PRS SOPs v1 1 - No Material Ethical Issues Tool

The following types of application always require review at a full REC meeting:

- Clinical trials of investigational medicinal products (CTIMP's)
- Clinical investigations of medical devices prior to CE marking
- Research involving adults lacking capacity and subject to the Mental Capacity Act 2005
- Invasive basic science studies involving healthy volunteers
- Research involving exposure to ionising radiation which could be additional to that received in routine clinical care for any participant
- Research tissue banks
- Research databases
- Prison research
- Studies funded by the US department for Health and Human Sciences

Otherwise, reviewers should use the table below as a guide

	RESEARCH TYPE	**Suitable for Proportionate Review?**	**Tick the 'No Material Ethical Issues' category met by this application**
I	Research using data or tissue that is anonymous TO THE RESEARCHER	**YES**	
II	Research using existing tissue samples already taken with consent for research	**YES**	
III	Research using "extra tissue" (e.g. further blood taken at time of routine sampling or tissue taken at "clinically directed" operation)	**YES**	
IV	Questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences	**YES**	
V	Research interview / focus group that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences	**YES**	
VI	Research surveying the safety or efficacy of established non drug treatments, involving limited intervention and NO change to the patients' treatment	**YES**	

N.B: Research involving children may be considered for Proportionate Review where it meets the above criteria.