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# Ten Simple Rules for Open Health Research

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| **Conceptualization** | Ideas; formulation or evolution of overarching research goals and aims. | Dusan Misevic<br>Arno Klein<br>Jason Bobe<br>Anna McCollister-Slipp |
| **Data Curation** | Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later reuse. | |

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|---|---|---|
| **Formal Analysis** | Application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data. | |
| **Funding Acquisition** | Acquisition of the financial support for the project leading to this publication. | |
| **Investigation** | Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection. | |
| **Methodology** | Development or design of methodology; creation of models | |
| **Project Administration** | Management and coordination responsibility for the research activity planning and execution. | Dusan Misevic<br>Arno Klein<br>Jon Clucas<br>Anirudh Krishnakumar<br>Ariel B. Lindner |
| **Resources** | Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools. | |
| **Software** | Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components. | |
| **Supervision** | Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team. | Arno Klein<br>Jason Bobe<br>Anna McCollister-Slipp |
| **Validation** | Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs. | |
| **Visualization** | Preparation, creation and/or presentation of the published work, specifically visualization/data presentation. | Arno Klein |

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| **Writing – Review & Editing** | Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre- or post-publication stages. | Jon Clucas<br>Arno Klein<br>Anirudh Krishnakumar<br>Dusan Misevic<br>François Taddei<br>Félix Schoeller<br>Irene Pasquetto<br>Gabriela Sanchez<br>Camille Nebeker<br>Anibal Sólon<br>Tohar Scheininger<br>Célya Gruson-Daniel<br>Aki Nikolaidis<br>John Naslund<br>Kathy Hudson<br>Anna McCollister-Slipp<br>Jason Bobe<br>Pattie Gonsalves<br>Matthieu Schapira<br>Aïda Bafeta |

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## Introduction

We are witnessing a dramatic transformation in the way we do science. In recent years, significant flaws with existing scientific methods have come to light, including lack of transparency, insufficient involvement of stakeholders, disconnection from the public, and limited reproducibility of research findings (1–7). These concerns have sparked a global movement to revolutionize scientific practice and the emergence of Open Science. This new approach to science extends principles of openness to the entire research cycle, from hypothesis generation to data collection, analysis, replication, and translation from research to practice. Open Science seeks to remove all barriers to conducting high quality, rigorous, and impactful scientific research by ensuring that the data, methods, and opportunities for collaboration are open to all. Emerging digital technologies and "big data" (see "Ten simple rules for responsible big data research" (8)) have further accelerated the Open Science movement by affording new approaches to data sharing, connecting researcher networks, and facilitating the dissemination of research findings.

Open scientific practices are also having a profound impact on the health sciences and medical research, and specifically how we conduct clinical research with human participants. Human health research necessitates careful considerations for practicing science in an ethical manner. There is also a particular urgency to human health research since the goal is to help people, so doing good science takes on a different meaning than simply doing science well. It also implores the scientist to reassess the conventional view of human health research as a pursuit conducted by scientists on human subjects, and lays a greater emphasis on inclusive and ethical practices to ensure that the research takes into account the interests of those who would be most impacted by the research. Openness in the context of human health research also raises greater concerns about privacy and security and presents more opportunities for people, including participants of research studies, to contribute in every capacity. At the core of open health research, scientific discoveries are not only the product of collaboration across disciplines, but must also be owned by the community that is inclusive of researchers, health workers, and patients and their families. To guide successful open health research practices, it is essential to carefully consider and delineate its guiding principles.

This editorial is aimed at individuals participating in health science in any capacity, including but not limited to people living with medical conditions, health professionals, study participants, and researchers spanning all types of disciplines. We present ten simple rules (see Figure 1) that, while not comprehensive, offer guidance for conducting health research with human participants in an open, ethical, and rigorous manner. These rules can be difficult, resource-intensive, and can conflict with one another. They are aspirational and are intended to accelerate and improve the quality of human health research. Work that fails to follow these rules is not necessarily an indication of poor quality research (9), especially if the reasons for breaking the rules are considered and articulated (see rule 6: document everything). While most of the responsibility of following these rules falls on researchers, anyone involved in human health research in any capacity (10) can apply them.

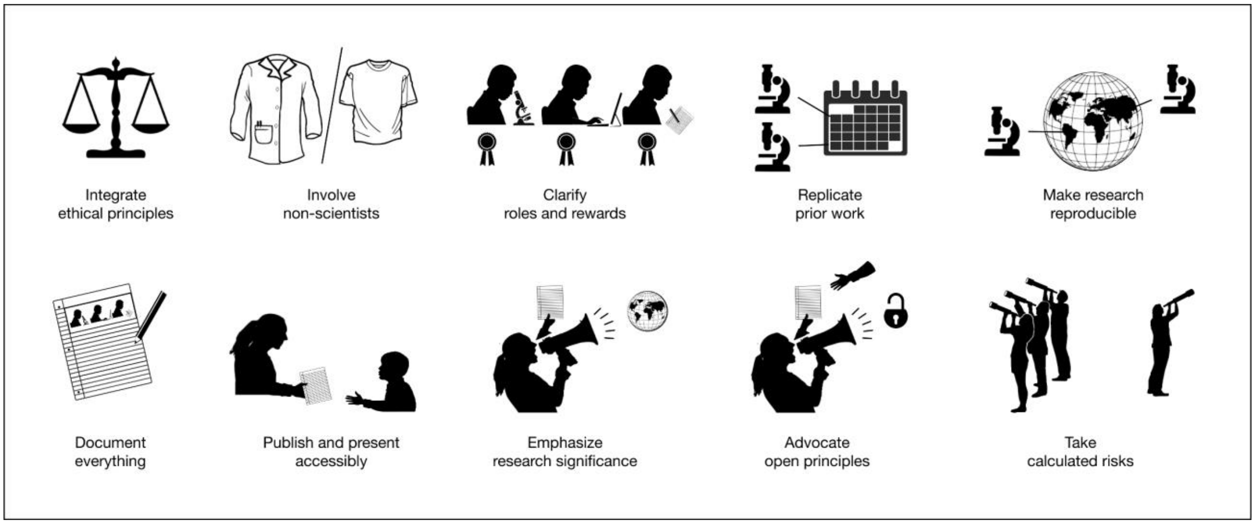

Figure 1[‡]. These 10 simple rules are presented graphically.

### 1. Integrate ethical principles

Health research is no longer exclusive to scholars or medical professionals; as technology developers are increasingly engaging in and leading biomedical research, participants are also taking on a more active role as partners in research, and citizens are even designing and deploying their own health research projects (11). In the absence of governance, norms and infrastructure to guide ethical and responsible practices, inherent threats could undermine privacy and safety. For example, the tech industry often leverages data from users of its devices or services, such as wearables, smartphones, social media platforms, or mobile apps, to examine trends or test new digital features with direct relevance to health and human behavior without direct, voluntary consent or clear information about how data will be used and reported. This can further lead to unintended consequences from data sharing and disclosing personal information, as well as spread of inaccurate information or overstatement of benefits without adequate acknowledgment of risks.

The design of human health research projects must integrate core ethical principles, including respect for persons, beneficence and justice (12), and respect for law and public interest (13). In a rapidly changing research landscape with shifting roles, emphasis on these core ethical principles becomes critically important. The well-established, tried and tested rules and regulations for behavioral and biomedical research involving human participants (14) must be followed. Namely, open health research must (a) demonstrate voluntary participation via informed consent (15–18), (b) perform risk assessment to determine if the probability and magnitude of potential harms are balanced against potential benefits, (c) include those who may benefit most from knowledge gained, (d) consider downstream societal implications, (e) conduct an external review of study procedures before initiating any project, and (f) develop additional protections for vulnerable stakeholders .

There is uncertainty and lack of consensus with how best to prevent and manage a wide range of ethical concerns in human health research. This is further complicated by the near-continuous introduction and premature adoption of increasingly sophisticated digital technologies, including pervasive sensing, web applications, and computational technologies producing a deluge of data and digitization of most aspects of daily living (19–22). The current bias towards "more is good" occurs even when there is no clear understanding of how those data might be used, linked, or repurposed by others. The Cambridge Analytica fiasco is a recent example of how vast repositories of personal data can be accessed and mined, and privacy ignored (23). We include below a few steps we can take to improve ethical standards in human health research.

Include people on your team who bring expertise in research ethics, methods, and data management. This is especially important for successfully guiding open health research, where efforts to mitigate risks for human participants and uphold key ethical principles must be kept open and transparent. Carefully choose what data to collect and how to represent and store those data, remembering that while data storage costs have rapidly shrunk, other costs, including but not limited to compromised privacy and unauthorized access, are inherent in any data collection (24–27).

Take responsibility for building a peer review process into each study design with periodic checks and balances. Do not simply delegate consideration of ethical and responsible research practices solely to research ethics boards (also known as institutional review boards (IRB)). The Connected and Open Research Ethics (CORE) (28) is a global community interested in collaborating to shape ethical practices in digital research. The CORE Resource Library is populated by researchers who are sharing their IRB-approved protocols and sharing questions and expertise via a forum. With the idea of supporting unregulated research and building in the ethics review process for the citizen science community, the Citizen Science Association has also developed and shared materials for conducting an IRB review (29).

Strive to outperform accepted ethical norms by drawing from the lessons of a number of growing efforts to advance our understanding of the ethical, legal and social implications of this emerging digital research ecosystem. These include the CORE initiative (30,31), MobileELSI (32), PERVADE (33), and CTTI (34), and can offer important mechanisms for ensuring scrutiny of research methods. Transparency, inclusivity, and empowering those who do not typically have a voice in biomedical research are fundamental aspects of open health research, and may substantially advance our understanding of how to monitor, respond to, and report on ethical concerns and risks.

### 2. Involve non-scientists

There are many roles non-scientists can take to advance human health research, beyond participation in traditional, computer task- or game-based citizen science projects. First and foremost are the patients who are best served by the research, who can not only enroll as participants, but also help define problems, goals, and measures of success. Any interested party can and should partner at the different stages of research — soliciting ideas for funding, designing or coordinating studies, recruiting participants, collecting or analyzing data, interpreting or broadcasting results, participating in the peer review process (35–37), and so on — including patients, clinicians, ethicists, policy makers, funding agencies, and individuals from the general public, among others (38). One resource for learning about the scientific method and methods which undergird ethical research practices, available through the Office of Research Integrity website at no charge, is Basic Research Concepts (39).
Include non-scientist stakeholders throughout the scientific process in meaningful, informative, accessible, and engaging ways. From the very inception of a study, encourage and support the active participation of patients and other interested parties in defining research questions. Patient-led innovation platforms and patient-driven networks in health, such as PatientsLikeMe (40), help connect people suffering from common diseases to share their experiences, and have spawned scientific studies (41). For community-facing projects, hold meetings with community members to allow for concerns and questions to be voiced and responded to. Collaborate with technology developers and end-users to ensure products are scientifically validated, evidence-based, and user-friendly. Strive to engage a diverse population (e.g., demographic, gender representation, employment, education, etc.). Such diversity will ensure a better informed approach to the research, and a greater interest in the research results, as well as broader generalizability of the research findings.

Seek out opportunities to bridge divides among communities and their access to resources. For example, work to match stakeholder ideas and needs to other stakeholders' skills and resources. Make efforts to raise awareness of complementary literatures and to overcome disciplinary divides. Participate in funding opportunities for projects that involve non-research stakeholders and patient-centered outcomes, such as from the Patient-Centered Outcomes Research Institute (PCORI) (42).

Invite non-scientist stakeholders to take part in scientific events, such as conferences, seminars, workshops, or lab meetings (43,44), and participate as a non-scientist in research outside of your areas of expertise (e.g., stepping outside of your 'comfort zone'). Actively engage with non-scientists and participants outside one's discipline; listen to, respect, and value their perspectives and opinions. This is especially important because the views and perspectives of patient groups who stand to benefit most from research are rarely considered or acknowledged, representing a persistent challenge across many areas of health research. Require researchers to spend a percentage of their time to engage with non-research stakeholders. Incentivize research contributions by non-scientists by reward and recognition systems.

### 3. Clarify roles and rewards

Rewards and recognition systems can be as simple as monetary incentives and explicit acknowledgment or as complex as verified badges and tiered reward systems (45–48). While many rewards will depend on resource availability and other factors potentially beyond one's control, we should strive to always have the capacity to recognize stakeholders who contributed to a project.

There are obvious benefits to clearly articulating what roles different contributors will play in a given research study and how they will be acknowledged or rewarded accordingly. Not only does it set up reasonable expectations for all parties, but it also avoids conflicts and misunderstandings commonly found in academia related to authorship and allocation of funds and other resources (49). Human health research raises the stakes considerably, given that it involves human participants, who are rarely acknowledged for their participation. Open human health research raises the bar further, as it engages many different stakeholders and increases the number of potential contributors who should be rewarded for their contributions.

At the outset of a research project, clarify contributor roles, acknowledgments, rewards, and code of conduct, e.g., (50). Use resources like "Ten Simple Rules for a Successful Collaboration" (51) and *Collaboration and Team Science: A Field Guide* (52) for guidance defining these roles. Also clarify when data or software can be released, and cite the resources you use (53). Think beyond the usual contributor acknowledgments of "author", "editor", "contributor", "acknowledgment", etc. (54), and reconsider author order. In other words, clearly define and state what contributions would lead to what acknowledgments or rewards (55). The International Committee of Medical Journal Editors provides guidance ("the Vancouver Recommendations") that many journals require for submissions and that are good practices to follow regardless of publisher requirements (56,57). The Committee on Publication Ethics also provides hundreds of guiding documents, including flowcharts, specifically relating to authorship and contributorship (58–60).

Even outside of your own research, acknowledge where good, open, ethical, inclusive human health research practices are conducted. Be especially mindful to acknowledge open practices (61–63), research in languages in addition to English (64) and research from non-traditional actors (65) . Point out where greater efforts could be made toward better scientific practices. Lead by example, but also, when attending another’s talk or lecture, do ask for clarification on who contributed what, so as to encourage this practice in others.

Engage in more quantitative approaches of acknowledgment and reward. For example, rigorously quantify the degree to which your research and contributed/adopted resources embrace openness, ethical practices, inclusiveness, etc. Think carefully about what "impact" means in relation to your work. For example, rather than (or in addition to) tracking academic citations, you may be more interested in fostering collaboration between particular previously siloed bodies of knowledge or in tracking some aspect of your research into practice. Make use of scientometric indicators that measure or estimate those types of impact (6,66–72).

### 4. Replicate prior work

It is incumbent on researchers to ground their work in the context of prior work. The first step is often to confirm prior work by reproducing past results (apply same methods to the same data to get the same results). To ensure that this prior work translates to a new study population or reimplementation of old methods, a researcher tries to corroborate prior work by replicating past results (collect new data, apply similar methods, to get similar results). Replication does not necessarily mean running a past study or its analysis again in exactly the same way — this may be a waste of resources if the original study was conducted on a small, non-representative population using outdated approaches. Instead, use best available practices and sufficiently powered sample sizes from relevant populations to evaluate the state of knowledge and to establish a sound foundation for a research program. Some conferences, such as the Organization for Human Brain Mapping, have given replication awards to encourage these studies (73).

Science is by its nature uncertain, improving and replacing current models with better models over time. When rationale, data, methods, and code are openly shared and explained, we reduce the uncertainty that is inherent in each of those aspects of research and increase our confidence in the findings (74–77). Further, past work can be reassessed in light of new findings (78) when the adequate components are accessible, and data collected by others can be independently reused or integrated with other datasets (79,80).

Replication in science is presently in a woeful but improving state (81,82). If your compensation structure allows, allot a percentage of your time and research efforts to replication and confirmatory studies. Find prior work related to your research questions. Carry out replication studies by following published methods with new or existing open data, explaining your deliberate data acquisition choices (80). Be mindful of the fact that validity and replicability are different, separable qualities and that the goal of replication is to test validity or generalizability of the models in question (78). Perform complementary analyses on published open data to further explore the data behind published findings (43).

### 5. Make research reproducible

Just as it is crucial to try to replicate prior work to ground current research, it is likewise crucial to make your own research work reproducible. Data and methods must be subjected to scrutiny, evaluated for robustness and generalizability, and provide a foundation that others can directly build on. This practice is not an act of generosity — if you do not make your data and methods available and clear to others, you undermine the credibility of your work and hinder the advance of science.

Follow FAIR (findable, accessible, interoperable, reusable) principles in your scientific practices (83,84). Of the other rules, the most pertinent to reproducibility regard clear, accessible, comprehensive, and accurate documentation and presentation. Specifically, for documentation to aid reproducibility, it must be shared, and shared in formats (languages, descriptions, parsable file types) that are easily accessible (85) . In practice, "data […] exist in small units, are linked to many other related units, and are difficult to interpret without considerable documentation and context" (53). Adequate data documentation and retention is difficult and resource intensive (80,86); however, inadequate data management reduces the scientific value of the associated research. See "Ten Simple Rules for the Care and Feeding of Scientific Data" (87) for guidance.

Share data in open-access repositories (87) when doing so will be unlikely to identify participants or otherwise potentially harm people directly involved with the research. At the very least, this practice enables consumers of your research to scrutinize your work. More importantly, by sharing your data and methods (including hypotheses and assumptions), other methods can be applied to your data, and your methods can be applied to other data. Each of these affordances bolsters the strength of your research.

In your published methods and results, be as clear as you can about the assumptions and hypotheses you are working with. Summary statistics and thresholds can be useful, but commonly-reported statistics such as *p* values are not one-size-fits-all measures of research quality or reproducibility (88–90). In addition to clarifying the assumptions and hypotheses in your work, clearly defining your measures is imperative. Where word limits or other constraints prevent adequate articulation for clarity, ensure that that clarity is published elsewhere (see rules 6: document everything and 7: publish and present accessibly).

### 6. Document everything

In service of the "kind of transparency which is the opposite of secrecy" definition of openness (91), each step of research requires clear, accurate, precise documentation. Comprehensive, clear, and accurate documentation is critical for replicability and reproducibility of research, but is also critical for communicating to a larger audience than the research community, and can encompass elements beyond those required to conduct the research. From formulating a research question through study design, data collection, analysis, and publication, retain artifacts of the entire process (92). These artifacts could be text, drawings, audio-video recordings or any other type of persistent data.

Prior to recruiting any participants and collecting any data, preregister your literature review, ethics statement (93) and methods. Preregistration is a process in which written study designs are submitted to a publisher prior to execution to be "externally reviewed, and those that meet criteria will be accepted in principle prior to data collection" (94) (See Figure 2). A preregistration manuscript submitted for review and accepted in principle by a publisher is called a "registered report" (95,96). Ideally the individuals collecting and analyzing the data are not the same people who write the registered report; assigning the roles of documentation and execution to nonoverlapping sets of individuals encourages generally understandable research methods documentation.

Figure 2‡. Each blue arrow in the diagram represents a research step that requires documentation. Each red arrow is an opportunity for a preprint.

To make the documentation process easier, seek out established templates (97–101). Document any change or amendment as the project progresses. Strive toward reproducibility (81) (even for oneself in the future!) by providing self-contained, clear, and updated documentation. Not only do protocols require documentation, but data, code, recruitment documents and other research artifacts need to be retained and intelligible to be built upon in the future (102–104). Major documentary components such as registered reports and articles submitted for publication should be posted to preprint servers, an opportunity both to share your knowledge and stake your claims without waiting for the full publication cycle (105,106).

Data, lab notebooks, protocol addenda, recruitment material, and code should be published in appropriate venues, including social media, blogs, collaborative references, and data and methods journals, as a project progresses (104,107–114). New outlets for the publication of creative research objects allow for wider recognition and dissemination of work that is not duly recognized in the paper publication process (115). Quite often, software, datasets, and packages are not well cited, but new efforts to resolve this problem allow for both makers and users of scientific objects to easily access the proper citation information (116). Even while data citation standards develop, evidence indicates broad gains to both data creators and the wider research community when research objects beyond books and papers are openly shared (69,117).

Errors occur in public and in private, and while "making code and data open does not prevent errors, […] it does make it possible to detect them. […] People often worry that if they make their code and data open, errors will be found, but that is really the whole point: We need to make code and data open because this is how the errors can be found" (118). By publishing often, widely, and in great detail, we can, through feedback, detect and resolve errors early in the process (119). Insist on publishing experimental protocols and negative results.

When citing sources, including your own, indicate which "references a[re…] open, rather than preferentially citing them over closed ones" (120). Link to your publications, shared data, and other documentation on your professional website, social media, and CV (106). Let colleagues know about innovative practices you are trying.

## 7. Publish and present accessibly

To best serve health research, communications at every stage of the research endeavor must be findable, accessible, interoperable, and reusable (FAIR; see rule 5: make research reproducible) (83,84). By accessible, we mean easily retrievable and expressed in a manner that is clear and intelligible to the widest possible audience without unduly compromising the integrity of the information to be conveyed. This is a challenge not only because there are technical and abstract elements to any scientific study, but also because many scientists consider scientific journals as the sole conduit by which they convey results of their research.

When you have control over the license under which your work is published, choose a permissive license (e.g., (121,122)) and encourage consumers to use and share your work. Publish in open-access journals, being careful to choose appropriate, non-predatory publications. Use checklists (123,124) to evaluate potential venues. Unless you must submit to a journal that disallows preprints, always submit your manuscript to a preprint server such as bioRxiv or arXiv, in parallel to a peer-reviewed journal. Tools like RoMEO can help navigate publisher licensing policies (125).

When you must publish under a closed license, deposit your article in a post-publication archive (eg, HAL (126)) or on your own website once you are legally able. Some jurisdictions legally grant you the right to openly publish your closed-license work after a specified embargo period; these laws may specify different embargo periods for different disciplines (127,128). Some institutions (e.g., (129)) require open access for non-commercial use of their research. Consider making your work (including protocols, negative and positive results) available in real-time on public platforms (104,107–115). The scientific community will be able to build upon your research more efficiently.

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Research publications and other informational websites are often dominated by a few languages, especially English. Translate your work and the work of others into different languages, and account for cultural and social factors; the French-language open-access publisher Science Afrique (130) is an example of a regionally focused effort. Create or update Wikipedia pages on published research findings (131,132), in multiple languages. Invite the public to provide feedback.

Strive to make research, including your work, accessible to non-scientists and scientists alike. Write a summary of your manuscript and/or a glossary of key terms (133) using language devoid of scientific jargon (134), add it as supplementary information to your submitted manuscript, post it on your lab website, and share a link through social media to relevant patient groups. Create and share engaging media, such as videos, animations, and websites. Consider using annotation tools (135–137) to make papers you are interested in accessible to a wider community. Demystify the scientific funding process by laying out research costs and citing successful examples of return on investment.

## 8. Emphasize research significance

Because health information is sensitive, the costs and risks of participating in open human health research must be documented and emphasized. Likewise, the real and potential benefits of the work must be shown to be justifiably greater than the costs. Some costs and benefits will be unique to a project; others are common to open practices or to human health research.

With social media, research participants are now able to tout their own contributions to health science in ways that were out of reach in the past, sharing how and why they participate and encouraging others to do so. Researchers all too often take for granted that the audience for their work is restricted to a narrow group of specialists who read and review their scientific articles, and that the implications and significance of their work is apparent.

A critique of null hypothesis significance reporting is beyond the scope of this editorial, but generally in statistical analyses, reporting a $p$ value and using that value as a binary threshold is insufficient at best (1,5,89,90,138,139). Do thoroughly articulate statistical significance, including an explanation for both the selection of and practical interpretation of the statistical tests you performed in the context in which you performed those tests, the assumptions involved, and any alternative tests and assumptions that were considered but rejected. Note both how your work converges with and diverges from existing research.

In addition to communicating the meaning of their analyses and results, researchers must communicate a clear context for their work to convey a strong sense of purpose and meaning that motivates an experiment's design and drives any applications that are derived from the work. Specify the intended and expected significance and impact of each project, both for the human participants and with regard to the greater good. Let others know why you are participating in the research you participate in. Clearly publicize to all stakeholders the physical, realizable benefits of individual involvement in the research. State succinctly the aims and goals of each project, so that individuals may understand not just their direct benefit, but how their contributions promote positive scientific research outcomes that advance a specific field. Be honest about the costs, including decreased local efficiency, and gains, including increased scientific reliability, of incorporating open practices (92).

### 9. Advocate open principles

Practicing open science is best done not in isolation, but in a community of open science practitioners. This is never more true than in human health research, where health data can be difficult to collect, share, and analyze, and the research itself is most often done in silos. Coordinating the activities among people, the interoperability of methods, the sharing of data, and the inclusion of more diverse stakeholders is not only desirable, but essential. For open health research to be successful we must build such a community, and this is possible only if we strongly and persistently advocate for principles of open health research. To assure our efforts are effective and genuine, we must identify and focus on priorities for advocacy.

Publicly acknowledge when open practices from others have benefitted you. Publishers have been working toward this task, where, "in principle, journals could provide incentives for scientists to adopt open practices by acknowledging them in publication. In practice, the challenge is to establish which open practices should be acknowledged, what criteria must be met to earn acknowledgment, and how acknowledgment would be displayed within the journal" (62). The Transparency and Openness Promotion (TOP) guidelines, released in 2015, provide community-driven standards for publishers and funders (92,140,141). For individuals, the task is somewhat simpler; we can acknowledge the open practices that benefit us as we use them, each step of the way.

For a variety of legitimate reasons, certain facets of research cannot ethically be openly shared, e.g., for privacy, security, or trade secrets (142). Thoughtful limitations are an essential component in ethical open practices (9). Reasons for closed components should not be sidestepped or minimized. Rather, we should openly explain and discuss these reasons and descriptions of relevant information that cannot be shared. Refer to data-specific research fields such as informatics and critical data studies (22,143) for guidance about how to balance other principles with open principles; cite these references.

Promoting open health research can be as simple as initiating discussions in classrooms, conferences, and social events, and can be exercised in informal gatherings, such as dedicated Wikipedia editing sessions on open science topics, or open review sessions of articles on PREreview (144,145) . The list of steps that anyone can take to lead by example and practice open science today is too long to include here (see (146) for a curated list).

### 10. Take calculated risks

A variety of risks are inherent in research with human subjects, in communications that can influence health practices, and in open practices. Honest and open deliberation of these potential risks across the lifespan of the research is essential to trustworthy, impactful human health research. These various risks can arrive in isolation or combination and be known in advance or realized over time. As such,we should justify the decision of whether to assume these risks based on the ability to mitigate potential harms against benefits of knowledge gained.

Return on investment must be considered in choosing which risks to take, and some risks may be too costly even if the potential rewards are great (78,147). Openness is a buzzword today, particularly in science, and as such openwashing ("to spin a product or company as open, although it is not" (148)) is both a practice to watch out for and an example of a risk that would be hard to justify in terms of value but easy to justify in terms of cost. Legal frameworks, particularly as relating to personal data and privacy, are a rapidly changing factor in assessing these risks; new risks may become apparent or out of proportion to estimates as research progresses. Consequently, cost-benefit analyses should be undertaken frequently.

These analyses should be documented (see rule 6: document everything) and shared (see rule 8: emphasize research significance).

Acknowledge good-faith efforts that fail and encourage publication of negative results. Push back against closed institutional traditions, challenge secretive practices (149) and explore nontraditional methods. Risks related to the other rules include going beyond accepted norms of ethical protections and partnership with non-scientists, systematically establishing greater clarity and accessibility of who does what and how for better appreciation, understanding, reproducibility, and advocacy.

Seek feedback from external stakeholders (i.e., target populations, funding agencies, local government and university officials) for your experimental design and methods before participating in or conducting an experiment; act on the feedback collected if deemed wise and not merely opinions or conventional wisdom. Also seek outside training for students and employees that includes options for non-academic paths.

Seek interdisciplinary collaborations and spend a percentage of time and research effort working on projects outside your comfort zone. For example, have researchers spend 10-20% of their time on other projects of interest that they are passionate about. These can include topics of research that have received push-back in the field, deemed "too large to tackle," or those unlikely to produce confirmatory results, but have the potential to incite new areas of research.

## Conclusion

We hope that the above list of simple rules is a helpful guide to follow best practices in human health research. More importantly, we hope that you will use these as a starting point to address broken conventional practices of science and where these rules fall short, share your own rules to improve the state of open, ethical, inclusive human health research. These rules are not comprehensive, but we are confident they capture the most salient, timely, and important principles that can guide open health research going forward. Be the change you seek in science (150), and strive to make human health research a more humane, effective, and open endeavor.

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## Glossary

academia - The community of people professionally involved in post-secondary educational institutions, e.g., people who work with and in colleges and universities.

accessibility - The property of being easily retrievable and expressed thoroughly and intelligibly.

affordance - Something made possible by some agent, object, context, or process. One thing affords another if the latter is made possible by the former.

beneficence - "Actions [… that] **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms" (12).

closedness - The property of being inaccessible, having restrictive access policies, or otherwise opposing openness. The degree to which something is unknowable.

confirmation - Providing new evidence for an assertion.
data - Information that is encoded and stored.
data science - A multidisciplinary field that uses statistics and visualization to extract insights from observations.
document - A persistent unit of information.
documentation - The process of creating persistent records of information. Where we use the term here, we typically mean to a level of specificity to afford a model or replication.
ELSI - Ethical, legal and social implications.
FAIR - Findable, Accessible, Interoperable, Reusable. Four principles that aim to enhance the reusability of data documenting (83,151).
findability - Having properties of being uniquely and persistently identified, thoroughly described, clearly and explicitly semantically identified, or indexed in a searchable resource (83).
generalizability - The capacity for research findings and conclusions from a study conducted on a sample to be extended to the population.
human health research - The structured pursuit of increased collective scientific understanding of individual and collective wellness of our species.
impact - The magnitude of influence or effect of a document on a community or body of knowledge.
informed consent - A good-faith effort to ensure a stakeholder in a research project understands and agrees to the foreseeable risks and rewards of that project, or documentation of such an agreement (15–18).
interdisciplinarity - The property of involving expertise from more than one specialty in a document, group, or project.
interoperability - Using a formal, accessible, accessible, shared, and broadly applicable language for knowledge representation, using vocabularies that follow FAIR principles, or including qualified references to related data (83).
IRB - Institutional Review Board, a team designated by an organization to oversee and adjudicate ethical considerations of research projects.
justice - "The principle […] that equals ought to be treated equally[, … that] burdens and benefits should be distributed" equitably (12).
linguistic translation - The conversion of a document from one language to another.
local efficiency - Short-term, personal return on investment, ignoring broader context and long-term repercussions.
metadata - Documentation of data form and context, e.g., units of measurement.
model - An abstraction from the complexity of the world used to explore or explain something specific.
null hypothesis - The supposition that there is no significant difference between populations.
null hypothesis significance reporting - Documentation "of statistical inference by which an experimental factor is tested against a hypothesis of no effect or no relationship based on a given observation" (152).
openness - The properties of being accessible, measurable, freely available, efficient, or reusable (153). The amount of ease with which something is knowable.
openwashing - The practice of "spin[ning] a product or company as open, although it is not (148)."
persistence - The property of maintaining presence over a long period of time. The opposite of ephemeral.
preprint - A scientific work published online as a work in progress or of a completed project before peer-reviewed publication.
preregistration - The process of documenting a research plan submitting that documentation for peer-review prior to collecting or analyzing data. Also a term used for a document created for this purpose.
provenance - Documentation of a document's source and history.

public interest - The welfare or well-being of society.
registered report - A manuscript "submitted before a study has been undertaken […]includ[ing] a slimline introduction, hypotheses, experimental procedures, analysis pipeline, a statistical power analysis, and pilot data where applicable", reviewed and accepted in principle by a publisher who agrees to publish the results of the research described therein (95).
reusability - The property of being richly described with accurate and relevant attributes, published with a clear and accessible data usage license, associated with detailed provenance, and meeting domain-relevant community standards (83)
replicability - The ability of a method to be repeated to obtain a consistent result.
replication - Repeating the same or method on the same or similar data as a previous experiment.
reproducibility - The extent to which repeated methods support earlier conclusions drawn from those same methods.
retrievability - The properties of being both findable and acquirable.
research - Systematic investigation to reach new conclusions, provide new evidence for current understanding, or to uncover current misunderstandings.
respect - "The requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy" (12).
return on investment (ROI) - The ratio of benefits to costs.
rigor - Designed and structured thoroughness.
robustness - The ability to withstand or overcome adverse conditions or rigorous testing.
ROI - Return on investment, the ratio of benefits to costs.
scrutiny - Intense, rigorous examination.
silo - A structure of isolation. Here, an isolated body of knowledge.
significance - The importance and meaning of something. Not to be confused with the technical phrase "statistical significance" (90).
specificity - The extent to which a document or model applies to a particular thing.
stakeholder - Any entity with the potential to be affected, directly or indirectly, by the project in question.
statistical significance - The extent to which a result deviates from that expected to arise simply from random variation or errors in sampling.
translation - "The conversion of something from one form or medium to another" (154). Without additional specifiers (eg, "linguistic translation"), in the context of human health research we mean converting information from research into actionable practice (155).
validity - The extent to which measurement or findings truly represent the phenomenon claimed to assess.

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*Figure 1*

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*Figure 2*

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