

Table S1. Modules of MIATA Guidelines

Module 1	Module 2	Module 3	Module 4	Module 5
<p>Minimal Information on the Sample</p> <p>1A: The Donor: <u>Required:</u></p> <ul style="list-style-type: none"> - Report all available donor information that is important for the interpretation of the data in the specific study context (e.g., age, gender, immuno-competence, many others), see examples. <p>1B: The Source and Processing: <u>Required:</u></p> <ul style="list-style-type: none"> - Report the source of the cell material and collection methodology including anti-coagulants, where applicable. - Report the conditions (e.g., temperature) the <u>unprocessed</u> specimen samples were transported / stored at if available, including cut-offs* if they were used. - Report basic information of the methodology used for cell processing (e.g., density gradient centrifugation). - Report the median time and time ranges from sample collection (e.g., venipuncture) until end of cell processing (e.g. until beginning of cryopreservation or assay) if available, including cut-offs if they were used. <p>1C: Cryopreservation and Storage <u>Required:</u></p> <ul style="list-style-type: none"> - Report whether fresh or cryopreserved material was used for testing. - In case of cryopreservation, report basic information on freezing process and medium (e.g., serum-supplemented or serum-free, self-made or commercial source) used for freezing of cell material. - Report the median time + temperature for each storing or transportation step of the processed samples, if available, including cut-offs* if they were used. <p>1D: Cell Counting <u>Required:</u></p> <ul style="list-style-type: none"> - Report median cell yield and viability, where available, including cut-offs* if they were used: <ul style="list-style-type: none"> • before freezing, • after thawing, • after overnight resting. - Report basic information on the methodology used for cell counting. <p><u>Optional:</u> Report additional assessments, if performed (e.g., apoptosis assessment).</p>	<p>Minimal Information on the Assay</p> <p>2A: Medium/serum: <u>Required:</u></p> <ul style="list-style-type: none"> - Report details about all media and sera (if applicable) used (e.g., source). - Report whether the medium or serum were pretested for assay performance. <p>2B: The Assay: <u>Required:</u></p> <ul style="list-style-type: none"> - Report details about treatment procedures of cells prior to assay (e.g., <i>in vitro</i> stimulation, overnight resting), if applicable. - Report details about assay procedures including all reagents and materials used, that would allow the repetition of the assay by others. (Example reports: ICS, Elispot, Multimer) <p>2C: Controls: <u>Required:</u></p> <ul style="list-style-type: none"> - Report details on all internal assay controls employed (e.g., mitogenic stimulation with PHA, control peptide pools) including any assay acceptance criteria associated with their use, if available. - Report details on external reference samples used (e.g., reference PBMC, T-cell line) including any assay acceptance criteria associated with their use, if available. 	<p>Data acquisition</p> <p>3A: Equipment and Software <u>Required:</u></p> <ul style="list-style-type: none"> - Describe the equipment and software version used for data acquisition (Flow Cytometer, Elispot Reader, other). - Report on basic settings of the equipment that enable the understanding of reported results, if available (for flow cytometry examples see MIFlowCyt, Section 3.3). <p>3B: Acquisition Strategy and Gating <u>Required:</u></p> <ul style="list-style-type: none"> - Provide a detailed description of the applied gating strategy (Flow cytometry) or strategy of establishing parameters for spot detection (ELISpot). - Display a representative raw data set (e.g., FACS plots or ELISpot photos). - Report the mean, median and ranges of the event counts for the most relevant cell populations acquired, if available. <p><u>Optional:</u></p> <ul style="list-style-type: none"> - In case an unusual gating strategy was applied comment on why the specific strategy was chosen. - State if raw data were checked for data consistency and plausibility. 	<p>The (interpretation of) results</p> <p>4A: Raw Data <u>Required:</u></p> <ul style="list-style-type: none"> - Provide the means, medians and ranges for both background (as per your lab definition and if applicable) and antigen-specific reactivity levels, if available. - In studies with pre-defined specifications (e.g., for background and specific reactivity levels, minimal event counts or cell number/well) provide the cut-off values for failure/pass and indicate how many tests were out of specification (OOS). - Provide a statement on the accessibility status of raw data of the assay: <ul style="list-style-type: none"> • Raw data is provided (e.g., in main article, supplemental data or online database). or • Raw data can be provided per request. or • Raw data cannot be provided due to confidentiality agreements, corporate policy, other conflicts. <p>4B: Response determination, statistical tests and empirical rules <u>Required:</u></p> <ul style="list-style-type: none"> - Describe how a positive reactivity (above background) for a given sample was defined including the statistical test(s) and/or empirical rule(s) applied. - Provide information on parameters (e.g., <i>p</i>-value, confidence interval), software and software version applied to support response determination, if applicable. - Provide a statement whether response definition criteria were pre-defined (before study), or defined post-hoc (after data were collected). - Provide the definition used to indicate that a response is induced by the treatment used. - Provide information on whether any data was excluded from the analysis, and if so the reason for the exclusion, if applicable. <p><u>Optional:</u></p> <ul style="list-style-type: none"> - Add an explanation for the choice of test(s) applied whenever there is a strong scientific base for doing so. 	<p>The laboratory environment</p> <p>5A: General Laboratory Operation <u>Required:</u></p> <ul style="list-style-type: none"> - Include a general descriptive statement about how laboratory operations are guided (GMP, GLP, GcLP, exploratory research, other), <u>such as</u>: These studies were conducted in a laboratory that operates under _____ principles. This statement should cite a published reference that describes the standard, if applicable. - Include a general descriptive statement about any laboratory accreditations and certifications (e.g., CLIA, CAP), if applicable, <u>such as</u>: The laboratory in which these studies were conducted has the following certifications: _____. <p><u>Optional:</u></p> <ul style="list-style-type: none"> - If laboratory is subject to regulatory audits by external agencies, list that information, specifying the agency, the procedure the audit was intended to evaluate, and the dates of the last audit. <p>5B: Laboratory Procedure Standardization <u>Required:</u></p> <ul style="list-style-type: none"> - Include a descriptive statement about the status of the methodological protocols (investigative protocols, established laboratory protocols, standard operating protocols, other) employed to generate the reported data sets, and the scope (which parts of the experiments) <u>such as</u>: These studies (or specific parts thereof) were performed using _____ protocols. <p>Note: This description can be included in this module, or added to the assay specific sections described in modules 1,2, 3,4.</p> <p>5C: Status of Assay Qualification and Validation <u>Required:</u></p> <ul style="list-style-type: none"> - Include a descriptive statement about the status of the assays employed (general research investigative, qualified, validated, other) to generate the reported data sets, <u>such as</u>: These studies were performed using _____ assays. <p>Note: This description can be included in this module, or added to the assay specific sections described in modules 1,2, 3,4)</p> <p><u>Optional:</u></p> <ul style="list-style-type: none"> - Specific performance criteria (e.g., Precision, Limit of Detection, etc.) for the assays employed may be described.

* **Definition “cut-off”:** Parameter that has to be met so that the assay read-out can be accepted.

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