must	should	may

MITAP Checklist

1) Cells before

a) Essential information about the donor

i) Species and strain

- Species
- Strain (if applicable)

ii) Characteristics of the organism

- Health
- Age
- Treatment/Environment
- Individual identifier number
- Source of purchase (if applicable)

b) Source of cell material

- Organ, tissue, fluid or blood product
  - Source (if applicable)
- Quantity (volume, size or weight)
- Anti-coagulant (if applicable)

c) Cell separation process

- Cell separation method
  - Equipment used
- Tissue conditions between tissue retrieval and cell separation
  - Duration
  - Temperature
  - Fluid
  - Container
- Purity of the cells after the separation process
  - Methodology

d) Phenotype

i) Morphology

- Shape and appearance of cells

ii) Cell surface and intracellular markers

- Molecules measured (using CD names)
  - Methodology
- Stimulus and time of stimulation (if applicable)

must	should	may

iii) Secreted molecules

- Molecules measured
  - Methodology
- Stimulus and time of stimulation (if applicable)

e) Cell numbers

i) Absolute cell number

- Total number of cells at the end of the isolation process
  - Methodology

ii) Viability

- Percentage of viable cells
  - Methodology

2. Differentiation and induction of tolerogenicity (diff/tol)

a) Pre-culture conditions

- Storage time
- Storage conditions
  - If fresh
    - Fluid
    - Container
    - Temperature
  - If cryopreserved
    - Freezing/thawing process
    - Freezing medium
    - Cell recovery & viability after thawing

b) Culture conditions

i) Cell number

- The total number of cells put into culture

ii) Cell concentration

- The number of cells per ml of medium at start of culture

iii) Culture medium

- Type(s) of medium
  - Source(s)
- Additives (excluding diff/tol agents)
  - Source(s)
- Refreshment of the medium

iv) Culture container

- Type of container
  - Size
  - Manufacturer
- Cell culture volume per container or well
- Total number of containers or wells

must	should	may

v) Culture environment

- Temperature and CO_2 concentration
- Use of pre-warmed medium
- Equipment

c) Differentiation/induction of tolerogenicity (diff/tol) protocol

- Protocol
- Name of cytokine(s) or other agent(s) used
  - Source
  - Concentration
  - Time-point(s) added to cell culture
- Total length of the culture period

d) Antigen

- Name
- Source
- Concentration
- Time point(s) added to culture
- Carrier (if applicable)

e) Storage

- Storage time
- Storage conditions
  - If fresh
    - Fluid
    - Container
    - Temperature
  - If cryopreserved
    - Freezing/thawing process
    - Freezing medium
    - Cell recovery & viability after thawing
  - Time point at which cells are stored if different to the end of the culture process

3. Cells after

a) Phenotype

i) Morphology

- Shape and appearance of cells

ii) Cell surface and intracellular markers

- Molecules measured (using CD names)
  - Methodology
- Stimulus and time of stimulation (if applicable)

must	should	may

iii) Secreted molecules

Molecules measured

Methodology

Stimulus and time of stimulation (if applicable)

b) Cell behaviour

Behaviour of cells in a functional assay

c) Cell numbers

i) Absolute cell number

Total number of cells at the end of the isolation process

Methodology

ii) Viability

Percentage of viable cells

Methodology

4. About the protocol

a) Regulatory authority

External authority that approved the protocol

Does protocol follow GMP?

b) Purpose

The reason for manufacturing the cells

c) Relationship between the source organism for the cells and the target organism

Allogeneic/Autologous/ Xenogeneic/Syngeneic

d) Contact details

Name(s) of the corresponding author(s)

Contact details of the corresponding author(s)