Guideline
For Completion of the Submission Form

Institutional Review Board
Institute for Population and Social Research
(IPSR-IRB)

Background and Objective

Every year hundreds of the research projects are submitted to IPSR-IRB for ethical approval. At least one-third of these projects failed to provide accurate information; some did not submit all required documents. This resulted in unnecessary delay in the process of ethical consideration, and hence ethical approval for such projects. The present Guideline is prepared to reduce this problem.

Although this guideline is aimed for the benefit of all researchers, it is especially designed by taking into account the needs of young researchers who have limited research experience. As such, young researchers and graduate students are advised to study the guideline thoroughly while preparing their Submission Form. From the past experience we have found that the projects with inaccurate information and missing documents are mostly those from the researchers who have limited research experience.

Content of this Guideline

This document consists of four parts. Please study the guidelines in each part carefully before preparing your Submission Form.

Part One: General Information of the Project (Items 1-6 in the Submission Form)

1) Project Title

Give full title of the project as it is given in your research proposal. In case name of a person or organization appears in the title, please make sure that it will not cause an ethical problem. We suggest that researchers avoid including name of specific person or organization in their research titles. If very necessary, use the term with neutral connotation instead. For example, in a study of industrial workers in a particular factory, avoid putting specific name of the factory in the title; instead use a neutral term or find a pseudonym for that factory.

In general, a good research title should not be too broad, nor too specific. Rather, it should reflect the kind of study population and/or the kind of data the researcher needs in the study. To be more desirable, the title of a research (research topic) should be on the issue that is of benefit to the public or society at large. The research aiming solely for personal interest of the researcher should be avoided as it could be considered unethical.

2) Name of Principal Investigator (PI)

Please include the title and full name of the principal investigator (PI) or the head of the research project, along with their telephone number, current employment status, and institutional affiliation. In the case of students, you must also provide the title of a study program and the name of faculty or institute you are affiliated with. For a co-investigator, please provide the same information of the investigator as the PI.

3) Funding Support and Source of Funding

Check the box applicable to your project. In case the project is funded, please specify the amount of fund received (in THB) and the source. If funding support is being applied for, specify the source where you applied. In such case, when funded, please notify IPSR-IRB about the amount of fund received. Choose “self-funded” if there is no funding support.

4) Summary of Research Rationale

Usually the rationale in your research proposal can be used here, but it should be summarized to only the points which succinctly tell why your research is important, and why the topic of your choice is worth doing research. For better clarity, you may include an extra page or so of your research rationale and submit it along with other documents for the committee’s consideration. In

such case please make sure that what you give in the extra page is essentially the same rationale as in your research proposal.

5) Research Objectives

Use the objectives as listed in your research proposal. Please be sure to make it concise.

6) Total Time from the Beginning to the End of the Project

What is needed here is the total time duration from the beginning to the end of your research project. Give time in year(s) and/or month(s). Note that this is not the same as the duration of data collection in item 7 below.

Part Two: Information on Research Methodology (Items 7-8 in the Submission Form)

Research methodology encompasses a wide range of important elements in the research process - from research method to target population of the study, sample size, method for recruiting sample, method and instrument for data collection and information on the research sites. Complete information about these elements is essential for the committee's assessment whether your project is, or is not, at ethical risk. In addition, complete and accurate information you provide will be helpful for assessing whether your research methodology sound enough. A sound research methodology is important as it can help you not only proceed with confidence in the research process, but it is also a basis of doing an ethical research. A simple fact is that the research that is methodologically weak is often weak in its ethical aspect.

It is, therefore, very important that you provide adequate information about your research methodology as required in items 7 & 8 below.

7) Research Method

In the Submission Form five research methods are given for you to choose. You can choose one or more of these methods that apply to your research. For the one you choose, please specify expected duration of time for data collection. Note that time for data collection must not begin before ethical approval is granted by the IPSR-IRB. This time duration is also not the same as 'total time of your research project' indicated in item #6 above.

For the projects that plan to collect quantitative data online, choose "Quantitative method involving primary data collection". Choose "Documentary research" if you are going to collect documentary data from existing sources including online sources such as data from Blog, Website or Twitter. If online documents are used, it is desirable to indicate type of the online source of your documents. Please also check whether the online documents are copyrighted; and if so, you should make sure to get permission from the copyright owner. Do not forget to attach permission document with your Submission Form.

8) **Target population, sample and method of data collection** (Items 8.1-8.5 in the Submission Form)

For projects that involve collection of primary data (quantitative or qualitative), please give adequate information for items 8.1 – 8.5.

8.1 Target population of your study – Target population of research refers to the category of population (in some cases, institution or organization) from which some people are selected to be sample population in the study. Target population may be people of any category, for example, undergraduate student of a university, corn farmers, or unmarried adults aged 30-45 years.

Here you are expected to clearly indicate target population of your study by providing a short description of that population together with the justification for choosing it as the target of

your study. Please be informed that your justification should be academically acceptable; avoid justification on the basis of the researcher's convenience.

If all or part of the target population are vulnerable people, caution must be taken that they are not negatively affected from participating in you research. Vulnerable population includes people who are unable to make independent decision by themselves or who have to depend on others for their daily activities. These include minors under 18 years of age, frail elderly, people with severe illness, people with physical or mental disability, etc. Research involving vulnerable people requires informed consent not only from them (when and where possible), but also from their parent or guardian. The informed consent from the parent or guardian must be submitted along with Submission form

8.2 Sample size and the method of sample size determination – Information needed here includes (i) number of cases in your research sample, and (ii) method that you will employ for determining the number of research sample.

The sample for a research project should be of reasonable number (size) to ensure sufficient data for analysis. Determination of the number of cases in the sample population should be made on the basis of a justifiable principle, and not arbitrarily.

In quantitative research, if any mathematic formula for calculating sample size is used, it is important to briefly elaborate on how the size of sample is derived through application of that formula.

In case of qualitative research, the number of research participants (sample) should be specified together with your justification on how that number is derived. For example, the number of participants may be determined on the basis of characteristics of the target population such as sex, education, and experience with certain events. A brief description should also be provided as to why you think the number of cases and the method of determining it is appropriate, given your research questions and objectives.

8.3 Method of selection and access to sample – The information needed here is a description of the method and criteria by which your eligible persons will be selected to form your study sample, taking into account the target population (in 8.1) and the sample size (in 8.2) specified above.

In case of quantitative research this may be different sampling strategies such as simple random sampling, stratified random sampling, systematic random sampling or any other methods suitable for your target population. Sample may be drawn without using a random sampling strategy, such as in the case of online data collection. However, those who plan to collect quantitative data online should provide information about the method that will be used to distribute questionnaire to potential respondents. It is not enough to just state that google form will be employed for data collection.

In case of qualitative research, the sample may be selected by using purposive technique which usually begin with a set of criteria for eligible persons to be taken as the study sample. It is on the basis of these criteria that the researcher will look purposively for the most appropriate candidates. Thus, purposive sampling does not mean sample selection without any solid criteria. (Purposive sampling without appropriate criteria cannot yield a good sample.) The same principle can be applied when using such technique as snow-balling, respondent-driven sampling technique (RDS) or other techniques for selecting sample.

Whatever the technique you use, adequate description of the sampling procedure must be provided.

8.4 Instrument and process of data collection – Generally, the instrument and data collection process depend on your research approach – whether it is quantitative or qualitative or both. Normally, quantitative and qualitative approaches use different instruments for collecting data which in turn require different process of activities in your data collection. Here what you need to do is to give a succinct description of the instrument and the process of data collection based on the research approach of your choice.

For quantitative research it is less than adequate to simply say that interview and questionnaire will be used. It is better to briefly elaborate on the kind of interview that will be used, for example, whether it is going to be face-to-face interview, interview through telephone, or self-administered questionnaire. Some description about content of the questionnaire (instrument for collecting data) is also needed.

Similarly, in qualitative research adequate information should be provided about your instrument and data collection process. Is the in-depth interview guide or focus group guidelines used? Who is responsible for conducting in-depth interview or the focus group discussion, and how? It is always important to give some ideas of the content of your instrument for data collection. If you are using participant observation for collecting data, please give a list of key issues or events that you will focus your observation on.

A copy of instrument for your data collection - questionnaire, in-depth interview guide, or focus group guidelines, etc. - must be submitted with your Submission Form for consideration. In case you are using more than one method of data collection, give adequate information for all, and submit a copy of instruments for all methods as well.

8.5 Study site -- Specify the site or area where your data collection will be carried out. Unless very necessary, there is no need to be very specific; just a relatively broad area is sufficient. In case data collection is to be carried out in more than one site, specify all sites. Note, however, that too board an area such as "in Thailand" does not help much in this case.

The projects that collect data online may indicate "online site" as the study site.

Part Three: Potential Risks and How to Manage Them. (Items 9-10 in the Submission Form)

There are 3 important principles of research ethics with which the researchers have to comply throughout the entire process of doing research. The 3 principles are[1]:

1) *Respect for person* – This requires that the researcher needs to gives due respect for the person's dignity as a human. Potential participants must be adequately informed about what they are expected to do if they agree to participate in the research. Participants' decision must be voluntary without being pressured or induced with any kind of promise. And most importantly, their decisions must be respected.
2) *Beneficence and no harms* – Practically this means that in the research process the researcher must give priority to participant's interest over his/her data. Any research activities that may cause undesirable effects to participant must be avoided. In case the research process may involve some inevitable risks to participant, such risks must be best prevented or minimized so that they cause no, or least, harms to participants.
3) *Justice* – Regardless of age, sexual orientation, and characteristics, all participants must be treated equally without discrimination. The research that involves vulnerable subjects must be carried out with extra care.

[1] Details of the research ethics are numerous. Those who are interested are recommended to read related articles in the IPSR-IRB website https://irb-ipsr.mahidol.ac.th/en/articles (click on). For those who can read Thai, Chapter 14 in *ศาสตร์และศิลป์ การวิจัยเชิงคุณภาพ* (ชาย โพธิสิตา, 2562) is also excellent source.

In the research process any activity that is in conflict with any or all of the 3 principles is considered unethical, and it should be avoided.

In the process of ethical assessment, IPSR-IRB makes use of your information in the Submission Form and in related documents. If there is anything that is at ethical risk, you will be asked to correct them and resubmit your documents all over again. That means delay in the assessment process which also delays your ethical approval. Because of this the information you provide in items 9 & 10 below is very important.

9) Potential Risks to Participants and How to Manage Them. (Items 9.1-9.2 in the Submission Form)

"Risk" here refers to all negative or undesirable things including harms that may happen to the people as a result of their participation in your research. It may happened in any stage of the research, such as in the process of sample selection, process data collection, data analysis and dissemination of the research results. The kind and extent of risk depends on the nature of data needed including activities in different stages of research.

Generally, all researches involving the use of human subjects have certain risks. Put in other words, there is no such thing as a risk-free research that involves the use of human subjects. As such, it is not accurate to report that your research "has no risk because it does not involve any experiment in humans or animals".

In social science research, the risks are usually not physical; rather they are largely of the psychological, social or economic nature, such as emotional stress, anxiety, loss of time, loss of income, loss of privacy, being targeted on, being stigmatized, etc. In addition, the risk may happen to the people to whom the research subjects are related, such as their families, groups or communities.

The information you are expected to provide below includes (1) the nature of potential risk to your research participants (answer to question 9.1) and (2) your measures to manage or minimize such risks (answer to question 9.2).

9.1 What are potential risks or harms that may happen to your research participants?

Because there is always some risk to participants in the research that involves human subjects, appropriate answer for this question is not saying that there will be no risk. Instead, it should be telling what you anticipate as potential risk to participants. It may not be physical harm, but may be loss of time to work or to rest, loss of privacy, emotional stress, or other uncomfortable feelings. It should not a concern for you that ethical approval will not be granted to your project if you report some potential risks. Ethical assessment will be done by taking into account the measure to manage risks that you will provide in 9.2 below.

9.2 What is your measure to prevent or minimize risks and protect your research participants?

Specify appropriate measures that you will use to prevent or minimize risks/harms and protect your research participants from them. What that measure will be depend on your anticipated risk.

10) Your Measures to Protect Data Confidentiality

** Note that adequate information on protection of data confidentiality is required for all projects submitted for ethical approval.

In research, any data /information that the researcher uses in his/her analysis are regarded as "confidential," regardless of their nature (quantitative or qualitative) and how they are obtained (whether through interview, participant observation, or other means). In this sense, both primary and secondary data are confidential; they should be given appropriate protection. Revealing such data/information to other individuals who are not directly involved in the research is a breach of the research ethics.

As the principal investigator, you are expected to provide adequate information on how to protect the data confidentiality here[2].

Part Four: List of documents submitted to IPSR-IRB for consideration.

11. Document Submitted to IPSR-IRB for Consideration

There are various documents that are required to submit together with your Submission Form. Some of these documents may not be applicable to all research projects. Make sure that you submit all that are needed for your projects, keeping in mind that missing any one or more of them may result in unnecessary delay in the ethical consideration of the committee.

[2] Details of methods to protect data confidentiality are available in 'related articles' published on the IPSR-IRB website https://irb-ipsr.mahidol.ac.th/en/articles.php