### SUBMISSION CHECKLIST FOR ETHICS APPLICATIONS

to be reviewed by the MS IDREC

**All MS IDREC applicants should complete this checklist prior to submission on the online ethics application system (Worktribe), to ensure the application is complete and ‘fit to submit’. The completed checklist needs to be attached to the application together with supporting documents. If anything on this checklist is marked as complete and not addressed in the application, it will be returned.**

**Ethics application (on Worktribe)**

|  |  |  |
| --- | --- | --- |
| **Tab** | **Elements to check** | **Confirm** |
| **Details** | Project Description - Includes research aim, background, justification/value of research, brief outline of research and plans to disseminate results/data |  |
| ‘Project Dates’* Start date at least 30 working days after submission date
* Achievable end date, based on current available resources
 |  |
| Auto-selected Ethics Committee as expected? |  |
| **Research Team** | Training details and dates entered for all core research team members* Ethics/integrity training/equivalent within past 36 months
* Information Compliance training within last 12 months
 |  |
| External researchers (if applicable) - equivalent courses in Research Ethics, Research Integrity and/or ICH-GCP entered |  |
| **Methodology** | ‘Research Methodology’ – *All* tasks included, with durations and frequency, and in the order in which they will occur |  |
| **Human Participants** | ‘Recruiting participants’ **–** *All* recruitment methods clearly stated and reflect recruitment material submitted |  |
| Gifts/Payments/Reimbursement – Payment/voucher amounts stated and payment method(s) included |  |
| **Data Management** | ‘What data will be collected and used during the project?’ – *All* types of data collected in the study are listed |  |
| ‘Where and how will data be stored during the project? – Answered for *all* data listed in the above question, including methods of storage and transfer between devices and security at all stages. |  |
| **Human Tissue** | If collecting, receiving, or holding human tissue samples, the scope question about samples has been answered ‘yes’ and the Human Tissue tab is visible on the application for completion.Researchers have considered whether the samples are relevant material under the Human Tissue Act. If they are relevant (or if the researcher is in doubt), the RGEA Human Tissue Governance team (hta\_help@admin.ox.ac.uk) has been contacted and arrangements made for the samples to be adopted onto the appropriate HTA license. Note: MS IDREC/CUREC ethics approval is not a substitute for HTA licensing. |  |

**Supporting documents**

|  |  |  |
| --- | --- | --- |
| **Please confirm** | Existing Template(s) PIS/consent forms/other templates have been used/consulted in preparation of supporting documents |  |
| **Quality** | Documents have been carefully spellchecked and proof-read prior to submission |  |
| **All include** | Study title (this may be the short title entered on the methodology tab of application) |  |
| Space for ethics reference |  |
| Document control - name, version number and date |  |
| Oxford Logo |  |
| Department name (and address where applicable) |  |
| Contact details for relevant researchers (PI as a minimum) |  |
| Group/cohort name in footer where multiple PISs/Consent Forms being used |  |
| **Recruitment /advertising material includes** | Inclusion/exclusion criteria |  |
| Location of research session (even if online) |  |
| Number and duration of sessions |  |
| Brief overview of what is expected of participants |  |

**Consistency across documents and the application**

|  |  |  |
| --- | --- | --- |
| **Check** | Project title matchesapplication - either full (on 'details' tab) or short title ('methodology' tab) |  |
| Age range of participants, including unit of age (e.g. years or months) |  |
| Inclusion/Exclusion Criteria |  |
| Participants referred to as ‘participants’ or ‘volunteers’ throughout (not ‘subjects’) |  |
| No other inconsistencies between documents |  |

**Supporting Documents submitted – Please select all that apply and are uploaded to the application in MS WORD FORMAT**

|  |  |
| --- | --- |
|  | Recruitment material: advert/poster, email invite text, social media text, letter to schools, etc. |
|  | Participant Information Sheet(s) |
|  | Informed Consent Document(s) |
|  | Assent Form (generally only for participants aged 6 to 16) |
|  | Screening Document(s) |
|  | Questionnaire content - Copies of standardised questionnaires do not need to be submitted |
|  | Demographic Questions |
|  | Interview questions |
|  | Debrief Script/plan |
|  | Any other participant-facing documents (e.g. reminder text, diary, task instructions) |
|  | Approvals from any other institution/collaborating institutions |
|  | Other: |

**Submission Declaration**

I confirm that this checklist and all required documents are complete and accurate to the best of my knowledge.

|  |  |
| --- | --- |
| Applicant name: |  |
| Date: |  |

**Please attach this completed form to your application on Worktribe**