being construed as encouraging terrorism or inviting support for proscribed organisations, or contains extremist views that risk drawing people into terrorism or are shared by extremist groups, needs to be carefully considered to ensure that the University complies with the Prevent Duty imposed on specified authorities including the University by the Counter-Terrorism and Security Act 2015.

You are required to complete the Stage 1, 2 & 3 Research Ethics Application Forms if your research contains such views. Additionally you will need to comply with the storage restrictions set out in Question 22 above.

Please also see guidance for Higher Education Institutions, available at*:*

https://www.gov.uk/government/publications/prevent-duty-guidance/prevent-duty-guidance-for-higher-education-institutions-in-england-and-wales

24. Involve you or participants a) activities which may be illegal and/or b) the observation, handling or storage (including export) of information or material which may be regarded as illegal?

Researchers should keep details of participant identities confidential unless they have agreed to be named in research outputs. However, under certain circumstances

researchers may be legally or professionally required to reveal (disclose) participant identities. If your research is likely to link participants to illegal activities you will need to ensure that you understand what information you may need to disclose and to make the potential participants aware of this before they agree to take part in your study.

It is also your responsibility to be aware and comply with legislation relating to export controls and obtain a licence if required. For further information, see:

https://www.gov.uk/government/publications/guidance-on-export-control-legislation-for-academics-and-researchers-in-the-uk

You must also take the data protection guidance into account.

25. Does your research involve the NHS (require Health Research Authority and/or NHS REC and NHS R&D Office cost and capacity checks)?

The Health Research Authority (HRA**)** is the new process for NHS approval in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent NHS Research Ethics Committee (NHS REC) opinion provided through the UK Health Departments' Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

In the first instance, you need to contact the R&D Office at each Trust where you will be doing the research to see if they are happy to support your research. If your research requires HRA, NHS REC and NHS R&D Approval,, this approval will be regarded as equivalent to our own, but you will still need to complete the Stage 1 Research Ethics Application Form and submit this to your FREP as a minimum requirement and the approval letters once you have received them.

You need to ensure that you are aware of the range of situations that require NHS REC review. For further details please refer to Section 2.3 of the below:
https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/GAfREC_Final_v2.1_July_2021_Final.pdf

If your research requires HRA Approval and/or NHS R&D Approval, but not NHS REC Approval, you will need to obtain the ethical approval component from your FREP.

For further information see:
http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

In the first instance, you need to contact the R&D Office at each Trust where you will be doing the research to see if they are happy to support your research.

https://rdforum.nhs.uk/rd-contacts-directory/

For information about how to apply for NHS REC approval, please see:

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

For further information and information about applying for NHS Research Passport please, refer to the Code of Practice on the research ethics website.

26. Require ethical approval from any recognised external agencies (e.g. Social Care, Ministry of Justice, Ministry of Defence)?

Certain types of research must be reviewed by specialised research ethics committees external outside of ARU. External ethical review may be necessary for research involving social care (e.g. councils) and the Prison Service. It is your responsibility to obtain any ethics or research governance approval required from these agencies and check with your FREP whether ethical approval from ARU is also required.

You must also check if carrying out research in a social care organisation whether they have their own ethical or governance review systems or whether you need to submit your application to the National Social Care Research Ethics Committee:

http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/

Review by social care organisations can be accepted as equivalent to that from ARU in some instances. However, in some cases a research governance as opposed to ethics review will be carried out only, in which case ethical approval from ARU is likely to be required. Please send your FREP Chair a copy of your application to the external committee/agency and any other documents in order that he/she can assess this.

You also need to consider whether social care is funding an organisation you are carrying out research at, in which case you may need approval from them.

Please refer to the Code of Practice for information about research that requires ethical approval by the National Offender Management Service (NOMS) and/or Ministry of Justice or Ministry of Defence and consult the below web-links.

For Ministry of Defence:

https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees

Please note that if your research involves **former** members of the Armed Forces (i.e., veterans, ex-services personnel) and is not conducted on MOD premises there is no need to seek ethical approval from MoDREC, although you must still submit Stage 1 and 2 ethical approval forms. or queries, please contact Toni Mawoyo, Project Manager, Veterans and Families Institute, on email address: antoinette.mawoyo@aru.ac.uk

For all external approvals, you need to submit the Stage 1 Research Ethics Application Form and evidence of the external ethical approval as a minimum requirement. In some instances e.g. where a governance only as opposed to ethical review is carried out by the external body, you will need to obtain ethical approval from a FREP at ARU. In other cases the external organisation may require evidence of university research ethics approval as well as issuing their own approval. Please speak to your FREP Chair if you have any queries.

27. Involve individuals aged 16 years of age and over who lack 'capacity to consent' and therefore fall under the Mental Capacity Act (2005)?

The Mental Capacity Act (2005) protects people who may be unable to make decisions for themselves. If your research involves such participants in England and Wales, it can only legally be ethically approved by an appropriate body, which is a Research Ethics Committee recognised by the Secretary of State or Welsh Ministers. Please see the Health Research Authority's website for further information.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act

Please also note that the Ministry of Defence Ethics Committee (MoDREC) is also recognised as an Appropriate Body under the Mental Capacity Act 2005 for review of research involving UK Armed Forces personnel who are unable to consent for themselves.

In Scotland, the inclusion of adults lacking capacity in research is governed by the provisions of Section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, it is currently governed by the Mental Capacity Act (Northern Ireland) 2016.

It is your responsibility to be aware of and comply with any legislation relating to people who lack capacity, in the country you are carrying your research out in.

Please also refer to the Code of Practice.

28. Involve processing special category data/and or you intend to recruit 100 or more participants?

If you say 'yes' to this question, you also need to complete the *Further Data Protection Questions* document and submit it with your ethics application. This is because it presents a higher data protection risk and there is a need to have in place additional safeguards as a result. This document can be obtained from:

https://myaru.sharepoint.com/sites/student-office-for/SitePages/data-protection-in-research.aspx#research-checklist-for-data-protection

If any of your answers on the Further Data Protection Questions document are 'no' you must submit the document and your ethics application to our Data Protection Officer at dpa@aru.ac.uk before proceeding with your ethics application.

Special category data is personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership; and the processing of genetic data or biometric data for the purpose of uniquely identifying a person; data concerning health or data concerning sex life or sexual orientation. The law requires us to apply security over our data handling which is 'appropriate' to its sensitivity, therefore special category data will need additional protection.

If you are using an online survey tool and will be collecting special category data please refer to the *Guidance for Online Surveys* on the research ethics website.

You also need an additional legal basis for processing special category data for research purposes. In all cases, this will be 'research purposes'. This is covered in the *Privacy Notice for Research Participants.*

Encryption of Special Category data

ARU does not have tools to encrypt emails, therefore:

- Personal or otherwise confidential data should be sent via ARU provided Office 365 accounts e.g. OneDrive (or a designated SharePoint or Teams site to which the recipient is given access).
- If for some reason Office 365 accounts are not available, then item sharing should be via email with the data contained in password protected documents (passwords communicated through separate means).
- Bulk outgoing transfers exceeding the capacity for Office 365 sharing should be made via ITS managed Secure File Transfer Protocol (SFTP), or if not feasible, through ITS procured encrypted memory stick and posted by special delivery evidencing receipt.
- Paper forms should be scanned and sent deliciously as above, or if they must be transferred in hard-copy, by special delivery evidencing receipt.

29. Pose any ethical issues not covered elsewhere in this checklist (excluding issues relating to animals and habitats which are dealt with in a separate form)?

Any other ethical issues may include social or political sensitivities or the consideration of stakeholders. If there are any ethical issues in your study that have not been covered by this checklist, please raise them in Section 4 of the Stage 1 Research Ethics Application Form.

Examples include the below.

- Are there any doubts over the ethical reputation of any partners in the research?
- Could the results be used for gain, openly or covertly? Does this raise any ethical issues?
- Could the results have a dual use? Might they be misused or used for undesirable purposes?
- Are politically, socially or religiously sensitive areas involved? Does the research have a deliberate political intent?
- Are there any doubts over the ethical reputation of any partners in the research?

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