

MIANKA & MIATA Sub-Modules

#	Required	If available	Optional	
<b>Module 1 - Sample</b>				
<b>Module 1A - Donor</b>				
1.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Essential donor info
<b>Module 1B Source</b>				
1.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Source of cell material
1.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Collection methodology
1.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	anti-coagulant, if available
1.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transportation/storage conditions for unprocessed samples, if available
1.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cell processing methodology
1.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Median time and ranges from sample collection until end of cell processing, if available
1.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cut-offs, if used
<b>Module 1C - Cryopreservation and Storage</b>				
1.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Fresh or cryopreserved
1.10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If cryopreserved
1.11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	devices used
1.12	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	freezing process
1.13	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	medium used for freezing
1.14	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Median time and temperature for each transportation and storage step, if available
1.15	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cut-offs, if used
<b>Module 1D - Cell Counting</b>				
1.16	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Median cell yield and viability (where available)
1.17	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	before freezing
1.18	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	after thawing
1.19	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	after overnight resting
1.20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cut-offs, if used
1.21	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Cell counting methodology
1.22	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Optional: Additional assessments</i>
<b>Module 2 - Assay</b>				
<b>Module 2A - Medium/serum</b>				
2.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Medium/(serum) details
2.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pretesting info
<b>Module 2B - Assay</b>				
2.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Treatment procedures of cells prior to assay, if applicable
2.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient assay details
<b>Module 2C - Controls</b>				
2.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Internal assay controls
2.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Acceptance criteria, if available
2.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	External reference samples, if used
2.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Assay acceptance criteria, if available
<b>Module 3 - Data Acquisition</b>				
<b>Module 3A - Equipment and software</b>				
3.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Equipment and software version
3.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Basic equipment settings, if available
<b>Module 3B - Acquisition Strategy and Gating</b>				
3.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Detailed gating strategy or strategy for establishing spot detection parameters
3.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Representative data set
3.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mean, median, ranges of event counts for relevant populations, if available
3.6	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Optional: Unusual strategies explained</i>
3.7	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Optional: Review of raw data</i>
<b>Module 4 - Results</b>				
<b>Module 4A - Raw data</b>				
4.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Background and ag-specific reactivity levels, if available
4.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cut-off specifications and # of tests OOS, if available
4.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Accessibility of raw data addressed?
<b>Module 4B - Response determination</b>				
4.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Definition of positive reactivity (above background) including tests applied
4.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Parameters, software and version used for response determination, if applicable
4.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Response definition predefined or post-hoc?
4.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Definition of response induced by treatment, if applicable
4.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any data excluded and why, if applicable?
4.9	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Optional: Why test was used</i>
<b>Module 5</b>				
<b>Module 5A - General Lab Operation</b>				
5.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Guidance of lab operations
5.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Laboratory accreditations and certifications, if available
5.3	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Optional: Details on audits</i>
<b>Module 5B - Standardization</b>				
5.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Status of protocols
<b>Module 5C - Qualification/Validation</b>				
5.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Status of assays
5.6	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Optional: Specific performance criteria</i>