Researcher Checklist of Ethics Applications for Research with Human Beings

An application for ethical review for a research project has three elements: the application detailing the study and its ethics protocol, participant information including recruitment material and the consent process.

All the information included should be understandable by non-specialists and contain no complex technical terms. While ethics protocols are assessed by ethics committees, others may do so as well to ensure that the research complies with ethical principles. These include institutions, sponsors, regulatory authorities, journal editors and publishers.

General issues a research ethics committee may consider when reviewing an application

	REC Standard		
	Fully Met	Partially Met	Inadequate/ Missing
Is the description of the project understandable?	○	○	○
Are the scientific end points clear?	○	○	○
Are the inclusion and exclusion criteria clear?	○	○	○
Has the research been adequately planned so it will be carried out in a timely manner?	○	○	○
Have the methods to collect and analyze data been outlined?	○	○	○
If relevant, is there an email or letter from the organization where the research is being undertaken agreeing that it can take place?	○	○	○
Are the sampling frame and the number of participants specified?	○	○	○
Are there issues of participant mental capacity to be considered and if so is the research design appropriate?	○	○	○
Is the recruitment process clearly described?	○	○	○
Is there a risk of coercion in the consent process?	○	○	○
Have potential participants been given adequate time to assess the information given about the research and their involvement?	○	○	○
Is it clearly stated that participation is voluntary and that there will be no adverse consequences of refusal?	○	○	○
Has the consent seeking process been adapted to cultural and local norms and expectations while respecting ethical standards?	○	○	○
Are the process and time point(s) for withdrawal from the project detailed, as well as rights to request destruction of already collected data or tissue samples?	○	○	○

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	REC Standard		
	Fully Met	Partially Met	Inadequate/ Missing
Does the research project involve deception and how will this be dealt with and justified to participants?	○	○	○
What provision is there for debriefing?	○	○	○
Does it detail and justify any inducements/rewards?	○	○	○
Is there detail of provision for benefit sharing?	○	○	○
What provision/ procedures are in place to assess risks and manage emergency situations/ unexpected findings/participant distress/disclosures?	○	○	○
Have the duration and security of storage of personal data, consent forms, transcripts, and audio and video recordings been specified and are they within recognized guidelines?	○	○	○
Have de-identification, data sharing and publication of the research been detailed?	○	○	○
Where participants wish to have their identity known and associated with their participation, is this adequately covered in the research design?	○	○	○
Are there risks of stigmatization? If so, has a mitigation strategy been specified?	○	○	○
If relevant, how will participants will be able to access the final study report/ findings?	○	○	○
Does management of the research comply with international, national and institutional guidelines eg GDPR, the UK Data Protection Act 2018, Prevent, Disclosure and Barring Service regulations, institution lone worker policy, safeguarding policy?	○	○	○

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Participant information (PIS) sheets and recruitment

	REC Standard		
	Fully Met	Partially Met	Inadequate/ Missing
Are information sheets for separate participant groups included? Information for children should be appropriate to their age-related cognitive and literacy level(s).	○	○	○
Are all recruitment materials included e.g. emails, advertisements including those on social media, posters?	○	○	○
Are the PIS title and text comprehensible and focused to individual participant groups?	○	○	○
Does it explain the study and rationale?	○	○	○
Does it clearly explain what will happen when the study finishes (e.g. publication, final report and where to access)?	○	○	○
Does it mention reimbursement of reasonable expenses for participants and if appropriate accompanying persons?			
Does it explain any inducements/rewards?	○	○	○
Does it address the limits to confidentiality in the event of disclosure e.g. harm to self or others, concerns for the neglect or abuse of children, security sensitive research, anti-terrorism legislation (Prevent) and the protocol for managing such events?	○	○	○
Are confidentiality, de-identification procedures and security procedures for data access clearly explained and sufficient?	○	○	○
Is it clear how long data or samples will be retained and by whom (institution or an archive)?	○	○	○
Does it explain the study publication policy (including where relevant maintenance of anonymity should quotations and images be published)?	○	○	○
Does it give details of any data sharing?	○	○	○
Does it refer to data protection legislation e.g. GDPR and the UK Data Protection Act 2018?			
Does it give details of how research findings and other outputs will be shared with participants?	○	○	○
Does it specify who to approach as an alternative, independent point of contact for further information or to discuss concerns?	○	○	○
Does it show that it will specify that the research has been given a favourable opinion by a REC, giving the name of the committee and reference?	○	○	○

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Consent forms

The following guidance should be carefully evaluated in relation to the cultural and local norms and expectations of participant groups in order to determine the most appropriate means of seeking and recording consent. Consideration should be given to consent renewal where participation is extended.

Consent forms should have separate clauses for which consent to specific elements of participation can be recorded as well as overall consent. Consent forms for individual participant groups should be included, and assent forms for children below the legal age of consent. If consent is provided by a legal representative, this should be stated and the reason given.

Key clauses to consider for inclusion in consent forms are that:

	REC Standard		
	Fully Met	Partially Met	Inadequate/ Missing
The participant has read and understood the participant information sheet or other mode of informing and has been able to ask questions about the research and have them satisfactorily answered.	◯	◯	◯
Participation is voluntary with no negative consequences for refusal.	◯	◯	◯
Participants can withdraw from the research and up to what time point without justification to the research team, and what will happen to the data/samples collected up to that point.	◯	◯	◯
Consent has been obtained for storage and destruction of data/ tissue samples/ recordings. The duration of storage and by whom should be specified.	◯	◯	◯
Where relevant, consent has been obtained for data sharing.	◯	◯	◯
Prospective consent has been obtained for all anticipated further studies, i.e. consent for future use of data or samples in other ethically approved studies.	◯	◯	◯