Research and Innovation Trial Feasibility proforma (IEC trial protocol review)

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IEC (Immune effector Cell) Trial Protocol Review

To be presented by PI/CI or suitable delegate – *10min overview to the group to cover the following:*					
TITLE					
Proposed PI					
Disease group					
SCIENTIFIC MERIT					
Type of IEC (Immune effector cell) 1) Eg. CAR,TCR,TIL 2) Autologous or Allogenic					
Type of the Vector					
PROTOCOL DESIGN To include details of expected inpatient stay					
Conditioning and/or additional treatment requirements (eg IL2) include regime and doses					
Anticipated in Patient length of Stay					
Description of Clinical Risk (include factors described in appendix 1)					
Level of care (please circle)	1	2	3	4	5

	Outpatient care anticipated	Additional level of ward care anticipated eg overnight stay	Outreach input on ward is probable	CCU admission significant possibility	CCU admission expected and with risk of patient death
RECRUITMENT TARGET (number of patients)					
Anticipated FPFV					
Recruitment period					
Protocol differed variance from standard of care SOPs Eg. Required access to 24 hour ECG)					
Apheresis/procurement comments (eg capacity or barriers)					
Nursing comments (eg. capacity or barriers)					
Pathology/Stem Cell laboratory comments					
Other comments eg CCU					

OUTCOME Accept/ reject onto ATMP portfolio or defer until further clarification	
Proposed clinical area for delivery if accepted	

Appendix 1

1. Intensity of pre-conditioning chemotherapy regime

    i. Level 1 = myeloablative

    ii. Level 2 = 'full dose' non-myeloablative cyclophosphamide (2 days 60mg/kg 5 days) fludarabine (3 days 30mg/m^2) or equivalent

    iii. Level 3 = reduced dose cyclophosphamide + fludarabine or equivalent

    iv. Level 4 = standard chemo or equivalent

    v. Level 5 = none

2. Additional combination therapies eg IL2 (high dose or low dose)

3. First in human

4. Anticipated toxicities with explanation as to why (or why not) these are anticipated

    a. CRS

    b. Neurotoxicity

    c. Other