MEMORANDUM CIRCULAR NO. 08
SERIES OF 2022

Subject: AMENDMENT TO MEMORANDUM CIRCULAR NO. 9, SERIES OF 2019, OTHERWISE KNOWN AS "THE DSWD RESEARCH AND EVALUATION POLICY", CREATING THE DSWD RESEARCH ETHICS COMMITTEE

I. RATIONALE

Through the years, the Department has refined its screening process for research and evaluation (R&E) studies in terms of scientific and social merit (i.e. objectives, methodology, design and overall value to Social Protection and the SWD sectors) as evidenced by the institutionalization and constant updating of several policies/guidelines pertaining to the conduct of research and evaluation studies in DSWD. The most recent addition to such extensive history of R and E guidelines in the Department are: (1) Memorandum Circular No. 9, Series of 2019 or the *"The DSWD Research and Evaluation Policy"*; (2) Memorandum Circular No. 10, Series of 2019 or the *"Protocol for the Conduct of Research Studies in DSWD Offices, Centers and Institutions"*.

However, there remains a gap in closely examining whether these studies uphold ethical standards. It is equally important to ensure that all research and evaluation activities, especially those including DSWD personnel, clientele, and beneficiaries adhere to the universally accepted ethical standards on studies involving human subjects. Consistent with the DSWD's mandate of protecting and promoting the rights of the vulnerable and marginalized sector of society, it must follow that all R&E activities should also give utmost importance to the safety, dignity, well-being, and rights of all parties involved in the studies.

While guiding ethical principles and standards have been documented in the *DSWD Research and Evaluation Policy (Section VIII of MC 9, s. 2019)* and the corresponding sanctions enumerated in the *DSWD Research Protocol (Section VI, Item 15 of MC 10, s. 2019),* there has yet to be an established process nor an institutionalized body in charge of conducting quality ethical review, monitoring and clearance of R&E studies in the Department.

Key international policies, particularly in setting forth universal ethical values in research, are outlined in the *2013 World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects* and *Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-Related Research Involving Humans (2016).*

Locally, the *Philippine National Health Research System (PNHRS) Act of 2013 (RA 10532)* was passed to ensure all phases of researches involving human participants

DSWD Central Office, IBP Road, Batasan Pambansa Complex, Constitution Hills, Quezon City, Philippines 1126
Website: http://www.dswd.gov.ph Tel Nos.: (632) 8 931-8101 to 07 Telefax: (632) 8 931-8191

are "anchored on inclusiveness, participation, quality, equity, efficiency and effectiveness which connect to, and converge with, the wider health, economic, political, educational and science and technology systems of the country". The prescribed procedures of ethics review were then detailed in the *Philippine Health Research Ethics Board (PHREB) 2017 National Ethical Guidelines on Health and Health-Related Researches.*

Based on the PHREB Guidelines, it is imperative for institutions engaging in biomedical and behavioral research to establish an institutional Research Ethics Committee (REC) that will provide independent, competent, and timely ethical review of proposed studies. Moreover, having its own REC ascertains the DSWD's reputation for maintaining ethical research practices and further legitimizes its R&E publications.

Currently, the review of ethical considerations and implications of DSWD-initiated studies are under the purview of the National Research and Evaluation Technical Working Group (NRE-TWG) as stipulated in Section IX, Item A.3.d of Memorandum Circular No. 9, s. 2019. However, to **manage the possible conflict of interest (COI), it is imperative that an ethics review** shall be given to a separate governing body.

To this end, the DSWD Research Ethics Committee (DSWD REC) shall be instituted as the overall ethics approving and clearing body for all research and evaluation studies funded and initiated by the Department.

II. LEGAL BASES

A. Republic Act No. 10532, or the "Philippine National Health Research System Act of 2013"

B. PHREB Policies and Requirements for Accreditation of Research Ethics Committees (2020)

C. National Ethical Guidelines for Health and Health-Related Research (2017)

D. Memorandum Circular No. 9, Series of 2019, or the "DSWD Research and Evaluation Policy"

E. MC 10 s2019 - Protocol for the Conduct of Research Studies in the DSWD Offices, Centers and Institutions, Amending Administrative Order No. 19 s2011 Including Request of SWD Data/Information

III. OBJECTIVES

This Circular is issued to guide the officials and staff of the Department on the needed enhancements in MC No. 9, series of 2019 to institutionalize the DSWD Research Ethics Committee (DSWD REC) as the overall ethics approving and clearing body for all research and evaluation studies conducted by the Department. Specifically, it shall:

1. Amend Section VII, Item A.3 of MC No. 9, series of 2019 to include the DSWD REC in the review process of research and evaluation proposals;
2. Amend Section IX, Item A.3.d of MC No. 9, series of 2019 to remove the review of ethical considerations and implications of DSWD-initiated studies from the function of the NRE-TWG;
3. Include a section establishing the DSWD Research Ethics Committee;
4. Outline the functions of the DSWD Research Ethics Committee, and;
5. Provide an overview of the ethics review process

IV. AMENDMENT OF SECTION VII, ITEM A.3

Section VII (Operationalization of Research and Evaluation Studies), Item A.3 (Development of Research and Evaluation Proposals) shall be amended as:

> After an initial review, research and evaluation proposals that are identified as priority topics[1] in the Agenda, as well as related studies that cover more than one region, shall be endorsed to the DSWD NREC and NR&E-TWG for review, prior to their approval. Studies proposed by the Field Offices covering only a particular region shall be reviewed by Regional REC and R&E-TWG and approved by the Regional Director.
>
> During the review process, the technical and scientific merit of the design, methodologies, objectives, and tools of the study, among others, shall be assessed by the National or Regional NR&E TWG. Meanwhile, proposals involving human participants, including the use of data derived from humans, shall be reviewed by the National or Regional REC for ethical approval.
>
> Consequently, all research and evaluation proposals developed by the PDPB shall be shared with the DSWD NREC and NR&E TWG for review.
>
> Once cleared by the DSWD NREC and NR&E-TWG, the proposals shall be endorsed to the Secretary or its assigned representative for final approval.

Subsequently, Figure 2 (Process Flow of Proposal Development and Approval shall be updated to reflect the inclusion of DSWD REC in review of proposals.

V. AMENDMENT OF SECTION IX, ITEM A.3.D

Remove from Section IX (Implementing Mechanisms), Item A.3.d (Functions of the NRE-TWG) the stipulation that the NRE-TWG must "*assess of ethical considerations of the different research and evaluation studies, and identify studies requiring ethical*

[1] Priority topics refer to the studies included in the Agenda that are intended to provide evidence and information on the outcomes and outputs of the organization as reflected in the Results Matrix of its Strategic Plan

approval." This shall be one of the functions of the DSWD REC and be further discussed in Section IX, Item A.9.

VI. CREATION OF THE DSWD RESEARCH ETHICS COMMITTEE

The provision establishing and outlining the functions of the DSWD Research Ethics Committee shall be included under Section IX (Implementing Mechanisms), Item A (Implementing Structures and Mechanisms), to read as:

> ***7.* Creation of the DSWD Research Ethics Committee (DSWD REC).** An essential component of a human protection system in research and evaluation, the DSWD REC shall be the ethics approving and clearing body for independent decisions regarding the review, approval and implementation of **all DSWD-funded and initiated research/evaluation studies**. While review of technical and scientific merit is within the purview of the National/Regional Research and Evaluation Technical Working Group (NRE-TWG), the DSWD REC shall focus on ensuring the protection of the rights, safety, and well-being of human participants/respondents as per national and international research ethics guidelines.
>
> Two (2) RECs are hereby created, i.e., National Research Ethics Committee (NREC) at the Central Office and the Regional Research Ethics Committee (RREC) at the Field Offices.
>
> **8. Composition of the DSWD REC.** The following shall be the guiding principles in establishing the DSWD REC, based on international (WHO[2]) and national (PHREB) regulations for the composition of institutional research ethics committees:
>
> > 8.a. Members shall have relevant technical and/or "scientific" expertise in social welfare and development (SWD), social protection, social and/or behavioral sciences, gender, and development (GAD), disaster/climate change adaptation and mitigation (CCAM); or other qualifications the areas of research and evaluation studies relevant to the DSWD. Members with expertise in ethics and law shall also be considered to reflect social and cultural diversity in research.
> >
> > 8.b. A "non-scientist" shall be included to represent the interests and concerns of the community and could serve as the voice of participants especially the vulnerable groups. The primary role of the "non-scientist" member shall be to share insights about the communities from which participants will be drawn, as well as the informed consent process and other forms.
> >
> > 8.c. Membership shall be multidisciplinary and multi-sectoral, with adequate age and gender representation.

[2] 2011 WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

8.d. At least one (1) member who is not affiliated with the DSWD shall also be invited to ensure independence of the REC.

8.e. Consultants/Resource Persons from either the DSWD's Core Group of Specialists (CGS) and/or external partners (e.g. academe, research institutions, NGAs, CSOs, etc.) may also be invited in some deliberations to meet the requirements for diversity and expertise. However, only actual REC members have voting privilege.

8.f. All in all, the DSWD NREC and RREC must each have at least five (5) members.

8.g. Given the abovementioned policies, the DSWD REC shall be structured as such:

Position	Roles and Responsibilities
Chair (Salary Grade 22-24)	• Preside semestral/special meetings • Lead in the review of research/evaluation studies as per ethical considerations • Finalize and sign the REC decision on the applications • Issue ethical clearance based on REC decision
Vice-Chair (Salary Grade 18-24)	• Represent the Chair in his/her absence, i.e. preside meetings and review decisions • Review applications/ proposals and make recommendations for the REC Chair • Participate in the semestral/special meetings and meetings to review applications
Member-Secretary (Salary Grade 15-24)	• Organize semestral/special meetings • Provide administrative and logistical support • Review the applications/proposals and make recommendations for the REC Chair • Coordinate REC processes and activities

Position	Roles and Responsibilities
Members (Salary Grade 15-24)	• Review the applications/proposals and make recommendations for the REC Chair • Participate in the semestral/special meetings and other activities of the REC

8.h. Nomination of members and election of officers are detailed in *Annex A – Terms of Reference for the Constitution of the Research Ethics Committee*.

9. Secretariat of the DSWD REC. The PDPB and PDPS shall provide secretariat services to the NREC and RREC, respectively.

10. Functions of the DSWD REC. The DSWD REC is expected to carry out the following functions:

10.a. Review ethical acceptability of all DSWD-funded and initiated research and evaluation studies involving human participants, which are conducted by DSWD Offices, Bureaus, Sections and Units. The scientific merits identified by the N/RRE-TWG shall also be considered in the ethical review (i.e. outcomes/benefits versus potential risks).

10.b. Issue ethical clearance required for the implementation of the study once the research is found scientifically and ethically sound based on criteria set by Section VIII of the DSWD R and E Policy (MC 9, s. 2019)", and other newly issued research ethical policies issued by PHREB. The Philippine Health Research Ethics Board (PHREB) 2017 National Ethical Guidelines on Health and Health-Related Researches shall also serve a complementary reference in setting requisite ethical practices.

10.c. Promote research integrity by identifying and resolving conflicts of interest (COI). The REC members are not allowed to review and vote on research or evaluation studies which they are involved in to avoid conflict of interest.

10.d. Establish appropriate mechanisms in all stages of the researches / evaluations to:

i. Ensure the safety, protect the rights, and promote the welfare and well-being of research proponents and participants;
ii. Provide counsel (i.e. inputs, recommendations) to research participants, including proponents and researcher;
iii. Ensure prompt reporting of changes in the proposal/design and unanticipated problems during data gathering;
iv. Monitor the compliance of ongoing studies to ethical standards until their completion

10.e. Report to the institutional or national authorities any matter that affects the conduct and ethics of research which in its view may affect the rights and safety of research participants.

10.f. Keep a systematic and organized record of all proposals reviewed, including actions taken and other pertinent information.

10.g. Develop a manual of Standard of Operations (SOPs) detailing the operations and processes of the REC to ensure its transparency, accountability, competency, timeliness and consistency.

10.h. Facilitate the obligatory application and consequent renewal of REC accreditation, in accordance with the requirements set by the PHREB Policies and Requirements for Accreditation of Research Ethics Committees.

11. Functions of the Secretariat. The Secretariat shall have the following functions:

11.a. Prepare notice of meeting, agenda and proceedings of the NREC and RREC meetings;

11.b. Provide administrative and logistical requirements for the REC;

11.c. Facilitate the obligatory application and consequent renewal of REC accreditation, in accordance with the requirements set by the PHREB Policies and Requirements for Accreditation of Research Ethics Committees; and

11.d. Once accredited by the PHREB, comply with reportorial requirements such as the submission of an annual report.

12. Meetings. There will be two (2) forms of meetings which the DSWD-REC shall participate in:

12.a. Regular Semestral Meetings - National and regional RECs shall physically or virtually hold one (1) regular meeting every semester. The meeting of the first semester shall be dedicated to work planning, REC capacity building, and the review and application process. There shall be a provision for holding special meetings to consider urgent matters as decided by the Chair.

12.b. Deliberation Meetings - The REC members will have meetings either in person or by remote (via teleconference) to review the applications. Deliberations of the REC shall take into serious consideration the transparency and collegiality of the process. A member who is involved in whatever capacity in the study or project under consideration shall inform the committee of this potential COI, and his or her further participation in the deliberations shall be determined accordingly. Those with COI shall not be present during the deliberations and decision-making. A member who is the principal investigator or researcher may

remain during the REC meeting to answer questions for clarification regarding his or her research but shall leave the room during the REC deliberation and decision making[3].

VII. THE ETHICS REVIEW PROCESS

The National and Regional RECs shall conduct the ethical review of studies based on an assessment of the research/evaluation activities described in the proposal and instruments submitted prior to the study implementation.

Since the quality of ethical review relies on the REC's keen attention to the application of universal ethical principles, the REC shall develop a manual of operations, which clearly details all areas of its work. Outlined hereunder are the processes that shall be instituted to ensure the efficient, transparent, and timely review of proposals:

1. Documentary Requirements

1.a. Application for review addressed to the DSWD National/Regional REC using the Application Form (Annex B);

1.b. Research/Evaluation proposal which must include the title, significance of the study, literature review, objectives of the study, methodology and procedures, description of the study, population/target participants, exclusion and inclusion criteria, data analysis, budget (if applicable) and ethical considerations;

1.c. Informed consent and assent documents;

1.d. Study tools (questionnaires, case report form, posters, advertisements for recruitment, etc.);

1.e. Curriculum vitae (CV) of researcher and co-researchers, which will also include relevant trainings;

1.f. Statement of on presence or absence of COI of the researcher;

1.g. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest;

1.h. Contracts and approval of relevant offices (Memorandum of Agreement (MOA) if study is collaborative or agency-to-agency in nature / Contracts with firms or individual consultants, etc.)

[3] 2017 PHREB National Ethical Guidelines on Health and Health-Related Researches (Guidelines for Research Ethics Committees, pp. 34)

2. Initial Review Procedure

2.a. After receipt of the application form and protocol package, the REC Secretariat shall check the submitted documents for completeness, for onward endorsement to the REC Chair

2.b. The REC Chair, or his or her representative, shall determine the proposal's exemption from review or the kind of review required – full or expedited review:

2.b.1 **Exempt from Review -** a proposal need not undergo either full or expedited review when it satisfies the following conditions:

2.b.1.1 The study involves neither human participants nor identifiable human data

2.b.1.2 Provided that minimal risks or harms are involved the following may be exempted from review:

2.b.1.2.1 Studies conducted for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and customer acceptability tests

2.b.1.2.2 Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), provided:

2.b.1.2.2.1 There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and

2.b.1.2.2.2 The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant

2.b.1.3 Protocols that involve the use of publicly available data or information

2.b.1.4 Studies exempted from review shall be processed within seven (7) days upon receipt of application

2.b.2. A **Full Review** shall be required for protocols that entail more than minimal risk to participants or those that involve vulnerability issues. In a full review, the proposal is assigned for primary review to all REC members or to at least two reviewers (a "scientist"/ "technical" and a "non-scientist" member) prior to the REC meeting. The reviewers shall

present their findings during the REC meeting for discussion and final action. Studies requiring full review shall be processed within twenty (20) days upon receipt of application.

2.b.3 An **Expedited Review** can be done by the REC for proposals that do not need a full review such as chart review, survey of non-sensitive nature, use of anonymous or anonymized data. Studies requiring expedited review shall be processed within fourteen (14) days upon receipt of application.

3. Proposal Review

3.a Research protocols are evaluated relative to the elements of research ethics (see Elements of Research Ethics, page 11[4]) and other considerations[5] such as social value, informed consent, risks, benefits, safety, privacy and confidentiality of information, justice, transparency, qualification of researcher, adequacy of facilities, and community involvement.

4. Action on Proposals

4.a The action of the REC shall be one of the following:

4.a.1 **Approval,** in which case, the REC shall inform the researcher in writing of the REC's requirements that must be complied with during the conduct of the research

4.a.2 **Modifications Required,** in which case, the REC shall clearly communicate to the researcher in writing, a clear description of the required major or minor modifications to the proposal, instrument/tools and other documents related to the study

4.a.3 **Disapproval,** wherein the REC shall clearly state the reason(s) for disapproval

4.a.4 **Deferred,** if clarifications are necessary, before a decision of the REC can be made

4.b An ethical clearance shall be valid for a period of one year which may be renewed if an application for continuing review is submitted before the expiration of the earlier ethics clearance

VIII. REPEALING/AMENDMENT CLAUSE

[4] Philippine Health Research Ethics Board National Ethical Guidelines (2017) pg. 11
[5] Philippine Health Research Ethics Board National Ethical Guidelines (2017) pg. 41

This Circular amends the provisions of MC No. 9, series of 2019 that are inconsistent herewith. The provisions of MC No. 9, series of 2019 shall thus remain in effect, unless specifically and expressly amended herein.

IX. EFFECTIVITY CLAUSE

This Circular shall take effect immediately upon signing and shall be in full force and effect until repealed.

Issued in Quezon City this 27 day of June 2022

ROLANDO JOSELITO D. BAUTISTA
Secretary
Department of Social Welfare and Development

Cert. True Copy:

28 JUN 2022

MYRNA H. REYES
OIC-Division Chief
Records and Archives Mgt. Division

Annexes:
Annex A - Constitution of DSWD Research Ethics Committee - Terms of Reference
Annex B - Ethics Clearance Application Form
Annex C – Informed Consent Form (ICF) Assessment Checklist
Annex D - Study Protocol Assessment Form
Annex E - Template for the Ethical Clearance Certificate

ANNEX A

Constitution of the DSWD Research Ethics Committee

(TERMS OF REFERENCE)

I. BACKGROUND AND RATIONALE

Given the evolving functions, mandates, composition and expanding clientele of the Department of Social Welfare and Development (DSWD), the demand for researches and evaluations concerning its policies and programs continues to rise over time.

Through the years, the Department has refined its screening process for research and evaluation studies in terms of scientific and social merit (i.e. objectives, methodology, design and overall value to Social Protection and the SWD sectors) as evidenced by the institutionalization and constant updating of several policies/guidelines pertaining to the conduct of research and evaluation studies in DSWD. The most recent addition to such extensive history of R and E guidelines in the Department are: (1) Memorandum Circular No. 9, Series of 2019 or the *"The DSWD Research and Evaluation Policy"*; (2) Memorandum Circular No. 10, Series of 2019 or the *"Protocol for the Conduct of Research Studies in DSWD Offices, Centers and Institutions"*.

However, there remains a gap in closely examining whether these studies uphold ethical standards. It is equally important to ensure that all research and evaluation activities, especially those including DSWD personnel, clientele, and beneficiaries adhere to the universally accepted ethical standards on studies involving human subjects. Consistent with the DSWD's mandate of protecting and promoting the rights of the vulnerable and marginalized sector of society, it must follow that all R and E activities should also give utmost importance to the safety, dignity, well-being and rights of all parties involved in the studies.

While guiding ethical principles and standards have been documented in the *DSWD R and E Policy (MC 9, s. 2019)* and the corresponding sanctions enumerated in the *DSWD Research Protocol (MC 10, s. 2019),* there has yet to be an established process nor an institutionalized body in charge of conducting quality ethical review, monitoring and clearance of R and E studies in the Department.

Key international policies, particularly in setting forth universal ethical values in research, are outlined in the *2013 World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects* and *Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-Related Research Involving Humans (2016).*

Locally, the *Philippine National Health Research System (PNHRS) Act of 2013 (RA 10532)* was passed to ensure all phases of researches involving human participants

DSWD Central Office, IBP Road, Batasan Pambansa Complex, Constitution Hills, Quezon City, Philippines 1126
Website: http://www.dswd.gov.ph Tel Nos.: (632) 8 931-8101 to 07 Telefax: (632) 8 931-8191

are "anchored on inclusiveness, participation, quality, equity, efficiency and effectiveness which connect to, and converge with, the wider health, economic, political, educational and science and technology systems of the country". The prescribed procedures of ethics review were then detailed in the *Philippine Health Research Ethics Board (PHREB) 2017 National Ethical Guidelines on Health and Health-Related Researches.*

Based on the PHREB Guidelines, it is imperative for institutions engaging in biomedical and behavioral research to establish an institutional Ethical Review Committee (REC) that will provide independent, competent and timely ethical review of proposed studies. Moreover, having its own REC ascertains the DSWD's reputation for maintaining ethical research practices and further legitimizes its R and E publications.

To this end, the DSWD Research Ethics Committee (DSWD-REC) is hereby instituted as the overall ethics approving and clearing body for all research and evaluation studies conducted by the Department.

This Terms of Reference outlines the roles, functions, and composition of the DSWD-REC, following the *2017 PHREB National Ethical Guidelines on Health and Health-Related Researches.*

II. PURPOSE OF THE DSWD NATIONAL AND REGIONAL RECs

An essential component of a human protection system in research and evaluation, the DSWD National and Regional REC (N/R-REC) shall be the ethics approving and clearing body for independent decisions regarding the review, approval and implementation of research/evaluation studies conducted by the Central and Field Offices, respectively. While review of technical and scientific merit is within the purview of the National/Regional Research and Evaluation Technical Working Group (NRE-TWG), the DSWD N/R-REC shall focus on ensuring the protection of the rights, safety, and well-being of human participants/respondents as per national and international research ethics guidelines.

Studies covering more than one region, shall be endorsed to the DSWD NREC for review and clearance, prior to the Secretary's approval. Studies proposed by the Field Offices covering only a particular region shall be reviewed/cleared by Regional REC before endorsing to the Regional Director for approval.

III. FUNCTIONS AND RESPONSIBILITIES

The DSWD N/R-REC shall at all times act in the full interest of potential research participants and affected communities and consider the welfare and needs of persons involved in the studies, while having due regard for the requirements of relevant regulatory agencies (e.g. PNHRS-PHREB, DOH-FDA, CHED, NCIP, etc.) [1] and

[1] 2017 PHREB National Ethical Guidelines on Health and Health-Related Researches (Guidelines for Research Ethics Committees, pp. 31-32)

Philippine laws and policies, especially those concerning vulnerable groups (e.g. women, children, elderly, indigenous peoples, persons with disabilities).

As to the specific tasks, the DSWD N/R-REC is expected to carry out the following functions:

1. Review ethical acceptability of all research and evaluation studies involving human participants, which are conducted by DSWD Offices, Bureaus, Sections and Units. The scientific merits identified by the N/RRE-TWG shall also be considered in the ethical review (i.e. outcomes/benefits versus potential risks).

2. Ensure that the proposed research/evaluation study is responsive to the priorities as well as the emerging concerns of the Department and the sectors it serves, as stipulated in the DSWD Research and Evaluation Agenda. That it meets the requisite ethical standards is an equally important consideration in reviewing these studies.

3. Issue ethical clearance required for the implementation of the study once the research is found scientifically and ethically sound based on criteria set by Section VIII of the *DSWD R and E Policy (MC 9, s. 2019)"*. The *Philippine Health Research Ethics Board (PHREB) 2017 National Ethical Guidelines on Health and Health-Related Researches* shall also serve a complementary reference in setting requisite ethical practices.

4. Promote research integrity by identifying and resolving conflicts of interest (COI). Note that REC members may not review and vote on their own projects due to COI issues.

5. Establish appropriate mechanisms in all stages of the researches/evaluations to:

    a. Ensure the safety, protect the rights, and promote the welfare and well-being of research participants
    b. Provide counsel (i.e. inputs, recommendations) to research participants, including proponents and researcher
    c. Ensure prompt reporting of changes in the proposal/design and unanticipated problems during data gathering
    d. Monitor the compliance of ongoing studies to ethical until their completion

6. Report to the institutional or national authorities any matter that affects the conduct and ethics of research which in its view may affect the rights and safety of research participants.

7. Keep a systematic and organized record of all proposals reviewed, including actions taken and other pertinent information.

8. Develop a manual of *Standard of Operations (SOPs)* detailing the operations and processes of the REC to ensure its transparency, accountability, competency, timeliness and consistency.

9. Facilitate the obligatory application and consequent renewal of REC accreditation, in accordance with the requirements set by the *PHREB Policies and Requirements for Accreditation of Research Ethics Committees.*

10. Once accredited by the PHREB, comply with reportorial requirements such as the submission of an annual report (within the first quarter of the year ending on March 31), which shall contain the following:

    a. The composition of the REC, including the curriculum vitae and term of office of each member
    b. Members of the REC secretariat, office and email addresses, and contact numbers
    c. Number of meetings (regular and special) held during the year, including the date and venue
    d. Number of studies reviewed by the REC during the year, classified by the types of study, REC decision or action (approval, minor or major modifications, disapproval), and other information required by PHREB

IV. MEMBERSHIP AND COMPOSITION

A. Composition

The following shall be the guiding principles in establishing the DSWD N/R-REC, based on international (WHO[2]) and national (PHREB) regulations for the composition of institutional research ethics committees:

1. Membership shall be multidisciplinary and multi-sectoral, with adequate age and gender representation.

2. Members shall have relevant technical and/or "scientific" expertise in social welfare and development (SWD), social protection, social and/or behavioral sciences, gender and development (GAD), disaster/climate change adaptation and mitigation (CCAM); or other qualifications the areas of research and evaluation studies relevant to the DSWD. Members with expertise in ethics and law shall also be considered to reflect social and cultural diversity in research.

3. To include a "non-scientist" who will represent the interests and concerns of the community and could serve as the voice of participants especially the vulnerable groups. The primary role of the "non-scientist" member shall be to share insights about the communities from which participants will be drawn, as well as the informed consent process and other forms.

4. To include at least one (1) member who is not affiliated with the DSWD to ensure independence of the DSWD N/R-REC.

[2] 2011 WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

5. May include Consultants/Resource Persons from either the DSWD's Core Group of Specialists (CGS) and/or external partners (e.g. academe, research institutions, NGAs, CSOs, etc.) in some deliberations to meet the requirements for diversity and expertise. However, only actual REC members have voting privilege.

6. All in all, the DSWD N/R-REC must have at least five (5) members.

7. National and regional RECs shall be created following this Terms of Reference.

B. Appointment

1. The selection of the DSWD N/R-REC members shall be through a nomination process that ensures representation of different disciplines (technical/"scientists" and non-"scientists"), sectors (male and female, older and younger age groups) and member/s who are not affiliated with the institution.

   To satisfy these requirements, two (2) representative OBSUs/ODSUs from all clusters of the Department/Regional Offices shall nominate regular and alternate representatives. The General Administration and Support Services Group (GASSG) cluster shall serve as the "non-scientist" member, while all other clusters will be considered "technical" or "scientists".

2. Each representative OBSU/ODSU shall submit a pair of regular and alternate members each. Field Offices may select members with a minimum Salary Grade (SG) of 15, while at Central Office, the lowest shall be SG 18. The maximum SG across all offices is SG 24 or Division Chief level.

3. The regular and alternate members shall serve for a period of three (3) years but may be renewed for two (2) terms. Alternate members shall attend meetings whenever called to ensure that the designated quorum is met.

4. Meanwhile, the non-DSWD affiliated member shall be identified and endorsed by the elected Chair, for the body's approval.

5. A Special Order detailing the names of the officers and members (including those with special roles e.g. non-scientist/non-affiliated) of the DSWD N/R-REC shall be issued and renewed every three (3) years, and amended as deemed necessary.

6. Prior to serving as a regular member, each member of the DSWD N/R-REC shall sign both a confidentiality agreement, as well as a disclosure agreement that states that he or she has no COI as a reviewer.

7. Procedures for renewal of appointment, resignation, replacement; grounds for disqualification; and procedures regarding COI due to financial gains shall be included in the SOP manual to be developed by the REC secretariat.

C. Committee Officers

1. The DSWD N/R-REC shall have a Chair, Vice-Chair, and Member-Secretary who shall be selected among the members who have been with the committee for, at least, one year, by election in a special meeting initially presided by an outgoing officer.

2. Note that senior decision-makers of the entity creating the DSWD N/R-REC (from Director up) or of any office which sponsors or conducts research and evaluation studies may not serve as members nor officers[3]. Thus, Divisions/Units which are mandated to regularly conduct researches and evaluations are excluded from the nomination for membership to the REC.

3. Furthermore, given the limitations in terms of position (see Item #2), the highest position to be considered for REC membership is up to Division Chief only.

4. Officers may be re-elected for a maximum of two (2) terms.

D. Structure

Given the abovementioned policies, the DSWD REC shall be structured as such:

Position	Roles and Responsibilities
Chair (Salary Grade 22-24)	• Preside semestral/special meetings • Lead in the review of research/evaluation studies as per ethical considerations • Finalize and sign the REC decision on the applications • Issue ethical clearance based on REC decision
Vice-Chair (Salary Grade 18-24)	• Represent the Chair in his/her absence, i.e. preside meetings and review decisions • Review applications/ proposals and make recommendations for the REC Chair Participate in the semestral/special meetings and meetings to review applications
Member-Secretary (Salary Grade 15-24)	• Organize semestral/special meetings • Administrative and logistical support

[3] 2017 PHREB National Ethical Guidelines on Health and Health-Related Researches (Guidelines for Research Ethics Committees, pp. 31)

Position	Roles and Responsibilities
	• Review the applications/proposals and make recommendations for the REC Chair • Coordinate REC processes and activities
Members (Salary Grade 15-24)	• Review the applications/proposals and make recommendations for the REC Chair • Participate in the semestral/special meetings and other activities of the REC

V. ACTIVITIES OF THE DSWD-REC

A. Meetings

There will be two (2) forms of meetings which the DSWD-REC shall participate in:

1. Regular Semestral Meetings - National and regional RECs shall physically or virtually hold one (1) regular meeting every semester. The meeting of the first semester shall be dedicated to work planning, REC capacity building, and the review and application process. There shall be a provision for holding special meetings to consider urgent matters as decided by the Chair.

2. Deliberation Meetings - The REC members will have meetings either in person or remotely (via teleconference) to review the applications. Deliberations of the REC shall take into serious consideration the transparency and collegiality of the process. A member who is involved in whatever capacity in the study or project under consideration shall inform the committee of this potential COI, and his or her further participation in the deliberations shall be determined accordingly. Those with COI shall not be present during the deliberations and decision-making. A member who is the principal investigator or researcher may remain during the REC meeting to answer questions for clarification regarding his or her research but shall leave the room during the REC deliberation and decision making[4].

B. Determination of Quorum

Quorum shall follow the "50% + 1" rule. However, it shall require the presence of at least one non-medical or non-scientist and one non-affiliated member(s) to make

[4] 2017 PHREB National Ethical Guidelines on Health and Health-Related Researches (Guidelines for Research Ethics Committees, pp. 34)

decisions about the proposed research[5]. Without these particular members, there shall be no quorum.

C. Capacity Building

Members shall be required to undergo initial and continuing training on the ethics on research involving human participants, before and as they serve in the REC. In case there is no basic ethics training available at the time of the appointment of new members, the REC Chair shall ensure that proper orientation of new members is done on basic ethical principles, international and national ethical guidelines, and REC SOPs. Additionally, the REC shall conduct capacity-building activities at least once a year.

VI. FUNDING

Regular meetings and other activities involving the REC, as well as the honoraria for the non-affiliated member of the DSWD N/R-REC shall be funded by the Policy Development and Planning Bureau.

VII. EFFECTIVITY

This Terms of Reference shall take effect immediately upon constitution of the DSWD-REC. All guidelines inconsistent with the provisions of this Terms of Reference are hereby repealed, modified, or amended accordingly.

[5] 2011 WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

ANNEX B – ETHICS CLEARANCE APPLICATION FORM
(For Initial Review and Resubmission)

1. Study Protocol Code:	1.1. Reference Number[1]	*N/RREC-YEAR-NUMBER*
2. Type of Submission	☐ 2.1 Initial Review ☐ 2.2. Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). NOTE: version and date of version must be inserted as a document footer for all resubmissions	
3. Date of Submission:	<dd/mm/yyyy>	
4. Sectors/Areas Covered by the Study	☐ 4.1 Children/Youth ☐ 4.2 Older Persons ☐ 4.3 Persons with Disability ☐ 4.4 Women ☐ 4.5 Family ☐ 4.6 Indigenous Peoples ☐ 4.7 Others: _____	
5. Type of Study:	☐ 5.1 Evaluation Study (Impact/Process, etc.) ☐ 5.2 Action Research ☐ 5.3 Policy Research ☐ 5.4 Operations/Program Research ☐ 5.5 Case Study ☐ 5.6 Longitudinal Study ☐ 5.7 Ethnography ☐ 5.8 Experimental Research ☐ 5.9 Descriptive Research ☐ 5.10 Others, please indicate: _____	
6. Category of Research (Based on Approach)	☐ 6.1 In-House ☐ 6.2 Fully Outsourced ☐ 6.3 Joint ☐ 6.7 Others, please specify:	
7. Study Title		
8. Study Protocol Synopsis *Please write a synopsis of the study in the space provided, and indicate page where this may be found in the full proposal or in annexes/appendices. Attach the full proposal to this application.*		

[1] To be provided by the N/R-REC Secretariat upon receipt of the documents

DSWD Central Office, IBP Road, Batasan Pambansa Complex, Constitution Hills, Quezon City, Philippines 1126
Website: http://www.dswd.gov.ph Tel Nos.: (632) 8 931-8101 to 07 Telefax: (632) 8 931-8191

8.1 Technical Synopsis a. Social Value	*Please write a summary regarding social value of the study.*
b. Objectives/ Expected output	*Please write the objectives of the study.*
c. Literature review rationalizing the design	*Please write a summary on the literature review rationalizing the design.*
d. Research design	*Please write a summary regarding the research design.*
e. Sampling design, sample size	*Please write the sampling design and sample size.*
f. Inclusion criteria, exclusion criteria, withdrawal criteria	*Please write the inclusion, exclusion and withdrawal criteria.*
g. Data collection and processing plan	*Please write a summary of the data collection and processing plan, including plans for data storage, duration of storage, and who has access to the stored data.*
h. Data analysis plan	*Please write a summary of the plan for data analysis including statistical basis for design, as applicable.*
i. Rationalization for choice of study site (Cross reference information with statements provided in the informed consent)	*Please indicate the specific study site/s and provide justification for the choice of site/s, including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable.*
j. Duration of human participant involvement	*Please indicate duration of human participant involvement.*
9.2 Ethical Considerations a. Protection of privacy and confidentiality of research information including data protection plan	*The section on ethical considerations should be stated in the study protocol. Please write a summary on protection of privacy and confidentiality of research information including data protection plan.*
b. Vulnerability of research participants	*Please write a summary regarding vulnerability of research participants, as applicable.*
c. Risks of the study	*Please write a summary on measures regarding risks of the study, including social risks and issues for safety.*
d. Benefits of the study	*Please write a summary regarding benefits of the study, including a statement justifying a favorable benefit-risk ratio.*

e. Respondent compensations/reimbursements/ entitlements	*Please write plans on patient-related compensations/reimbursements/entitlements.*
f. Informed consent process and recruitment procedures	*Please write a summary regarding process of recruitment and informed consent, including how potential participants will be identified and what information will be made available to the participants, who will obtain informed consent and how this will be done.*
g. Community considerations	*Please write a statement regarding community considerations, as applicable.*
h. Dissemination/ data sharing plan	*Please write a summary regarding plans on dissemination and data sharing.*
i. Terms of reference of collaborative study	*Please indicate terms of reference of collaborative study, as applicable, such as intellectual property agreements and similar concerns.*
j. Terms of available study-related insurance	*Please indicate the terms of available study-related insurance, as applicable.*
10. Study Duration	(in months)
11. Use of Special Populations or Vulnerable Groups	☐ 11.1 Children (under 18) ☐ 11.2 VAWC victims/survivors ☐ 11.3 Indigenous People ☐ 11.4 Elderly ☐ 11.5 People on welfare/social assistance ☐ 11.6 Poor and unemployed ☐ 11.7 Homeless persons ☐ 11.8 Refugees or displaced persons ☐ 11.9 Women in especially difficult circumstances ☐ 11.10 Others (indicate): ☐ 11.11 Not applicable
12. Involvement of Children and Adolescents	☐ 12.1 Children aged less than 7 years old ☐ 12.2 Children aged 7 years old to less than 12 years old ☐ 12.3 Children aged 12 years old to less than 15 years old ☐ 12.4 Children aged 15 years old to less than 18 years old ☐ 12.5 Not applicable
13. Endorsing DSWD OBSU/FO	☐ 13.1 Central Office ☐ 13.1.1 Specify OBSU: _____ ☐ 13.2 Field Office ☐ 13.2.1 Specify ODSU: _____
14. Funding Agency:	**(NAME):** **TYPE OF FUNDING AGENCY**

	☐ 15.1 OBSU/ODSU ☐ 15.2 PHL Government agency/office/entity ☐ 15.3 Development Partners (e.g. UN Agencies) ☐ 15.4 Private company or Non-governmental organization (NGO) ☐ 15.6 Others (indicate):
15. Study Budget	NOTE: This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet
16. Previous ethics approval or clearance issued by other sites (if any)	☐ 17.1 Name of Institutional Review Board or Ethics Review Committee: ☐ 17.2 Date of ethics approval: ☐ 17.3 Date of expiration of ethics approval: ☐ 17.4 Not applicable
17. Principal Investigator (PI) / Project Leader	<Title, Name, Surname>
18. Birthday	<dd/mm/yyyy>
19. PI Address	<Institutional Address>
20. PI Telephone:	
21. PI Facsimile:	
22. PI Mobile:	
23. PI Email:	
24. Other Ongoing Studies/ Engagements with DSWD	Title:
25. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Task description:
	Co-Investigator: Task description:
26. Submitted by:	<Title, Name, Surname>
	Study designation:
27. PI signature	

ANNEX C

INFORMED CONSENT FORM (ICF) ASSESSMENT CHECKLIST

STUDY PROTOCOL INFORMATION
Reference No.[1]: *N/RREC-YEAR-NUMBER*
Study Protocol Title:
Principal Investigator:
Study Protocol Submission Date:

ESSENTIAL ELEMENTS (As applicable to the study)	**Indicate if the ICF has the specified element**		**Page and Paragraph where element is found**	**REVIEWER COMMENTS**
	YES	**NO**		
1. Is it necessary to seek the informed consent of the participants?	☐	☐	**N/A (not found in the ICF)**	**If NO, please explain:**
If YES, are the participants provided with sufficient information regarding:				
a. Purpose of the study	☐	☐		
b. Expected duration of participation	☐	☐		
c. Methodology/procedures to be carried out	☐	☐		
d. Discomforts and inconveniences	☐	☐		
e. Risks (including possible discrimination)	☐	☐		
f. Random assignment to trial treatments (if any)	☐	☐		
g. Reasonable benefits to the participants; or absence of direct benefit to participants as applicable	☐	☐		

[1] To be provided by the N/R-REC Secretariat upon receipt of the documents

DSWD Central Office, IBP Road, Batasan Pambansa Complex, Constitution Hills, Quezon City, Philippines 1126
Website: http://www.dswd.gov.ph Tel Nos.: (632) 8 931-8101 to 07 Telefax: (632) 8 931-8191

h. Expected benefits to the community or to society, or contributions to scientific knowledge	☐	☐		
i. Compensation or insurance entitlements of the participant in case of study-related injury	☐	☐		
j. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount	☐	☐		
k. Anticipated expenses, if any, to the participant in the course of the study	☐	☐		
l. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled	☐	☐		
m. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's	☐	☐		

ability to guarantee confidentiality				
n. Statement describing extent of participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure)	☐	☐		
o. Person(s) to contact in the study team for further information regarding the study	☐	☐		
p. Statement that the DSWD Research Ethics Committee Panel has reviewed and approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: *Name of N/R-REC Chair* *Address:* *Email:* *Tel:* *Mobile:*	☐	☐		
2. Is the informed consent written or presented in lay language that participants can understand?	☐	☐	**N/A**	
3. Do you have any other concerns?	☐	☐	**N/A**	

RECOMMENDATION:

(use a separate/additional sheet if necessary)

☐ APPROVED

☐ Minor Modifications:

_____
_____
_____
_____
_____

☐ Major Modifications:

_____
_____
_____
_____
_____

☐ DISAPPROVED

Reasons for Disapproval:

_____
_____
_____
_____
_____

_____ _____

NAME, POSITION AND SIGNATURE OF REVIEWER

REVIEW DATE

ANNEX D

STUDY PROTOCOL ASSESSMENT FORM

STUDY PROTOCOL INFORMATION
Reference No.[1]: *N/RREC-YEAR-NUMBER*
Study Protocol Title:
Principal Investigator:
Study Protocol Submission Date:

ASSESSMENT POINTS	To be filled be the REC			REVIEWER COMMENTS
	Indicate if the ICF has the specified element		Page and Paragraph where element is found	
	YES	NO		
DESIGN/METHODOLOGY				
1. Objectives: *Is/Are the proposal's scientific question(s) reasonable?*	☐	☐		
2. Target Participants: *Does the research need to be carried out with human participants?*	☐	☐		
3. Inclusion criteria: *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection*	☐	☐		
4. Exclusion criteria: *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*	☐	☐		
5. PI qualifications: *Review of CV and relevant certifications to*	☐	☐		

[1] To be provided by the N/R-REC Secretariat upon receipt of the documents

DSWD Central/Field Office __ , (address), Philippines (Zip Code)
Website: http://www.dswd.gov.ph Tel Nos.: _____ Telefax: _____

ascertain capability to manage study related risks				
6. Duration: *Review of length/extent of human participant involvement in the study*	☐	☐		
ETHICAL CONSIDERATIONS				
7. Conflict of interest: *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site*	☐	☐		
8. Privacy and confidentiality: *Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans*	☐	☐		
9. Informed consent process: *Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require*	☐	☐		

additional clearances				
10. Vulnerability: *Review of involvement of vulnerable study populations and impact on informed consent; Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of hierarchical group*	☐	☐		
11. Recruitment: *Review of manner of recruitment including appropriateness of identified recruiting parties*	☐	☐		
12. Assent: *Review of feasibility of obtaining assent vis à vis incompetence to consent;* *Review of applicability of the assent age brackets in children:* *0-under 7: No assent* *7-under 12: Verbal Assent* *12-under15: Simplified Assent Form* *15-under18:Co-sign informed*	☐	☐		

DSWD Central/Field Office __ , (address), Philippines (Zip Code)
Website: http://www.dswd.gov.ph Tel Nos.: _____ Telefax: _____

consent form with parents				
13. Risks: *Review of level of risk and measures to mitigate these risks (including physical ,psychological, social, economic), including plans for adverse event management*	☐	☐		
14. Benefits: *Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant*	☐	☐		
15. Incentives or compensation: *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses*	☐	☐		
16. Community considerations: *Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to*	☐	☐		

cultural traditions, and involvement of the community in decisions about the conduct of study				
17. Collaborative study terms of reference: *Review of terms of collaborative study especially in case of multi country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building*	☐	☐		
18. Do you have any other concerns?	☐	☐	**N/A**	

RECOMMENDATION: ☐ APPROVED

(use a separate/additional sheet if necessary)

☐ Minor Modifications:

_____

_____

_____

_____

_____

_____

_____

_____

_____

☐ Major Modifications:

_____

_____

_____

_____

_____

_____

_____

DSWD Central/Field Office __, (address), Philippines (Zip Code)
Website: http://www.dswd.gov.ph Tel Nos.: _____ Telefax: _____

☐ DISAPPROVED

Reasons for Disapproval:

NAME, POSITION AND SIGNATURE OF REVIEWER

REVIEW DATE

ANNEX E

Clearance No. N/RREC-YEAR-NUMBER

ETHICAL CLEARANCE CERTIFICATE

This is to certify that the research entitled, "____", of the (OBSU/Field Office Name) has been reviewed and approved by the National/Regional Research Ethics Committee as to its ethical acceptability.

The researchers involved in the aforementioned study should abide by the approved ethical considerations at all times during the conduct of their study.

This certificate is valid until (one year after issuance), and to be renewed on a yearly basis as needed.

This clearance is issued on (date), (city/municipality).

(signature)
NAME
Chair
DSWD National/Field Office REC

DSWD Central/Field Office __ , (address), Philippines (Zip Code)
Website: http://www.dswd.gov.ph Tel Nos.: _____ Telefax: _____