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Response to the NIH draft policy on sharing study results

NOT-OD-26-113
Official response from the PHUSE Data Transparency Working Group

The five sections below correspond to the NIH response fields and present recommendations from the PHUSE Data Transparency Working Group for consideration.

Draft Policy Components

The PHUSE Data Transparency Working Group welcomes the opportunity to comment on NOT-OD-26-113. We support sharing clear, accurate and accessible study results with research participants. Our contributors bring practical experience of developing and disseminating clinical trial summaries. Contributors include professionals from pharmaceutical companies, service providers, academic and other organisations, contributing their individual expertise rather than organisational positions. We offer these lessons to support implementation across NIH-funded research, recognising that academic institutions and other research settings may have different resources, study designs and participant relationships. We encourage NIH to build on established practices while providing proportionate guidance for the wider range of research covered by the proposed policy.

1. Scope across study types

We recommend that NIH provide practical examples distinguishing covered clinical research from excluded secondary research, including examples involving observational, retrospective, behavioural and biospecimen studies. We suggest that NIH consider phased implementation, beginning with research where practices for returning summary results are more established, such as clinical trials, followed by other research types as suitable approaches are developed. Any phasing should be time-limited, so that participants in all covered research ultimately receive the results.

Further guidance would also be helpful where researchers have no direct participant relationship or lawful means of recontact.

We recognise that NIH's existing dissemination policy covers NIH-funded clinical trials regardless of phase, including Phase 1 trials. If plain language summaries are required for Phase 1 trials, we encourage NIH to consider alignment with applicable international timelines and approved reporting delays, such as in the EU, where the summary of results, including the lay summary, for adult-only Phase 1 (Category 1) trials is expected within 12 months of the end of the trial but published 30 months after it [new ref: EMA, Revised CTIS transparency rules, EMA/263067/2023, https://www.ema.europa.eu/en/documents/other/revised-ctis-transparency-rules_en.pdf]. [1]

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2. Timing and complete results

We suggest that NIH consider global study completion date (end of study as defined in the protocol), rather than primary completion date, as the usual trigger for the final clinical trial plain language summary. Studies whose design includes a long-term follow-up or extension phase may need particular consideration, as participants could otherwise wait many years for results. For such studies, we suggest regular updates to participants (e.g. via a newsletter) on study progress and on when the full results are expected, with the plain language summary shared at the end of the study.

Releasing multiple summaries while follow-up continues can create confusion, complicate version control and risk influencing ongoing participation or study conduct. Guidance on the relevant completion milestone, the deadline after it and the relationship with existing technical results-reporting deadlines would support consistent implementation.

3. Evidence underlying a summary

We recommend basing a summary on a finalised, appropriately reviewed analysis or source for the results being communicated, with sufficient documentation to verify its accuracy. Examples of acceptable sources would be helpful for studies without a clinical study report, formal database lock or conventional study endpoint. For ongoing research, guidance could address the analysis cut-off, minimum results to communicate, use of status updates and subsequent material changes. This could help prevent premature communication while accommodating the documentation used in different study types.

It is a best practice to refer the reader to the scientific results summary for more information should a reader wish to find more details. NIH should provide more guidance in this regard.

4. Content and neutral interpretation

We encourage alignment of clinical trial summary content with EU Clinical Trials Regulation Annex V and established lay-summary guidance. In particular, further explanation or refinement of “relevance” and “potential implications” in the definition of a plain language summary could help avoid speculative statements or overstating benefit or certainty, whether or not the research involves an investigational product. We recommend that explanations remain grounded in the study evidence, communicate uncertainty and acknowledge limitations. Adapted examples would be helpful for research outside the clinical-trial setting. [2–4]

5. Coordinating responsibilities

For collaborative studies, including co-sponsored studies, we suggest identifying the entity coordinating preparation, approval, release and maintenance of the summary in the award or collaboration arrangements. This could help establish clear responsibilities and avoid duplication.

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6. Proportionate review arrangements

We encourage NIH to rely on existing quality assurance processes at the researcher's or institution's end. Existing scientific, statistical and plain language review processes can support quality, with institutionally approved templates helping to maintain accuracy and non-promotional communication. Please clarify whether any additional external review of summary content is envisaged. If additional external review is envisaged, guidance on its scope, criteria, use of source results, turnaround times and resolution of disagreements would help institutions plan effectively and avoid duplication.

7. Offering results and documenting the approach

We suggest that explaining during consent where and how a summary will be available, followed by posting it at the stated location, could be accepted as an offer of results. We encourage an approach that does not create a general obligation to send summaries proactively to every participant or to prove receipt. Guidance on proportionate documentation and the distinction between an offer, access and reading would be helpful. We also recommend accessible alternatives for participants who cannot use the stated digital route. Where direct contact is chosen, communication through sites or an authorised intermediary could help minimise the handling of participants' personal data by those preparing the summary.

8. A transparent exception process

We recommend that NIH publish examples and a consistent process for requesting exceptions to support fair and practical implementation, including guidance on justification, decision ownership and timing. Possible circumstances for consideration include privacy risks in small or highly identifiable populations, infeasible recontact and studies without an appropriate finalised analysis. It would be helpful to explain when adaptation, delay or an alternative communication route may be appropriate before considering an exception, including where an issue becomes apparent after enrolment.

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Participant Preferences and Experiences

1. Choice and accessibility

Contributors described increased use of digital channels, including QR codes in consent materials and thank-you letters, and difficulties tracking paper distribution. These operational observations should not be taken as evidence that all participants prefer digital delivery.

Participants' preferences vary with age, health, language and access to technology. It is best practice to understand the study population and provide a choice of format and channel where possible, including non-digital options, and to involve participants or patient representatives in planning how results will be returned. This could be encouraged through supplemental guidance and existing resources on health literacy, rather than built into consent processes or the tracking of individual choices. Published research on participant preferences, and ongoing PHUSE work gathering feedback from readers of published plain language summaries, can inform the supplemental guidance. Summaries should also be accessible to people with disabilities, in line with applicable accessibility requirements, for example screen-reader compatible documents and text descriptions of graphics.

2. Understanding and authorised sharing

Please share guidance on explaining uncertainty, inconclusive findings and limitations that could support participant understanding, alongside a route for questions where results may be difficult to interpret. Further guidance on consent and privacy considerations when communicating with parents, guardians, caregivers or other relevant persons would also be helpful, reflecting the study population and participants' circumstances and preferences.

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Best Practices for Researchers

1. Established resources

We recommend the MRCT Center Return of Aggregate Results guidance and toolkit and Good Lay Summary Practice as starting points for supplemental resources. For medicinal-product clinical trials, alignment with the EU Clinical Trials Regulation Annex V content framework could support consistency. Examples tailored to observational, behavioural and longitudinal research would help accommodate different study designs. [2–4]

2. Proportionate content expectations

A clear distinction between core content and optional detail would support consistent implementation. Guidance could illustrate how to select finalised, predefined secondary outcomes that are meaningful to participants and support a fair and balanced account of the findings. We suggest allowing institutions to use existing templates where these meet the agreed content expectations.

3. Traceability within existing workflows

An internal source-to-summary record could help link key findings, important safety statements and material limitations to supporting results and source versions or dates. A short optional example could fit into existing scientific review workflows. We suggest presenting this as a practical aid, without introducing an additional NIH submission or duplicating analysis validation.

4. Understanding beyond reading scores

We recommend encouraging short sentences, clear structure, familiar words and explanations of essential technical terms, supported by participant or public review where feasible. Readability scores can assist editing but may be distorted by medicine names, disease terms or official study titles. We suggest using them alongside assessment of accuracy and understanding, rather than as the sole basis for rejecting a summary. Examples of acceptable written, visual and verbal formats, and guidance on any minimum durable record, would be helpful. We also ask NIH to clarify whether translation of summaries is expected; in our view, summaries should be offered in the language(s) used in the consent process.

5. Privacy and updates

Existing institutional privacy processes could provide a foundation for assessing re-identification risks, particularly in small, rare disease or genomic populations. Aggregation and suppression of small counts may be appropriate where a meaningful and accurate account can be preserved. Guidance on when remaining risks may justify an exception would be useful. For revised or staged summaries, we recommend identifying the study, analysis cut-off, version and date. Guidance could also address how to identify the current version, handle earlier versions and notify participants of material corrections.

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Implementation Needs

1. Planning responsibilities and resources

We encourage integration of results sharing into study plans, award arrangements and institutional procedures. Identifying a coordinating owner and the roles of source-data reviewers, plain language writers, participant reviewers, translators and sites could support efficient delivery. Plans could cover development, approval, dissemination, maintenance and responses to participant questions, with the level of effort matched to the study. Innovative technology, e.g., LLMs, could support plain language drafting, with experienced writers and study teams reviewing and validating all content for accuracy, clarity and suitability for participants.

2. Costs and resource assumptions

Good Lay Summary Practice offers a useful framework, including effort estimates, for planning development, translation and dissemination. [3] Relevant cost considerations include study complexity, languages, review rounds, communication channels and repeat summaries. Costs can also vary by geographical region and the use of technology. We therefore suggest describing costs through these activities and assumptions, as a single standard estimate is unlikely to reflect the range of research settings. While costs vary, we recommend that NIH consider this framework as a model for estimating the effort involved.

Guidance on including reasonable results-sharing costs in funding requests would be welcome, particularly where analyses or dissemination extend beyond the funded period.

3. Practical support across research settings

Optional templates, worked examples, review checklists and dissemination planning tools could help researchers build on existing resources. Study-specific examples could cover completed interventional studies, studies needing staged communication and open-ended research without a conventional final analysis. These could illustrate practical ways to meet the policy across different documentation models and resource levels in academic and other research settings.

4. Accessible dissemination and maintenance

Further guidance on public posting, direct provision or a combination of approaches, and on whether any particular repository is envisaged, would support dissemination planning. Examples of proportionate documentation could help institutions demonstrate compliance while protecting privacy. We encourage approaches that accommodate both digital access and participants who need alternatives.

5. Consultation on supplemental guidance

We encourage NIH to make proposed supplemental guidance available for public comment before implementation. Feedback could help assess feasibility across research settings and support institutions in preparing procedures, training staff and budgeting for the work. A clear distinction between binding requirements, recommended practices and optional tools would also be helpful.

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Other Comments

We encourage NIH to retain flexibility in implementation while setting clear expectations for accuracy, neutrality, accessibility, privacy and accountability. Harmonisation with existing approaches can reduce duplication and support timely, meaningful communication with participants.

Contributors

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Contributors participated in their individual capacity, based on their professional expertise. Their views do not necessarily represent those of their employers.

References

[1] NIH. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/reporting/nih-policy

[2] MRCT Center. Return of Aggregate Results project, including guidance and toolkit. https://mrctcenter.org/project/aggregate-results/

[3] European Commission. Good Lay Summary Practice. https://health.ec.europa.eu/system/files/2021-10/glsp_en_0.pdf

[4] Regulation (EU) No 536/2014, Annex V. https://eur-lex.europa.eu/eli/reg/2014/536/oj/eng