MIATA Reporting Framework

**Module 1: Minimal Information on the Sample**

***1A: The Donor:***

Required:

- Report all available donor information that is important for the interpretation of the data in the specific study context (e.g., age, gender, immunocompetence, many others), see examples.

***1B: The Source and Processing:***

Required:

- Report the source of the cell material and collection methodology including anti-coagulants, where applicable.
- Report the conditions (e.g. temperature) the unprocessed 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.

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

***1C: Cryopreservation and Storage***

Required:

- 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.

***1D: Cell Counting***

Required:

- Report median cell yield and viability, where available, including cut-offs* if they were used:
    - before freezing,
    - after thawing,
    - after overnight resting.
- Report basic information on the methodology used for cell counting.

Optional:

- Report additional assessments, if performed (e.g., apoptosis assessment).

**Module 2: Minimal Information on the Assay**

***2A: Medium/serum:***

Required:

- Report details about all media and sera (if applicable) used (e.g., source).
- Report whether the medium or serum were pretested for assay performance.

***2B: The Assay:***

Required:

- Report details about treatment procedures of cells prior to assay (e.g., in vitro 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)

***2C: Controls:***

Required:

- 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.

**Module 3: Data acquisition**

***3A: Equipment and Software***

Required:

- 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).

***3B: Acquisition Strategy and Gating***

Required:

- 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.

Optional:

- 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.

**Module 4: The (interpretation of) results**

***4A: Raw Data***

Required:

- 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:
    - 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.

***4B: Response determination, statistical tests and empirical rules***

Required:

- 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., *p*-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.

Optional:

- Add an explanation for the choice of test(s) applied whenever there is a strong scientific base for doing so.

**Module 5: The laboratory environment**

***5A: General Laboratory Operation***

Required:

- Include a general descriptive statement about how laboratory operations are guided (GMP, GLP, GcLP, exploratory research, other), such as: 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, such as: The laboratory in which these studies were conducted has the following certifications: _____.

Optional:

- 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.

***5B: Laboratory Procedure Standardization***

*Required:*

- 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) such as: These studies (or specific parts thereof) were performed using _____ protocols.

*Note: This description can be included in this module, or added to the assay specific sections described in modules 1,2, 3,4.*

***5C: Status of Assay Qualification and Validation***

Required:

- Include a descriptive statement about the status of the assays employed (***general research investigative, qualified, validated, other***) to generate the reported data sets, such as: These studies were performed using _____ assays.

*Note: This description can be included in this module, or added to the assay specific sections described in modules 1,2, 3,4)*

Optional:

- Specific performance criteria (e.g., Precision, Limit of Detection, etc.) for the assays employed may be described.