**UK Study Wide Review Template**

**How to use this document**

Please provide answers to the questions in the form if your study will make use of NHS organisations in England, Scotland and/or Wales (and/or NHS/HSC organisations in Northern Ireland) as research sites and/or participant identification centres. Questions are in plain text. Question specific guidance is provided *in italics*.

Sections and/or questions that are not applicable should be marked as Not Applicable / NA.

1. **Insurance**

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| 1.1 | What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?    *Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.* |
| |  |  | | --- | --- | | NHS indemnity scheme will apply (NHS sponsors only) |  | | Other insurance or indemnity arrangements will apply (give details below)  Click or tap here to enter text. |  | | |
| 1.2 | What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?  *Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.* |
| |  |  | | --- | --- | | NHS indemnity scheme will apply (NHS sponsors only) |  | | Other insurance or indemnity arrangements will apply (give details below)  Click or tap here to enter text. |  | | |
| 1.3 | What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?  *Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.* |
| |  |  | | --- | --- | | NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only) |  | | Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)  Click or tap here to enter text. |  | | |
| 1.4 | Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?  *This question addresses the possibility of compensation where no legal liability arises for any person, e.g. a participant has suffered harm as a result of taking part in the research but there has been no negligence in its management, design or conduct and no other liability arises such as product liability. This compensation is commonly known as "no fault compensation".*  *Sponsors are not obliged to offer no fault compensation in all cases. The REC will inform you if they consider that provision for no fault compensation is needed.*  ***Commercially sponsored trials***  *In the case of commercially sponsored CTIMPs or medical device studies, arrangements for no fault compensation will normally be provided in accordance with the Association of British Pharmaceutical Industry (ABPI) or Association of British Healthcare Industry (ABHI) schemes. Tick the response to indicate that arrangements for compensation have been made, and confirm that the ABPI/ABHI guidelines will be followed. A copy of the form of indemnity (unsigned) to be used should be enclosed with the application.*  ***Non-commercial research***  *In the case of non-commercial research, arrangements for no fault compensation cannot be made in advance by the NHS or other public bodies (e.g. MRC). Such organisations, although not accepting liability, may consider making an ex gratia payment on a voluntary basis in the event of a claim.*  *Some Higher Education Institutions may choose to provide no fault compensation for research involving their employees. If this is the case, tick the response to indicate that arrangements for compensation have been made. A copy of the policy should be provided.*  *Where no organisation has arranged or is able to provide no fault compensation, tick the response to indicate that no arrangements for compensation have been made.*  ***Information for participants***  *Before agreeing to take part, participants should be made aware of any provision (or lack of provision) for no fault compensation. If no such provision is available, participants should be aware that in the unlikely event of a claim, for which negligence could not be demonstrated, they might need to take legal action for which they would need to pay.*  *Health Research Authority (HRA) guidance on the participant information sheet is available at:* [*http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/*](http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/)  ***REC responsibilities***  *For non-commercial research, there are no guidelines on whether provision for no-fault compensation should be in place. It is an ethical issue for the sponsor and the REC to consider on a case by case basis, taking into account the potential risk to participants. In most studies this will not be necessary.*  *The REC may decide that participants should be protected by no fault compensation arrangements. If so, the research could go ahead only if a body was willing and able to make provision for compensation, backed by adequate insurance or indemnity arrangements.* |
| Click or tap here to enter text. | |

1. **Information Governance**

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| 2.1 | **Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?**  *(Tick as appropriate)*  *Under the General Data Protection Regulation (GDPR), there is a strong emphasis on implementing safeguards for personal data for research. Safeguards are the measures that are taken to ensure that data is processed securely, accurately and in accordance with data protection principles. Please refer to the* [*Health Research Authority (HRA) website*](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/safeguards/) *for further guidance.* |
| |  |  | | --- | --- | | **Access to medical records by those outside the direct healthcare team**  *This should only be undertaken with consent or Section 251 approval.* |  | | **Access to social care records by those outside the direct social care team** |  | | **Electronic transfer by magnetic or optical media, email or computer networks**  *Where personal data is transferred electronically, data should be encrypted during transfer.* |  | | **Sharing of personal data with other organisations**  *Except where such disclosure has consent or approval under Section 251, only anonymised data should be shared.  Where data has been effectively pseudonymised it should only be shared on the basis that the recipient cannot disclose pseudonymised data to third parties and is not permitted to link the data with other data which might render the information more identifiable.* |  | | **Export of personal data outside the EEA** |  | | **Use of personal addresses, postcodes, faxes, emails or telephone numbers**  *It should be remembered that such personal contact details can be sensitive information, either because individuals are concerned about identity theft or because of domestic violence etc.* |  | | **Publication of direct quotations from respondents**  *Should be anonymised* |  | | **Publication of data that might allow identification of individuals**  *In general, publication of case histories should be effectively anonymised.  Where identification is possible it is essential that this is only undertaken with consent.* |  | | **Use of audio/visual recording devices** |  |   2.2 **Storage of personal data on any of the following:**   |  |  | | --- | --- | | **Manual files (includes paper or film)**  *Paper and other manual files should be appropriately filed and stored securely*. |  | | **NHS computers**  *Appropriate access controls need to be in place to ensure that access to confidential research information is restricted to those who need access.* |  | | **Social Care Service computers** |  | | **Home or other personal computers**  *Under no circumstances should patients'' or research participants'' personal data be stored on a home or other personal computer.* |  | | **University computers**  *Appropriate access controls need to be in place to ensure that access to confidential research information is restricted to those who need access.* |  | | **Private company computers**  *Appropriate access controls need to be in place to ensure that access to confidential research information is restricted to those who need access.* |  | | **Laptop computers**  *Use of laptops and other portable devices is to be avoided.  Where it is necessary for them to be used, data must be encrypted and the data uploaded onto a secure server or desktop as soon as possible and the data removed from the portable device as soon as possible and using appropriate data destruction software* |  | | |
| 2.3 | **Please describe the physical security arrangements for storage of personal data during the study**  *Please describe where all personal data of participants will be stored. Explain if filing cabinets, cupboards and/ or rooms will be locked and who has access. Give details of security arrangements for personal data held on computer, especially where laptop computers are used.*  *Information about security arrangements should not be detailed enough to enable access by anyone viewing this application.* |
| Click or tap here to enter text. | |
| 2.4 | **How will you ensure the confidentiality of personal data?**  *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*  *Please give details of the overall arrangements to respect confidentiality of personal data and meet the requirements of GDPR and the Data Protection Act.  Give details of policies or guidance that will be followed, e.g. NHS Code of Confidentiality.* |
| Click or tap here to enter text. | |
| 2.5 | **Who will have access to participants' personal data during the study?**  *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*  ***Access to data for monitoring and audit***  *Monitors and auditors from pharmaceutical companies, trial centres and NHS R&D offices, and regulatory inspectors may require access to patients’ clinical notes to verify or cross check data.  Review bodies are likely to accept protocols that incorporate such arrangements provided that the following guidelines are observed:*   * *Participants are told in the information sheet who may have access to their medical records and trial data, and why.* * *Such individuals must have an appropriate professional background.* * *Participants have signed a consent form to state they have read the participant information sheet and understood the information it contains.*   *In some circumstances it may be appropriate to add that the data in an anonymous form may be used for preparation of the trial report, and for submission to Government agencies as part of the procedures for marketing any new medicine.* |
| Click or tap here to enter text. | |
| 2.6 | **Where will the data generated by the study be analysed and by whom?**  *Explain where the data will be analysed and the arrangements for ensuring confidentiality of personal data during transfer of data.  Give details of any plans to export data outside of the UK.*  *For guidance about transfer of data outside of the European Economic Area (EEA) please refer to the* [*Health Research Authority website*](https://www.hra.nhs.uk/) |
| Click or tap here to enter text. | |
| 2.7 | **How long will personal data be stored or accessed after the study has ended?**  *Please note this question only relates to retention of personal data.*  *GDPR and the Data Protection Act allow for personal data to be retained for scientific purposes for as long as this is necessary for those purposes. The principle of data minimisation requires however that the least processing of the least personal data take place for the purpose and consideration should be given to whether it is possible to reduce the identifiability of data retained following record linkage and validation.*  *Where data is to be processed without consent using Section 251 support (please refer to:* [*https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/*](https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/)*), there is a requirement to reduce the identifiability of the data at the earliest reasonable point and to anonymise/pseudonymise the data effectively at the end of the study.*   |  |  | | --- | --- | | Less than 3 months |  | | 3 – 6 months |  | | 6 – 12 months |  | | 12 months – 3 years |  | | Over 3 years |  | |
| 2.8 | **For how long will you store research data generated by the study?**  *Please indicate in your answer whether the proposed retention period and storage arrangements are subject to any policy or guidance from the research host or your employer. Explain how and when data will be destroyed.*  ***Audio/video recording and the observation of patients***  *Informed consent should be obtained from the research participant(s) involved. The participant information sheet should specify the uses to which the material might be put, how the material will be stored and how and when it will be destroyed. It should be noted that videos should not be used for commercial purposes.* |
| Click or tap here to enter text. | |
| 2.9 | **Please give details of the long term arrangements for storage of research data after the study has ended.**  *Say where data will be stored, who will have access and the arrangements to ensure security.*  *Please indicate in your answer whether the proposed retention period and storage arrangements are subject to any policy or guidance from the research host or your employer. Explain how and when data will be destroyed.*  ***Audio/video recording and the observation of patients***  *Informed consent should be obtained from the research participant(s) involved. The participant information sheet should specify the uses to which the material might be put, how the material will be stored and how and when it will be destroyed. It should be noted that videos should not be used for commercial purposes* |
| Click or tap here to enter text. | |
| 2.10 | **If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?**  *Care should be taken when considering publishing data or case histories to ensure the anonymity of the relevant patients.  For example, where tables of data are to be published, care should be taken where the values of cells are small numbers as, in combination with other information, this could render information potentially identifiable. Particular care needs to be taken in relation to 0 as this can create an inference in relation to other cells. For further information on this, please see the Office for National Statistics (ONS)  guidance at:* [*http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-of-health-statistics/index.html*](http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-of-health-statistics/index.html)*.*  *In relation to case histories care should be taken that the combination of incidental details e.g. details about occupation, location, age and ethnicity, do not lead to individuals being identifiable.* |
| Click or tap here to enter text. | |

1. **Children**

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| 3.1 | What is the age span of the trial subjects?  Include approximate number of participants.  List grouped ages less than 18 years, eg 0-2 years, 3-5, 7-10 etc. | |
| Click or tap here to enter text. | | Click or tap here to enter text. |
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1. **Tissue**

**This section should be completed for all trials which involve the removal and storage of tissue samples.**

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| 4.1 | Please explain what licensing arrangements apply to the procurement, processing, distribution or import of the tissues and cells to be used in the research. |
| Click or tap here to enter text. | |
| 4.2 | Who is the holder of the samples? |
| Click or tap here to enter text. | |
| 4.3 | Please give details of where the samples will be stored, who will have access and the custodial arrangements.  *Describe the arrangements for preserving the condition of the samples and for ensuring security and confidentiality of the samples and any linked data. Say who will be responsible for these arrangements and who will have access to the samples.* |
| Click or tap here to enter text. | |
| 4.4 | What will happen to the samples at the end of the research?   |  |  | | --- | --- | | Transfer to research tissue bank  *(If the bank is in England, Wales or Northern Ireland the institution will require a licence from the Human Tissue Authority to store relevant material for possible further research.)* |  | | Storage by research team pending ethical approval for use in another project  *(Unless the researcher’s institution holds a storage licence from the Human Tissue Authority, or the tissue is stored in Scotland, or it is not relevant material, a further application for ethical review should be submitted before the end of this project.)* |  | | Storage by research team as part of a new research tissue bank  *(The institution will require a licence from the Human Tissue Authority if the bank will be storing relevant material in England, Wales or Northern Ireland. A separate application for ethical review of the tissue bank may also be submitted.)* |  | | Storage by research team of biological material which is not “relevant material” for the purposes of the Human Tissue Act |  | | Disposal in accordance with the Human Tissue Authority’s Code of Practice |  | | Other |  | | Not yet known |  |   Please give further details of the proposed arrangements: |
| Click or tap here to enter text. | |