This overview has been developed by EQIPD and is provided as a general guidance for those organizations and researchers willing to evaluate to what extent their current research environment and research practices comply with the EQIPD expectations

Key terms

EQIPD defines **research quality** as the extent to which research data are fit for intended use. Fitness, in this context, is defined by the stakeholders, who can be scientists themselves, but also patients, funders, sponsors, publishers and collaboration partners (e.g., peers in a multi-site research project).

Research rigor refers to measures against systematic error(s) in the estimated effect of an intervention, caused by inadequacies in the design, conduct, or analysis of an experiment.

Raw data (LINK) means all original records and documentation, which are the result of the observations and activities in a study, such as:

- photographs, videotapes, blots, chromatograms, computer readable media, dictated observations, recorded data from automated instruments, or any other medium capable of providing secure storage of information for a time period required by law or other applicable regulations;
- data directly entered into a computer through an automatic instrument interface, which are the results of primary observations and activities in a study;
- copies of original laboratory records and documentation that are complete and of good quality.

Knowledge-claiming research (LINK): EQIPD requires that the maximal rigor possible is applied (and exceptions explained / documented in the study plan) to research that is conducted with the prior intention of informing a knowledge claim.

Examples of research requiring the maximal rigor possible include:

- Experimental studies to scrutinize preclinical findings through replication of results alongside investigations into boundary conditions and robustness through conduct of additional (control) conditions and multicenter studies (Kimmelman et al. 2014)

- Research aimed to generate evidence that enables decisions such as critical studies that, dependent on the outcome, will trigger a chain of activities and events associated with significant resource and time costs (e.g. a decision to initiate a new drug development project or to initiate GLP safety assessment of a new drug candidate)
- Studies for which any outcome would be considered diagnostic evidence about a claim from prior research (Nosek and Errington 2020)
- Labor-, resource- and/or time-intensive studies that cannot be easily repeated

Must vs should (or strongly recommended)

Must indicates actions that EQIPD considers as imperative and mandatory or as a requirement.

In some cases, the research environment, specific of a research project or research organization do not allow or make it less relevant to adhere to the requirements formulated below.

In such cases, instead of using the word "must", the expectations are communicated as "**should**" or "**strongly recommended**". This means that failure to comply with these expectations will not be automatically regarded as a "red flag" but the research organization may need to present a good rationale for not following this strong recommendation.

For definitions, supporting resources and up-to-date information, please visit the EQIPD page – link

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#	Quality System	Purpose-fit assessment	**Core requirements** *(key self-assessment points in italics)*	**Must**[1] be described in a dedicated stand-alone document?	Verified during assessment?	Guidance & further information
1	Required	n/a	**Process owner must be identified for the Quality System**	No	Yes	link
2	Required	n/a	**Communication process must be in place**	Yes	Yes	link
3	Required	Advisable	**The research unit must have defined quality objectives**	Yes	Yes	link
			Members of my research team are aware of the quality objectives	No	Yes	
			For my research unit, incentive/award/reward structure is aligned with the quality objectives	No	Yes	
4	Required	Required	**All activities must comply with relevant legislation and policies**	No	To some extent	link
			To the best of my knowledge, my research unit complies fully with all applicable national and international legislation and policies	No	No	
			To the best of my knowledge, there were no compliance issues with applicable legislation and policies observed since the last self-assessment	No	To some extent	

[1] Even in cases when a dedicated stand-alone piece of document is required, research units may still decide to create written descriptions of policies and practices as it makes the procedures more transparent and may facilitate the assessment (internal or external)

5	Required	Strongly recommended	**The research unit must have a procedure to act upon concerns of potential misconduct**	No[2]	Yes	link
			Our research unit (or parent organization) has an anonymous reporting / whistleblower policy in place and members of my research unit are aware of this policy	No	Yes	
			Members of my research unit receive training on responsible conduct of research	No[3]	Yes	
6	Required	Required	**Generation, handling and changes to data records must be documented**	No[4]	Yes	link
			For my research unit, I regularly perform spot checks on integrity of data records to make sure that each data record: • *identifies author(s) / owner(s)* • *is saved at the time of generation and is time stamped* • *is readable and permanent*	No	Yes	
7	Required	Required	**Data storage must be secured at least for as long as required by legal, contractual or other obligations or business needs**	No[5]	Yes	link
			For my research unit, I regularly perform spot checks on security of storage of data records and make sure that the data records are stored in an un-editable format	No	Yes	

[2] It is expected here that the requirement is met by availability of a research integrity policy of the parent organization, an intranet site that presents the research integrity office, officer or the policy, a set of slides used in research integrity training, and/or a summary provided to all employees

[3] Not beyond the training documentation itself

[4] For a Quality System, it is expected that a separate documentation is established describing data handling practices. For a purpose-fit assessment, such data handling practices can be part of study plans or protocols for experimental methods

[5] Same as above

8	Required	Required	**Reported research outcomes must be traceable to experimental data**	No[6]	Yes	link
			Every study is assigned a unique ID	No	Yes	
9	Required	Required	**Reported data must disclose all repetitions of the test regardless of the outcome**	No	To some extent	link
			For my research unit, I ensure that all repetitions are reported and conduct spot checks on reported studies	No	No	
10	Required	Strongly recommended	**Investigator must declare in advance whether a study is intended to inform a formal knowledge claim**	No	Yes	link
			All study plans in my research unit clearly indicate when studies are intended to inform a formal knowledge claim	No	Yes	
			I regularly conduct spot checks of the completed studies	No	No	
			The following applies to all knowledge-claiming studies:			
			• Study (experimental) plan must be defined and documented before starting the experiments			
			• Study hypothesis must be pre-specified			
			• Blinding should be implemented, exceptions must be justified and documented			
			• Randomization should be implemented, exceptions must be justified and documented			
			• Sample size and power analysis must be defined and documented before starting the experiments (e.g. included in the study plan)			
			• Data analysis must be defined and documented before starting the experiments (e.g. as a			

[6] Same as above

			formal statistical analysis plan and/or included in the study plan)			
			• Inclusion and exclusion criteria must be defined and documented before starting the experiments (e.g. included in the study plan)			
			• Deviations from study (experimental) plan must be documented			
			• Pre-registration should be implemented			
11	Required	Required	**All personnel involved in research must have adequate training and competence to perform assigned tasks**	No	Yes	link
			To the best of my knowledge, all legally required / mandatory training is provided and is properly documented	No[7]	Yes	
			For training other than legally required, I have reviewed the need, set the content and ensured the compliance and documentation	No[8]	Yes	
			I make sure that all members of my research unit received training on what is considered to be raw data and how to record and handle data	No	Yes	
			My research unit has a dedicated training program for the new members	No	Yes	
12	Required	Required	**Protocols for experimental methods must be available**	No[9]	Yes	link
			For all experimental (research) methods, I conduct spot checks to make sure that my research unit has up-to-date protocols	No	No	

[7] Not beyond training documentation itself
[8] Same as above
[9] Not beyond protocols themself

			in electronic or paper form and these protocols are fully accessible to members of my research unit			
13	Required	Required	**Adequate handling and storage of samples and materials must be ensured**	No[10]	Yes	link
			Internal spot checks are conducted regularly	No	No	
			I regularly discuss with members of my research unit importance of adequate handling and storage of samples and materials	No	Yes	
14	Required	Required	**Research equipment and tools must be suitable for intended use and ensure data integrity**	No	Yes	link
			Protocols of experimental methods clearly state whether calibration is needed and, if yes, describe the procedure	No[11]	Yes	
			My research unit has a process in place that ensures adequate maintenance of the research equipment and tools and I conduct regular spot checks	No	Yes	
15	Required	Strongly recommended	**Risk assessment must be performed to identify factors affecting the generation, processing and reporting of research data**	No	Yes	link
			All study plans in my research unit include a risk assessment section and I have regularly conducted spot checks of the completed studies	No[12]	Yes	
			My research unit follows practices recommended by EQIPD	Yes[13]	Yes	

[10] Although there is a general requirement to have
[11] Not beyond protocols themself
[12] Not beyond study plans themselves
[13] In case of deviations only

			(deviations from strongly recommended practices are justified and documented)			
16	Required	Strongly recommended	**Critical incidents and errors during study conduct must be analyzed and appropriately managed**	No[14]	Yes	link
			Members of my research unit are aware of the internal process for analyzing, recording and dealing with the errors and critical incidents	No	Yes	
			I regularly check documentation of critical incidents and errors in the laboratory notebooks	No	No	
			Management of critical incidents and errors is part of the training received by new members of my research unit	No	Yes	
17	Required	n/a	**An approach must be in place to monitor the performance of the EQIPD Quality System, and address identified issues**	No	Yes	link
			Self-assessment is conducted according to the pre-defined frequency	Yes	Yes	
			With the help of the EQIPD Quality System, my research unit reaches its self-defined quality goals and objectives	No	Yes	
			I conduct spot checks of the completed studies for potential issues	No	Yes	
18	Required	n/a	**Resources for sustaining the EQIPD Quality System must be available**	No	Yes	link
	(Note: Lack of resources is not an acceptable argument for not following the best research practices)					

[14] Not beyond documention of errors