

## Above Minimal Risk

The ethical review and approval process provides alternative routes for the approval of proposals, dependent on the level of risk presented. Above minimal risk is automatically identified by a researcher selecting 'yes' to one or more of the below questions on a completed ethics checklist:

- Does your research specifically involve participants who are considered vulnerable (i.e. children, those with cognitive impairment, those in unequal relationships—such as your own students, prison inmates, etc.)?
- Does the study involve participants age 16 or over who are unable to give informed consent (i.e. people with learning disabilities)? NOTE: All research that falls under the auspices of the Mental Capacity Act 2005 must be reviewed by NHS NRES.
- Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited (i.e. students at school, members of self-help group, residents of Nursing home, etc.)?
- Will it be necessary for participants to take part in your study without their knowledge and consent at the time (i.e. covert observation of people in non-public places)?
- Will the study involve discussion of sensitive topics (i.e. sexual activity, drug use, criminal activity, etc.)?
- Are drugs, placebos or other substances (i.e. food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?
- Will tissue samples (including blood) be obtained from participants? Note: If the answer to this question is 'yes' you will need to be aware of obligations under the Human Tissue Act 2004.
- Could your research induce psychological stress or anxiety, cause harm or have negative consequences for the participant or researcher (beyond the risks encountered in normal life)?
- Will your research involve prolonged or repetitive testing?
- Will the research involve the collection of audio materials?
  - Is the audio collection **solely** for the purposes of transcribing/summarising and will **not** be used in any outputs (publication, dissemination, etc.) and will **not** be made publicly available? (*If yes, minimal risk*)
- Will the research involve the collection of photographic or video materials?
- Will financial or other inducements (other than reasonable expenses and compensation for time) be offered to participants?
- Will your research involve experimentation on any of the following: animals, animal tissue, genetically modified organisms?
- Will your research take place outside the UK (including any and all stages of research: collection, storage, analysis, etc.)?