International research projects: Ethics Checklist

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This checklist should be used for all studies which are planned to take place outside of the UK. There are often additional risks and complexities to international studies, in terms of risk to researchers, ability to safeguard participants, data transfer and data management processes and additional in-country permissions required. These aspects need to be considered and the relevant documentation included with your ethics application when it is submitted within Worktribe. Applications which do not have the required documentation attached will be returned to applicants and no review will commence until the necessary information is provided.

	Document	Further information
	Risk Assessment	Risk Assessments - All Documents (sharepoint.com) Risk assessments should cover all aspects of the research project and travel and should be completed at the above link. Supervisors will need to complete the risk assessment with their PhD students and sign it off as their supervisor and approver of the risk assessments. PhD students do not have access to the risk assessment database and will not be able to be granted it. The degree regulations are clear on the role the first supervisor should take in ensuring students understand and follow DMU policies and that includes for health and safety. We recommend that supervisors and students meet together to discuss the risks and mitigations and the supervisor can then input these into the form and then approve the risk assessment once complete. Staff can complete the form themselves and have it signed off by their line manager/local approver. Either download the completed and signed risk assessment or provide the link to the risk assessment in the database in the Worktribe ethics application. The risk assessment process should also ensure that government travel advice is considered for the country in question. Please note: The university will not support travel to 'Red Zone' countries for research activities as designated by the Foreign Office. For details of travel advice please visit: Foreign travel advice - GOV.UK (www.gov.uk)
	In- country agreements	Permissions to use particular locations for research or specific organisations (for example hospitals, workplaces, schools etc) should be provided. These should provide the specifics of the agreement. Where a gatekeeper is being used to recruit participants- for example in a clinical setting where the research would not have legitimate access to patient details, the gatekeepers' agreement to undertake this role should also be provided. All necessary gatekeeper agreements will need to be uploaded to Worktribe with the ethics application. Where ethical approval is also required in the country the research is proposed to be conducted in, the application for this approval and approval should be included in the DMU Worktribe ethics application. DMU is the approving authority for ethics in most instances, as many countries ethics processes do not have equivalence with our own. Even if in-country approval is received this does not mean the research can begin until ethical approval is granted by DMU.
	Data Transfer Agreements	Where data is being transferred into DMU from another country, it is important to ascertain whether an international data transfer agreement (IDTA) is required. As well as an IDTA a Transfer Risk Assessment (TRA) *may* also be needed. The requirement for an IDTA will depend on the country information is being sent to, however even a minimal sharing of data may require an IDTA. All IDTAs/TRAs need to go through Information Governance (IG's) and IG's advice on whether one is required should always be sought.

		The transfer of information from another country to the UK will not usually require an IDTA (unless there's some reciprocal sharing) However researchers need to be cognisant of local data protection legislation that may apply and may impact on sharing information to the UK, for example China's Personal Information Protection Law (PIPL). Applicants should also speak to the research compliance team (research.contracts@dmu.ac.uk) to ensure all contractual aspects of the research are completed before submission of their ethics application, and append the relevant information (e.g. emails or funding contracts) to show that this has been done. Where an International data transfer agreement is required, this should be set up and the completed agreement documents appended to the documents section of Worktribe.
	Data Protection Impact Assessment (DPIA)	Research being conducted under the auspices of DMU in countries other than the UK affords the same level of data protection to subjects as per those in the UK. Therefore, Data protection legislation, including UK GDPR compliance, should be adhered to in international research projects. All research projects involving personal data, wherever they are conducted, should have a screening checklist completed and submitted to Information Governance who will decide whether a full DPIA is required. The DPA screening checklist should be submitted at the time of the ethics submission. If the Information Governance team have indicated that a full DPIA is needed, then no processing can begin until the final DPIA has been signed off even DMU ethics approval has been granted. The final DPIA should be uploaded to the documents section of WorkTribe as evidence that it has been approved. We recommend that supervisors and students meet together to discuss the risks and mitigations to any data processing because the supervisor will be responsible for supporting the student to comply with it. The DPIA checklist form can be found here: https://demontfortuniversity.sharepoint.com/sites/DMUHome/org/ITMS/Documents/DPIA%20Checklist%20RESEARCH.docx. Please note that students cannot currently access the screening checklist on DMUConnect so they will need support from their supervisors to access and complete the documentation.
	Participant facing documentation	If Participant facing documents are planned to be used in a language other than English, the translated documents which are anticipated to be used must also be provided alongside the English version of this documentation within the ethics application. This may include, Participant information sheets, data collection tools (e.g. surveys), consent forms, debrief forms, advertisements for the research.
	Cultural sensitivities	Any specific cultural sensitivities, stigma, potential persecution or discrimination to researchers and/or participants should be carefully considered within the ethics application. Topics of research which may be accepted in the UK may not be normalized in other countries. Careful consideration of any potential harm to the research and/or participants as a result needs to be clearly articulated and any mitigations put in place to minimize any such risks. The DMU Research code of practice has useful advice on this. Please see: https://www.dmu.ac.uk/documents/research-documents/dmu-research-ethics-cop.pdf
	Confidentiality agreements	If any translators or professional transcribers are planned to be used to facilitate the project, then confidentiality agreements may need to be put in place to ensure that the participants confidentiality and anonymity is preserved, this should be considered in relation to the sensitivities identified above.