

CHECKLIST FOR RESEARCH ON STEM CELL AND CELL-BASED THERAPIES

NMRR ID:	
Study Protocol Title:	
Principal Investigator:	

NOTE: Study Principal Investigator (PI):

Please indicate whether the ITEMS outlined are present in the study protocol or any other documents; if present, state the page number of each item. Once completed, please submit the completed form to MREC/IRB/IEC to be checked and forwarded to NCERT.

ITEMS	To be completed by Study PI			To be completed by MREC/IRB/IEC
	State (Y) for 'Yes', (N) for 'No', (NR) if not relevant	Document name and page number	Other Remarks (if any)	State (Y) for 'Yes', (N) for 'No', (NR) if not relevant
1. Pre-clinical studies (investigators must show their own data and not from other laboratories)				
1.1 Approval letter from animal ethics committee is recommended				
1.2 Testing in animal research facility which is GLP compliance				
1.3 Evidence that the pre-clinical studies was subjected to rigorous and independent peer review and regulatory oversight				
1.4 Safety data in small animals				
1.5 Safety data in large animals				
1.6 Comprehensive toxicology data in small animals (including contamination, acute infusional toxicity, deleterious immune responses, unexpected behaviour of the cellular product, and tumorigenesis)				
1.7 Comprehensive toxicology data in large animals (including risks of contamination, acute infusional toxicity, deleterious immune responses, unexpected behaviour of the cellular product, and tumorigenesis)				
1.8 Proof of principle of the desired effect (that the cells have repaired the damage/ disease) – unequivocal efficacy data				
1.9 Show biological distribution data				

1.10	Show evidence of physiologic integration and long-lived tissue reconstitution				
1.11	Show that differentiation (either in vitro before transplantation or in vivo after transplantation) occur only along the desired lineages				
1.12	Design based on clinical expectations				
1.13	Mechanistic studies to show biology (done by the group)				
1.14	GLP compliant for testing				
1.15	Evidence that the pre-clinical data has been submitted to the NPRA				
2. Phase I trials					
2.1	For first in human studies conducted locally, to provide accreditation of Phase I FIH facility(ies)				
2.2	Comprehensive pre-clinical studies have been done and data showed safety and efficacy in animals (performed by the group) is recommended				
2.3	Procedures on how the cells be tracked in terms of homing to the target area, viability and longevity of the cells				
2.4	Procedures on how the safety be monitored				
2.5	Procedures to assess risks of tumorigenicity by an independent body must be implemented				
2.6	Procedures to assess short-, medium- and long-term side effects				
2.7	GCP compliance for investigators				
3. Phase II trials					
3.1	Data from Phase I trials (performed by the group themselves and if the trial is not performed by the group, explain why the data should be used for this trial)				
3.2	Procedures on how the cells be tracked in terms of homing to the target area and viability of the cells				
3.3	Optimisation of dose, route, regimen, patient population, endpoints, and controlled				
3.4	Procedures on how the safety be monitored				

3.5	Independent data safety monitoring board				
3.6	Plan to assess short-, medium- and long-term side effects				
3.7	GCP compliance for investigators				
4. Phase III trials					
4.1	Data from Phase II trials (performed by the group themselves)				
4.2	Conduct 'randomized' control				
4.3	Design to show safety and efficacy				
4.4	Independent data safety monitoring board				
4.5	GCP compliance for investigators				
5. Cell processing and manufacturing					
5.1	Evidence by a letter of conformance for GMP compliance and issued by relevant authority				
5.2	Show evidence of relevant processes: Standard operating procedures, quality standards, environmental control, equipment qualification, analytical methods, audits, staff training, etc.				
5.3	Cell processing and manufacture of any product must be conducted under scrupulous, expert, and independent review				
5.4	Demonstrate that the product is safe, pure and potent				
6. Product registration					
6.1	Show that the product has been registered with the National Pharmaceutical Regulatory Agency before use in human trials				
6.2	License for clinical trial has been obtained (CTIL/CTX)				
7. Cell characterization (pre-requisite to clinical trials)					
7.1	History of the cells in the stem cell or cell-based product				
7.2	Biological characterisation of cell type				
7.3	Demonstration of purity				
7.4	Demonstration of potency (e.g., cells produce insulin in a physiological manner)				
7.5	Manufacturing standards and independent certification, where relevant				

7.6	Evidence that cells are free from contamination				
7.7	Evidence of viability and longevity of cells after transplantation (to determine the likely duration of the therapeutic effect)				
7.8	Evidence that cells will home into the area of damage or repair				
7.9	Evidence of genomic stability during culture				
8. Investigators and researchers					
8.1	Is the Principal Investigator trained in cell transplantation? (Show evidence of credentialing)				
8.2	Are other investigators trained in cell transplantation? (Show evidence of credentialing)				
8.3	Qualifications of scientists and researchers				
8.4	Registration with National Medical Research Register, Ministry of Health				
9. Centres performing therapy (Information for patients)					
9.1	Registration with PHCFS Act, Ministry of Health				
9.2	Informing subjects about the human embryonic cell source, if applicable				
9.3	The unique risks and disclose honestly that the treatment have not been tried before				
9.4	Utmost clarity on the potential benefit				
9.5	Disclosing financial and non-financial conflicts of interest				
9.6	Provide monitoring patients long term				
9.7	Providing a clear, timely, and effective plan for adverse event reporting				

Disclaimer:

1. Extracted from Guidelines on Stem Cell and Cell-Based Research and Therapy 3rd Edition, Ministry of Health Malaysia
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