Created Date December, 2024

How to fill in MU CIRB Submission Form

MU Central Institutional Review Board – MU CIRB

This information is prepared to help researchers submitting their research projects for IRB review understand the purpose of information required in each item listed in the submission form. This guideline enables researchers to accurately complete the submission form, ensuring MU CIRB receives sufficient information to review the submitted projects effectively.

Explanations

The explanations are arranged in the order on the submission form.

You can follow the explanations and fill in the submission form in the respective order.

Different submission forms are required for two types of research projects:

01 Submission form for research projects with interventions for research participants/subjects

02 Submission form for research projects without interventions for research participants/subjects

Researchers are required to choose a submission form that applies to their projects because each form partially requires different details.

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Item 1: Project title,

Item 2: Name, and personal information of the principal investigator

- Item 2 If the principal investigator is a student, specify the department and faculty he/she is studying.
- Item 2.1
  - The number of research projects and the number of participants/subjects selected for the projects during the same period to determine whether the researchers have enough time to look after the participants/subjects.
  - Training experience in good clinical practice (GCP) is required only for clinical research concerning the treatment and preventive process, particularly research on drugs, vaccination, and new types of medical devices that require registration with the Food and Drug Administration.
- Item 2.2 Information regarding ***the conflict of interest***, which may lead to bias in the research implementation process, or the interpretation of the research results must be identified.

Item 3: Names of co-investigators

- Names of all researchers in the team are required because all co-investigators share the responsibility of the research project as assigned by the principal investigator, which may affect the management of the participants/subjects. This information allows the IRB to know about each co-investigator in terms of their knowledge and experience, including their background training in human research ethics.
- If the principal investigator is a student, the advisor's name is required as a co-investigator because research is conducted as part of the study program requirements. ***The student has no experience in implementing research alone, and needs an advisor's supervision in all the research process.***

Item 4: Research funding sources

- Information on research funding sources indicates *that the projects have sufficient resources to be completed and provide appropriate care to participants/subjects.* However, for projects with minimal expenses, the principal investigation may use personal funds (self-funding). Thus, an application for external funding sources is not required.
- Providing detailed information on funding sources is helpful for tracking the project's progress, making amendments to the project, and managing benefits derived from the research as each funding source may have different terms and conditions in its funding agreement.

Item 5: Research background and rationale

Item 6: Research objectives

- **The background and rationale highlight key points, the background, and principles, and the justification of the research project.** A synopsis covering the research's background, knowledge gap, rationale, and conceptual framework is necessary to demonstrate the research's significance and contribution to new knowledge.
- If additional details are required to elaborate on the provided synopsis, please specify the page number and headings in the proposal so the committee can easily reference them during the review.
- **Research objectives** should be listed as individual items, aligned with the key issues to be studied, and consistent with the information provided in the research proposal.

Item 7: Research design includes the following subtopics:

7.1 Types of research projects

This item requires different details for research with interventions and research without interventions.

7.2 Research participant selection and allocation

- 7.2.1 Inclusion criteria
- 7.2.2 Exclusion criteria
- 7.2.3 Withdrawal criteria for individual participants
- 7.2.4 Termination criteria for the whole research project
- 7.2.5 Subject allocation

7.3 Sample size

7.4 Types of research participants/subjects (vulnerable subjects VS healthy volunteers)

7.5 Actions to be taken if any participants/subjects withdraw from the study – *whether additional participants/subjects will need to be selected.*

Item7.2 Subject selection and allocation

7.2.1 Inclusion criteria

- Specify the characteristics of participants/subjects **to be used as the criteria for their selection from the general population** such as gender, age, and other specific qualifications.
- If multiple stages or selection methods are used, clearly define the criteria for each stage separately.
- Inclusion criteria should be written as affirmative statements, not negative ones. For example, the inclusion criteria **will not specify what characteristics are not included**, such as 'not colorblind.' Instead, ***if individuals with color blindness are to be excluded, it should be stated in the exclusion criteria as 'has colorblindness'.***

7.2.2 Exclusion criteria

- Exclusion criteria identify characteristics or qualities that disqualify an individual from participating, as their involvement might pose a risk to the individual with such characteristics or qualities, or may impede the research process. These characteristics or qualities may be present even in individuals who otherwise meet the inclusion criteria; for example; individuals over 60 years without hypertension as a pre-existing condition. Therefore, the inclusion criterion will be individuals aged 60 or older, and the exclusion criterion will be individuals with blood pressure over 135/85 mm.
- Exclusion criteria are not necessarily the opposite of inclusion criteria. For example, if the inclusion criterion is that participants must be aged 18 or older, there is no need to specify that the exclusion criterion is participants under 18.

Item7.2 Subject selection and allocation

7.2.3 Withdrawal criteria for individual participants: This item refers to criteria, behaviors, or symptoms that, if observed during the research process, require the withdrawal of certain participants/subjects from the study, effectively terminating their participation. Continuing the participation may adversely affect the specific participants as individuals or interfere with the overall research process. These criteria differ from exclusion criteria established prior to participation. For example, in a clinical research study, a participant whose blood pressure exceeds 150/90 mmHgiu8uytrjh during the study may need to be withdrawn.

- The project should indicate that the volunteer participants can withdraw from the research whenever they want.
- Withdrawal is needed for research in social science when certain participants become stress or cry because the research process triggers their past memory ; or because information cannot be completely collected. This could potentially affect the analysis or interpretation of the data, for example.

7.2.4 Termination criteria for the whole research project: This criterion is often outlined in high-risk research projects. If multiple participants experience similar serious adverse events and continuing the research may result in more harm than the anticipated benefits. In such cases, it would be appropriate **to terminate the project prematurely and not proceed with future activities.**

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7.2.5 Subject allocation

- In cases where participants/subjects in each group are treated differently to compare those receiving interventions with those not receiving interventions, or with different types of interventions, the participant/subject **selection must be fair, consistent, and without bias. All the participants/subjects must have an equal chance of being randomized with proportions maintained consistently throughout the project** to ensure valid and reliable results.
- ***If participants/subjects are not allocated into groups, and everyone is treated the same way, include the statement: "No allocation of participants/subjects into groups".***
- Researchers are recommended to use random numbers to create the randomization schedule, and the person responsible for assigning participants to groups should not be the same person who provides the intervention or analyzes the research results.
- Researchers are not advised to use **a raffle method**, as the odds of entering each group change with every draw, leaving the last participant with only one option.
- Researchers are not advised to use **a coin toss method** as it cannot control any factors and may result in unequal numbers of participants in each group.

Item 7.3 Sample size

- *The sample size is the number of individuals included as participants in the research.* It serves as **an indicator of the reliability of research results. Therefore, the specified sample size** must be justified, for example, by **using calculation formulas or appropriate estimations based on the research methodology and academic principles. Reference documents must be attached.**
- **Sampling procedures must be specified.**
- *A sample size specified by researchers without justification is considered unreliable for the following reasons:*
  - ✓ If the sample size is too small, it may fail to adequately represent the actual population.
  - ✓ If the sample size is too large, it increases risks for the participants as they are experimental subjects in the research process.
  - ✓ In research comparing groups, the sample size is crucial to determine the statistically significant differences between them.

Item 7.3 Sample size,

Item 7.5 Actions to be taken in the event of participant withdrawal from the research

- In the calculation of sample size, provisions may be made to account for the possibility that participants might withdraw from the study. The reasons for withdrawal may include voluntary *drop out* by the participants or withdrawal based on withdrawal criteria established by the researchers from the outset.
- The percentage allowance for dropouts from the calculated sample size must be specified, such as 10%.
- The dropout allowance should be reasonable.
- The estimation of a dropout allowance ensures that the specified sample size remains sufficient even when some participants/subjects withdraw from the study prematurely, eliminating the need for additional participant recruitment.
- *The premature withdrawal of a high number of participants may reflect that the research process is overly disruptive to the participants, or that the research involves greater risks than it should.*

Sample size in qualitative research

- The nature of qualitative research involves selecting participants through a purposive sampling procedure. Determining the sample size follows key principles specific and deliberate to qualitative research methodology. Researchers must clearly specify the criteria for purposive selection and provide a rationale for the sample size determination. Relevant references supporting qualitative research principles must be provided.
- Since the IRB committee is responsible for ensuring the protection of research participants, researchers must clearly specify the number of research participants involve in the study. Avoid using vague statements like "at least ... participants." Instead, provide a specific number to clearly define the scope of the research. This helps demonstrate the extent of the work and the number of participants requiring protection.

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Item 7.4 Types of research participants/subjects

- Specify the characteristics of the target participants/subjects and whether they require special precautions, such as being a vulnerable group that may be at greater risk than others.
- Vulnerability is not limited to age, underlying medical conditions, pregnancy, or disabilities. It also encompasses social vulnerabilities including stigmatization, discrimination, or characteristics that may be socially exploited, individuals unable to partially or completely protect their own benefits, individuals with limited power, insufficient intelligence and knowledge, lack of education, resources, strengths, or any other essential attributes needed to safeguard their own benefits.
- Vulnerable individuals include those with impairments in perception, communication, and decision-making abilities.

Item 8: Interventions

8.1 Information about the interventions: Interventions include products to be tested for their efficiency and safety such as medications, medical devices, herbs, foods, dietary supplements, cosmetics, health-promoting and rehabilitation programs, teaching and training programs, robots, and applications used in the experiments and tests with target participants/ subjects.

- For products regulated by the Food and Drug Administration (FDA) used in research, researchers must comply with FDA regulations and provide the IRB with relevant information about the products.

8.2 Administration procedures, dosage, and duration: Detailed information on product administration and dosage must indicate whether they comply with FDA's recommendations. If not, researchers must provide a rationale for the deviations and submit evidence to the IRB to ensure participant/subject safety.

Item 9: Research process

(For the submission form of projects without interventions, this will be Item 8, as there are no details regarding interventions.)

- This item presents the overall picture of the projects, procedures, and process from the beginning through the data analysis stage. Researchers are encouraged to create a flowchart outlining all steps, including interventions at each stage, in chronological order. Researchers may reference details in the proposal by specifying page numbers and headings so that the committee can refer to additional relevant information as needed.
- Researchers are advised not to copy all the information from the proposal into the submission form.

Item 10: Research location

(For the submission form of projects without interventions, this will be Item 9.)

- The research maybe conducted at more than one research location, as appropriate to the research design.
- *The research location impacts participant/subject safety and ability to provide assistance in the event of adverse events during the research process*
- If the research is conducted at a location outside the principal investigator's affiliated institution, permission must be obtained from the authorized person to use the site for research purposes, and evidence of this approval must be submitted to the IRB.
- In cases where research is conducted in collaboration with external organizations, either domestically or internationally, the following formats may apply:
  - ✓ Single-team research (single center study): The research can be conducted at a single site or across multiple sites.
  - ✓ Mahidol research team in multi-team collaboration (multicenter study): The research can be conducted in parallel alongside other teams across multiple sites.

Item 10: Research location

(For the submission form of projects without interventions, this will be Item 9.)

- **Single center, single site:** If the research is conducted within the facility to which the principal investigator is affiliated, separate site approval is not required, as approval has already been granted by the principal investigator's immediate supervisor.
- **Single center, multi sites:** Approval is required for the use of sites outside the principal investigator's affiliated institution. If additional research assistants are assigned to each site, their roles at each of the sites must be clearly specified.
- **Multicenter study:** Each research team will operate within the facilities to affiliated with their site's principal investigator. The Mahidol University Institutional Review Board (MU IRB) will certify only the teams affiliated with Mahidol University and operating within Mahidol facilities. Separate site approval is not required, as approval has already been granted by the principal investigator's immediate supervisor. However, details about other research teams must be provided, including their affiliations, the number of participants/subjects recruited at each site, and whether each team has been certified by their respective institution's IRB.

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Single center

Single site

If research is conducted at the site to which the principal investigator is affiliated, **no additional site approval is required** as approval has already been granted by the principal investigator's immediate supervisor.

Multi sites

Approval for the use of **sites outside the principal investigator's affiliation** is required. If additional research assistants are assigned to each site, and their roles at each site must be specified.

Multicenter

MU research team

Research conducted solely within Mahidol University only **does not require additional site approval**, as it has already been granted by the principal investigator's immediate supervisor.

Specify the affiliations of other research teams, the number of participants/subjects recruited at each site, and the certification status from each team's respective institution's IRB.

Item 11: Delivery of specimen outside Mahidol University

Item 12: Data sharing with other researchers/ sponsors/organizations

(For the submission form of projects without interventions, these will be Items 10 and 11.)

- Since the specimens and data collected during the research contain personal information, for which the researchers have obtained consent from participants/subjects for research purposes, any transfer or sharing with others must be carefully managed to respect the personal rights of the data or specimen owners.
- The university's requirement for Material Transfer Agreement (MTA) and Data Sharing Agreement (DSA) aims to protect its intellectual property. Since the process is overseen by the Center of Ethical Reinforcement for Research, Office of the President, Mahidol University, rather than the IRB, researchers must contact the center to manage the matter in parallel with the submission for the IRB certification process.
- In cases where research funding is received, a Trial Agreement is required to define the rights of access to specimens and/or data between the funder and the recipient, which the researcher must adhere to.

Item 13: Research duration

(For the submission form of projects without interventions, this will be Item 12.)

- *The duration of research and the period of data collection from research participants/subjects **are usually not the same.** Some researchers include the time spent on research proposal preparation, data analysis, writing the research report, and drafting articles for publications in academic journals.*

- The Institutional Review Board (IRB) focuses primarily on overseeing processes involving research participants/subjects to protect their rights and welfare. *The board does not play a role in supervising data analysis or the publication of research findings.*

Item 13: Research duration

(For the submission form of projects without interventions, this will be Item 12.)

- The IRB's oversight period starts from the date of approval—before the recruitment of participants/subjects until the completion of research processes with the last participant/subject – the submission of the study closure report.
- The analysis, interpretation, and public dissemination of research findings are the responsibility of the researcher, who must uphold ethical standards to ensure the validity and reliability of the research (Research Integrity).
- Falsification, fabrication, and plagiarism are considered violations of research ethics. Such misconduct has far-reaching consequences for society and is subject to penalties.

Item 14. Data collection process

(For the submission form of projects without interventions, this will be Item 13.)

- The data collection process must align with Item 9: Research process.
- Specify the details of each step that will be conducted with the research participants/subjects.
- If participants/subjects are required to meet the researcher multiple times, specify the number of appointments and the interval between each appointment.
- If different procedures are applied at each appointment, clearly outline the details for each one, specifying the processes participants must follow, the time required for each appointment, and the research instruments or questionnaires are used for each procedure.
- When questionnaires are used for data collection, specify whether participants/subjects must complete them independently (self-administered) or if the researcher will read aloud the question aloud and record the participants' responses.
- When questionnaires are used for data collection, **specify whether they are developed by the researchers** (requiring verification of validity and reliability), **adopted from other researchers' questionnaires –evidence of permission for use must be attached, or translated from other languages into Thai, evidence of permission from the copyright holders must be provided.**

Item 15. Outcome measurement/ Data Analysis

(For the submission form of projects without interventions, this will be Item 14.)

- Primary outcomes refer to data or expected outcomes upon the completion of the research project. They should align with the research objectives and variables studied.
- Secondary outcomes (if any)
- Assessment of efficacy
- Assessment of safety
- Statistics or process for data analysis

****For qualitative research, specify procedures of qualitative data analysis.

Item 16. Recruitment process

(For the submission form of projects without interventions, this will be Item 15.)

- Specify a formal permission request and specify the individuals and organizations with the authority to grant permission for data collection/access the research site.
- The location where participants will be accessed should align with the research site. If these are different, an explanation must be provided.
- The process of accessing research participants/subjects –specify the person responsible for providing the initial explanation and details of the methods thoroughly.
  - *The individuals inviting participants/subjects should not be those whom the target participants/subjects feel obligated toor dependent on,* such as their attending medical doctors or nurses. To ensure that the decision to participate in the research is truly voluntary, this responsibility should be assigned to other members of the research team
  - When research is conducted at a location outside the researchers' affiliated institution, a person from that location may assist by introducing the researcher to the target participants. However, it is the researcher's responsibility to invite them to participate. *For example, in research involving company personnel, a coordinator may introduce the researcher to the target group, after which the researcher continues the process.*

Item 16. Recruitment process

(For the submission form of projects without interventions, this will be Item 15.)

- Using media for public relations to invite research participants can be an effective way in helping researchers reach their target group, especially when leveraging widely publicized media.
- *The invitation message must be accurate and not mislead or confuse the target group into thinking that the research involves medical treatments, services, or activities for other purposes. It must neither deceive incentives that can influence their decision to participate in the research.*
- Researchers must submit media promotional materials to the IRB for approval. Only the approved message may be used to invite participants to join the research.

Media used to publicize and invite participation in the research

Contents to be included

- Research title and name of the principal investigator
- Research location
- Duration of research: specify the time period.
- Qualifications of individuals eligible participate in the research (aligned with the inclusion criteria)
- A synopsis of the key research process in a simple and understandable manner
- Methods of contacting the researcher to request additional information such as telephone number, and email address

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- Messages that create confusion, suggesting that the activity is something else such as training, group discussion, or medical treatment.
- Offering money or incentives that attract attention, or using the word "free"
- Statements indicating that participating in the research will be beneficial, such as chronic diseases/ diseases or conditions without a definitive cure

Item 17. Informed consent process

(For the submission form of projects without interventions, this will be Item 16.)

- This process is important in **showing respect for the personal rights of the research participants/subjects.**
- Researchers must provide ***sufficient information*** to the target group to help them decide whether to participate in the research. The information must ***be explained accurately, and participants should be given the opportunity to ask questions before making their decision.***
- In cases where the target group includes children and youth, researchers must obtain consent from their parents and collaboratively explain the research to children aged 7 or older to understand that they can independently express their opinion on whether to participate in the research and should not be forced to participate, even though their opinions are different from their parents.
- In cases where the target group consists of vulnerable individuals at risk of direct or indirect pressure that could prevent them from expressing their opinions freely, ***researchers must prepare appropriately to the research context and environment to facilitate a fully voluntary decision to participate in the research.***

Item 17. Informed consent process

(For the submission form of projects without interventions, this will be Item 16.)

- Preparing an information sheet for research participants in clear, easy-to-understand language appropriate for the target group's age is essential.
- Consent is usually provided by signing a consent form to participate in the research, which serves as official documentation for the study.
- **If signing a consent letter is not possible** for any reason such as participants/subjects cannot read or write, completing the questionnaire online, or situations where signing the letter may increase risks to the participants/subjects, **researchers must have additional preparation to gain evidence showing that the research participation is fully voluntary.**
- If researchers wish to request **a waiver of the required signature** on a consent form to participate in the research, they must provide justification in the research submission form, referencing relevant criteria from ethical guidelines for human subject research.

Item 18. Ethical Consideration

(For the submission form of projects without interventions, this will be Item 17.)

18.1 Rationale and significance of conducting research in humans This is different from the research rationale and background, which addressed the established research questions. Since research can be conducted using different methodologies--laboratory research, research in experimental animals, or research in humans--researchers must justify why their research needs to be conducted specifically in humans. Similarly, for research in social science research that requires human opinions and where other methodologies are not applicable, detailed elaboration must be provided on why human involvement is essential.

18.2 Expected benefits of research include benefits for individual participants/subjects as well as the general population, any potential benefits for participants/subjects after the completion of the research (if any). **Since all research involves some degree of risk,** the details in this item should clarify how the expected benefits are balanced against the potential risks. ***Even in cases where research projects involve high risks, the IRB can approve them if the expected benefits sufficiently outweigh the risks.***

Item 18. Ethical Consideration

(For the submission form of projects without interventions, this will be Item 17.)

- 18.3 Potential risks of adverse events to research participants/subjects. For the submission form of projects without interventions, this corresponds to Item 17.3. See details on the next page.
- 18.4 Evidence or data (Referenced documents) showing that this research is safe and/or beneficial for research participants/subjects must be specified, using appropriate referencing formats. For the submission form of projects without interventions, this corresponds to Item 17.4.
- 18.5 Procedures to protect the confidentiality of the participants' personal information. For the submission form of projects without interventions, this corresponds to Item 17.5.

Item 18.3 Potential risks of adverse events to participants/subjects

(For the submission form of projects without interventions, this will be Item 17.3.)

- 18.3.1 Specify whether similar research has been conducted and whether such research caused any adverse events/how that happened. Also, specify the Reported frequency of such events. This information is important for assessing potential risks. If researchers indicate that this kind of research has never been previously carried out, an extensive literature review must be submitted.
- 18.3.2 Preventive and corrective measures established for the research project are vital in showing that researchers prioritize the welfare and safety of participants/subjects. **Even if some research projects may involve risks, whether high risks or low risks, the IRB can approve them if the researchers demonstrate thorough awareness and careful preparation of preventive and corrective measures in address anticipated adverse events.**

Item 18.3 Potential risks of adverse events to participants/subjects

(For the submission form of projects without interventions, this will be Item 17.3.)

- 18.3.3 Names, contact addresses, and telephone numbers of persons in charge of managing financial compensation for participants/subjects in case of adverse events caused by the research (For student researchers, also include the name and address of the principal advisor.)
- 18.3.4 Names of persons in charge or medical doctors, along with their telephone numbers that can be reached at any time in case of adverse events or if participants have questions about the research. (For student researchers, also include the name and address of the principal advisor.)
- 18.3.5 In the case of clinical research, researchers must specify how they will inform the attending doctors or other doctors responsible for treating the participants/subjects that the particular individuals are currently involved in a research study. (Please specify.) ICH GCP E6(R2) Addendum Step 4 version 2016 4.3 Medical Care of Trial Subjects

The telephone number provided in Items 18.3.3, and 18.3.4 must be accessible to IRB staff for contacting the researchers.

Item 18.5 Procedures to protect the confidentiality of the participants' personal information

(For the submission form of projects without interventions, this will be Item 17.5.)

- Identifying researchers who have access to the participants' personal information helps reduces the risk of data disclosure. Researchers named in this process and the principal investigator share the responsibility of protecting the confidentiality of the participants' personal information.
- The careful implementation of measures to protect the confidentiality of personal information in all steps reflects the researchers' sense of responsibility.
- *Using codes to replace the participants' names* in data records in different forms accessible to multiple individuals is a standard practice for protecting confidentiality. The principal investigator is responsible for *securely storing the codes* that link to participants' personal information in a separate, restricted-access location.
- The same measures must be applied to protect the confidentiality of the data recorded in the form of pictures, sound, and video.
- **When researchers wish to present data, in the form of pictures, audio, or videos recorded during the research, at academic conferences, or in publications, they must obtain additional consent from the participants beyond the consent provided for data collection.**

Item 19 Terms and conditions

Item 20 Approval from the division head, immediate supervisor or the thesis advisor authorizing the implementation of the research

- Signing in Item 19 indicates the researchers' acknowledgment of the terms and conditions specified in the research submission form. Therefore, all co-researchers are required to sign.
- Signing in Item 20 Indicates the approval from the principal researcher's supervisor for the research to be conducted, confirming that the research is part of the university staff's main responsibility. In cases of adverse events resulting from the research, the principal investigator can notify the immediate supervisor to request resource or budget support to assist the research participants/ subjects.

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