International Initiative for Impact Evaluation

Transparency, Reproducibility and Ethics (TRE) Policy
September 2021 (Version 2)

Overview[1]

Established in 2008, the International Initiative for Impact Evaluation (3ie) supports the generation and effective use of high-quality evidence to inform decision-making and improve the lives of people living in poverty in low- and middle-income countries. To this end, 3ie has long recognized that the rigor and credibility of social science methods are critical for evidence-based policy.

Beginning in 2015, 3ie staff[2] identified a need to understand and begin to tackle threats to the credibility of social science research, such as p-hacking, publication bias and lack of reproducibility (Miguel et al. 2014; Nosek et al. 2015; Christensen et al. 2019). By 2017, 3ie had embraced the movement toward improved research transparency to mitigate these challenges and strengthen the credibility and quality of 3ie-funded and -managed research by strengthening how 3ie research teams design, implement and share study materials.

During the same time frame, along with other international development institutions (Barnett and Munslow 2014; DFID 2016), 3ie staff reflected on the need for stronger definition of ethical research principles and integration of best practices into 3ie's evaluation and research activities. From these efforts, 3ie codified several ethical values:

- 3ie believes that everyone with whom it comes into contact, regardless of sex, age, gender identity, disability, sexual orientation, ethnic origin, religion or caste has the right to protection from all forms of harm, abuse, neglect and exploitation.[3]
- Research transparency, reproducibility, and ethics are integral to research rigor.
- Foundational ethics – respect for persons, beneficence and justice – are standards based on fundamental human rights.
- Ethics should be considered at the macro-level of any 3ie research activity, where *macro-level ethics focus on the **purpose of the research activity and producing meaningful analyses** to improve development effectiveness*.

[1] This policy replaces Version 1 (18 April 2019). 3ie welcomes feedback on this policy. Please send your comments to 3ie@3ieimpact.org, with 'TRE feedback' in the subject line.
[2] <https://www.bitss.org/events/transparency-and-reproducibility-of-impact-evaluation-a-turning-point-for-the-evaluation-community/>.
[3] <https://www.3ieimpact.org/about-us/policies-reports>.

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- Ethics should be considered at the micro-level of any 3ie research activity, where *micro-level ethics focus on the internal processes of a research activity; in particular, ensuring* ***protection of human subjects and the health and safety of research teams****. Micro-level ethics focus on why and how to assign treatment and control groups; understanding respondent vulnerabilities and the power dynamics that exist within study teams; as well as foundational elements of informed consent, confidentiality, and balancing benefits with costs*.
- Both macro- and micro-level ethics need to consider the potential unintended consequences of conducting research activity and weigh these as additional benefits and/or costs.
- Ethics require explicitly incorporating the voices and needs of key stakeholders – including decision makers and potential beneficiaries – into the design, implementation and dissemination of research.
- Ethical standards require the means to monitor and address concerns throughout the research activity life cycle – from funding decisions to the design, implementation, dissemination and use of research activity findings.

Objectives

3ie's Transparency, Reproducibility and Ethics (TRE) Policy articulates its commitments to research rigor and credibility through transparent, reproducible and ethical practices, aligning these practices with funders' policies to the extent that is feasible and appropriate. The primary objectives of 3ie's TRE Policy are to:

1. Ensure the rigor and credibility of 3ie research activities by asking demand-driven questions and mitigating intentional and unintentional scientific misconduct – including p-hacking, failure to reproduce results, and falsification of data and/or results – as well as publication bias.
2. Ensure 3ie research activities follow the principles of research ethics: respect for persons, beneficence and justice.

Scope

Generally, the 3ie TRE policy applies to all:

1. **3ie-managed research activities** – these are activities where 3ie leads or co-produces the design, implementation and dissemination of research. The responsibility to follow 3ie's TRE Policy lies with the 3ie program manager, 3ie staff and 3ie consultants.
2. **3ie-coordinated studies** – these are studies where 3ie manages donor funds and issues the funding to an external team to design and implement the research activity. The responsibility to follow 3ie's TRE Policy lies with the lead researcher's institution.

specific research activities will have distinct TRE requirements under the 3ie TRE Policy. The research activities are distinguished by:

1. **Research activity type** – 3ie research activity types are grouped into: (a) impact evaluations; (b) process and formative evaluations; (c) observational studies; (d) systematic reviews and meta-analyses; and (e) evidence gap maps and rapid evidence assessments. 3ie may undertake other research activities[4] and require assessment for TRE Policy requirements on a case-by-case basis.

[4] Such as replication studies.

2. **Human subjects or no human subjects** – if a study involves human subjects,[5] specific TRE practices are required. However, if the study does not involve human subjects, those TRE practices are not required.

In cases in which 3ie study teams are subject to multiple TRE policies – such as those of other funders or journals – 3ie research teams are responsible for applying the more stringent of those policies to each TRE task.

Governance

As per the 3ie Duty of Care Policy,[6] the 3ie TRE team will be tasked with oversight and compliance of TRE Policy by 3ie research teams, review and propose responses to reported ethical incidents and prepare quarterly reports for the 3ie Senior Management Team on the status of TRE practices at 3ie.

Summary[7]

TRE tools

3ie has established the following TRE tools to support the 3ie TRE Policy:

1. **Registry for International Development Impact Evaluations (RIDIE)** – RIDIE is a registry of impact evaluations related to development in low- and middle-income countries. It houses both the registration and pre-analysis plans of 3ie impact evaluations.
2. **3ie Dataverse** – The 3ie Dataverse repository provides access to the de-identified data and statistical code for 3ie research activities.
3. **Development Evidence Portal (DEP)** – The DEP is a repository of public knowledge resources comprising impact evaluations, systematic reviews, and evidence gap maps conducted in low- and middle-income countries, including those produced by 3ie.
4. **Protecting Human Research Participants (PHRP) training** – 3ie provides access to training on protection of human subjects for 3ie staff and consultants.
5. **3ie examples and templates** – The TRE team has examples and templates to serve as resources for teams implementing TRE practices, including: (a) **pre-analysis plan (PAP) and protocol template** – outlining the minimum information required to build a PAP or study protocol; (b) **standardized reporting templates** – several templates for different stages of an evaluation are available to standardize reporting across projects; and (c) **TRE review template** – for documenting 3ie research team TRE issues and independent TRE Review assessments.

[5] HHS regulations define human subject at 45 CFR 46.102(f) as follows: 'Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.' Available at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html>.

[6] <https://www.3ieimpact.org/about-us/policies-reports>.

[7] The original 3ie research transparency policy relied on the Center for Open Science's Guidelines for Transparency and Openness Promotion (TOP) for funders. OSF | TOPLevel3Funders.gdoc.

TRE objectives and practices

Objective 1: Ensure the rigor and credibility of 3ie research activities by asking demand-driven questions and mitigating intentional and unintentional scientific misconduct – including p-hacking, failure to reproduce results, and falsification of data and/or results – as well as publication bias.

- **Demand-driven and inclusive design** – complementing the TRE Policy, 3ie research teams are governed by multiple 3ie policies and guidelines that prioritize local stakeholder engagement on the design and implementation of research activities to work toward meaningful research activity analysis.[8]
- **Study registration** – impact evaluations must be registered in RIDIE. 3ie encourages the registration of other research activities in relevant registries outside 3ie.
- **Pre-analysis plan or protocol** – relevant research activities must develop a PAP. For impact evaluations, PAPs will be published in RIDIE. Instead of a PAP, systematic reviews must publish protocols with the International Development Coordinating Group (IDCG).
- **Standardized reporting** – evaluation studies must publish a comprehensive description of the study context, design, analysis methods and findings in the DEP using standardized reporting templates.
- **Responsible data management and push-button replication (PBR)**: – relevant research activities must conduct secure and responsible data storage and transfer during the life of the research activity. On completion, to the extent feasible while still maintaining promises of confidentiality, research activities must facilitate access to the de-identified data and documentation underlying the analysis on the 3ie Dataverse in adherence with 3ie's push-button replication (PBR) protocol.
- **Citation** – adhering to appropriate citation of any data, program code and other methods.

Objective 2: Ensure 3ie research activities follow foundational principles of research ethics, including respect for persons, beneficence and justice.

- **Conflict of interest** – in adherence with 3ie's Conflict of Interest Policy,[9] all staff and consultants must declare any conflict of interest that arises during the review, selection and management of research activities. If the conflict of interest cannot be mitigated, staff and consultants are asked to recuse themselves from the research activity.
- **Training in foundational research ethics principles** – all 3ie staff and consultants must complete training on protection of human subjects through the PHRP training program. This program focuses on the foundational principles of respect for persons, beneficence and justice.
- **Ethical assessment and documentation** – research activities must demonstrate consideration of specific issues linked to both rigor and ethical research practice, including assessing and mitigating risk for vulnerable study populations, conducting formative work to ensure contextual and cultural appropriateness, piloting test questionnaires, informed consent, and interview protocols prior to implementation, and conducting quality spot checks of data collection and entry. Relevant research activities must complete the 3ie TRE Review template to document their consideration of ethical issues.

[8] <https://www.3ieimpact.org/about-us/policies-reports>.
[9] <https://www.3ieimpact.org/sites/default/files/2018-05/3ie_conflict_of_interest_policy.pdf>.

- **Informed consent process** – following standard principles for research ethics, relevant research activities must ensure a comprehensive informed consent process.
- **Data use and/or sharing agreements** – when research activities rely on existing, secondary data, 3ie staff and consultants will work with the data owner to define who has access to what data, for what purpose, and determine if those data can be prepared for public and/or restricted access use.
- **Independent ethical review, monitoring and reporting** – relevant research activities must (a) adhere to local ethical review options and requirements; and (b) adhere to Institutional Review Board (IRB) options and requirements. In addition to these required reviews, 3ie has established the TRE Review to review and assess 3ie research activities at key milestones in the research activity life cycle. In addition, as per the 3ie Duty of Care Policy,[10] the 3ie TRE Review will review and act on any reported ethical incidents and prepare quarterly reports for the 3ie Senior Management Team. Data confidentiality practices are informed by the responsible data- and code-sharing practices and any ethical incidents related to data confidentiality will be included in 3ie TRE Review reporting.

Table 1 defines what TRE practices are required by study type and reliance on human subjects. It defines TRE requirements tied to funding triggers for both 3ie-managed and -funded research.

Table 1: Summary of TRE requirements by 3ie study type

Funding requirements	Study type	Impact evaluations		Process and formative evaluations		Observational studies		Systematic reviews and meta-analysis	Evidence Gap Maps and rapid evidence assessment
		Human subjects	No human subjects	Human subjects	No human subjects	Human subjects	No human subjects	Aggregate data only	Aggregate data only
	TRE tasks								
Prior to each data collection funding	Conflict of Interest Assessment	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Study registration	Yes	Yes	No	No	No	No	No	No
	Preanalysis plan or protocol	Yes	Yes	Yes	Yes	No	No	Yes	Yes
	Ethical assessment and documentation	Yes	Yes	Yes	Yes	Yes	Yes	Maybe	Maybe
	Training in protection of human subjects	Yes	No	Yes	No	Yes	No	Maybe	Maybe
	Institutional Review Board (IRB)	Maybe	No	Maybe	No	Maybe	No	Maybe	Maybe
	Ethics review	Yes	No	Yes	No	Yes	No	Maybe	Maybe
	Informed consent	Yes	No	Yes	No	Yes	No	No	No
	Data Use/Sharing Agreement	Yes	Yes	Yes	Yes	Yes	Yes	Maybe	Maybe
Prior to final payment	Standardized reporting	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Citation standards	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Push Button Replication	Yes	Yes	No	No	No	No	Yes	No
	Responsible data and code sharing	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[10] <https://www.3ieimpact.org/about-us/policies-reports>.

Objective 1: Ensure rigor and credibility

Study registration

3ie requires all impact evaluations to be registered, preferably before the start of data collection. 3ie-funded impact evaluations must be registered in RIDIE*. 3ie-funded systematic reviews must publish their protocol with* IDCG*. Other 3ie-funded research activities that do not qualify for* RIDIE *may be registered in a relevant registry.*

Study registration is a means by which the research community mitigates publication bias and p-hacking. The goal of study registration is to provide a public mechanism for identifying and characterizing all studies conducted to answer specific questions (i.e. the denominator for all such studies) and their summary findings (i.e. the evidence base). This is the motivation for many study registries that serve different types of research; for example: RIDIE, ClinicalTrials.gov, OSF, AEA RCT Registry and EGAP.

The details provided in a study registration should include descriptions of: (1) the research design and study materials, including planned sample size; (2) motivating research questions or hypotheses; (3) outcome variable(s); and (4) predictor variable(s), including controls, covariates and independent variables (conditions). Whenever possible, the study materials themselves should be included in the registration.[11]

3ie has a strong preference for preregistering relevant research activities before baseline data collection begins. However, any ongoing impact evaluation that is unregistered should be registered in RIDIE at the earliest date feasible.

Pre-analysis plan (PAP)

Research teams must develop and publish a PAP before midline and/or endline analysis of underlying data sets. For impact evaluations, the PAP should be published on the study registration page in RIDIE. 3ie-funded systematic reviews must publish their protocols with IDCG. For other studies, the PAP, or PAP equivalent, can be published on DEP.

Pre-analysis plans are means by which the research community mitigates publication bias, p-hacking, as well as failure to replicate due to poorly specified analysis. The goal of a PAP is to improve the documentation of research design choices (such as the definition of variables, covariate selection, etc.), increase research transparency and allow other researchers to replicate research activity analysis.

For relevant 3ie research activities, the PAP should describe the hypotheses to be tested and specifications, as well as the sequence of all planned statistical analyses. It should clearly describe primary and secondary outcomes, covariates and any planned subpopulation analysis. In developing the PAP, researchers should consult the 3ie PAP template and other publicly available templates or guidance from organizations such as Berkeley Initiative for Transparency in the Social Sciences (BITSS) and the Center for Open Science.[12]

[11] <OSF | Badges to Acknowledge Open Practices Wiki>.

[12] Open Science Framework 2016. *Openness is a core value of scientific practice*. Charlottesville: Center for Open Science. Available at: <https://osf.io/tvyxz/wiki/home/> [Accessed 1 March 2018].

For evidence synthesis products, the protocol is the equivalent of a PAP. The protocol should clearly describe the search strategy and inclusion/exclusion criteria. If a meta-analysis is to be performed, the specifications of all planned statistical analyses should be described. To develop the protocol for systematic reviews, researchers should consult resources from IDCG on submitting a proposal.

Note that the requirement to develop a PAP or protocol does not imply that researchers are prevented from conducting additional exploratory analyses. If any post-hoc analyses are conducted, those results should be transparently reported as such in the study report and any additional associated publications.

For relevant 3ie research activities, the PAP or protocol must be date-stamped prior to analysis. If 3ie research teams determine the PAP or protocol should not be made public immediately, the PAP or protocol can remain marked as private on the RIDIE or DEP system, with a publication date set for an agreed date prior to the closing of the grant.

Standardized reporting

Research teams must publish a comprehensive description of the study context, design, analysis methods and results in study reports on DEP to ensure studies are transparent, reproducible and useful.

3ie requires authors to follow standards for disclosing key aspects of their research to ensure studies are transparent, reproducible and useful. Highly structured study reports using standardized headings and terminology will enhance the discoverability of studies and data, increasing the potential for automatic indexing and data extraction in the future. 3ie provides researchers with templates for study reports, which have been developed to be consistent with best-practice reporting standards published by the Equator Network.[13]

3ie-funded researchers are encouraged to review these standards. During the proposal and report submission stages, researchers should confirm that they have reviewed the standards; report whether any standards are relevant to the research application; and confirm that they will follow (at proposal stage) or have followed (when reporting) those standards in the final report.

Responsible data management and sharing

To protect the confidentiality of human subjects involved in research activities, 3ie research teams must conduct secure and responsible data collection, storage, transfer and sharing during the life of the evaluation. On completion of the study, and to the extent feasible while still maintaining promises of confidentiality, 3ie aims to make de-identified data and documentation underlying analysis reports, publications or other communications available on the 3ie Dataverse for purposes of replicating the results and reusing these data. This requires consideration of both data de-identification efforts and use of public and/or restricted-access data-sharing functions.

[13] The following reporting standards are particularly relevant: via the Equator Network, Describing interventions in sufficient detail to allow their replication, Reporting of pragmatic trials in healthcare, Cluster randomised trials, Reporting of intervention effects in randomised trials where health equity is relevant, PRISMA guidelines for systematic reviews and meta-analyses; and via the Campbell Collaboration, MECCIR Standards for systematic reviews.

For responsible data collection, storage and transfer during the research activity life cycle, 3ie research teams are encouraged to document a data management plan to define who will have access to which data when and for what purpose. The primary goal is to responsibly manage personally identifiable information and sensitive data on human subjects throughout the research activity life cycle to mitigate risk of harm due to loss of confidentiality. This requires careful consideration of how data – both identified and de-identified – are securely stored and transferred across the required data handlers in accordance with promises of confidentiality that will be made during the informed consent process.

For responsible data sharing, the goal is to facilitate computational reproducibility of analysis and to maximize the use of 3ie-produced data for additional evidence generation. The 3ie Dataverse adheres to policies that make data discoverable, accessible and usable, and ensure the data will be preserved for the long term. To allow for the replication of 3ie research, 3ie requires the following (as feasible):

1. 3ie researchers reusing data available from public repositories must provide program codes, scripts for statistical packages, data dictionaries or codebooks and other documentation sufficient to allow an informed researcher to reproduce all published results precisely.
2. 3ie researchers using original data must:
    a. Submit to 3ie all de-identified data sets,[14] data dictionaries or codebooks, including data collected but not used in the analysis. 3ie expects researchers to budget to cover these costs in funding proposals. De-identification requires the removal of direct identifiers and careful consideration regarding indirect identifiers that may support re-identification risk within the study populations.
    b. Include all variables, treatment conditions and observations described in the final report to 3ie.
    c. Provide a full account of the protocols and tools used to collect, preprocess, clean or generate the data and metadata, including the collecting agency, time frame of the project and data collection activities, and training provided to the survey team.
3. 3ie researchers working on synthesis studies and meta-analyses must submit to 3ie:
    a. Data extraction templates for all synthesis or meta-analysis work.
    b. All analysis data (quantitative and qualitative datasets, which include effect sizes where relevant) and analysis program codes used in the meta-analysis.

These materials must be submitted to 3ie before payment of the final tranche of the grant. 3ie will make them available on 3ie Dataverse as early as possible after publication of the final technical report on 3ie's website. In some cases, 3ie may allow researchers to embargo data publication for up to 12 months from the date of publication of the final technical report.

[14] Suggested resources: (a) ICPSR Guide to Social Science Data Preparation and Archiving; Dryad *Human Subjects Data*; (c) AJPS *Guidelines for Preparing Replication Files*; (d) List of data types from the Qualitative Data Repository..

Exceptions to data sharing due to confidentiality or ownership

3ie recognizes there may be legal or ethical reasons that limit data sharing. In such cases, the researchers must inform 3ie as early in the research activity life cycle as feasible. To be considered exempt from data- and code-sharing requirements, research must:

- Explain the restrictions on the data set or materials.
- Provide a public description of the steps others can follow to request access to the data or materials.
- Publicly post statistical code and other documentation that precisely document analysis.
- Provide access to all data and materials for which the constraints do not apply.

In cases in which 3ie funds studies jointly with other donors, decisions on intellectual property and data sharing will be agreed on at the time of the proposal's approval. 3ie's TRE team will review requests for exclusions to this policy during TRE review.

Push-button replication (PBR)

Relevant 3ie research activities must follow 3ie's PBR protocol as a condition of final payment. In the PBR, 3ie aims to computationally reproduce study analyses using the de-identified data, cleaning codes and analysis code submitted by research teams. 3ie will only conduct minor troubleshooting of code during the PBR (e.g. changing the file path in scripts), with the expectation that the research teams will provide adequate materials to replicate their findings. Results that cannot be replicated will be returned to researchers with a requirement that they provide additional materials or revise their report so that the PBR results match the report.

PBRs will also be performed on all 3ie-funded meta-analyses.

Citation standards

3ie assigns digital object identifiers (DOIs) to all reports, pre-registrations and data sets that it publishes. All 3ie-funded study reports must adhere to appropriate citation referencing of any data, statistical code and other methods.

Data, statistical code and other methods materials are recognized as original intellectual contributions, which should be cited in the text and listed in the references. References for data sets and program code must include a persistent identifier, such as a DOI. Persistent identifiers ensure future access to unique published digital objects, such as a text or data set. Persistent identifiers are assigned to data sets by digital archives, such as institutional repositories and partners in the Data Preservation Alliance for the Social Sciences (Data-PASS).

Here is an example of an appropriate data set citation using 3ie-compliant Harvard referencing:

> Campbell, A and Kahn, RL, 1999. *American national election study*, *1948*. ICPSR-7218-v4. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor]. Available at: <https://doi.org/10.3886/ICPSR07218.v4> [Accessed 13 April 2018].

Objective 2: Ensure research follows foundational principles of research ethics

Conflict of interest

3ie requires its staff and consultants to declare any conflict of interest that may arise during the review, selection and management of research activities. 3ie management will then determine if recusal is necessary or if appropriate risk mitigation efforts can be introduced to mitigate the influence of any conflict of interest over the integrity of the study.

Training in foundational research ethics principles

All 3ie staff and consultants must complete training on protection of human subjects that focuses on the foundational principles of respect for persons, beneficence and justice. 3ie has made training available through PHRP training. However, staff and consultants can also document compliance with this requirement with a valid training certificate from other qualified training resources that reflect the most up-to-date regulations regarding protection of human subjects.

Ethical assessment and documentation

Research activities must demonstrate their consideration of specific issues linked to both rigor and ethical research practice, including:

1. **Assessing the vulnerability of study populations** and integrating appropriate risk mitigation efforts for protecting vulnerable populations during data collection, analysis and dissemination.
2. **Conducting formative work to ensure contextual and cultural appropriateness** of questionnaire design, informed consent and interview protocols before data collection starts.
3. **Piloting survey instruments** before fielding them for the full study.
4. **Conducting quality spot checks** of data collection teams and management. This includes spot checks of processes to ensure: representativeness of data; use of data collection protocols; field manuals; adequate study team quality and presence on the ground; training of data collection teams; translation of survey instruments into local languages and back; ensuring that field enumerators submit data to supervisors at the end of the day (e.g. double data entry; spot checks on use of consent forms and spot checks and validation of a small percentage of data collected); and quick analysis of raw data to understand contradictions that may be quickly corrected in the field. 3ie staff themselves do this when they are able to during their monitoring visits. Otherwise, this is ensured through setting standards and deliverables for study grantees.

To facilitate this assessment, 3ie requests research teams to complete the 3ie TRE review template. As discussed below, the 3ie TRE Review will periodically review this TRE review document to assess and monitor risks relevant 3ie research activities face. The research team's TRE Review can also search as future documentation, such as an Ethics Appendix[15] to final published reports.

[15] For example, see discussions in Aseidu, Karlan, et al 2021 - https://www.nber.org/papers/w28393

Informed consent

Following standard principles for research ethics, relevant 3ie research activities must ensure a comprehensive informed consent process. Each research activity will customize consent language so that the study population understands it; and ensure that study participants are informed of any risks, benefits and costs of participating in the study. 3ie will review the language in the consent form to ensure that study participants are made aware of the study's compliance with data sharing policies. 3ie may advise researchers to amend consent language based on the review. Following the 3ie review, informed consent statements should be submitted as part of any required IRB review process. Any IRB-required edits to the informed consent should be reviewed by 3ie before finalizing.

3ie staff will review informed consent forms that grantees submit with survey tools for review or when they are making monitoring visits to study sites. On field visits, 3ie staff will spot check informed consent with study participants.

Data-sharing and use agreements

For relevant 3ie research activities, the 3ie research team may identify secondary data sources. In such cases, 3ie staff and consultants should develop a documented data-sharing and/or use agreement between 3ie and the owner of the existing data source. The agreement should include documented understanding of: (1) who owns the data; (2) whether the data can be prepared for public and/or restricted access use; and (3) whether the data can be made available through the 3ie Dataverse or other mechanisms (such as the data owner's platform).

Independent ethical review, monitoring and reporting

Relevant 3ie research activities must: (1) assess local ethical review options and requirements; and (2) assess IRB options and requirements. Confirmation of IRB clearance and researcher responses to the 3ie TRE review template must be provided to 3ie prior to each data collection round. In addition, as per the 3ie Duty of Care Policy,[16] the 3ie TRE team will review and act on any reported ethical incidents and prepare quarterly reports for the 3ie Senior Management Team. Data confidentiality practices are informed by responsible data- and code-sharing practices and any ethical incidents related to data confidentiality will be included in 3ie TRE Review reporting.

3ie is fully committed to the value and importance of monitoring and ensuring ethical standards during the entire research activity cycle. Macro- and micro-level ethical issues are considered at multiple points in the study life cycle, including:

- **Proposal preparation phase for 3ie-managed studies** – the study team may identify ethical issues with the program to be evaluated. The team must report them in the proposal preparation phase final report and/or in their proposal. 3ie staff should ensure issues are explicitly noted for the review.
- **Proposal review for 3ie -coordinated studies** – this step also includes a close look at any ethical issues grantees raise in a proposal. Written comments are compiled, and discussions are held internally and with grantees to ensure that ethical issues and risks are managed before any proposal is approved for funding. All documents are kept in a secure online grant information management filing system.

[16] <https://www.3ieimpact.org/about-us/policies-reports>.

- **Review of survey tools and approvals** – this review is part of regular grant management by 3ie staff and reviewers. 3ie staff and reviewers pay particular attention to vulnerable interviewees (e.g. victims of sexual or gender-based violence). Any concerns identified are addressed through comments and discussions to achieve a satisfactory outcome.
- **During study implementation** – 3ie requires teams to complete a progress report to trigger the next tranche of funding based on a template provided. There is a section in the progress report where they are asked about problems encountered and solutions implemented or planned. This progress report is reviewed by at least two 3ie staff and the external advisor. Any ethical questions arising are addressed in comments and possibly during a direct discussion.
- **Ongoing monitoring during implementation** – 3ie may ask about ethical challenges at any time, including checking/confirming participants' consent during field visits.

3ie is instituting a monitoring and reporting system for 3ie research activities, for data collectors and study participants to report ethical issues and concerns to the 3ie TRE team.

Additional suggestions

Open access publishing

3ie policy is to ensure unrestricted access to and reuse of all 3ie-published research funded, in whole or in part, by 3ie.

3ie will publish the final approved technical report from 3ie grants and contracts on its website, which may include being published in one of 3ie's publication series. These publications comply with Creative Commons Attribution-Non-commercial 4.0 International (CC BY NC 4.0).

In addition, 3ie-funded researchers are encouraged to publish their research in recognized peer-reviewed journals. 3ie strongly encourages researchers to include open access publishing fees when budgeting for research projects and encourages publishing in open access publications.

Registered reports

3ie encourages 3ie research teams to submit registered reports to a qualifying journal – such as the *Journal of Development Economics* – but this is not compulsory.

Glossary

3ie Dataverse – the 3ie Dataverse repository provides access to the de-identified data and statistical code for 3ie research activities.

Beneficence – an ethical principle of research that incorporates two ideas: (1) do no harm and (2) maximize possible benefits.

Computational reproducibility – the practice of running the same code over the same data and obtaining the same results as those presented in the originally reported analysis.

Data de-identification – general term used for any process of removing association between a set of identifying data and the data provider.

Development Evidence Portal – the DEP is a repository of public knowledge resources produced by 3ie's impact evaluations, systematic reviews and evidence gap maps conducted in low- and middle-income countries.

Direct identifiers – data that directly identify a person (individual or legal). These data may include full name, date of birth, mailing or home address, email address, telephone number, GPS coordinates, national identification number and physical/biological identifiers (e.g. physical appearance, through photo or video data collection, fingerprints, DNA, etc.). Depending on the study and data needs, direct identifiers can also include the name of the school, health facility, community, etc. that directly identify the location of data collection or extraction.

Evidence gap maps – thematic collections of information about impact evaluations and systematic reviews that measure the effects of international development policies and programs. They present a visual overview of existing and ongoing studies or reviews in a sector or subsector in terms of the types of programs evaluated and outcomes measured. Evidence is mapped onto this framework, graphically highlighting gaps where few or no impact evaluations or systematic reviews exist; and where there is a concentration of impact evaluations but no recent high-quality systematic review.

Final report – evaluation reports compiled at the end of a study documenting all details about the study submitted to 3ie as a contract deliverable to be published on 3ie's website.

Formative evaluation – usually undertaken early in the development of a program to inform providers and stakeholders about trends in results, whether the goals of the program are likely to be fulfilled, and to identify barriers to and facilitators of implementation. Results of the formative evaluation are then incorporated into the program with the necessary adjustments made to improve program implementation. These evaluations are usually less formal and more likely to be internal than summative evaluations; while they are often mentioned in descriptions of new programs, the evidence is rarely published.

Human subject – HHS regulations define human subject at 45 CFR 46.102(f) as follows: 'Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information'.[17]

[17] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html

Impact evaluation – research activity that measures the net change in outcomes among a particular group (or groups) of people that can be attributed to a specific program using the best methodology available, feasible and appropriate to the evaluation question that is being investigated and to the specific context.

Indirect identifiers – data used to identify a person (individual or legal) through association with other variables. These include unique, observable or other characteristics that may identify a specific data provider (or household, community, school, etc.) even when direct identifiers have been removed.

Informed consent – informing research participants about the key elements of the research study, its expected risks and benefits, how data collected will be shared, promises of confidentiality and voluntary participation.

Institutional Review Board – an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which the IRB is affiliated.

Justice – in research, refers to the just distribution of the risks, burdens and expected benefits of the research.

Meta-analysis – systematic analysis of a set of existing evaluations of similar programs to draw general conclusions, develop support for hypotheses and/or produce an estimate of overall program effects.

Observational studies – a type of study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (e.g. no treatment is given).

P-hacking – known also as data mining or specification search; defines all analytical alternatives that research might test to obtain a statistically significant result. Examples include restricting samples, testing subgroups or redefining variables after looking at the final data.

Personally identifiable information – information that can be used on its own or in conjunction with other information that is or can be linked to a specific individual (or household, community, school, etc.) to determine the identity of a data provider or otherwise locate or contact the data provider. It includes both direct and indirect (or quasi-) identifiers.

Publication bias – when the findings of a study affect its likelihood of being published.

Pre-analysis plan (PAP) – to improve the documentation of research design choices (such as the definition of variables, covariate selection, etc.), increase research transparency and allow other researchers to replicate research activity analysis. For relevant 3ie research activities, a PAP should describe the hypotheses to be tested and specifications, as well as the sequence of all planned statistical analyses. It should clearly describe primary and secondary outcomes, covariates and any planned subpopulation analysis.

Process evaluation – determines whether program activities have been implemented as intended and resulted in certain outputs. Researchers may conduct a process evaluation periodically throughout the life of their program and start by reviewing the activities and output components of the logic model

Protecting Human Research Participant (PHRP) training – 3ie provides access to training on protection of human subjects for 3ie staff and consultants.[18]

Protocol – for 3ie systematic reviews, a document describing the rationale, hypothesis, design, methods and data extraction framework.

Push-button replication – PBR research attempts to confirm the validity of published results using both the original data and the programming code from a study.

Rapid evidence assessment – a targeted systematic review on a rapid timeline. Like a systematic review, a rapid evidence assessment uses a systematic approach to search for and screen studies for inclusion. To make it rapid, the search strategy may be limited to certain databases and the scope may be narrowed to focus only on a few intervention types.

Registry for International Development Impact Evaluations – RIDIE is a registry of impact evaluations related to development in low- and middle-income countries. It houses the registration plans and PAPs of 3ie impact evaluations.

Respect for persons – an ethical principle of research that incorporates at least two ideas: (1) individuals are treated as autonomous agents; and (2) individuals with diminished autonomy are entitled to protection. In most cases, respect for persons requires that research subjects or data providers enter into research voluntarily and with adequate information.

Reproducibility – a general term to describe several problems in research credibility, including low rates of replicability and low rates of computational reproducibility.

Sensitive data – information that may pose a risk to the data provider if it is collected or released in a way that links it to the data provider (e.g. income, assets or health status).

Study registration – to provide a public mechanism for identifying and characterizing all studies conducted to answer specific questions (i.e. the denominator for all such studies) and their summary findings (i.e. the evidence base). The details provided in a study registration should include: (1) a description of the research design and study materials including planned sample size; (2) a description of the motivating research question or hypothesis; (3) a description of the outcome variable(s); and (4) a description of the predictor variables including controls, covariates and independent variables (conditions). When possible, the study materials themselves should be included in the registration

Systematic review – a synthesis of the research evidence on a particular topic, such as the effectiveness of water supply and sanitation, obtained through an exhaustive literature search for all relevant studies using scientific strategies to minimize errors associated with appraising the design and results of studies. A systematic review is more thorough than a literature review. It may use the statistical techniques of a meta-analysis, but need not necessarily do so.

Vulnerability – of research participants; refers to a diminished ability to fully safeguard one's own interest in the context of a specific research project. This may be the result of limited decision-making capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances.

[18] https://phrptraining.com/