IDinsight Research Ethics Policy

This document governs all IDinsight client-facing work

IDinsight

Contents

1 Overview

The IDinsight Research Ethics Policy[1] governs all IDinsight client-facing work. All IDinsight staff, as well as other individuals engaged in research studies under the auspices of IDinsight (referred to as "staff" below), are required to read and become familiar with this policy. Staff are responsible for understanding how each element of this policy applies to them and their work.

This policy explicitly applies to staff who work directly with research human research participants, through research design, piloting, primary data collection, program design or program implementation.

This policy also applies to staff who interact with individuals indirectly—those who have access to the information human research participants share including data, transcripts, any audio or visual records, or access to the identities of research participants[2].

After reviewing this policy, update the corresponding acknowledgement in Bamboo HR.

The first section, Motivation, describes the justification for such a policy and the general principles that govern research ethics for working with human research participants. The second section, Application and Scope, describes when and to whom this policy applies. The third section, Requirements and Recommendations, describes what staff must do to comply with this policy. The fourth section, IDinsight Ethics Approval Process, describes the institutional governance systems that enforce this policy.

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[1] We would like to thank Paul Ndebele, George Washington University, Douglas MacKay, University of North Carolina, and Barun Mukhopadhyay, Indian Statistical Institute for their inputs into this policy.

[2] We do not expect surveyors or temporary field supervisors to read this policy. However, IDinsight is responsible for organizing human research participants training as part of every surveyor training to ensure surveyors understand the relevant sections and act accordingly. If field staff will be interacting with children, training should include specific **child protection modules.**

2 Motivation

2.1 Research participants

In most cases, the information IDinsight collects comes from questioning or observing individuals, within the context of observational or experimental research. We should never take for granted the willingness of respondents to take time out of their day to interact with us and entrust us with their information and experiences. But being grateful isn't enough. Legal and contractual obligations aside, we also need to act ethically. Fortunately, others have been thinking about this for many decades and have developed a list of principles to serve as our moral compass when conducting research.

2.2 General Ethical Principles

Scientific inquiry aimed at developing generalizable knowledge that improves human wellbeing typically involves human participants. In such research, human participants must be protected from harms in the design of the study, and any risks to study participants must be weighed against the benefits to society of the research. A set of general ethical principles are used to guide study design and implementation; these have been operationalized in a range of ways across disciplines and institutions, with most of the developments originating in biomedical research (see UNESCO Universal Declaration on Bioethics and Human Rights, 2005).

For IDinsight, a useful point of departure for our ethical research practices is the **Belmont Report,** first crafted in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and created as part of the National Research Act of 1974 by the United States government. The Act introduced and passed after a long history of unregulated and unethical research practices, of which the **Tuskegee Syphilis Experiment** may have been the final straw. Many efforts to stop unethical research existed beforehand and outside of the United States (e.g. the **Nuremburg Code** and **Declaration of Helsinki**). We choose to follow the principles laid out in the Belmont report as it has become a cornerstone for Institutional Review Boards (IRBs) in US universities and government agencies (and beyond). It clearly lays out three key principles to which researchers must adhere, which are meant to inform the selection of participants, the informed consent process, and the assessment of risks imposed on participants.

- **Respect for persons**: This requires treating research participants as autonomous individuals who should not be coerced or unduly induced into participating, who should be guaranteed privacy and confidentiality, and who should be treated with courtesy and respect[3]. This principle is operationalized primarily by requiring that participants go through an informed consent process in which they learn about the full extent of the research, presented comprehensively and truthfully.
- **Beneficence**: Beneficence requires that the benefits of the study to society and participants outweigh any risks to the research participants. This principle is operationalized by simultaneously minimizing risk and ensuring that the research leads to knowledge that could be used to improve health and wellbeing.
- **Justice**: This requires that there be a fair distribution of the benefits and burdens of research, including the burdens of participation and the benefits from evidence-based interventions that may eventually result from the research. This principle is operationalized by ensuring that the population participating in the research is representative of future beneficiaries of generalizable knowledge, and that research procedures are administered equally, fairly, and in a non-exploitative manner.

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[3] Autonomous individuals are capable of making informed decisions about their participation. Vulnerable populations, in contrast, might include children, prison inmates, those with diminished mental capacity, etc.

3 Application and scope of this policy

3.1 Human Research Participants

In research, human research participants are living individuals who take part in research studies (knowingly or unknowingly) from which, or on which, information is gathered. For IDinsight's work, this definition should be broadened to include individuals on which data are gathered regardless of whether the evaluation is considered "research" (i.e. monitoring and evaluation activities led by IDinsight and/or, in some cases, as discussed below, M&E data used by IDinsight).

The definition of human research participants does not necessarily encompass all individuals affected by a program—specifically those from whom we are not collecting data. However, as discussed below, we must still take those individuals' welfare into account (and our work's impact on their welfare) when considering our involvement in any engagement[4].

This policy is relevant for all data we collect on individuals or, if we have subsequent access to the data, any M&E design work that affects how and from which individuals' data are collected (even if we are not directly responsible for data collection).

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[4] See McKay, Douglas and Averi Chakrabarti. 2018. "**Government Policy Experiments and Informed Consent.**" Public Health Ethics 12: 188-201.

3.2 IDinsight Activities: Research and Evaluation

General research ethics principles have been developed to govern research, or the intentional generation of knowledge. However, much of the work of IDinsight falls into a "grey area" because we may be working to answer questions asked by specific clients for their own use (rather than to contribute to the body of evidence). Therefore, we extend ethical principles over all activities that involve information-gathering from human participants.

According to the Belmont Report, research "designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."

> Our work should be classified as research if the results are to be published as a public report or in an academic journal, or shared through a blog post, project webpage, webinar, or other media. (See the **IDinsight Research Publication Policy.**)

For research ethics, the distinction between "research" and "non-research evaluation" is not   relevant. According to the UNICEF Procedure for Ethical Standards in Research, Evaluations and Data Collection (2015), "it is the process of data collection, analysis and communication that raises ethical issues and not the nature of the evidence generation (e.g. research or evaluations)." Except for the section below on IRBs, most of the principles apply to evaluation activities we do—data collection, evaluation—regardless of whether those activities technically qualify as research. In this document, we may use the terms research and evaluation interchangeably.

In the case of evaluations, ethical considerations relate both to the evaluation design and implementation *and* to the intervention or program being evaluated. For much of the work we do—specifically evaluations, IDinsight has little to no control over the design of the policy or program being evaluated. And in many cases, the intervention would be implemented with or without IDinsight involvement. Arguably, in those cases IDinsight would therefore not be responsible for the ethics of a program being implemented[5]. However, we extend our ethical practices to incorporate attention to the intervention itself in several ways:

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[5] In fact, if a program is harmful, IDinsight impact evaluations could directly lead to a decision to discontinue the program and produce general knowledge of the program's harm. See Glennerster, Rachel and Shawn Powers. 2018. "**Balancing Risk and Benefit: Ethical Tradeoffs in Running Randomized Evaluations**," The Oxford Handbook of Professional Economic Ethics

First, if as part of the research, individuals are subjected to a state (e.g. receiving a service) that is knowingly worse than the status quo (i.e. the "standard of care"), this research would violate research ethics, and therefore not something we should do[6].

Second, the implementation of a likely positive intervention—in particular, who receives it—may be directly impacted by IDinsight's research design, especially with randomized controlled trials. If we have reason to believe that implementation changes required by a certain research design could lead to individuals being worse off, IDinsight should consider alternate research designs.

Third, services such as Program Design support, Process Evaluations, and Monitoring could change intervention design, and could also facilitate higher intensity implementation. If the program is harmful to individuals, our work would potentially amplify that harm. It is therefore incumbent on IDinsight to consider the potential harm of a program for which IDinsight provides direct design or implementation support.

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[6] See MacKay, Douglas. 2018. "**The ethics of public policy RCTs: The principle of policy equipoise**," Bioethics 32: 59-67.

4 Requirements and Recommendations

4.1 Determination of which review is required

Before any data collection activities commence, the project team must submit a form to the Ethics Review Committee proposing the "ethics review status": internal ethics review (exempt, expedited, or full review), or review from an Institutional Review Board (IRB), or both. As part of the decision, the team must document evidence of any ethical research practices stipulated by or normative in the host country. The ethics review status, and review must be completed, and approval granted, *before any primary data are collected from respondents*. The IRB process is discussed in the next subsection. Internal ethics review is discussed in the next section below.

- The Project Director is responsible for documenting evidence of in-country research ethics requirements and norms.
- The Research Evaluation and Data (RED) Team Point Person is accountable for determining the proper ethics review status, and if required, ensuring review happens and approval obtained before data collection begins.
- The RED Team Point Person is accountable for updating the Global Data Hub with the ethics review status and notifying the IDinsight Ethics Review Committee of this status.
- The RED Team Point Person is accountable for updating the ethics review status if any substantial changes in the project design or scope justify doing so

- The full team should also take responsibility for ensuring timely ethics review and approval.

Refer to **Appendix A: IRB Decision Tree** for whether the project requires IRB or internal ethics review.

4.1.1 IRB review and approval

IDinsight requires projects to obtain review and approval from formal IRBs in the following cases:

1. If the country in which we are working requires IRB review and approval for the work that we are conducting[7];
2. If the work is considered research—it is explicitly intended to produce generalizable knowledge (i.e. with an intention to share the results publicly)—and the professional norms in the country are to obtain IRB for any research activities;[8]
3. If a non-IDinsight researcher (e.g. academic) is partnering on the project and that researcher comes from an institution that requires IRB approval. In this case, the external researcher is responsible for obtaining IRB approval from their institution.

If projects chose to obtain IRB,

- The RED Team Point Person is accountable for ensuring teams update the Global Data Hub with the appropriate information including the IRB name, protocol number, expiration date, and attached application and approval letter

The following requirements and recommendations apply whether or not we obtain IRB or internal approval.

4.1.2 Informed consent

Human research participants (from whom we wish to collect data directly) must be _invited_ to participate in the evaluation. They must give their consent to participate and have the opportunity to withdraw their participation for any reason at any point. This requirement is guided by the research ethics principle of "respect for persons."

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[7] If it is not clear whether a country requires IRB approval for a certain engagement, we should err on the side of caution and obtain IRB approval.

[8] We may not always know ex-ante whether a project will be shared publicly and therefore may not think to get IRB approval for standard evaluation work. Our default should be that the work will be shared in some media. At worst, failure to get IRB approval may limit our ability to share evaluation results more broadly.

There are important exceptions related to situations in which the risk of participation is zero and there are large logistical challenges of identifying and communicating with individuals whose information is being used. For example, this does not apply to data collected for routine administrative purposes by implementing organizations *unless* the administrative data or implementation of a program has been altered for the purposes of an evaluation. This also may not apply in the case of a cluster randomized study, in which information is collected at the level of a health facility, school, community, or other aggregate entity.

Consent may be written or oral in different situations and may be given by the participant. If the research subject is not able to give "legal" consent on their own behalf (e.g. children), and we require consent from an authorized individual (e.g. a parent), we may still require "assent" (i.e. agreement to participate) from the respondent.

To ensure that the study participant is truly *informed and understands,* the information provided for consent should be communicated in the respondent's language and usually includes:

- The research purpose,
- The study procedures (e.g., interviews or focus group discussion),
- The estimated time and effort of involvement-the duration of the study and time required,
- An assessment of the potential risks,
- Projections about potential benefits to participants and to society,
- Information about the participant's right to refuse to answer any question or to stop at any time without negative consequence from the research team or the implementing organization,
- A contact for if a participant has a question about the specific research project, and a contact for the participant if s/he has general questions about the rights of a research participant.

It is expected that the informed consent language will be read verbatim by surveyors, so the importance of each piece of information must be balanced against the need for brevity. It is also expected that participants are given an opportunity to display understanding, and that study staff invite and answer any questions participants might have.

Under the Belmont Report definitions, "coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance." The decision to participate should be free of coercion and/or undue influence:

- Compensation for participation should not be excessive and "hard to refuse."[9]
- There should be no suggestion or indication of punishment or loss for refusing to participate.

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[9] As a heuristic, one day's wage for participation in a long survey (one that takes one to several hours) would be considered reasonable.

- There should be no suggestion of future individual benefits for participating.

Please see IDinsight's **Informed Consent Checklist and Template** for more details.

In IDinsight's work, informed consent typically applies to human research participants who are existing or target beneficiaries of a service or program (for example households, mothers, farmers, etc).[10] However, when conducting research for a client, employees of the client's organization may be required to participate by organization leadership. For example, if our client is a school district, the head of the school district may require teachers to respond to a questionnaire -- for example, about their own or student attendance -- on which IDinsight is playing a consultative role. In such cases, we may not give target respondents the alternative of opting out – but we will still explain to them the purpose and importance of their participation in the evaluation.

This exception only applies if the information collected is directly relevant to respondents' work (e.g. not about their health or family). If IDinsight project teams have reason to believe that mandatory participation could unjustly harm respondents, those teams have an obligation to inform the Ethics Review Committee, and the Ethics Review Committee must weigh in on which data are appropriate and ethical.

If information about individuals is obtained outside of primary data collection – i.e. administrative data, secondary sources or public data, this would usually not be considered "Human Research Participants" research and therefore IDinsight project teams are not required by default to obtain informed consent. This is the case unless identifying information is obtained, in which case all protections related to human research participation apply. For sensitive information, project team members must be aware of whether the data they receive violates any norms, rules, or laws, and should seek advice from IDinsight leadership and/or General Counsel if they suspect this is the case. The IDinsight Ethics Review Committee may also wish to add informed consent as an additional requirement.

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[10] Target beneficiaries may also include individuals in the comparison group.

4.2   Data Security

Protection of human research participants' privacy and anonymity is covered by the research ethics principles of "respect for persons" and "beneficence." The primary tools of data security include encryption, de-identification, and password protection.

4.2.1   Digital Data Collection

The following data security measure must be taken for all primary data collected digitally:

- All data collection devices must be encrypted so that if the device is lost human research participant identities and information is inaccessible to others.
- Access to device must be password protected with a secure password (See **IDinsight Appropriate Use Policy** as part of its **Data Security Policies**).
- The transfer of data from data collection devices to cloud servers or local networks must be secured (encrypted).

4.2.1.1   Digital Data Storage

For digital data obtained through primary data collection or receipt of non-public administrative data, the following requirements hold:

- The storage of raw data on cloud servers or local networks must always remain encrypted. Other than the project team, no one should have access to this data, including platform administrators that host the data.
- Transfer of raw data from the cloud or local networks to local devices such as laptops or desktop computers must be secure (encrypted).
- Storage of raw or identifying data must be encrypted on local devices. Local devices must be password protected with a secure password.
- Ideally, data would be collected or shared without personal identifiers. However, if personal identifiers are part of the data set, data must be de-identified (personally identifiable information, or "PII", must be moved into a separate dataset) as soon as possible. This can be programmed into the digital data collection software. If not pre-programed, ideally datasets should be de-identified as soon as it is downloaded from cloud servers.
    - o   "PII" is defined as any variable or set of variables that, alone or in combination, can be used to identify individuals. These include names, address, identification numbers, GPS coordinates, etc. The Healthcare Portability and Accountability Act (HIPAA), which sets up privacy rules for medical records in the US has identified **18 personal identifiers** that must be encrypted when working with medical information in the US. This list is not always applicable in our study regions. However, it can serve as a useful guide.

- o   Note: In some studies, we must be able to re-identify responses for quality control purposes, data cleaning, and for follow up surveys when needed. We must therefore ensure there is a unique ID for each respondent that can link the observations in the dataset with survey information to those in datasets with identifiers (link files or link-logs). The unique ID variable must exist in both datasets.
- PII must remain encrypted in separate encrypted volumes or folders (using **Boxcryptor**) when shared between local devices and cloud sharing systems (i.e. Dropbox).
- Note: while Dropbox encrypts data on its servers, Dropbox for most accounts, administrators have back-door access, which is not permitted.
- The password protected encrypted volumes must be secure and if shared, must be shared through a secure password management system (such as **LastPass**) or non-digitally. Passwords should not be shared through email or file-sharing software. Sharing passwords with written notes, by phone and through text (e.g. Whatsapp) are acceptable.

4.2.2   Paper Surveys

For paper surveys, there are additional requirements that precede those for digital data collection. [11]

- Within the paper questionnaire, PII should be kept on separate pages from most of the private information respondents share.
- Completed survey responses should be separated from PII as soon as possible after data collection (e.g. in the physical location where data will be digitized). Ideally, de-identification   should happen before data entry. Note: ensure there is a common unique ID for each survey respondent, on all pages.
- During data entry, PII and survey responses should ideally be entered into separate data entry forms.
- The data entry software and devices must follow the remaining steps described in the above section on Digital data collection.
- When not being transported or entered, copies (of both PII and the survey responses) should be stored in locked cabinets. We recommend destroying paper surveys (and PII) after the engagement is complete and, if appropriate, data published, or roughly 3 years after data collection. Documents should be destroyed in a way that does not allow reconstruction (e.g., shredded).

Please see the **IDinsight Data Security Policy.**

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[11] Paper surveys are strongly discouraged if digital data collection is possible.

5 Adverse events and unforeseen challenges

IDinsight project staff are required to report any adverse event or unforeseen challenges to the rest of the team including the project Director and/or Partner, as well as the IDinsight Ethics Review Committee. For any events involving volunteers' safety, the project team should take corrective actions immediately and report to the Ethics Committee describing the corrective measures taken. For other adverse events, the project team should report to the Ethics Review Committee and suggest corrective measures. The Ethics Review Committee must review such a report in a timely manner and recommend corrective action to the CEO, Ruth Levine, and provide recommendations to the project team.

The recommendation will be determined on a case-by-case basis, and may include:

- Referring harmed human research participants to support services
- Reporting offending individuals to client leadership
- Reporting ethical violations to official or legal authorities
- Suspending or terminating the project or client engagement
- Developing and executing a harm-mitigation plan in case of data breaches
- Informing human research participants of data breaches
- Terminating employment of those who violate research ethics

If any staff member does not feel comfortable reporting directly to the Ethics Review Committee, or if they are deeply unsatisfied with the resolution at that level, they may also report adverse events through the internal **ombudsman portal**.

Adverse events include (a) incidents that harm individuals because of their participation in research, (b) incidents where individuals are harmed due to the intervention or behavior of intervention staff/personnel, or (c) any serious violations of protocol (including related to data privacy and security) or ethical violations by research personnel, regardless of harm to individuals.

Please see the **IDinsight Data Breach Policy.**

5.1 Harm to human research participants

Harm may come to research participants because of the information they share, external knowledge of their participation, or direct interactions with research personnel.

- If we discover that any harm comes to human research participants as a direct or indirect result of their participation in the study or program, that is considered an adverse event. For example, if respondents become distraught due to questions asked in a survey, that would be considered harm directly due to our study, and an adverse event. If we learn that a household member is punished by family members, community members, or authority figures (physically, emotionally, financially or reputationally) because of their participation in the study, that would be harm indirectly due to our study, and would be an adverse event.
- If research personnel (such as surveyors) cause harm (physically, emotionally, financially or reputationally) to human research participants, that is an adverse event.

5.2 Harm from non-research activities

Project teams may *observe* harm to program beneficiaries directly (e.g. visual observation) or indirectly through analysis of data.

- If an individual is physically or emotionally harmed by activities that are part of the intervention or by deliberate actions of program staff (e.g., abuse), that is an adverse event.

5.3 Research ethics violations

Adverse events include instances even when there is no observed impact on human research participants.

- If any human subject does not have the opportunity to give informed consent or is coerced to participate, this would be considered an adverse event. (Note: this does not apply for operations research when employers may compel employees to respond, as long as the information is directly relevant to their work.)
- If data security measures are violated such that PII is made accessible to members outside of the project team, this would also be considered an adverse event.

5.4 Ethical research practices training

To be up-to-date on how IDinsight operationalizes ethical principles, all Client-Facing, RED Team, Data Science/Engineering, and Innovation staff must take and pass an online "research with human research participants" training course. IDinsight staff have access to the **CITI Program Human Subjects Research** courses.

- IDinsight staff should take the **Social-Behavioral-Educational (SBE) Basic** course or the **Social-Behavioral-Educational (SBE) Refresher** course if they have already taken the basic course.
- The certificate of completion must be uploaded to the **Human Subjects Training Certificates** folder on our Knowledge Management drive.

- Staff must then update the **Human Subjects Training Certificate Tracker** with the date of completion and a link to their certificate.
- All staff must take and pass a refresher course when their certificate has expired (i.e. after three years of obtaining their last human subjects training course certificate).

5.5 Monitoring of compliance with Research Ethics Policy

All IDinsight staff are responsible for conducting their work in line with this ethics policy. Beyond individual responsibility, IDinsight Operations Team will:

- Ensure all client-facing staff and RED Team staff have completed a "research with human subjects" training course, and
- Track the completion and expiration date of certificates in the Global Data Hub.

In addition, RED Team members on each project are required to monitor and report on compliance with research activities. Specifically, the RED Team Point Person on each project must:

- Propose the ethics review status to the Ethics Review Committee—IRB, full internal ethics review, expedited review, and/or exemption—and update the Global Data Hub with the appropriate ethics review status,
- Ensure necessary review and approval is received *before any primary data are collected from respondents* (unless the project is determined to be exempt), and update the Global Data Hub accordingly,
- Include an informed consent form that complies with **Informed Consent Template and Checklist,** and
- Follow all relevant data security practices listed in the **Data Security Policy**.

6 IDinsight Ethics Approval Process

6.1 Client Development Assessment Form

When initially proposing a client engagement, all IDinsight staff must fill out the **Client Development Assessment Form**. (This is part of the "new client approval process," on which positive impact potential and risks are evaluated across several categories—research ethics being only one.) Within the form, client development leads must indicate whether the project requires expedited or full internal ethical review.

6.2 Internal Ethics Review

Before a contract with a client is signed, the RED Team Point Person must apply and receive the ethics review status of a project with the Ethics Review Committee: whether it will obtain IRB or be submitted to the Ethics Review Committee for internal review. In the case of Learning Partnerships, opportunity for review should be given when a particular service is agreed-upon.

Before any data collection activities commence, the RED Team Point Person must re-confirm the ethics review status and obtain review if the status has changed accordingly.

The RED Team Point Person is accountable for ensuring review happens when required, however the rest of the team should also consider itself responsible.

6.2.1   Exempt from Internal Ethics Review

The project is by default exempted from internal ethics review if it is receiving formal IRB approval. However, the team may request internal ethics review in addition to the formal IRB review.

If IRB approval is not obtained, and there are minimal ethical risks[12], the RED Team Point Person can apply for an exemption using the appropriate form in the global data hub. A single member of the ethics review committee can approve an exemption request. Exemptions may be granted when the activities pose minimal risk to research participants and, for example,

- Administrative data are used,
- The research activities are in partnership with, or on behalf of, the government of a country and government authorization has been obtained,
- The research is conducted in "established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction."[13]
- PII is not collected as part of the research activity.

Some exemptions may be reviewed using the Expedited review policy (below).

6.2.2   Expedited Review

For projects not seeking IRB approval, expedited review is the most common option. Expedited review is appropriate for projects where ethical risks are minimal and of low consequence (unlikely to cause significant personal, financial or psychological harm to participants). A project can receive expedited ethics review from one member of the IDinsight Ethics Review Committee.

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[12] Minimal risk is defined as: "the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater . . . than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations and tests" United States Office for Human Research Protections, (45 CFR § 46.102(i))

[13] Language taken from MIT Committee on the Use of Humans as Experimental Subjects (COUHES). **https://couhes.mit.edu/definitions**

Criteria for expedited review include[14]:

- Research involving data, documents, and records that have been collected, or will be collected solely for non-research purposes,
- Research on individual or group characteristics (e.g. demographics) and knowledge, or *non-sensitive* attitudes and practice and behaviors, with non-vulnerable populations[15]

For expedited review, project teams should share the concept note (or whatever written explanation of the engagement exists) and a written description of ethical risks to the Ethics Review Committee, including a record of any ethical research practices stipulated by or normative in the host country. This should then be followed by a conversation between the project Director and/or RED Team Point Person on the project side, and the selected member of the Ethics Review Committee member. Ethics Review Committee member can formalize approval by email.

6.2.3   Full Review

If a project is identified as moderately risky or risky, project teams must seek full ethical review from IDinsight's internal Ethics Review Committee. The Ethics Review Committee is made up of the RED Team Director (Marc Shotland), the General Counsel (Anna Myles-Primakoff), a second REDTeam member (Heather Lanthorn), a regional representative (Alison Connor for Africa, and Karan Nagpal for South Asia, and Crystal Huang for Southeast Asia), and one external member not affiliated with IDinsight.

As with expedited review, project teams should share the concept note (or whatever written explanation of the engagement exists), a detailed written description of ethical risks, and questionnaires, and all informed consent forms to the Ethics Review Committee. This should then be followed by a conversation between the RED Team Point Person on the project side, and the Ethics Review Committee. Ethical approval must be unanimous. Any member of the Ethics Review Committee can formalize approval by email.

The **Ethics Review Form** can be found in our Global Data Hub in AirTable.

See **Appendix A: IRB Decision Tree** for guidance on which review process is right.

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[14] Criteria come from Harvard's office protection of research subjects.

[15] Sensitive (in contrast to non-sensitive) topics include those that could affect health and safety, financial standing, career or economic prospects, personal relationships, insurability, reputation, be stigmatizing or place the subject at risk of significant criminal or civil liability.

7 Conclusion

IDinsight's vision is to improve millions of lives by transforming how the social sector innovates, learns, and improves. As part of that, IDinsight has an obligation to ensure the work it does follows ethical best practices. This policy has been designed to fulfill that obligation. For any comments, concerns or suggestions regarding this policy please contact **operations@idinsight.org**.
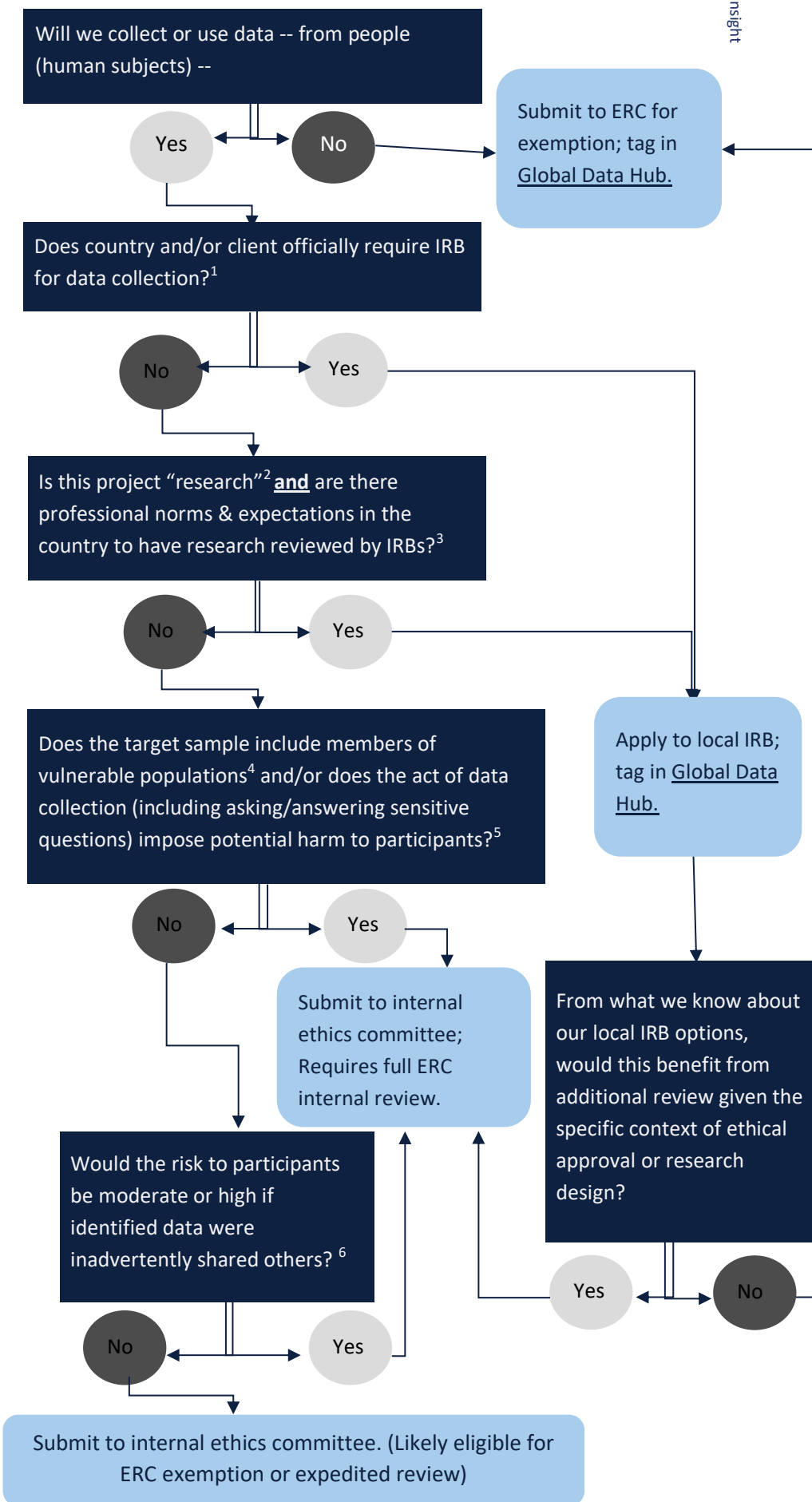
Appendix A: IRB Decision Tree

[1] Double-check with client as part of contracting or early conversations. For country requirements, visit our database [FORTHCOMING]. If -- after looking at the database -- you have questions, please email ethics.committee@idinsight.org.

[2] Research generates knowledge through systematic investigation. If we may we want to share out that knowledge -- results and/or process and methods lessons -- and/or we expect the client to want to share results or process lessons externally, we should designate the work as research.

[4] Vulnerable groups include peoples considered "particularly susceptible to coercion or undue influence in a research setting" because of limited agency. "They may be incapable of understanding what it means to participate in research and/or who may not understand their rights during consent." All minors are considered vulnerable unless they are taking a test in school they would have had to take anyway. Anyone with decisional impairment should be considered vulnerable.

[6] The content of some data could be damaging if released in an identifiable way and are therefore moderate or high risk. These include data that could, as per Harvard Information Security, hurt a subject's health and safety, financial standing, career or economic prospects, personal relationships, insurability, reputation, be stigmatizing or place the subject at risk of significant criminal or civil liability.

Flowchart:

Will we collect or use data -- from people (human subjects) --
- Yes → Does country and/or client officially require IRB for data collection?[1]
- No → Submit to ERC for exemption; tag in Global Data Hub.

Does country and/or client officially require IRB for data collection?[1]
- No → Is this project "research"[2] **and** are there professional norms & expectations in the country to have research reviewed by IRBs?[3]
- Yes → Apply to local IRB; tag in Global Data Hub.

Is this project "research"[2] **and** are there professional norms & expectations in the country to have research reviewed by IRBs?[3]
- No → Does the target sample include members of vulnerable populations[4] and/or does the act of data collection (including asking/answering sensitive questions) impose potential harm to participants?[5]
- Yes → Apply to local IRB; tag in Global Data Hub.

Does the target sample include members of vulnerable populations[4] and/or does the act of data collection (including asking/answering sensitive questions) impose potential harm to participants?[5]
- No → Would the risk to participants be moderate or high if identified data were inadvertently shared others?[6]
- Yes → Submit to internal ethics committee; Requires full ERC internal review.

Apply to local IRB; tag in Global Data Hub. → From what we know about our local IRB options, would this benefit from additional review given the specific context of ethical approval or research design?
- Yes → Submit to internal ethics committee; Requires full ERC internal review.
- No

Would the risk to participants be moderate or high if identified data were inadvertently shared others?[6]
- No → Submit to internal ethics committee. (Likely eligible for ERC exemption or expedited review)
- Yes → Submit to internal ethics committee; Requires full ERC internal review.

Appendix B: Checklist and Roles

Requirement/Recommendation	When	Accountable
IDinsight Research Ethics Policy		
• Read entire policy • Sign acknowledgement on Bamboo HR	Immediately	All IDinsight staff
Ethical Research Practices Training		
• Take CITI Program Social-Behavioral-Educational (SBE) Basic course	Immediately	Client Facing, RED and Innovation Teams
• Take CITI Program Social-Behavioral-Educational (SBE) Refresher course	3 years after taking the Basic course,	
• Upload certificate to Human Subjects Training Certificates folder on KM drive	After taking course	
• Update the Human Subjects Training Certificate Tracker	After taking course	
Determination of Which Ethics Review is Required		
• Document evidence of in-country research ethics requirements and norms	Project inception	Project Director
• Select ethics review status in Client Development Assessment Form		Project Development Lead
• Determine preliminary ethics review status		Ethics Review Committee
• Update Global Data Hub with preliminary ethics review status		RED Team Point Person
• Submit new form proposing ethics status	Before data collection	RED Team Point Person
• Determine ethics review status		Ethics Review Committee
• Update Global Data Hub with ethics review status		Ethics Review Committee
IRB Review and Approval (If Ethics Review Status = IRB)		
• Apply to IRB and obtain IRB approval	Before data collection	Project Director
After IRB approval, • Update Global Data Hub KM: IRB Name, IRB Protocol number, IRB approval date, IRB expirations date		RED Team Point Person
IDinsight Internal Ethics Review (If Ethics Review Status ≠ IRB)		
• Complete Ethics Review Form • Upload Informed Consent forms to Global Data Hub KM	Well before data collection if changes	RED Team Point Person
• Respond to Project Team with decision or questions	Within one week of submission	IDinsight Ethics Review Committee
• Enter Ethics Review Status on Global Data Hub	Project Inception	Project Development Lead
• Update Ethics Review Status on Global Data Hub	Before Data collection	RED Team Point Person
Informed Consent		
• Draft Informed Consent Use: IDinsight Informed Consent Checklist and Template • Upload Informed Consent to Knowledge Management	Before ethics review, or before data collection (whichever first)	RED Team Point Person
Data Security		
• Follow IDinsight Appropriate Use Policy	Immediately	Client Facing, RED and Innovation Teams
• Follow Data Security Policies • Encrypt identified data at every stage • Protect encryption with a strong password • Store password securely (coming soon) • De-identify data as soon as possible	Whenever managing any project data	Client Facing, RED and Innovation Teams (RED Team Point Person ultimately accountable)

IDinsight