Structured project templates with integrated responsible research & innovation (RRI) and open sciences (OS) criteria and corresponding assessment aids for reviewers for (intramural) research funding lines at Charité and BIH

Working paper – currently updated

- Currently in internal revision and update

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Background

The aim of the structed project templates with corresponding assessment guidelines is to support quality-oriented research assessment and to increase fairness and robustness of the selection process of projects for (intramural) funding.

In terms of binding award procedures, it is crucial that concrete measures are aligned with the principles of good assessment practice.

The five relevant principles are (the principles have been derived from the literature and are a deliverable of the WT MERIT project):

Transparency: Transparency refers to a) the traceability of the procedures externally (applicants) and internally (reviewers) and b) the explicit communication of the objectives, target values and applied criteria. Transparency increases the fairness of the procedures and the justifiability of the selection decision. Transparency is a basic prerequisite for reliable and meaningful procedures and a fair competition.

Openness: Openness refers to inclusive strategies towards new topics and fields of research, individual biographies and professional careers, origin, gender and a changing concept of excellence. Openness means engaging with a dynamic science and society without bias.

Fairness: Fairness relates primarily to how the assessment is carried out. Strategies to reduce the risk of (unconscious) bias, diverse selection committees and the consistent avoidance of conflict of interests are measures that, in addition to generally ensuring a level framework conditions for all applicants, help to achieve an unbiased view of the applicants' performance and the quality of their work. Fairness in assessment is the basic prerequisite for selecting the best.

Commitment: Commitment refers to the fact that specific measures and processes are bindingly aligned with the aforementioned principles. They must also be supported by a common will and basic understanding. This operationalization should be made explicit and communicated transparently. This creates a basis that, on the one hand, makes it possible to contribute to the discourse and further development of the concept of excellence in science and, on the other hand, holds the institution accountable. Both aspects are crucial for

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functioning self-regulation in academia and therefore make an important contribution to academic self-governance.

Appropriateness: Appropriateness refers to a) the selection of quality-oriented and suitable assessment criteria and objectives and b) a suitable, accessible compilation of the application documents (basis for assessment), which presents the assessment criteria requested from the applicants in a comprehensible and comparative manner.

The implementation of the principles in the usual procedural steps in the evaluation of project applications shows section **Principles of good assessment practice (table 1).**

In addition to the selection of appropriate assessment criteria, structured assessment aids help to increase the informative value and transparency of the assessments. Open feedback of the assessments to the applicants increases the reliability and quality of the assessment (open peer review). Also, the transfer of knowledge between applicants and assessors is promoted (see **overview of criteria and structured assessment aids**).

Qualitative assessment (e.g. strong - medium - weak) is to be preferred in order to avoid a false sense of accuracy and objectivity, as is the case with numerical grading. Also, rankings of applications and cut-offs based on vague (numerical) grading should be avoided during decision-making. Instead strengthen and facilitate reflexive content-oriented peer review through structured procedures and strategies to reduce risk of bias (i.e. partial anonymization of applications, diverse composition of boards etc..)

The assessment criteria relate to the important project phases in biomedical research. They were derived from the relevant literature, textbooks and recommendations from international and national funding bodies **(see methods and literature section)**. The project team included a biostatistician.

With reference to the above principles, quality-oriented (robustness and transparency) evaluation criteria (so-called QUEST criteria) and evaluation procedures with structured evaluation aids have been jointly integrated and checked for feasibility into the procedures with over 6 funding lines (MERIT IMF project). Between 2018 and 2022 the project templates were used in n= 556 applications and n=158 applications reviewer used the assessment aides and provided open feedback to the applicants (open peer review) (status 2022). Currently the MERIT structured project templates or adaptations of it and corresponding assessments aids including open peer review are standard practice in n= ?? funding lines at I and Charité.

> **Kommentiert [KM1]:** update

> **Kommentiert [KM2]:** Numbers are currently updated

The implementation and use of structured project templates ("QUEST criteria") has been evaluated in a time-series evaluation to analyze the feasibility, quality of applications, to identify knowledge gaps and the potential impact on decision making and selection before and after including structured assessment aids.

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Principles of good assessment practice

Principles of good assessment practice and their implementation for the assessment of project proposals in the context of intramural funding lines

GERMAN ONLY

| Verfahrensschritt	Umsetzung	Grundsatz
Ausschreibung	• **Festlegung von Ausrichtung und Zielvorstellungen** der Ausschreibung	Verbindlichkeit
	○ **Beachtung neuer Themen**, oder gesellschaftlich relevanten Themen oder sog. Randthemen wie z.B. die Erforschung von seltenen Erkrankungen, oder Erkrankungen und Gesundheit innerhalb marginalisierter Bevölkerungsgruppen	Offenheit
	○ **Bezug zur Mission** des BIH herstellen	Verbindlichkeit, Angemessenheit
	• **Explizite und konkrete Kommunikation von Ausrichtung und Zielvorstellungen** der Förderlinie nach außen (Bewerber*innen) und innen (Kommissionsmitglieder)	Transparenz
	• **Expliziten Bezug zur Mission** des BIH herstellen	Transparenz
	• **Explizite und konkrete Benennung aller angelegten Bewertungskriterien und Indikatoren und ihre Rationale** nach außen (Bewerber*innen) und innen (Kommissionsmitglieder)	Transparenz
	• Gender-neutrale Sprache verwenden	Offenheit
	• Je nach Ausschreibung breite versus gezielte Verbreitung abwägen	Offenheit
Bewertungskriterien/ Indikatoren	• A priori Festlegung der **Bewertungskriterien und Indikatoren und ihre Rationale** mit Bezug zu Ausschreibung	Verbindlichkeit
	• **Auswahl wissenschafts-adäquater** und zielführender **Bewertungskriterien/Indikatoren** unter Beachtung ihrer Limitationen	Angemessenheit
		Angemessenheit

	• **Auswahl qualitäts-orientierter Bewertungskriterien/Indikatoren** (siehe Beispiele aus dem CSP im Anhang)	
Angeforderte Unterlagen	• **Strukturierte** Projekttemplates mit konkreten Angaben und expliziter Abfrage der qualitäts-orientierten Bewertungskriterien	Fairness, Verbindlichkeit
	• **Umfang** begrenzen auf Informationen, die für die Projektbewertung und Auswahl tatsächlich benötigt werden	Angemessenheit
Zusammensetzung der Kommission/des Boards/Auswahl der Gutachter*innen	• **Qualifizierte und unabhängige** Kommissionsmitglieder identifizieren	Fairness
	• **Diverse Zusammensetzung** anstreben hinsichtlich Gender, Nationalität, beruflichem Hintergrund (Berücksichtigung von Expert*innen aus der akademischen, und nicht-akademischen Forschung, Vertreter*innen aus dem privaten Sektor, und anderen relevanten Gesundheitssektoren), Forschungsschwerpunkte (z.B. Grundlagen-, klinische und Versorgungsforschung)	Offenheit, Fairness
	• **Festlegung und Ausschluss Interessenskonflikten/Befangenheiten** (Kommissionsmitglieder mit Befangenheiten können NICHT teilnehmen, auch nicht beratend)	Fairness, Verbindlichkeit
Auswahl und Bewertung der Anträge	• **Projektanträge anonymisieren** (soweit wie möglich (mindestens für die Vorauswahl)	Fairness
	• Bewertung ausschließlich nach den vorher festgelegten und kommunizierten Bewertungskriterien und Indikatoren	Fairness, Verbindlichkeit
	• Berücksichtigung des **akademischen Alters**	Fairness
	• **Strukturierte Bewertungshilfen** mit direktem Bezug zu den Bewertungskriterien/ Indikatoren und Zielen aus Ausschreibung und dem Projekttemplate verwenden inklusive strukturiertem Feedbackfeld (Begründung der Bewertung)	Verbindlichkeit, Angemessenheit
	• **Feedback** der vorgenommenen Bewertungen durch die Gutachter*innen **inklusive ihrer Begründung** als Narrativ an alle Bewerber*innen	Verbindlichkeit, Transparenz

	• Qualitative Bewertungen (z.B. stark – mittel – schwach) bevorzugen, um Scheingenauigkeit und Scheinobjektivität wie bei Benotungen durch Zahlen zu vermeiden	Angemessenheit
	• Getrennte Bewertung je Kriterium, um differenzierte Bewertung abzubilden	Angemessenheit
	• Visualisierung der Bewertungen als Heatmaps, als Entscheidungsgrundlage, Rankings vermeiden	Angemessenheit
	• Anzahl der Bewerbungen auf 5 pro Gutachter*in begrenzen und 3 Gutachten pro Bewerbung sicherstellen	Angemessenheit, Verbindlichkeit
Umgang mit (unconscious) Bias	• Kurzintervention vor und während eines jeden Verfahrens mit allen Boardmitgliedern/Gutachter*innen • Unabhängiger Besitz und Beratung durch eine(n) Good Evaluation Practice Officers (ohne Stimmrecht)	Fairness
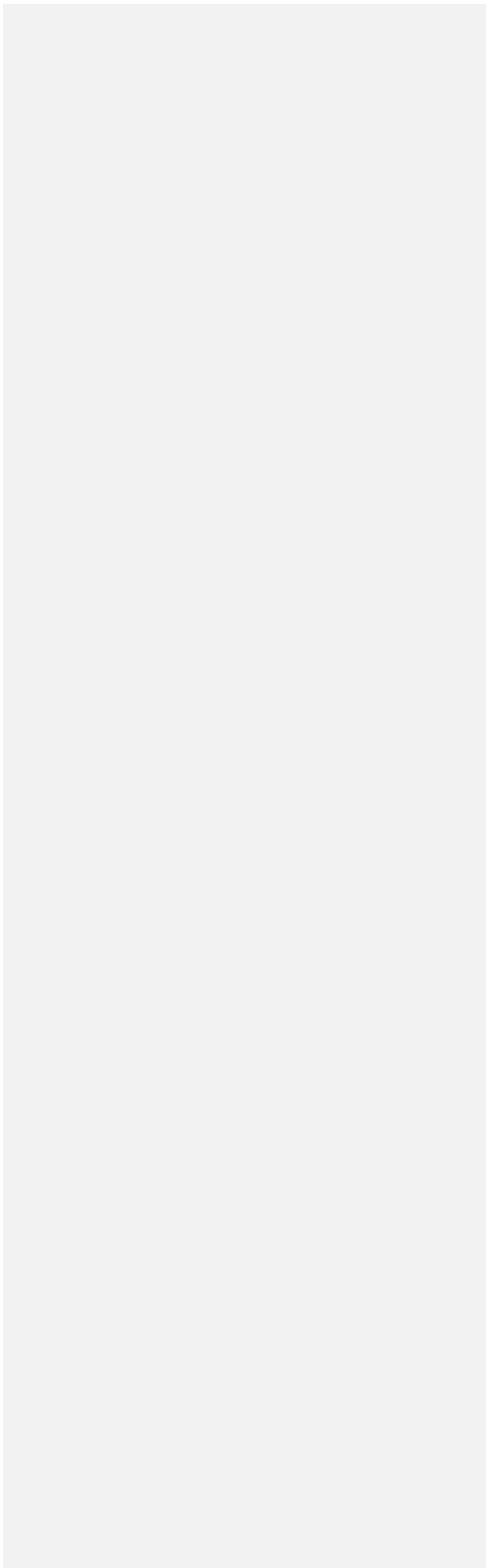
Overview of criteria and examples for operationalization

1. Derivation of the research question

1.1. Example 1

A: Directions for the Applicant

In this section, summarize how you systematically reviewed already existing evidence (e.g. literature, data, expert opinions, registries etc.) regarding your research question and how you took such results into account when devising your research question.

If your research question is based on unpublished data (e.g., data collected as part of a validation study) or expert/stakeholder opinions, explain how you used the available data/evidence to devise your research question.

Based on the previous points, identify the knowledge gap and/or unmet (medical) need that your research question aims to address.

Discuss risk of bias in previous studies/evidence and how this informs your proposed project. In case you are planning an animal study, discuss "Replacement" in the framework of the 3R principle.

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B: Structured assessment guidelines for the Reviewer

Derivation of the research question, originality and unmet (medical) need
Excerpt of the project template:
In this section, please summarize how you systematically reviewed already existing evidence (e.g. literature, data, expert opinions, registries etc.) regarding your research question and how you took such results into account when devising your research question. If your research question is based on unpublished data (e.g., data collected as part of a validation study) or expert/stakeholder opinions, explain how you used the available data/evidence to devise your research question. Based on the previous points, identify the knowledge gap and/or unmet (medical) need that your research question aims to address. Discuss the risk of bias in previous studies/evidence and how this informs your proposed project. In case you are planning an animal study, discuss "Replacement" in the framework of the 3R principle.

Reviewer assessment (open peer review) *Mandatory field, this information will be communicated to the applicant.*	strong ☐ middle ☐ weak ☐

Feedback to the applicant (narrative) regarding the derivation of the research question and originality: *Mandatory field, this information will be communicated to the applicant.*	**The following items are suggestions you might consider for your evaluation.** • Systematic review of existing evidence (e.g. according to PICOS scheme or alternatives for animal/cell studies) • Multiple data sources applied • Results considered when devising research question • Transparent display and discussion of expert stakeholder opinion and/or unpublished data • Knowledge gap identified • Unmet (medical) need identified • Risk of bias in previous studies/evidence discussed • For animal studies: 3R principle "Replacement" discussed

1.2. Example 2

A: Directions for the Applicant

Describe the unmet (medical) need that your project addresses and explain your focus on sex/gender aspects. How does your research question relate to the BIH mission (focus areas, platforms)? Please place your project in a section/phase of the translation chain.

> a. Make sure that your question is as clear, systematic and comprehensible as possible. Only projects with a clear reference to the mission of the BIH and a focus on sex and gender aspects can be funded.

B: Structured assessment guidelines for the Reviewer

Unmet (medical) need, BIH mission, translational chain		
Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	strong ☐ middle ☐ weak ☐	
	The following criteria are suggestions you might consider for your evaluation.	

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Feedback to the applicant (narrative) regarding unmet (medical) need, BIH mission *Mandatory field, this information will be communicated to the applicant.*	• Systematic and comprehensive derivation of the unmet (medical) need • Reference to the mission of the BIH • Placement in a section/phase of the translation chain

2. Status of the project, translational state, fit for organizational mission

A: For the Applicant

Describe the phase your project is in, e.g. what preparatory work has already been done and what work is due in the next few months. Place your project a long the translational chain. Describe how your project relates to the BIH mission.

B: For the Reviewer

Status of the project, translational state, fir for the organizational mission			
Excerpt of the template: Describe the phase your project is in, e.g. what preparatory work has already been done and what work is due in the next few months. Place your project along the translational chain. Describe how your project relates to the BIH , Charité or programs mission.			
Reviewer evaluation *Mandatory field, information will be communicated to the applicant.*	**strong** ☐	**middle** ☐	**weak** ☐
Feedback to the applicant (narrative) regarding the detailed description of the study design, setting and methods: *Mandatory field, this information will be communicated to the applican*	**The following items are suggestions you might consider for your evaluation.** • Translational state • Fit for BIH or Charité or programs mission?		

3. Detailed description of the study design, setting and methods, strategies to reduce risk of bias
   3.1. Example 1

A: For the Applicant

Describe as specifically as possible the research question, study design and setting of your research project.

Please specify if your research project is:

a)   Hypothesis-generating/explorative

b)   Hypothesis-testing/confirmatory

c)   Using quantitative or qualitative or both methods (mixed-methods) or

d)   If you cannot place your project to one of the options a) or b), describe it in your own words.

Describe the hypotheses or general assumptions underlying your research question (whatever is applicable to your specific project).

Describe primary and secondary outcome measures and endpoints as well as possible confounders (if applicable).

Concentrating on the main points, provide a detailed overview of the strategies for reducing the risk of bias that you will use for your specific project, e.g. for randomized studies, blinding (after allocation to groups) is a strategy to reduce the risk of detection bias.

Integrate gender aspects (humans) and sex as a biological variable (cells, animals, humans) in the specific project context and explain strategies to reduce risk of bias.

Provide a short overview of how you plan your (statistical) analyses, e.g., „We will use a logistic regression analysis with X as dependent and Y as independent variable. We will adjust for confounder Z"; "We will report adjusted p-values and confidence intervals"

Briefly discuss sample size calculation and its realization, effect estimates etc.

B: Structured assessment guidelines for the Reviewer

Detailed description of the study design, setting and methods
Excerpt of the template:
Describe as specifically as possible the study design and setting of your research project. Please specify if your research project is: a) Hypothesis-generating/explorative b) Hypothesis-testing/confirmatory c) Using quantitative or qualitative or both methods (mixed-methods) or d) If you cannot place your project to one of the options a) or b), describe it in your own words. Describe the hypotheses or general assumptions underlying your research question (whatever is applicable to your specific project). Describe primary and secondary outcome measures and endpoints as well as possible confounders (if applicable). Concentrating on the main points, provide a detailed overview of the strategies for reducing the risk of bias that you will use for your specific project, e.g. for randomized studies, blinding (after allocation to groups) is a strategy to reduce the risk of detection bias. Integrate gender aspects (humans) and sex as a biological variable (cells, animals, humans) in the specific project context. Provide a short overview of how you plan your (statistical) analyses, e.g., „We will use a logistic regression analysis with X as dependent and Y as independent variable. We will adjust for confounder Z"; "We will report adjusted p-values and confidence intervals". Briefly discuss sample size calculation and its realization, effect estimates etc.

Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	**strong** ☐ **middle** ☐ **weak** ☐

Feedback to the applicant (narrative) regarding the detailed description of the study design, setting and methods:
Mandatory field, this information will be communicated to the applicant.
	The following items are suggestions you might consider for your evaluation.
	
	• Research question including study design and setting described
	
	• Characterization of the project as hypothesis-generating/explorative, hypothesis-testing/confirmatory or other
	
	• Hypotheses or general assumptions described
	
	• Outcome measures, endpoints, confounders described
	
	• Strategies for reducing the risk of bias provided, e.g.
	  1. for randomized studies before allocation to groups
	  2. for randomized studies after allocation to groups
	  3. for non-randomized studies
	  4. for qualitative studies
	
	• Discussed gender/sex considerations
	
	• Overview of a (statistical) analyses plan provided
	
	• Discussion of sample size calculation, realization, and effect estimates

Strategies to reduce the risk of bias with special focus on sex and gender aspects	
Reviewer assessment *Mandatory field, information will be communicated to the applicant.* strong ☐ middle ☐ weak ☐	
Feedback to the applicant (narrative) regarding strategies to reduce the risk of bias with special focus on sex and gender aspects *Mandatory field, this information will be communicated to the applicant.*	**The following criteria are suggestions you might consider for your evaluation.** • Consideration(s) of sex as a biological variable and/or gender aspects • Strategies to reduce the risk of bias was given

3.2. Example 2

A: For the Applicant

Explain the hypotheses or assumptions, methods and statistical planning of the study.

    a. Describe the setting of your project in concrete terms.

        i. Is a study planned vs. an experiment?

        ii. In vitro, in vivo, in humans, other

        iii. How many and which groups do you plan to examine?

        iv. How many individuals (experiments, other experimental units) do you plan to examine?

B: For the Reviewer

Details of the research project: hypotheses, design, methods and statistical planning	
Reviewer assessment *Mandatory field, information will be communicated to the applicant.* strong ☐ middle ☐ weak ☐	
Feedback to the applicant (narrative) regarding hypotheses, design, methods and statistical planning *Mandatory field, this information will be communicated to the applicant.*	**The following items are suggestions you might consider for your evaluation.** • Description of research questions including study design and setting, e.g. clearly formulated in as concrete and quantifiable terms as possible • Comprehensive build-up of research question(s) study design(s) and setting(s) • Characterization of proposed study/studies (hypothesis generating/explorative, hypothesis testing/confirmatory or other) • Description of hypotheses or assumptions • Description of primary and secondary outcomes and possible confounders • Description of methods • Details of the sample size, feasibility of the sample size, and effect estimates • Plan for the statistical analysis was outlined

4. Open Science, data sharing, research data management /Transparency and dissemination of results

A: For the Applicant

Briefly describe strategies for transparency of your research project and for the dissemination of your results (expected and unexpected results). Include an open science and/or data sharing strategy to the scientific community as well as a research data management plan.

B: For the Reviewer

Open Science, data sharing, research data management
Excerpt of the template: Please briefly describe strategies for transparency of your research project and for the dissemination of your results. Include an open science and/or data sharing strategy to the scientific community as well as a research data management plan.

Reviewer Assessment *Mandatory field, this information will be communicated to the applicant.*	**strong** ☐ **middle** ☐ **weak** ☐
Feedback to the applicant (narrative) regarding open science, data sharing, research data management: *Mandatory field, this information will be communicated to the applicant.*	**The following items are suggestions you might consider for your evaluation.** • Strategy for transparency of the presented study design, methods and results (e.g. preregistration study protocol, open data, open code) • Transparent reporting of all expected and unexpected results • Presented data sharing strategy • Open science strategy to the patients/public presented, e.g. lay persons summary results • Presented research data management plan • Reporting guidelines • Reproducible reporting of all data points and their distribution in graphs • Timely publication of all results

5. Patient and Stakeholder engagement

A: For the Applicant

Active involvement of patients and other stakeholders can increase the relevance and benefit of research for the affected patient groups and other interest groups. In the following section, explain how and where you plan to actively involve stakeholders in your research project e.g. derivation of the research question, study design etc...
If the involvement of relevant interest groups plays no role in your research project, briefly explain why.

B: For the Reviewer

Patient and Stakeholder Engagement
Excerpt of the project template:
Active involvement of patients and other stakeholders can increase the relevance and benefit of research for the affected patient groups and other interest groups. In the following section, explain how and where you plan to actively involve stakeholders in your research project e.g. in the planning phase, derivation of the research question, study design, defining relevant outcome parameters etc... Please describe the level of involvement e.g. (no participation - consultation - cooperation - equal cooperation - control/initiation). If the involvement of relevant interest groups plays no role in your research project, briefly explain why.

Reviewer evaluation *Mandatory field, this information will be communicated to the applicant.*	strong ☐	middle ☐	weak ☐

Feedback to the applicant (narrative) regarding the patient and stakeholder engagement of the research project: *Mandatory field, this information will be communicated to the applicant*	**The following items are suggestions you might consider for your evaluation.**
	In summary, how would you rate the strength of participation and the assumed influence of the stakeholders on the research process – if applicable? - Identification of research questions - Planning and design - Data collection, conduct of the study - Analyses and interpretation or results - Dissemination - Implementation - Evaluation - Phase(s) not mentioned here, if applicable:

6. Project partner and collaborations

A: For the Applicant

Please briefly describe how the partnership between you and your cooperation partner at BIH looks like and how it contributes to the success of the research project.

B: For the Reviewer

6. Project partner

Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	strong ☐	middle ☐	weak ☐

Feedback to the applicant (narrative) regarding impact narrative *Mandatory field, this information will be communicated to the applicant.*	**The following criteria are suggestions you might consider for your evaluation.**
	Description of partnership between applicant and cooperation partner and its contribution to the success of the research project

Transparenz — Verbindlichkeit — Offenheit — Fairness — Angemessenheit

7. Innovative potential of the research project

A: For the Applicant

Based on points I-III, briefly describe in this section how you think your project contributes to the further development of, for example, mechanisms, methods, processes, diagnostics, therapies or health services in the field in which your project takes place. Possible criteria to assess the innovation of a project are integration or use of new technologies, participatory and interdisciplinary projects or the extent to which the project explores a new approach to address an unsolved question or unmet research or medical need. Answer this question as specifically (project- and field-related) as possible.

B: For the Reviewer

Innovative potential of the research project
Excerpt of the project template:
Based on points I-III, please briefly describe in this section how you think your project contributes to the further development of, for example, mechanisms, methods, processes, diagnostics, therapies or health services in the field in which the project takes place. Possible criteria to assess the innovation character of a project are integration or use of new technologies, participatory and interdisciplinary projects, or the extent to which the project explores a new approach to address an unsolved question or unmet research or medical need. Answer this question as specifically (project- and field-related) as possible.

Reviewer Assessment *Mandatory field, this information will be communicated to the applicant.*	strong ☐ middle ☐ weak ☐
Feedback to the applicant (narrative) regarding the innovative potential of the research project: *Mandatory field, this information will be communicated to the applicant.*	**The following items are suggestions you might consider for your evaluation.** • The project explores a new approach to address an unsolved question/unmet research or medical need • The project uses new or integrates new technologies, procedures, methods etc. • The project is participatory, i.e. includes different important stakeholders such as patient organizations, other researchers who might use the results later, etc. • The project is interdisciplinary and/or intersectoral

8. Milestones und timetable for the research project

A: For the Applicant

Make sure that the activities that you discussed in your project proposal are also considered adequately in this section.

B: For the Reviewer

Milestones and timetable for the research project (Item XI project template)
Excerpt of the project template:
Make sure that the activities that you discussed in your project proposal are also considered adequately in this section.

Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	strong ☐ middle ☐ weak ☐

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Feedback to the applicant (narrative) regarding milestones and timetable for the research project: *Mandatory field, this information will be communicated to the applicant*	**The following items are suggestions you might consider for your evaluation.** • Feasibility of the project • Contribution of the applicant to the project • Are all relevant work packages considered in the milestones and timetable?

9. Use of funds

A: For the Applicant

Please provide specific information on how you plan to use the funding in personnel and consumables during the funding period. Please give a brief overview about work packages and milestones during the funding period and the estimated costs.

B: For the Reviewer

Use of funds Excerpt of the project template:		
Please provide specific information on how you plan to use the funding in personnel and consumables during the funding period. Please give a brief overview about work packages and milestones during the funding period and the estimated costs.		
Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	**strong** ☐	**middle** ☐ **weak** ☐
Feedback to the applicant (narrative) regarding use of funds *Mandatory field, this information will be communicated to the applicant.*	**The following criteria are suggestions you might consider for your evaluation.** • Description of the use of funds • Description of contribution of the fund to a relief in the project • Feasibility	

10. Assessment of the applicant`s contribution to the project

A: For the applicant

Please describe your own contribution to the writing of the project proposal and your planned role and task during the project duration. Describe your own role in balance with the collaborative nature of the project and in alignment with your competencies and qualifications.

B: For the reviewer

Applicants contribution to the project Excerpt of the project template:
Please describe your own contribution to the writing of the project proposal and your planned role and task during the project duration. Describe your own role in balance with the collaborative nature of the project and in alignment with your competencies and qualifications.

Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	**strong** ☐	**middle** ☐	**weak** ☐	

Feedback to the applicant (narrative) regarding use of funds *Mandatory field, this information will be communicated to the applicant.*	**The following criteria are suggestions you might consider for your evaluation.**
	• Description matches assumed competences and qualifications • The assumed own contribution is in balance with the team science and the collaborative nature of the project

11. Assessment of the applicants track record

11.1. Impact Narrative

A: For the Applicant

Describe briefly what you consider to be the most significant scientific contribution you have made so far.

B: For the Reviewer

Impact Narrative
Excerpt of the project template:
Describe briefly what you consider to be the most significant scientific contribution you have made so far.

Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	**strong** ☐	**middle** ☐	**weak** ☐	

Feedback to the applicant (narrative) regarding impact narrative *Mandatory field, this information will be communicated to the applicant.*	**The following criteria are suggestions you might consider for your evaluation.**
	• Statement is reproducible and substantiated (see e.g. Top 5 publications) • Methodological soundness • Soundness of reporting • Relevance to stakeholders and interest groups • Potential • Assumed motivation, mindset • Humbleness, realistic account of own contribution

11.2. TOP 5 publications

A: For the Applicant

Please list up to 5 of your most important scientific publications. In addition to journal articles, you can also list other relevant research output such as data publications, reports, or policies etc. here. Under "impact of the work", describe the influence that this work has had on e.g. healthcare, science, teaching or society, and under "Own contribution", describe what contribution you have made to the work (regardless of your author position).

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The reviewers will have the opportunity to view the original work via the DOI. The evaluation of the quality of your previous scientific work takes place at this point.

1
Titel
DOI
Impact

500 Zeichen (inkl. Leerzeichen)

Own contribution

500 characters including spaces

B: Assessment of full text article to substantiate impact story

Top 5 publications
Excerpt of the project template

Please list up to 5 of your most important scientific publications. In addition to journal articles, you can also list other relevant research output such as data publications, reports, or policies etc. here. Under "impact of the work", describe the influence that this work has had on e.g. healthcare, science, teaching or society, and under "Own contribution", describe what contribution you have made to the work (regardless of your author position). The reviewers will have the opportunity to view the original work via the DOI. The evaluation of the quality of your previous scientific work takes place at this point.

Reviewer assessment *Mandatory field, information will be communicated to the applicant.*	**strong** ☐ **middle** ☐ **weak** ☐
Feedback to the applicant (narrative) regarding impact narrative *Mandatory field, this information will be communicated to the applicant.*	**The following criteria are suggestions you might consider for your evaluation.**
	e.g. • Soundness of research question • Methodological soundness • Soundness of reporting • Abstract and fulltext are concordant • Informative and usable for future research

Methods

Derivation of criteria

"QUEST" – criteria – broader topics

- Priority setting/Derivation of the research question
- Strategies of scientific rigour/robustness
- Transparency and dissemination of results – Open Science, data sharing
- Participation/Patient and stakeholder engagement
- Innovation

Literature base (manual search)
Internal documents Charité: (Fakultätsrat, 2020, Promotionsbüro, 2021, Promotionsbüro, 2019, Charité, 2020, Charité3R, 2021, BIH@Charité, 2021, Charité, 2021)
National organisations, societies and funding bodies: (BfArM, 2019, Cochrane-Deutschland, 2021, DFG, 2019, IQWIQ, 2020, AWMF, 2021, ÄZQ, 2021, GBA, 2021, BMBF, 2020)
International organisations, societies and funding bodies (CIOMS, 2016, EMA, 2014, EU, 2014, EU, 2020, European Commission, 2005, European Science Foundation, 2011, European-Commission, 2013, European-Commission, 2014, European-Commission, 2016, ICMJE, 2019, Lindsey et al., 2018, Ludolph et al., 2010, National Academies of Sciences, 2019, National Academies of Sciences, 2020, NHS, 2018, NHS-Digital, 2020, NIDCD, 2018, NIH, 2016, NIH, 2017, NIH, 2018a, NIH, 2018c, NIH, 2018b, NIH, 2019c, NIH, 2019a, NIH, 2019b, NIH, 2020, NIH, 2021, NIHR, 2021, NIMH, 2021, O'Brien et al., 2014, Schulz et al., 2010, Smith et al., 2018, Schünemann et al., 2015, Bossuyt et al., 2015, von Elm et al., 2007, Moher et al., 2020, Brouwers et al., 2016, Chan et al., 2013, DGEpi, 2018, Moher et al., 2009)
Literature: Lancet series 2014 (Chalmers et al., 2014b, Chan et al., 2014, Glasziou et al., 2014, Ioannidis et al., 2014, Al-Shahi Salman et al., 2014, Moher et al., 2016),

Concretisation of criteria[2]:

1. **Priority setting / "derivation of the research question"**
Systematic and comprehensive review of evidence, assessment of the evidence available, the research question accordingly and unambiguously devised etc. (European-Commission, 2013, Bossuyt et al., 2015, DFG, 2019, Percie du Sert et al., 2020, Schulz et al., 2010, NIH, 2021, Chalmers et al., 2014b, NIH, 2019c, NIDCD, 2018, CIOMS, 2016, Lapchak, 2012, Cohen, 2018, European Science Foundation, 2011, DFG, 2020, BMBF, 2020, GBA, 2021, Chan et al., 2013, Moher et al., 2009, NIHR, 2021, Yanagawa et al., 2018, IQWIQ, 2020, DGEpi, 2018, Hoffmann et al., 2005)

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[2] Scoping search: literature searches are currently updated, non-systematic initial searches were performed 2019 – 2021 and manually updated. Database: Dimensions database (4.1.2021): Systematic literature search of publications of biomedical research in the Dimensions data base (2011-2021, "biomedical '(robust* OR rigour OR rigor OR bias*) AND strateg* AND (research OR method* OR science* OR scientific* (refer to Metho) 128 Hits, after checking for eligibility 26 paper found and 17 papers considered as relevant for strategies of robust and transparent research: Database Pubmed: 2020 Pub med search string #Research AND (robust OR reproducible OR responsible OR translational) AND guideline (10.6.20 11:45), the first 12 publications (, sorted by best match next to one guideline. Database: textbooks.

Consideration of unpublished data (Al-Shahi Salman et al., 2014, Chan et al., 2014, Glasziou et al., 2014, Moher et al., 2020, Chan et al., 2013, Li T, 2020, Swaen et al., 2018, Wild et al., 2005, Yanagawa et al., 2018, IQWIQ, 2020, CIOMS, 2016, Moher et al., 2016, McKenzie et al., 2021).
Assessment of bias in previous research (Boutron I, 2020, Chalmers et al., 2014b, Higgins JPT, 2020, Ioannidis et al., 2014, Schmucker C, 2016, Brouwers et al., 2016, Yanagawa et al., 2018, IQWIQ, 2020)
In animal experiments: consideration of 3R-Principle "Replacement" considered (Smith et al., 2018, Brown, 2012, Charité3R, 2021, Harte-Hargrove et al., 2017, Ludolph et al., 2010, Percie du Sert et al., 2020)
Possible benefit for patients or society discussed when devising the research question (Chalmers et al., 2014a)
2. **Strategies of scientific rigor**
Description of study design, setting and methods of research project. (Schulz et al., 2010, DFG, 2019, Percie du Sert et al., 2020, von Elm et al., 2007, Lindsey et al., 2018, O'Brien et al., 2014, Lapchak, 2012, Bossuyt et al., 2015, Smith et al., 2018, NIH, 2021, Ioannidis et al., 2014, Strech et al., 2020, NIH, 2019c, Li T, 2020, NIDCD, 2018, NHS, 2018, NIH, 2019a, NIH, 2019b, NIH, 2018a, NIH, 2018c, NIH, 2018b, NIH, 2017, NIH, 2016, Cohen, 2018, European Science Foundation, 2011, CEBM, 2009, DFG, 2020, BMBF, 2020, Chan et al., 2014, Chan et al., 2013, Moher et al., 2009, NIHR, 2021, Yanagawa et al., 2018, DGEpi, 2018)
Specification of research approach: **exploratory or confirmatory** (Percie du Sert et al., 2020, Schulz et al., 2010, DGEpi, 2018, Hoffmann et al., 2005) or other, such as using **quantitative or qualitative** or **both methods** (mixed-methods (Schulz et al., 2010, O'Brien et al., 2014)
Hypotheses or general assumptions underlying the research question **addressed** (Schulz et al., 2010, O'Brien et al., 2014, Bossuyt et al., 2015, Lapchak, 2012, Smith et al., 2018, BMBF, 2020, Chan et al., 2013, Moher et al., 2009, Brouwers et al., 2016, Yanagawa et al., 2018)
Primary and secondary outcome measures and endpoints as well as possible confounders. (Schulz et al., 2010, Lindsey et al., 2018, Percie du Sert et al., 2020, Lapchak, 2012, Sparks et al., 2020, Bossuyt et al., 2015, Smith et al., 2018, NIH, 2019c, NIH, 2018c, NIH, 2018b, NIH, 2016, BMBF, 2020, Chan et al., 2014, Chan et al., 2013, Moher et al., 2009, Schmucker C, 2016, NIHR, 2021, Brouwers et al., 2016, Yanagawa et al., 2018, DGEpi, 2018, Hoffmann et al., 2005)
Risk of bias and /or external validity. (Schmucker C, 2016, Schulz et al., 2010, Percie du Sert et al., 2020, Lindsey et al., 2018, Lapchak, 2012, Sparks et al., 2020, Bossuyt et al., 2015, Boutron I, 2020, Higgins JPT, 2020, Ioannidis et al., 2014, Strech et al., 2020, NIH, 2016, Chan et al., 2014, Chan et al., 2013, Moher et al., 2009, Brown, 2012, Meyerholz and Beck, 2018, Wirkus et al., 2020, Brouwers et al., 2016, Yanagawa et al., 2018, DGEpi, 2018, Hoffmann et al., 2005, BMBF, 2020, AWMF, 2021, ÄZQ, 2021, Cochrane-Deutschland, 2021, IQWIQ, 2020)
Integration of gender/sex aspects in the specific project context (DFG, 2019, Potluri et al., 2017, NIH, 2021, NIH, 2019c, CIOMS, 2016, NIH, 2019b, NIH, 2018a, DFG, 2020, BMBF, 2020, Wirkus et al., 2020, Chan et al., 2014)
Overview of (statistical) analyses (Schulz et al., 2010, Percie du Sert et al., 2020, Lindsey et al., 2018, Lapchak, 2012, Bossuyt et al., 2015, NIH, 2017, DFG, 2020, Chan et al., 2013, Yanagawa et al., 2018, DGEpi, 2018, IQWIQ, 2020, Smith et al., 2018)
Sample size calculation and their realization, effect estimates etc. (Schulz et al., 2010, Lindsey et al., 2018, Lapchak, 2012, Bossuyt et al., 2015, Smith et al., 2018, GBA, 2021, McPartland et al., 2020, Medland et al., 2014, Wirkus et al., 2020, Chan et al., 2013, Moher et al., 2009, DGEpi, 2018, IQWIQ, 2020)
Application of standardized protocols (Wirkus et al., 2020, Brayton et al., 2018, Bregenzer et al., 2019, Brown, 2012, Chalmers et al., 2014b, Eggert and Hutmacher, 2019, Harte-Hargrove et al., 2017, Ji et al., 2017, La Salvia et al., 2020, Lapchak, 2012, Lindsey et al., 2018, McPartland et al., 2020, Medland et al., 2014, Meyerholz and Beck, 2018, Mothet et al., 2019, Nadeau and Auwerx, 2019, Pirisinu et al., 2020, Stripecke et al., 2020, Sweeney et al., 2017, Witwer and Halushka, 2016, Zeiss, 2017, Smith et al., 2018, NIH, 2019a, NIH, 2018a, NIH,

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2018c, NIH, 2018b, NIH, 2017, NIH, 2016, Cohen, 2018, DFG, 2020, Chan et al., 2014, Chan et al., 2013, Moher et al., 2009, NIHR, 2021, Boparai et al., 2018, Sousa and Rojjanasrirat, 2011, Wild et al., 2005, Moher et al., 2016, BMBF, 2020, Bossuyt et al., 2015, Brouwers et al., 2016, Ioannidis et al., 2014, Schulz et al., 2010, DFG, 2019)
„Reduction" / „Refinement": 3R-princples (Ludolph et al., 2010, Percie du Sert et al., 2020, Meyerholz and Beck, 2018, Lindsey et al., 2018, Harte-Hargrove et al., 2017, Zeiss, 2017, Brown, 2012, Smith et al., 2018, Ioannidis et al., 2014, Strech et al., 2020, DFG, 2020)   #Charité Dokumente, Charité-3R-Gutachterbogen)
Consideration of ethnicity, race (Wild et al., 2005, Sousa and Rojjanasrirat, 2011, CIOMS, 2016, DFG, 2019, NIDCD, 2018)
Consideration of cultural issues (Wild et al., 2005, Sousa and Rojjanasrirat, 2011, CIOMS, 2016, DFG, 2019, Walley et al., 2018, Boparai et al., 2018)
3. **Transparency and dissemination of results/open sciences data sharing**
Strategies for transparency:
(Pre)-registration of the study/project (Percie du Sert et al., 2020, NIH, 2021, Ioannidis et al., 2014, Strech et al., 2020, Glasziou et al., 2014, EMA, 2014, Cohen, 2018, DFG, 2020, BMBF, 2020, Chan et al., 2014, Moher et al., 2009, NIHR, 2021)
Availability of a study protocol (Percie du Sert et al., 2020, NIH, 2021, Ioannidis et al., 2014, Strech et al., 2020, Glasziou et al., 2014, European Science Foundation, 2011, DFG, 2020, Chan et al., 2014, Moher et al., 2009, Yanagawa et al., 2018, Bossuyt et al., 2015, Brouwers et al., 2016, Chan et al., 2013, Schulz et al., 2010)
Reporting guidelines (refer to 'Application of Standardized protocols')
Availability and/or reuse of raw data (open data), analysis protocols and codes (DFG, 2019, NIH, 2021, Ioannidis et al., 2014, Remick et al., 2019, Strech et al., 2020, Glasziou et al., 2014, NHS-Digital, 2020, NIH, 2017, EU, 2020, DFG, 2020, BMBF, 2020, Moher et al., 2009, NIHR, 2021, Moher et al., 2016)
Open access publications, open source (Percie du Sert et al., 2020, DFG, 2019, NIH, 2021, Ioannidis et al., 2014, Strech et al., 2020, BfArM, 2019, NIH, 2017, European-Commission, 2014, EU, 2020, DFG, 2020, BMBF, 2020)
Reporting of all data points and their distribution in graphs (Weissgerber et al., 2015)
Reporting of all results, including so-called null and unexpected results (Percie du Sert et al., 2020, DFG, 2019, NIH, 2021, Glasziou et al., 2014, Chan et al., 2014, BfArM, 2019, Brown, 2012, Cohen, 2018, BMBF, 2020, Moher et al., 2009)
Research data management plan (Chan et al., 2013, CIOMS, 2016, Strech et al., 2020, Swaen et al., 2018, Al-Shahi Salman et al., 2014, O'Brien et al., 2014, DGEpi, 2018)
Timely reporting (Chan et al., 2014, Chan et al., 2013, CIOMS, 2016, Glasziou et al., 2014, Walley et al., 2018, DGEpi, 2018)
Preprints (Strech et al., 2020)
Plain Language (CIOMS, 2016, Cochrane-Deutschland, 2021)
4. **Stakeholder engagement and participation**
How and in which stages of the research relevant stakeholders (e.g., study participants, patient organizations, funders, researchers etc.) will be **involved and contribute** to the project. (EU, 2014, DFG, 2019, Bundesregierung, 2017, ICMJE, 2019, Schünemann et al., 2015, CIOMS, 2016, European-Commission, 2014, European Science Foundation, 2011, European-Commission, 2016, EU, 2020, DFG, 2020, BMBF, 2020, GBA, 2021, Bossuyt et al., 2015, Brouwers et al., 2016, Chan et al., 2013, Moher et al., 2009, Schulz et al., 2010, NIMH, 2021, DGEpi, 2018)

5. Innovative potential
Innovative potential of the research project, new approach to address an unsolved question/unmet research or medical need described. (EU, 2014, European-Commission, 2013, BMBF (Federal Ministry of Education and Research), 2017, Bundesregierung, 2017, NHS, 2018, NIH, 2020, NIH, 2019a, NIH, 2019b, NIH, 2018a, NIH, 2018c, NIH, 2018b, NIH, 2017, NIH, 2016, European-Commission, 2014, EU, 2020, DFG, 2020, BMBF, 2020, GBA, 2021, Charité, 2020, Fakultätsrat, 2020, BIH@Charité, 2021)
6. Responsible research assessment practice and risk of bias
(European University Association [EUA] and European Sciences, 2022, Schmid, 2017, Moher et al., 2020, Zhang et al., 2017, Schekman and Patterson, 2013, San Francisco Declaration on Research Assessment, 2012, Benedictus et al., 2016, Larivière and Costas, 2016, Hicks et al., 2015, ACUMEN, 2014, 2022) (ACUMEN, 2014, National Academies of Sciences, 2020, National Academies of Sciences, 2019, Ferretti et al., 2018) (European Commission, 2005, Benedictus et al., 2016, DFG, 2013) (Wissenschaftsrat, 2011) (Begley et al., 2015, Sarewitz, 2016) (Wissenschaftsrat, 2015) (Junge Akademie, 2010) (DFG, 2010) (Wissenschaftsrat, 2005). (Wissenschaftsrat, 2005, Wissenschaftsrat, 2011) (Wolgast et al., 2017) (Dana et al., 2013) (Deutsche Forschungsgemeinschaft [DFG], 2022) (Reuben et al., 2014) (Gluszek and Dovidio, 2010, Weyant, 2019), (Bornemann, 2004) (Wahls, 2018) (FitzGerald et al., 2019) (Viadrina, 2014) (European Commission, 2005) (DFG, 2023, Elwood, 2017, Bell, 2023)
7. Use of metrics
(Langfeldt et al., 2021) (Heidenreich et al., 2023) (Gorraiz et al., 2022) (Zhang et al., 2017, Vinkers et al., 2021, Severin et al., 2023, Kavic and Satava, 2021, Dougherty MR, 2022, Llewellyn et al., 2023, Bornstein et al., 2017, Paulus et al., 2018, Mech et al., 2020) (Biagioli, 2016, 2020, Macdonald, 2022)

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