IFPRI'S Principles, Policies and Procedures for the Protection of Human Research Subjects IRB Standard operating procedures

Covid-19 and Human Subject Research Review at IFPRI. At this time a decision has been made to suspend face-to-face interviewing of subjects out of an abundance of caring concern and caution for the safety of our researchers and for research participants with whom they may interact. The IRB has made some necessary adjustments to our operation and has implemented some guidance on phone/video, surveys and mailings that may be used during this time in furtherance of research. Please see the What's New section of this webpage and the Quick Links to view recommendations.

April 27, 2020

International Food Policy Research Institute Institutional Review Board (IRB)

IRB Contacts

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Please forward all submissions and questions to IFPRI-IRB@cgiar.org. Questions can also be forwarded to the IRB coordinator

April 27, 2020

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What's New @IFPRI IRB

COVID-19 has substantially changed the way we interact with subjects involved in human subject research. As such the face-to-face interviewing that was the norm has now given way to more studies using telephone interviews, video and surveys. This transition to alternate ways to conduct our research provides IFPRI researchers to capitalize on emerging themes and trends as world events evolve as well as design more meaningful studies considering the lives and challenges faced by the populations we serve. Still all studies involving human subjects must be reviewed by the IRB.

- Since it may not be possible to obtain local IRB/ethics (ie. may have currently suspended their activities, long approval wait times) the IRB has adjusted the requirement to submit to local IRB review to allow research to progress in a more timely fashion. As of now for all COVID related research IFPRI IRB will accept a letter of approval from the government before starting any research activities. All letter of approval will be forwarded to the IFPRI IRB to be kept on file. The same government approval process will apply for all non-COVID research for a time.

- The IRB will be incorporating a limited review process for Covid-19 and other studies that meet the criteria as set out in the federal guidelines. It should be noted that not all studies will qualify for limited review. For all other studies, the IRB has attempted to adjust our assignment process so as to move the process along more quickly when possible. If the phone survey is novel, the usual submission for study protocols is required

- All previously approved human subject research studies that are replacing face to face interviews with phone surveys must submit to the IRB a modification to the study as well as a copy of the consent script and survey instrument. Plans for documenting consent should also be included in the documentation. These modifications will be processed quickly and will reflect the original IRB approval date so as not to cause a disruption to other critical areas of the research (ie funding, implementation schedules). An email from IFPRI-IRB will be sent notifying the approval of such changes. Researchers will be responsible for communicating planned study changes involving face to face interviews with phone surveys or to study plan to funders if and when necessary.

IRB Reminders and Tips for Designing and Conducting Human Subjects Research

The IRB offers the following guidance as a practical consideration when designing research that may make the review process go more smoothly:

- When selecting subjects be reminded to make certain recruitment is fair and equitable chosen with the highest ethical and scientific standards.

- Keep in mind that telephone/video interviews bring unique challenges to adequately protecting the privacy of human subjects and the confidentiality of the data. Please make sure that study protocols adequately address these areas in full detail.

- The consent script should be shortened without leaving out any of the detail participants have a right to know. The informed consent process should incorporate all 8 elements of consent including (researcher/organization name, purpose, what they are being asked to do, risks, what will happen to their answers, will they be identified, compensation etc.) A 6th grade reading level is recommended although in some case that will need to be considered due to varying levels of education, challenges to comprehension and other factors.

- Oral consent is permissible with proper witnessed documentation.

- Good practical study design is key. Know your purpose and design the best way to get there. Short surveys possibly no longer than 20 minutes may work best. This will in most cases allow that the study will not interrupt the daily routine of the family or persons involved.

- Telephone interviews allow both parties to be anonymous to a certain extent. Probing questions can become overly intrusive ways to get information about peoples' health. Please make sure that whatever is revealed by a participant (no violation of HIPAA) is voluntary and is in no way coercive. In cases where the study may involve vulnerable persons, women or children who have reached the country's age of majority questions should be asked with sensitivity and discretion.

OHRP Guidance

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/effects-of-disasters-on-human-research-protections-programs-guidance/index.html

Executive Summary

Introduction

The International Food Policy Research Institute (IFPRI), holds a Federalwide Assurance Agreement with the Office for Human Subjects Research (OHRP) in the U.S. Department of Health and Human Services (DHHS)[1], and thereby provides assurance that it will comply with:

1. DHHS federal policy regulations for the review and approval of all research activities involving human subjects regardless of the source of support outlined in the Belmont Report and the DHHS regulations at 45 CFR Part 46 Subpart A known as the Common Rule with the compliance date of January 21, 2019

[1] FWA #00005121.

2. The Food and Drug Administration (FDA) regulations for the protection of human subjects[2] and Institutional Review Boards for all human subjects research involving articles regulated by FDA, where applicable;[3] and
3. Additional federal, state, and local regulations, where applicable, that relate to research involving human subjects.

In addition IFPRI Institutional Review Board (IIRB) also incorporates the GDPR as a matter of practice in accordance with global research activities.

At institutions that operate in compliance with federal regulations, the collection of private, identifiable medical information for research must be reviewed and monitored by an institutional review board according to a detailed set of standards listed in *The Federal Register*. The purpose of this Standard Operating Procedure is to outline the responsibilities of the IRB in upholding the ethical principles regarding research involving human subjects, that are described in DHHS regulations 45 CFR 46 and FDA Part 50 and 52 as well as the *Ethical Principles and Guidelines for the Protection of Human Subjects for Research* ("the Belmont Report"). The IRB reviews all human subject research protocols initiated by IFPRI and/or others that utilize the data, resources, staff, or facilities of IFPRI.

Institutional Commitment and Responsibility

The responsibility of ensuring compliance with federal regulations and ethical principles for human subjects research is the responsibility of the institution. IFPRI acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects.

IFPRI assures that before human subjects are involved in research covered under the auspices of this authority, proper consideration will be given to:

1. The risks to the subject(s);
2. The anticipated benefits to the subject(s) and others;
3. The importance of the knowledge that may reasonably be expected to result; and
4. The informed consent process that will be employed.

The IRB's Standard Operating Procedure ("SOP") manual is written and maintained by the IRB staff. This manual outlines the specific details of the IRB's policies and procedures for following Federal, state, and local regulations for the ethical and safe conduct of research and the protection of human participants. The IRB SOP manual is provided to new members during orientation to the board. The manual is available on the IRB's website and in the IRB's office.

IFPRI acknowledges that it is responsible for complying with this SOP manual.

[2] 21 C.F.R. § 50.
[3] 21 C.F.R. § 56.

Key Definitions

1. *Institution* means any public or private entity or agency (including federal, state, local, or other agencies).
2. *Research* means a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge. 45CFR46.102(1)
3. *Not Research is defined as the following activities (4 new categories)*
    - Certain scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
    - Certain public health surveillance activities, including the collection and testing information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
    - Collection and analysis of information, biospecimens, or records by or for certain criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigating purposes.
    - Certain authorized operational activities in support of intelligence, homeland security, defense, or other national security missions
4. *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45CFR46.102.(1)
5. *Identifiable biospecimen* means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen
6. *Vulnerable Populations means* populations that are potentially vulnerable to coercion or undue influence (excludes pregnant women and physically handicapped persons). The term “individuals with impaired decision making ability” describes and replaces the term “mentally disabled persons.”
7. *Legally Authorized Representative* means an individual or body authorized under applicable law to consent on behalf of a prospective to the subject’s participation in the procedure(s) involved in the research. *If there are no applicable laws addressing this issue legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.
8. *Intervention* includes both physical procedures by which data are gathered and manipulations of the human subject or the human subject’s environment that are performed for research purposes.
9. *Interaction* includes communication or interpersonal contact between an investigator and the human subject.
10. *Clinical Trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.

11. *Private information* refers to information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable, such that the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
12. *Nonpublic information* refers to information that is not intended for public use.
13. *Minimal risk* means that both the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.
14. *The IRB* means the Institutional Review Board established in accordance with and for the purposes expressed in this Standard Operating Procedure.
15. *Limited IRB* review means a process that is required only for certain exemptions. The IRB must determine that certain conditions, and/or primary adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
16. *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
17. *Board* means group of individuals that convenes to for the purpose of reviewing review research protocols submitted to the IRB.
18. *Qualified Researcher* means the researcher has received certification in human subjects research, is affiliated with a reputable academic/ NGO/, humanitarian organization or governmental agency or has carried out human subjects research previously.

Mission of the IFPRI IRB

The IFPRI IRB seeks to create an institutional culture that promotes and upholds the highest ethical standards in the conduct of human research. The primary purpose of the IRB is to protect the rights and safety of human subjects involved in research activities conducted by the institution through reviewing and approving research protocols. The IRB shall work in collaboration with Principal Investigators (PI) by providing education and consultation about research regulations. The IRB shall require additional safeguards to protect the rights and welfare of human subjects who are likely to be vulnerable to coercion or undue influence. These categories of human subjects include: prisoners, children, and the mentally ill.[4] Additional protections pertaining to research activities involving fetuses, pregnant women, and human in vitro fertilization may be required.[5] Finally, additional protections may vary for research involving children.[6] The IRB shall approve research protocols involving vulnerable populations only when it is determined that the additional requirements of the regulations and adequate provisions for privacy and confidentiality have been met.

[4] 45 C.F.R. § 46.111(b)
[5] 45 C.F.R. § 46 subpart B.
[6] 45 C.F.R. § 46 subpart C.

The IRB shall ensure that:

1. Physical, psychological, and social risks to human subjects are minimized, and, where present, are justified by the importance of the research and/or the knowledge to be gained; and
2. Participating and potential human subjects are appropriately informed of the research purpose, the risks and benefits involved, that participation in research is voluntary and their rights as human subjects.

Principles that Govern Human Subject Research IRB Review

Although there is much complexity to the types of studies conducted at IFPRI the focus of the IRB continues to be to maintain the safety of all involved in the research and to preserve scientific integrity as well as compliance with all applicable laws, rules and regulations. In order to achieve that the IRB must ascertain that:

1. The participation in research studies by human subjects is voluntary;
2. The rights and welfare of all human subjects participating in research studies are adequately protected;
3. An appropriate informed consent process is in place and research protocols are in conformance therewith; and
4. Risks to the human subjects participating in the studies are reasonable relative to the anticipated benefits.

The IRB will provide training of the research staff engaged in human subjects research through lectures, seminars, and the dissemination of relevant educational materials.

Authority of the IRB

At IFPRI the IRB is administratively located under the Department of Finance and Administration. The function of the IRB is to address the ethical and regulatory complexities in conducting human subject research studies. IRB may use federal regulations, available guidelines, state laws, and ethical principles governing human research in evaluating studies. The IRB has the authority to review study design and quality. The IRB will use the research categories of exempt, expedited, and full board review to conduct approvals of studies. Should the research not qualify as human subjects research the IRB may determine that the study is not under IRB purview and will issue a letter to the PI advising him of the determination. IFPRI supports the IRB Coordinator's decisions within the scope of this authority and oversight of research activities. The IRB Coordinator may notify the IRB Chair with respect to any action taken and if necessary the Director of Finance should other actions be necessary. All studies involving human subjects, regardless of the sources of funding, shall be reviewed by the IRB. The IRB is the authority for the approval of research involving human subjects. The IRB's policies are applicable to **all** research involving human subjects, and **all** other activities that in whole or in part involve such research, if either

1. The research is sponsored by IFPRI;
2. The research is conducted by or under the direction of any employee or agent of IFPRI using any property or facility of this institution;

3. The institutional research involves the recruitment of human subjects or the use of IFPRI data, facilities, or personnel; or

Please note the following areas that the IRB has authority over:

- Authority to approve, disapprove, or modify studies -The IRB shall review and either approve, disapprove, or require modifications of research activities under its jurisdiction according to the provisions of 45 C.F.R. 46. The IRB may not necessarily approve a research study or consent document that has been accepted by an IRB of another institution.

- Authority to require progress reports from investigators and oversee the conduct of the study in accordance with policies or as needed. For certain studies and under certain conditions DHHS regulations require the IRB to conduct "review of research . . . at intervals appropriate to the degree of risk, but not less than once per year. However, for studies posing no more than minimal risk and that are reviewed under the expedited review process the IRB may require an annual update/progress report from the research investigator. FDA regulations remain unchanged and require the IRB to conduct "review of research . . . at intervals appropriate to the degree of risk, but not less than once per year. The IRB shall have the right to observe or have a third party observe the conduct of an approved research study, including the informed consent process. The IRB may also conduct compliance reviews and for cause reviews of any research approved by it.

- Authority to suspend or withdraw approval from a study- The IRB may suspend, withdraw approval, or otherwise restrict the ability of a research investigator or investigators to continue any research under its jurisdiction, if the researcher violates any of the OHRP, FDA or local regulations, or IRB guidelines, and ethical, moral humanitarian principles (i.e. Belmont Report, Declaration of Helsinki) whether explicitly mentioned in this policy or not. The IRB has the authority to investigate any allegations of suspected or reported research misconduct/violation by any researcher and may suspend enrollment in a research study, suspend or withdraw approval of research activities, or suspend or withdraw approval of parts of a research study that are not being conducted according to the IRB's requirements or which have been associated with both anticipated and unanticipated harm to human subjects until such time that the issue is corrected.

- Authority to place restrictions on a study/research investigator -The IRB may impose any restriction or stipulation on any protocol/researcher that the IRB determines may be necessary to protect the human subjects who are enrolled in a study or may potentially be enrolled in a study. The IRB Coordinator may take this action initially until such time as the matter can be reviewed at the next meeting and discussion by full board. The PI shall be notified of the restrictions by the IRB either by phone or in writing. The IRB Coordinator will notify both the IRB Chair and the Director of Finance regarding any suspension, withdrawal or action taken to halt a study by the IRB. Further notification and additional sanction decisions will be left to upper management if necessary depending upon the severity of the case. Such disciplinary actions can range from a

informal discussion up to losing research privileges at the institute based on the number of occurrences and/or the severity of the non-compliance.

Management of the IFPRI IRB

The IRB Coordinator with vested authority from the Director General of DGO and/or the Director of Finance is responsible for establishing and implementing IRB policy. The Director of the DGO as the institutional official represents the institution in discussions with federal authorities. The IRB Coordinator will follow the director's instructions in such cases. The Chair is expected to direct full committee IRB meetings and is responsible for the accurate recording of the minutes. The IRB Coordinator should review all protocols presented to the full committee and is expected to have read the protocols making sure that important issues are communicated to board members and members of the IRB staff. The Chair may also in accordance with the agenda sent out from the IRB Coordinator identify issues of interest to the board. The IRB Coordinator should review and sign IRB response letters in a timely fashion.

Membership of the IFPRI IRB

The IRB shall maintain a roster of board members. All IRB members at IFPRI are volunteers with other work full time responsibilities. Board members receive no compensation for their service. Roster information shall include, but is not limited to, the member's name, credentials representative capacity on the IRB (scientific, non-scientific, or legal), and any employment or other relationship with IFPRI. Members are also expected to disclose any and all conflicts of interests that may arise from their taking part in reviewing research. Changes in IRB membership shall be reported to the OHRP in a timely manner by the IRB Coordinator. All members of the IRB Board are expected to complete CITI training related to human subjects prior to their appointment.

Federal regulations mandate that institutional review boards have at least five members of varying backgrounds to provide adequate review of research activities commonly conducted at the institution. Health and Human Services regulations state that the IRB consist of at least 5 members. [(section 107) (a)] The IRB at IFPRI has 9 members. Quorum requirement is satisfied at 5 persons. Length of service for IRB board members shall be 3 years. In order to maximize the level of expertise on the board members will be rotated off making for smooth transitions.

The IRB must be sufficiently qualified through the experience and expertise of its members, and the diversity of the members to ensure that using procedures minimizes risks to human subjects that are consistent with sound research design. The IRB may not consist entirely of members of one profession. The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The regulations require that an IRB include at least one scientist, one non-scientist, and one person not affiliated with the institution and that the IRB have sufficient expertise and diversity to evaluate ethical issues involved in protocols sent for IRB review. IFPRI has a diversified group of professionals assigned to human subjects research review and has met its obligation with respect to requirements for constitution of the board. The IRB must include at least one member who is not otherwise affiliated with IFPRI and who is not part of the immediate family of a

person who is affiliated with IFPRI. The members must be diverse in terms of gender, race, and cultural background.[7]

- Alternates - IFPRI IRB may make use of the alternate reviewer system. An alternate member or members may be present at a convened meeting with the regular member and may participate in the deliberation. However, if the regular member is present at the meeting, the alternate cannot vote. The alternate member may vote only in the absence of a regular member. A list of prospective alternate IRB members will be submitted to the IRB Coordinator for review and approval. The Director of Finance will be advised of the candidates selected for and can make the final decision. IFPRI may use consultants on occasion.

- Consultants -The IRB shall use consultants to the board when it is necessary. Consultants are not members of the IRB Board and thus have no rights afforded to members. The IRB Coordinator for protocols that require specialized expertise that is not available on the board will identify consultants. The IRB Coordinator will call a person who is unbiased and knowledgeable about the issue in question and ask that person to provide an opinion to the IRB. The IRB Coordinator will notify management about these individuals. The consultant may be located internally or at another institution. The consultant will be provided only if the relevant expertise is not found on the board and only if the materials are of good quality so as to sufficiently form an expert opinion. The consultant may also be invited to present to the full board. There is no compensation for their participation.

Operational Functions of the IRB

All studies involving human subjects require review by the IRB, unless the IRB determines otherwise. If there is any question on whether a review is required, the request must be submitted in writing to the attention of the IRB Coordinator via the IRB inquiry process at ifpri-irb@cgiar.org.

An application must be submitted along with appropriate documentation as outlined in the section below ("Information the Investigator Provides to the IRB") to the IRB according to the guidelines. Investigators in research involving human subjects that falls under the jurisdiction of the IRB shall be provided with instructions for the submission of protocols and informed consent documents for review and approval by the IRB. All research studies submitted to the IRB for review shall thereafter be given a reference number by the staff of the IRB. The office of the IRB shall maintain a database of submissions, including, but not limited to, the reference numbers assigned to each submission, the names of PIs and co-investigators, titles of each research protocol, investigator contact information, and expected approval dates from the IRB.

The IRB shall follow written procedures for performing continuation of review and/or annual update/progress reviews of research activities at appropriate intervals related to the degree of risk, but not less than one a year. The IRB shall decide if continuing review and/or progress

[7] 45 C.F.R. § 46.107.

report review of studies requires verification from sources other than those provided by the investigator and that there has not been any material changes since the prior IRB review especially those not authorized by the IRB.

The IRB reviews and investigates all privacy and confidentiality issues involving research and research compliance. All disclosures of identifiable health and/or personal information to third parties for research purposes must be reviewed and approved by the IRB before any disclosure is made. In its review, the IRB will approve such disclosures only if the requesting party is a qualified researcher and if the research to be undertaken by the third party will benefit public health. Based upon its review of the study and any new information gathered since the previous IRB review, the IRB shall decide to approve or disapprove continuation of the research, or shall recommend specific modifications of the research and/or informed consent document(s) needed to secure IRB approval for continuation of the study. The IRB coordinator will inform the IRB Chair, Director of Finance as well as the Director General DGO and make a recommendation upon becoming aware of violations of privacy and confidentiality to take whatever other corrective measures the institution seems fit.

Reporting findings and actions of the IRB

The IRB shall notify investigators in writing of its decision to approve or disapprove the research study or continuation of the research, or of modifications necessary to secure IRB approval for the research or continuation of the study. In the case of full board reviews the IRB will notify the PIs in writing within 7 days following the meeting. The IRB will also use the following procedures with respect to conducting human subject research at IFPRI:

- **Studies involving progress review -** The IRB shall receive progress reports from investigators and conduct reviews of approved human subjects research at appropriate intervals relative to the degree of risk (mostly minimal risk) no less than once per year. The IRB reserves the right to forgo such progress review for less than minimal risk studies as it deems appropriate. The IRB may also request more frequent progress reports from PIs as a result of issues (historical/previous) involving non-compliance, adverse events, and other issues.

- **Reporting changes in research activities -** The IRB shall require that changes in approved research for which approval has previously been given **may not be initiated until they have been reviewed and approved by the IRB**, unless they are necessary to eliminate an immediate hazard to the human subjects. A written letter outling approval or disapproval will be issued to the researcher.

- **Initiating changes in approved research -** The IRB shall follow written procedures for performing its review of proposed modifications to an approved research study and/or informed consent document(s). Based on its review of the proposed modifications, the IRB shall decide to approve or disapprove the modifications, or shall stipulate other revisions of the proposed modifications needed to obtain approval of the modifications. The IRB shall provide written notification to the investigators of its determination of minor modifications. Such modifications are defined as changes that do not substantively

change or alter the study, such as changes in study personnel or typographical errors. For amendments to studies that required full board review that are not minor modifications, such as changes in study design, major changes to the consent document, or inclusion and exclusion criteria modifications, the study will be submitted again to the full board. For expedited or exempt studies, the IRB Coordinator may make the determination as to whether the changes are minor. All changes are to be submitted to the IRB in hard copy or electronically via e-mail. ***No changes may be implemented until IRB approval is received.***

IFPRI IRB Meetings

Federal regulations require a majority of members to convene a full committee meeting.[8] A majority of members (or alternates) of the IRB must be present for a quorum, and a majority of the members at the meeting must agree to approve a study.[9]

The members of the IRB shall convene on the third Thursday of each month to discuss and deliberate on protocols submitted for review. These meetings are closed to the public. However, the IRB may invite researchers to the meetings to present protocol submissions or clarify aspects of the research for the members of the IRB. All discussions at meetings shall be treated in a confidential manner and the contents may not be disclosed to outside parties.

Under some circumstances, the full board meeting may be held over the telephone or via video conferencing, as long as the members are informed of the format ahead of time and have received the materials to be discussed in advance of the meeting.

IFPRI IRB meetings shall proceed normally for no longer than 3 hours.

The responsibilities of the members of the IRB pursuant to meetings are:

1. To review all materials and notify the IRB if any problems occur with the materials received;
2. To keep all full board meeting discussions confidential and not disclose status to inquiring PIs, instead directing research investigator(s to the IRB for further information;
3. To notify the IRB of any conflict or potential conflict or involvement or role with a protocol scheduled to be reviewed (for example, with the design, advisory function, legal function, and drafting documents);
4. To notify the IRB in advance if unable to attend meetings;
5. To remain engaged and active during meetings; and
6. To maintain a collegial, respectful, and professional manner.

Pre-meeting requirements

A regulatory quorum must be achieved before the meeting shall be called to order. The minutes of the previous month shall be reviewed and voted on. In the event that the review and adoption

[8] 45 C.F.R. § 46.108(b).
[9] "Majority" means more than half.

of minutes does not take place at the meeting, the review shall take place at the next meeting based on member availability.

The IRB Coordinator will provide the board with the list of protocols that were reviewed by designated member or members, and the decisions made regarding those protocols. The files will be made available to the members for review if requested.

The IRB shall require that research activities will not begin until the investigator has been notified in writing that the research study has been approved, or that it has been determined by the IRB that the research does not need its review or approval.

Protocol Submission Review Timelines and IRB Process

The IRB does not give retroactive approvals for human subjects research that has not been approved by its review. If unsure about a study's status, a researcher should send an inquiry to the IFPRI-IRB@cgiar.org or to the IFPRI IRB Coordinator. The inquiry will be assigned a number and will be reviewed. Based on that review, a determination will be made as to whether the IRB needs an application for review. The inquiry process may take up to 72 hours for a reply.

The IRB will accept protocol submissions via electronic submission process on a rolling basis, with the exception of studies requiring full board review. For those studies the protocols should be submitted 6 weeks prior to the board meeting. **The expected timeline for completion of study reviews for expedited and exempt studies will be no more than 22 days but is dependent on the timely manner in which researchers respond to reviewer questions or requests for additional information.** For those studies requiring full board review, the research investigator should be aware of the deadlines for submission posted on the IRB website.

In the case of full board reviews all protocols must be submitted in accordance with the guidelines set forth for submitting studies requiring full board review. No late submissions will be accepted for consideration at that month's meeting. In addition, **for all categories of review no incomplete studies will be accepted** (the only exception would be for emergency research or exigent circumstances at which time the IRB staff would forward the study for review). **All submitted studies that are inactive for a period of at least 30 days without explanation will be closed.** The PI will be notified by e-mail or letter, and may re-submit the full proposal to the IRB at any time.

All decisions and determinations made by the full board will be disseminated by the IRB Coordinator to PIs. No members should contact or be contacted by research investigators who have submitted protocols for full board consideration for updates on the status of studies. Research investigators seeking information about protocols should contact IFPRI-IRB@cgiar.org office directly.

Investigator Submission Procedures and Guidelines

The IRB submission package contains complete instructions for submitting a new study protocol to the IRB, including sample formats. Submissions must include the required number of all items for each reviewer or member of the IRB. Each set should include:

1. A completed IRB Cover Sheet
2. A completed IRB Application form (new study)
3. An IRB Protocol;
4. Consent forms (if applicable);
5. Assent forms (if applicable);
6. Recruitment materials (flyers, posters, advertisements, letters, telephone scripts, etc.); and
7. Curriculum vitae and Human Subjects Research Training certificates for all key personnel.
8. Certification that local ethics review will be obtained.

The application may be submitted at any time for review and approval. Applications requiring full board review must be received by the IRB at least 6 weeks prior to the full board meeting. The board meets monthly; however, under emergency circumstances, the IRB may call a special meeting. These meetings may be held over the phone, so long as a quorum is achieved.

An application for continuing review (if applicable) should be submitted six weeks prior to the study's expiration date. For studies requiring continuing review proof of current certification is required otherwise the continuation may not be granted.

Researchers submitting annual review/progress reports for current studies being conducted will be required to forward the reports to the IRB as directed in their IRB approval letter. Research investigators are responsible to re-certify themselves in CITI Human Subjects Research Training.

The study Closure form should be submitted to the IRB no more than 6 weeks after data collection ends. If analysis of the data from the study is still outstanding a written note should be submitted to the IRB electronically notifying the activities that are still in process at which time the IRB will note the file.

The consent forms and any recruiting materials (letters, flyers, poster, etc.) must be submitted electronically to ifpri-irb@cgiar.org when the hard copy of the application for both new and continuation protocols is submitted. If medical record review is conducted for research, or if applicants are unsure about the role of research in projects, review requests should be forwarded to the IRB.

Categories of Protocol Review

Full Board Review: The IRB will use the primary reviewer system for full board review studies. The primary reviewer provides comments and makes recommendations to the full board. All members of the full board will receive the consent forms and information about the protocol to conduct a substantial review. The IRB staff to determine if it qualifies for expedited review or exempt status shall initially screen an application submitted for full board review. The IRB staff to the next scheduled full board meeting shall assign human subjects research requiring full

board review and approval. Each proposed research study may be assigned to a primary reviewer and review materials shall be prepared accordingly.

Each research proposal requiring initial full board review and approval shall be addressed separately at a convened IRB meeting. The IRB may not issue a conditional approval for a study. The research investigators must satisfy all concerns and submit all required documents before an approval is issued.

Expedited Review: Expedited review procedures may be initiated to review either research studies that involve no more than minimal risk and are included in HHS/FDA publications on expedited review (see Appendix),[10] or previously approved research that requires minor changes during the period of one year or less for which approval is authorized. The IRB Coordinator or one or more members designated by the Coordinator may conduct expedited review using the same criteria as for non-expedited review. Protocols submitted must include all of the materials that are required for full board review. The reviewer(s) may exercise all the authority of the IRB except disapproval of the study, which may only be done in full board review. All comments or concerns of the reviewer shall be communicated in writing to the PIs and responses by the PIs reviewed by the same assigned reviewer. Expedited approval of human subjects research shall be granted for a period of one year, unless the reviewer specifies a reduced approval period. The IRB is responsible for keeping members of the IRB advised of research proposals that have been approved pursuant to expedited review by distributing a list of protocols at each meeting and allowing members to request the entire protocol if desired.

Expedited Review (Continuing): For studies (not FDA) submitted after January 20, 2019 in certain cases the IRB may forgo continuing review. In such cases the IRB reserves the authority to request and receive annual update/progress report to use as a tool so as to monitor studies.

Continuing Review: In certain cases the IRB will conduct continuing review of all approved research at intervals appropriate to the degree of risk, but not less than once per year. Research investigators are advised that they must cease all research activity of the project after the expiration date if they have not submitted a progress report. At the time of approval researchers are notified that they are to send in continuation of review approximately 6 weeks before the study's expiration. If time allows the IRB may notify the PIs that the study is due for renewal or final report. All PIs at IFPRI will be notified via e-mail; PIs at other institutions may be notified by mail.

Research previously approved by the IRB and submitted by the investigator for continuing full board IRB review shall initially be screened by the IRB's office to determine if it may qualify for expedited review. The research materials submitted for continuing a member of the IRB's office to ensure that the most current version of the research protocol and informed consent document(s) were submitted and that no outstanding issues or deficiencies exist shall review IRB review and approval.

[10] The publication that lists these types of research is entitled "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure".

For continuing review for all research categories the primary reviewer shall provide a brief summary of the research and progress of the study, followed by a presentation of comments and concerns related to the research, informed consent document(s), plans for continuation of the research, and a recommendation for full approval, approval subject to modifications or disapproval of continuation of the study. The assigned reviewer and/or the IRB Coordinator for comments and recommended action will review the protocol

Previous research approved by the IRB requiring continuing full board review shall be assigned to the next scheduled full board meeting. Each such research submission shall be assigned to a primary IRB reviewer and materials should be accordingly prepared. Each research study requiring full board continuing review shall be addressed separately at the convened meeting.

Following the primary reviewer's presentation, the protocol shall be opened for discussion. An IRB staff member shall record the discussion to be included in the minutes of the meeting. The discussion will also be tape-recorded. Once the tapes are transcribed and the minutes approved, the tapes will be destroyed. Following open discussion, the Chairperson shall call for a vote by the committee to grant full approval, approval subject to modifications, or disapproval of continuation of the study. The vote of the majority of the members of the IRB present at the meeting shall determine final approval status. Following the vote, the minimal risk status of the study shall be documented, with justification in the research protocol and/or the meeting minutes. The IRB Coordinator shall grant final expedited approval of continuation. Expedited approval of continuation of a study shall be granted for a period of one year unless the IRB Coordinator specifies a reduced approval period.

Exempt Research

Some research is exempt from review by the IRB under federal regulations. Institutions, not investigators, must certify that a research study qualifies as exempt. Research that qualifies as exempt includes:

1. Normal educational practices in established educational settings.
2. Educational tests, surveys, interviews, or observation of public behavior, unless identified and sensitive.
3. Research involving the collection or study of existing data, documents, or records, if publicly available or recorded by the investigator. Research may not be exempt if information is recorded in a form that identifies the subject by name or through a code. Federal regulations require approval when identifiers are present at any point in records created by the researcher, not just at the time of study presentation. Even when study data are recorded without subject identifiers, approval may be required if the researcher takes medical records out of the room where they are kept as part of the research process.[11]
4. Research on elected or appointed public officials or candidates for public office.
5. Evaluation of public benefit service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

[11] 45 C.F.R § 46.101.

Informed Consent

Informed consent is a process by which information is presented that will enable people to voluntarily decide whether or not to participate as a human subject in a study. The procedures used in obtaining informed consent should be designed to educate the subject population in terms it understands. Therefore, the language and documentation of the informed consent, particularly the explanation of the research activity, its purpose, its duration, any experimental procedures, the risks, the benefits, and any alternatives must be written in a manner that is understandable to the population asked to participate. The design and format of the written information should be presentable to the human subject population for future reference and as documentation for the basis for consent.

The IRB requires information given to potential research subjects as part of the informed consent process to include the necessary elements addressed in the federal regulations.[12] The IRB may further request that additional elements be included in the consent document or that more information be given to potential human subjects, if the IRB determines that the information would meaningfully add to the protection of the rights and welfare of the human subjects. The IRB may require changes to the consent form even if the IRB or another institutional review board previously approved it.

The IRB shall require that informed consent be obtained from each prospective human subject or the legally authorized representative of the human subject prior to participation in research activities, except if the IRB determines and documents that the research activity meets the criteria for a waiver of informed consent for a minimal risk study and waives the requirement to obtain informed consent.[13]

The IRB has the authority to require revisions to the informed consent document(s) as a condition for approval of the study, even if it was approved previously by another IRB. The IRB will not direct the revision process, especially if changes are extensive, but will describe the general nature of the problems in the document(s) and will require the investigator to provide detailed revisions. Informed consent documents should contain the following 8 points of information in "lay language" generally understood by the public:

1. A statement that the study involves research.
2. An explanation of the purposes of the research.
3. The expected duration of the human subjects' participation in the research.
4. A description of the procedures that will be followed.
5. A description of any reasonably foreseeable risks or discomforts to the human subjects.
6. Any alternative procedures or treatment that could be advantageous to the human subjects.
7. A statement describing the extent, if any, to which confidentiality of data, information, and records of human subjects will be maintained or kept.

[12] The process of obtaining informed consent is addressed in 45 C.F.R § 46.116, and if applicable, 21 C.F.R. § 50.20, and the documentation of informed consent must comply with 45 C.F.R. § 46.117.
[13] The criteria for a waiver of consent for a minimal risk study is described in 45 C.F.R. § 46.116(c) and 45 C.F.R. § 46.116(d)(1-4).

8. An explanation of compensation should a human subject become injured while participating in the study.
9. Up-to-date contact information for answers to questions about the research, human subjects' rights, and whom to contact in the case that a human subject sustains a research-related injury.
10. A statement that:
    a. Participation in the research is voluntary;
    b. Refusal to participate will not result in any loss of benefits or status to which human subjects are otherwise entitled;
    c. A subject can withdraw at any time and without penalty and the circumstances under which that event may occur;
    d. Participation can be terminated by the research investigators;
    e. Costs may be incurred as a result of participation;
    f. New findings developed during the course of research which may be related to the human subjects' willingness to continue in the study will be shared with the human subjects;
    g. Discloses the number of human subjects involved in the research or targeted for recruitment; and
    h. Discloses the risks involved with participation.

No incomplete consent forms will be reviewed by the IRB. For new investigators, the IRB may make necessary changes and send the approved revisions to the research investigators or the IRB may return the document to the PIs requesting that changes be made. If revisions made by the research investigators are deemed inadequate, the IRB will contact the research investigators to discuss the changes as a tutorial for drafting consent documents.

The informed consent document(s) may not contain exculpatory language through which a human subject or a representative therefor is made to waive or appears to waive any legal rights or is made to release or appears to release the investigators, the sponsors, the institutions, or its agents from liability for negligence.

The informed consent document(s) should be at a 6th grade reading level. Research investigators should review the document(s) before submitting it to the IRB to confirm that all of the requisite elements of informed consent are included. The document should be a record of what was communicated to the participants, what will be done, or what the human subjects have agreed to do. The research investigators, while keeping the original consent form with the letter of approval or determination from the IRB for their records, shall copy the approved form for use and shall not use the form after the expiration date of the approval.

Quick Link on Informed Consent

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html

Consent Criteria for IRB Approval

In granting approval for proposed research, the IRB shall require that the research meet the regulatory criteria for approval.[14] The IRB may impose additional requirements on the research, if in its judgment, it would significantly add to the protection of the rights and welfare of the human subjects.

The criteria upon which studies will be reviewed include:

1. The minimizing of risks to the human subjects using procedures which are consistent with sound research design and which do not unnecessarily expose human subjects to risk and whenever appropriate, using procedures already performed on the human subjects for diagnostic and treatment purposes.
2. The reasonableness of risks to human subjects in relation to anticipated benefits, if any, and the importance of the knowledge that may be reasonably expected to result.
3. The equitable selection of human subjects by taking into consideration the purposes of the research, where the research will be conducted, and the special problems of research involving vulnerable populations, such as children.
4. The obtaining of informed consent from the subject or a legally authorized representative. For studies involving minors, parental permission is required unless the IRB waives this requirement. In studies involving children and adolescents, the appropriate assent of the minor shall be obtained in addition to the parental permission.
5. The informed consent documents, unless the IRB waives such documentation. All waiver requests should be submitted in writing to the IRB with the application.
6. The inclusion and appropriateness of provisions that protect the subject's privacy and maintain the confidentiality of the data. Any data leaving the study site should be specified and any possible data encryption should be provided with the methods therefor.
7. Research protocols that involve collection of data from the medical records of deceased patients also does not require IRB approval, with the exception of certain infectious diseases or genetics research or research that links back to living individuals. However, researchers interested in data from next-of-kin must develop a separate consent form for follow-back or present a strong justification for not seeking consent.
8. The certification of all research investigators and co-investigators to conduct human subjects research, including the obtaining of human subjects research training certificates from required certificate sources, prior to the approval or initiation of research.

Voting at IRB Meetings

Federal regulations address the different determinations that the IRB may make regarding a research protocol.[15] A majority of IRB members must be present for a quorum in order to

[14] 45 C.F.R § 46.111, and if applicable, 21 C.F.R. § 56.111.

[15] 45 C.F.R. § 46.109(a); *accord* FDA Regulations (stating that "[a]n IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy").

convene a full committee meeting, and the majority of those members must approve of a protocol in order for the research to receive IRB approval.[16]

All votes shall be recorded in the minutes. Voting options are as follows:

1. Approved;
2. Approved pending changes;
3. Not approved;
4. Recuse; and
5. Abstain.

The options and rationales to justify each option are given as follows:

Approved: The study has been approved as submitted and the investigator is not required to change any aspect of the protocol or consent document. The approval date is the date of the IRB meeting. The approval is valid for one year, unless the committee designates a shorter period due to the risks associated with the study. An approval letter will be sent to the investigator.

Minor Revisions Required: Approval may be granted pending minor revisions of the application and resubmission to the IRB. The full committee does not need to review the study again, unless the researcher does not provide a "simple concurrence" with the requested revisions. A letter describing the concerns of the committee will thereafter be sent to the investigator clarifying that the study may not begin until the IRB has completed a second review and issued a letter of approval. Because the requests are minimal, the second review may be conducted as expedited by the IRB Coordinator. The research investigators' response will be reviewed for appropriateness and concurrence, without which the response will again necessitate review by the full committee. Once the response has been approved, a final IRB approval letter will be sent to the investigator and the study may begin at that time. However, the approval date will be retroactive to the original meeting at which the determination of "minor revisions required" was made, even in the event that it may take several months to receive the minor revisions from the investigator. This approval is valid for one year, unless the committee designates a shorter period due to the risks associated with the study.

Not approved: If the number of concerns, questions, or problems are such that minor revisions alone are insufficient to approve the study. A letter describing the reasons the study was not approved is sent to the investigator that expresses the issues the IRB encountered and the reasons why the IRB considered the items problematic. The research investigators will be notified of the opportunity to the IRB in writing or in person with regard to the IRB determination. The full committee for full board reviews must review the resubmission of the study. If a study is resubmitted for full review and the study is approved at the second meeting, the date of approval is the date of the second meeting. For expedited reviews the IRB Coordinator shall notify the researcher as to the reason the study is not approved.

Recuse: If a member of the IRB has a conflict of interest with any part of the study, the member may not participate in the initial or continuing review of the study, except to provide information requested by the IRB. The member must leave the room and not participate in the final vote.

[16] A majority means more than half of the members. 45 C.F.R. § 46.108(b).

This is considered a "recusal" and will not be counted as part of the voting quorum. Conflicts of interest include financial interest, active participation in the trial as a principal investigator or co-principal investigator, or any other issue for which the member's vote could be considered potentially conflicted.

Abstain: If a member of the IRB does not have a conflict sufficient for recusal, but feels unable to vote (for reasons such as the member left the room during discussion, the member does not comprehend the study or the issues, etc.), the member may abstain from voting. An abstention will be included as part of the voting quorum.

Recording IRB Meeting Minutes

The use of audio recording of IPRI IRB meetings is permitted. For each of the meetings schedule the IRB Chair will preside over the meetings and is responsible for the accurate recoding of minutes. Attendance shall also be part of the IRB meeting. The minutes of the meetings will include all the information stipulated by HHS regulations.[17] Separate deliberations, actions, and votes for each protocol undergoing initial and continuing review will be noted at the meetings or via telephone conference call. Meeting minutes should be circulated to board members for comments or changes one week after the meeting is held. Comments/changes shall be submitted within 10 days of receiving the minutes from the Chair. Finalized reports of the meeting minutes shall be reviewed and approved by the board at the next scheduled IRB meeting. The IRB shall provide snacks or meals during the monthly meetings. Monies spent on transcription services shall be reimbursable or petty cash may be used.

IRB Correspondence Requirements

The IIFPRI RB will direct all written correspondence to research investigators. Any discussion about the protocol will be between the IRB Coordinator and the research investigators or other designated persons. Designated persons are defined as the individuals listed on the protocol as contacts.

Procedure for Determination of Exempt Research

The IFPRI IRB requires that research investigators submit their projects for a determination of exemption. The request can be sent either by hard copy or electronically to the IRB.

Once the application is reviewed, the IRB shall send a "Letter of Determination" to the research investigators indicating this determination. Although continual review of these studies is no longer a requirement IFPRI IRB does require periodic progress reports/updates on research for quality assurance purposes. Researchers are required to submit a progress report 4 weeks before the date specified on the approval letter or a final report within 30 days of the completion of the research. If the approval letter does not contain a date then the researcher need not submit a

[17] *See* 45 C.F.R. § 46.115(a)(2).

progress report to the IRB. Only a final/closure report will be required. The IRB may also make periodic audits of the research from time to time.

The research investigators shall not change the protocol or enroll more subjects than approved by the IRB. The research investigators must notify the IRB and wait for written approval should any change(s) be made before implementing them. Under no circumstances will verbal communication regarding modification(s) and/or approval be accepted. Any deviation from the written approval process will be considered non-compliance and a report will be generated to sent to the appropriate persons.

Research involving human subjects must be reviewed by the IRB if private information is recorded in a manner that is individually identifiable with specific human subjects.[18] Information from medical records is private information. Research is not exempt from IRB review if study data are linked to identifying information at any point in records created by the researcher. These studies fall under full board or expedited review.

The research investigators must comply with all conditions of approval from the IRB, institutional policy, and state and federal laws. The research investigators shall respect all changes in protocols made by the IRB and submit protocols and continuations for review to the IRB in a timely fashion. Research investigators should not begin any research or research related activities before receiving IRB approval. Research investigators must report all adverse events and problems involving risk, violations of privacy and confidentiality in the research to the IRB for review in writing within 48 hours. The report should contain at least the following: time, place of the event, who was involved, name of the participant, name of the study, a brief description of the circumstances, how it was handled, physical or psychological harm etc. The research investigator must also submit a corrective plan of action as well as a timetable for taking the action. The IRB will monitor the adverse event and may subsequently launch a brief investigation into the event so as to prevent future adverse events. The IRB may require more steps to be taken to correct the problem than is proposed by the research investigator. The research investigator will submit a written report to the IRB within 10 calendar days after the corrective action has been taken to advise the IRB about the disposition of the event. If the event has not resolved by then the research investigator will have an additional 5 days to successfully resolve the adverse event. Serious adverse events (including breaches in confidentiality and privacy in the research) may be reported by the IRB to the IRB Chair and/or Director of Finance for further action.

Notification Procedure for IRB Approval/Disapproval Protocols

If the IRB decides to fully approve a research activity, it must include in its written notification the date on which full IRB approval was granted and the date on which such approval will terminate. For research that requires full board review and approval, the termination date shall be based upon a continuing review interval of one year from the date of granting full approval or approval subject to modifications, unless a shorter continuing review period is specified. For research that qualifies for expedited review and approval, the termination date shall be based on

[18] 45 C.F.R. §§ 46.101(a), 46.101(b)(4), 46.102(f).

a continuing review interval of one year from the date when full approval was granted, unless the person responsible for the expedited review and approval specified a shorter continuing review period.

If the IRB decides to disapprove a research study, it must include in its written notification a statement of the reasons for its decision, and give the researcher an opportunity to respond to the IRB in writing and in person.

If the IRB decides to approve a study subject to modifications, it must include in its written notification the specific revisions stipulated by the IRB to obtain full approval. The written notification shall direct the investigator to revise the research and/or informed consent document(s) accordingly, and to resubmit the material for expedited review to obtain full approval.

The PIs shall be notified in writing of the IRB's decision to approve, approve subject to modifications, or disapprove the continuation of research. Written notification documenting full board approval of continuation for research should include the number assigned to the submission, the approval date, and the date on which the approval expires. Written notification documenting approval subject to modifications shall include the specific revisions requested by the IRB, instructing the research investigators to revise the research and/or informed consent document(s) and resubmit for final approval. Written notification documenting the disapproval of a study shall include a statement of the reason(s) for disapproval, problems or deficiencies identified by the IRB, and instructions for resubmitting the research for full board approval.

In cases of new expedited review, the research investigator shall be notified of approval of the research and informed consent document(s) by a letter prepared by the IRB's office and signed by the individual reviewer(s) who granted the approval. This letter should include the number assigned to the protocol, the basis for granting expedited approval (or category of expedited activities), and the approval and expiration dates. Expedited review of continuing research requires that the PIs be notified of the expedited approval by a letter prepared by the IRB office and signed by the IRB Chairperson, including the number assigned to the study, the basis for granted expedited approval (or category of expedited activity), and the approval and expiration dates. ***All appeals of IRB decisions should be forwarded in writing to the IFPRI-IRB. Appeals will be completed in 2-3 weeks after receipt.***

Adverse/Unanticipated Event Reporting and Documentation

While conducting research, adverse or unexpected events may occur. Some examples of adverse include: the death of a research participant involved in a study, physical injury, emotional trauma or upset, or depression. IFPRI IRB shall require a researcher to promptly report any adverse event of moderate or greater severity for either expected or unexpected, related to a research intervention or unexpected problems involving human subjects to the IRB. The IRB will review and acknowledge the receipt and review of the report. IRB shall follow written procedures for handling and reporting serious or continuing non-compliance with the federal regulations or the IRB's requirements governing human subjects research to the OHRP, FDA, and authorized institutional official.

In The IRB will communicate to the research investigator the disposition of the full board meeting deliberation of the report, if any. The IRB will notify OHRP of any serious adverse events and also of suspensions or terminations of its approval of a research project. In the case of an adverse or unexpected event, the IRB shall follow written procedures for handling and reporting unexpected problems involving risks to human subjects and others.

The IRB shall require that serious, expected adverse events related to a research intervention, unexpected adverse events of moderate or greater severity related to a research intervention, and other unexpected problems involving human subjects be promptly reported to the IRB.

The research investigator is to report the adverse event to the IRB in writing within 3 calendar days (holidays and weekends excluded) after becoming aware of the incident. The written report is to be followed by a call to the IRB office during the same 3 calendar day period (holidays and weekends excluded). The written report should contain the following information:

1. A description of the person affected;
2. A description of the adverse event (i.e. date, time, place of occurrence, staff involved); the nature of the adverse event (i.e. death, emotional trauma, physical injury); what interventions were involved, and what resources were utilized or accessed;
3. A description of measures taken by the research investigator to resolve the situation; and
4. Any corrective action taken by the research investigator and an assessment of the action taken.

A second written report is to be filed with the IRB no later than 10 calendar days after the incident. This report will update the IRB regarding any outreach efforts to the person, the emotional and physical health status of the person, the effectiveness of the intervention, and whether the research investigator recommend modifications to the protocol as part of the corrective action plan. Any modifications must be reviewed and approved by the IRB, except in rare cases.

At the conclusion of the investigation, a detailed report on the resolution of the adverse event must be submitted to the IRB within 10 days. After reviewing the report, the IRB may make additional requirements to ensure the health and safety of other participants involved in the research. The IRB will conduct an investigation into the adverse or unexpected event and its circumstances, and may request more information from the research investigator. If the IRB determines that the actions taken were not sufficient, the IRB after bringing the matter to the IO/Director of Finance may place restrictions on the research protocol until such time as a more suitable corrective action plan is crafted and implemented for the protection of human subjects. The PIs will be required to make changes recommended by the IRB.

The IRB will make a recommendation to the SMT and shall notify the PIs in writing with respect to the disposition of the adverse or unexpected event when it becomes available but no later than 21 days after completing its investigation. The IRB also reserves the right to have any and all adverse events thoroughly reviewed by the full board and will solicit recommendations from board members. In such cases, notification to the research investigator will occur in writing within 45 calendar days. Failure to comply with the policy and procedures as outlined will be

deemed non-compliance and may be subject to a recommendation for further disciplinary action to the IO, Director of Finance and the Chair.

Records Retention

The records retention process begins at the creation of a record and ends when the record is no longer needs to be retained. All IRB records are stored in secured electronic secure computer systems within IFPRI. Record access is limited to:

1. The IRB Coordinator for QA/QI and audit/compliance purposes
2. Members of the SMT for inspection in cases of misconduct, fraud plagiarism and determination of discipline
3. The members of the IRB (for review or determination purposes only);
4. Officials of federal regulatory agencies conducting reviews, such as the OHRP and FDA;
5. Research investigators (for reasonable access to files related to their research); and
6. Appropriate accreditation bodies for audit or inspection

The IRB office shall be responsible for the maintenance of records related to the functions of the IRB. All IRB study records are to be maintained at the IRB office as long as the law requires but no less than for 5 years after the completion of the study. Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted (may contain notation). The IRB will keep records of unapproved protocols on file as pending for no more than 1 year from the date of submission. After that time, records will be considered closed, unapproved, and archived.

The following documents are retained indefinitely:

- IRB meeting minutes
- Previous versions of IRB Rosters
- A resume or cv for each IRB member

A report of all IRB files eligible for conversion to open source database or destruction of files will be prepared by the IRB coordinator and will be given to the SMT. All studies that will be converted to open source database or destroyed must be stripped of all personal identifiers. Failure to do so may result in actions against the researcher.

Record retention for adverse/unanticipated events

The IRB shall maintain a database of adverse events reported in compliance with the IRB's policies for reporting of adverse events. Written copies of such reports shall be maintained on file until 3 years following the termination of the research study in question

Data/Specimens Used in Research and Non-Research

Confidentiality and privacy even after a person ceases to participate in research is of major

concern in this area. The banking of specimens/data refers to the creation of banks and/or databases (repositories) to collect, store, and distribute human biological materials (specimens) and data for future research purposes. Repository activities involve three components: (1) Collection of specimens/data; (2) storage and management of the specimens/data; and (3) distribution of specimens/data to recipient investigators for use in a future research project.

Collection of Human Specimen/data for a Repository:

Researchers who collect directly or indirectly identifiable human specimen/data must request IRB review and approval of the activity. Under most circumstances, written informed consent and HIPAA Authorization from the subject is required and should include information about the repository, the conditions under which the specimens/data will be shared with others and if the specimen/data will be store for future use beyond the current research.

Non-Research Repositories - are defined as if specimens or data were originally collected for non-research purposes AND were added to a non-research repository/database without any identifiable private data or information or links (ie codes, record numbers) to identifiable private data or information, it is a "non-research" repository/database.

Research Repositories – are defined as if human specimens or data were collected for research purposes, it is a research repository. Collection of specimens/data, repository storage or data management and use of specimens or disclosure of data are all considered "research activities" and require IRB review and approval.

Human specimen/data repositories may include two kinds of specimens/data: a) those collected with the expressed purpose of distribution to other investigators, and b) those collected by individual investigators, and not originally intended to be shared with others, but which are subsequently shared as part of a repository.

Any collection which contains human specimens/data that are potentially identifiable (i.e. directly or indirectly with a code or link) and are distributed to someone other than the original named investigator(s) making the collection, regardless of the original intent, may be considered to be a repository requiring IRB oversight.

If the original named investigator(s) wishes to use the potentially identifiable human specimens or data for any future use that is not part of the original IRB approved protocol then the subsequent use will also require IRB approval and oversight.

Data Security

Identifiable health and/or personal information may be used for various types of research, including health and nutrition, epidemiological, medical services and available treatments, farms, geographical points etc. All research should protect the confidentiality of information learned about human subjects during the course of a study and to oversee the researchers' access to information about human subjects from other sources, particularly from medical records created in non-research settings. All researchers must therefore establish the secure maintenance of the data and the prohibition of disclosure and re-disclosure using methods to protect confidentiality

of individually identifiable research data. Some of these options include security precautions such as locked cabinets, substituting codes for individual identifiers, and waiving the requirement for obtaining a signed informed consent form.[19]

Investigator Information

Modification to Existing Study Protocols

All modifications or revisions, major and minor, must be submitted to the IRB for approval and must be submitted by the IRB submission deadlines so as to ensure thorough review. The determination as to whether a modification is major or minor is made by the IRB Coordinator or designee thereof and is based on whether the modification involves minimal risk or affects the risk-benefit ratio of the study.

The request for approval of a modification must be made in writing by the research investigator and describe the change(s) and indicate the reasons for the change(s). The only type of modification that does not require written IRB approval prior to implementation is that which is necessary for the safety of a subject. In that event, the change may be implemented immediately, and the IRB notified after the fact no longer than 3 calendar days. At that time a report outlining the unsafe conditions should be forwarded to the IRB for review.

Progress Reports and Continuing Reviews

The IRB will conduct continuing review of all approved research at intervals appropriate to the degree of risk, but not less than once per year. The IRB will determine the date by which research must be reviewed. The research investigator must submit a progress report no less than 6 weeks prior to the assigned date. The report must specify any conditions that have interfered with the rights and safety of the human subjects involved. If the required progress report is not submitted in a timely fashion, the research will be suspended. In this case, research investigators may be required to retake the CITI Human Subjects Research Training if expired before the protocol can be approved.

Final (Closure) Report

The research investigator shall submit a final (closure) report within 30 days of completion of the research project (includes analysis). This must be done regardless of research category. The IRB will send a notification letter to the research investigator if the report is found to be satisfactory and the file closed. No activity other than publication preparation should be done once a study is closed.

Conflict of Interest Policy

Disclosure to the IRB is required if a conflict exists in any form. The member should disclose the conflict as soon as they become aware of the conflict. The member of the IRB with the conflict of interest should not be involved in any aspect of the research that is implicated in that

[19] 45 C.F.R. §§ 46.117(c)(1).

conflict. Members should be excused immediately and are prohibited from participation in IRB deliberations and voting by investigators in which there is a conflict. The IRB shall exclude any individual with a conflict of interest from all discussions of a study pertaining thereto.

Board members are not compensated for their participation in research review. However, the institutions that allow their members to participate in the protocol review process at IFPRI should allow adequate time for protocol review preparation and travel. Light refreshments may also be provided.

Privacy Violations and Breaches of Confidentiality

All breaches of privacy and confidentiality occurring within the research context should be reported via written correspondence to the IRB within five days. The IRB will review all such occurrences and take appropriate action, including:

1. Contacting the PIs for further information;
2. Investigating the activity;
3. Notifying the Board to solicit its further recommendations, if necessary; and
4. Notifying the Chair, Director of Finance and the Director General of DGO (Institutional Official)

The Coordinator/Chair may also notify the compliance officer if necessary.

Audits

The IRB has the authority and does utilize random audits of studies for issues of compliance and quality assurance.

Researchers at IFPRI

If you are a member of the IFPRI research community (i.e. research intern, staff, or approved external research collaborating investigator) conducting research involving human subjects or data acquired from human subjects these policies and procedures apply to you. Approved external researchers or unaffiliated researchers must have a recommendation from the IFPRI division head involved in this activity to support their participation. The letter also needs to be signed off on by the IRB Chair who will then forward the information to the IRB. The IRB will keep the information in a file. Institutional agreements for collaborative research should also be submitted to the IRB for approval and should be included among study documents along with study protocols. **The IRB requires notification of any researcher leaving IFPRI so that they can be removed from the approved researcher list. The notification can come from either the division/team level or from the researcher.**