**Adjudication decisions**

As foreseen in the draft protocol and the final protocol, there are ambiguous or borderline cases in which it is not immediately obvious how to score a given policy element in the assessment scoring sheet. To ensure the consistency of scoring decisions across funders and policy elements, we list adjudication decisions below to document how the ratings team resolved such cases. Rather than adopting a literalist approach, adjudications took into account both the letter and the spirit of the WHO Joint Statement, and the likely impact of the policy element on researchers’ actions in research practice. All dates stated for adjudication decisions are in the year 2022.

2022 Gamertsfelder et al US funder decisions

Trial registration not prospective (21 days)

* **Challenge**: Several funders (NIH, FDA, JDRF) require trials to be registered within 21 days of the start of the trial. This is not prospective and does not meet the following WHO criteria: “Before any clinical trial is initiated (at any Phase) its details must be registered in a publicly available, free to access, searchable clinical trial registry complying with WHO’s international agreed standards ([www.who.int/ictrp)](http://www.who.int/ictrp)). The clinical trial registry entry must be made before the first subject receives the first medical intervention in the trial *(or as soon as possible afterwards)*.” The last part (italicized) is up to interpretation.
* **Decision**: If funder requires all trials to be registered within 21 days, the full point was awarded - within 21 days should fulfil the requirement for “as soon as possible afterwards”. However, this was decided to be the maximum allowable timeframe. If no specific time frame was given, or the time frame was >21 days, no points were awarded.

*NIH*: Several policies (protocol onto registry, trial ID, PI past reporting record, monitoring and reporting registration/results) are linked to external documents or webpages, but not explicitly stated on NIH’s website

* **Challenge**: Clear, comprehensive policies exist within FDA Amendments Act (FDAAA) document. The NIH funding policy states: "compliance with FDAAA is a legal requirement and a term and condition of the NIH award" and includes steps laid out to achieve full compliance. However, many of the policy items (protocol onto registry, monitoring, and trial ID in publication) are not explicitly stated outside of the FDAAA document or contained within NIH [Grants Policy Statement](https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).
* **Decision**: The FDAAA document is explicitly stated as a legal requirement and a condition of NIH grants. It is heavily referenced throughout NIH Policies (such as the NIH [Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) on the Dissemination of NIH-Funded Clinical Trial Information) “NIH-funded awardees and investigators will be expected to follow the provisions of the rule in terms of when they register their trials, what information they provide as part of the registration process, when they submit their results information, and what results information is submitted.” Though not contained within the Grants Policy Statement, a summary comparing NIH Policy to FDAAA requirements did contain information on protocol submission. More could be done to emphasize these requirements directly in NIH’s grants policy, but the following was awarded a score of “yes/*full*”:

*Protocol onto registry*

* *Trial ID in publications* was only found in the FDAAA document which was linked on the NIH grants policy page. Thus, a *supportive/non-binding* score was given
* The language was weak for monitoring compliance; though FDAAA has clear repercussions for non-compliance and uses enforceable language (“will not be released”, etc), the NIH policy uses non-binding language such as “can be considered”, “may lead to”, etc). Thus, the following elements were awarded a *non-binding* score:

*Monitor trial registration*

*Monitor results reporting*

Monitoring in practice

* **Challenge**: DoD states “all trials… are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per the US Public Law 110-85”. In theory, this means registrations are being monitored. However, no mechanism or further explanations were given. The language of “may result in” also implies less stringent adherence. Similarly, VA policy for results monitoring states: “The VA ART Program sends the PI an automated email notification approximately 3 months prior to the results submission due date.” – an automated email notification may not constitute monitoring. VA policy for monitoring registration of clinical trials is more rigorous: PI must either “upload proof of registration receipt” or use the automated ART system to move forward with grant receipt.
* **Decision**: DoD (monitors trial registration) and VA (monitors results reporting) were awarded a *non-binding* score. The VA (monitors trial registration) was awarded the full point.

Prospective registration: VA

* **Challenge**: Policy states "PIs of ORD funded clinical trials are responsible for registering their trials with and submitting summary results to the National Library of Medicine's (NLM) public registry, ClinicalTrials.gov, as a condition of funding.” The timeframe is not mentioned initially but comes later: “ORD uses the same definition of a clinical trial as the World Health Organization. This definition is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." VA PIs should note that by applying this definition and registering a clinical trial prior to enrollment of the first participant, the trial will be eligible for publication in International Committee of Medical Journal Editors (ICMJE) member journals "
* **Decision**: Full point awarded for prospective trial registration

Monitoring: FDA

* **Challenge**: The FDA states: “Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the grant, including those which state that future funding of the study will depend on recommendations from the OPD project officer.” Additionally: “There are also provisions regarding when agencies within HHS, including FDA, are required to verify compliance with the database requirements before releasing funding to grantees. OPD program staff will be providing additional information on these requirements, including the appropriate means by which to certify that a grantee has complied with the database requirements.”
* **Decision**: Full point awarded for PI’s past reporting record; however, wording is too vague to award a full point for monitoring of trial registration and results reporting. These were awarded a *non-binding* score.

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2021 Bruckner et al European funder decisions:

Pilot phase decisions

**Different policies in different language versions of funder websites (11 Feb)**

* ***Challenge:*** During the pilot ratings, the Swedish Research Council and the Research Council of Norway were each assessed in the national language by one rater, and in the English language version by the other rater(s). There appeared to be differences in the availability and content of policy items in different languages.
* ***Adjudication:*** We will adopt a conservative (i.e. generous) approach to scoring. Any policy found in any language will be assessed and scoring will be based on the strongest policy found, regardless of availability of in all languages.

**Partial inclusion only of WHO Joint Statement commitments for an item (11 Feb)**

* ***Challenge:*** During the pilot ratings, we found with reference to the policy element “registry records must be kept up to date” that Wellcome Trust’s policy states that: “If a clinical trial is terminated, you must update the status in the registry to note the termination date report the number of participants enrolled on the trial up to the termination date.” According to the WHO statement: “Clinical trial registry records should be updated as necessary to include final enrolment numbers achieved, and the date of primary study completion (defined as the last data collection timepoint for the last subject for the primary outcome measure). If clinical trials are terminated, their status should be updated to note the date of termination, and to report the numbers enrolled up to the date of termination.”
* ***Adjudication:*** Wellcome’s policy only applies to some trials, i.e. trials that were terminated; we did not find an equivalent policy covering completed trials. We thus scored the policy as relating to “some trials” rather than to “all trials”.

**Requirements to publish research results (11 Feb)**

* ***Challenge:*** Wellcome’s policy stated that “Grantholders must maximise opportunities to make their research findings freely available.” Similarly, the Norwegian Research Council stated that “Results from studies funded by the RCN must be published as soon as possible," and its Swedish counterpart stated that “The scientific responsibility of the applicant includes publishing the results of the research in scientific journals… or making them available in another corresponding way.”
* ***Adjudication:*** None of the above statements explicitly require researchers to make trial results public in peer-reviewed journals. Researchers may gain the impression that publication in other formats such as conference abstracts is an acceptable substitute for journal publication. *Note: In the case of some trials terminated early after only a few participants were recruited, a requirement for journal publication may (or may not) be misplaced; we do not take any position on this.*

**Broad requirements that do not refer to the specific item being scored (11 Feb)**

* ***Challenge:*** Wellcome states that "researchers should make sure their shared outputs: are discoverable [and] use persistent identifiers for these outputs wherever possible". This has relevance to the WHO commitment that “The Trial ID or registry identifier code/number should be included in all publications of clinical trials, and should be provided as part of the abstract to PubMed…”
* ***Adjudication:*** We did not award any points for the above statement because it does not specifically refer to registry numbers. As currently formulated, this recommendation is unlikely to be understood by researchers to require inclusion of the Trial ID in all publications.

**Monitoring of trial registration only in future (22 Feb)**

* ***Challenge:*** The Research Council of Norway’s relevant policy only came into force in 2020. RCN publicly states that it will monitor compliance and “will regularly publish aggregated figures indicating the degree of compliance with the guidelines” in the future.
* ***Adjudication:*** We awarded full points for those this item even though no monitoring reports are yet available because RCN clearly commits to publishing such reports in future.

**Funders strengthen policies post assessment (06 June)**

* ***Challenge:*** Wellcome updated its policy shortly after we contacted them, and the Swedish Research Council informed us that it was currently reviewing its policies. This raised the question of whether and under what circumstances we should re-assess funders’ policies.
* ***Adjudication:*** We decided to stick with the original protocol and not perform re-assessments to determine a new score for such funders. However, we also decided to flag such updates in the text of the study publication as they are salient information that can help to place our assessment results into context.

Phase I decisions

**Use of the word “should” in policies (06 June)**

* ***Challenge:*** BHF and CRUK each used the word “should” in at least one policy item. Similarly, BMBF used the German word “sollen” in one policy item. These wordings raised the question of whether we should rate such policy items as ‘non-binding’ or award full points.
* ***Adjudication:*** We rated such policy items as ‘non-binding’ and thus did not award any points for them. In the ‘notes’ column of our assessment sheets shared with the three funders, we flagged this ambiguity and encouraged the funders to consider adopting clearer wording in future.

**Registry reporting requirement without timeframe (06 June)**

* ***Challenge:*** Institut Pasteur’s policy requires “Results reporting to the public, through the registry,” but does not provide a timeframe.
* ***Adjudication:*** We awarded no points for the above statement. The WHO Joint Statement explicitly requires registry reporting within 12 months of trial completion; a key benefit of this timeframe is more rapid sharing of trial results than is commonly possible through peer-reviewed journals. Furthermore, non-compliance with this requirement by grantees cannot assessed if no deadline for compliance is provided; grantees could always argue that they plan to do this at some point in future.

**Open access repositories versus open access journals (06 June)**

* ***Challenge:*** Institut Pasteur’s policy states that “all scientists are asked to submit their publications to the HAL-Pasteur open archive as soon as they have been accepted by a publisher.” Similarly, SNSF’s policy states that *"SNSF requires grantees to make the results of SNSF-funded projects available in an open access (OA) publication or database”.*
* ***Adjudication:*** While publication in an open access repository arguably falls short of the ideal of publication in an open access journal, we awarded full points as trial outcomes will be made publicly available without paywall.

Phase II decisions

**Taking into account PIs’ past trial registration record for future funding decisions (06 June)**

* ***Challenge:*** FWO’s policy states that "The registration of clinical trials must be reported to the FWO during the project period and the completeness of the registration can be taken into account by the expert panels in deliberations about the allocation of future grant applications." Our relevant rating item was “Funder considers PIs’ past reporting record,” based on the WHO Joint Statement which in this context also exclusively mentions PIs’ past reporting records.
* ***Adjudication:*** We awarded zero points for this policy item because trial registration and trial reporting, which are both important, are separate issues. In the assessment sheet shared with FWO, we noted that FWO’s policy of taking into account the completeness of past trial registrations is a fantastic policy innovation that goes beyond the requirements of the WHO Joint Statement.

**Funder requires trial registration to be reported but monitoring mechanism unclear (06 June)**

* ***Challenge:*** FWO’s policy states that "The registration of clinical trials must be reported to the FWO during the project period." This leaves unclear whether or not FWO systematically collects and analyses these data, as per our scoring item “[Funder] Monitors trial registration”.
* ***Adjudication:*** We awarded zero points for this policy item because it is unclear whether FWO systematically collects these data for monitoring purposes. We noted in the scoring sheet supplied to the funder that we were open to re-considering this decision pending further information supplied by the funder in its response to us.

**Funder requires publication of trial protocols, but not explicitly in a trial registry (06 June)**

* ***Challenge:*** BMBF and SNSF both require the publication of trial protocols, but neither explicitly requires publication in a trial registry.
  + BMBF: "Die Publikationen des Studienprotokolls und der Ergebnisse sollen in wissenschaftlichen Fachzeitschriften so erfolgen, dass der Öffentlichkeit der unentgeltliche elektronische Zugriff (Open Access) auf den Beitrag möglich ist.”
  + SNSF: “All clinical trials funded through the IICT programme must be registered and trial protocols made publicly available before the first participant receives an intervention."
* ***Adjudication:*** We awarded zero points for these policy items against our assessment criterion “Protocol onto registry in 12 months”. The WHO Joint Statement explicitly states that “protocols are made publicly available no later than the time of the summary results disclosure as part of the clinical trial registry summary results information,” i.e. specifically requires publication on a trial registry.

**Funder requires results publication but does not mandate where (06 June)**

* ***Challenge:*** DFG requires the publication of trial results, but states that publication only in a registry or only in a journal is acceptable. In addition, DFG sets 24 month as the deadline for results reporting in either format, which falls short of the WHO Joint Statement which mandates results sharing on a trial registry within 12 months.
* ***Adjudication:*** We scored DFG’s policies as ‘non-binding’ with regard to the two scoring items in question, “Results onto registry in 12 months” and “Results published in journal”.