GUIDANCE NOTES:

Project Filter:

1. Research OR Audit/Service evaluation/Service Improvement?

Please refer to the definitions below to help you decide if your project is **research that requires review** by the RTST, **OR** whether it is some other activity such as **audit, service evaluation, or service improvement**.

Research:

- Aims to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methodology
- Usually involves an attempt to test a hypothesis or identifies/explores themes
- Involves selecting patients/volunteers using strict inclusion/exclusion criteria
- Participants may be grouped into different groups to receive different treatments/ assessments
- May involve treatment/samples/investigations apart from routine care
- May require access to patient medical records
- May involve experiments on human subjects whether patients or healthy volunteers
- May involve a completely new treatment

Clinical Audits/Service evaluations: Assess a health treatment /service either against a standard, or without reference to a standard. Here, the treatments/services are used according to routine clinical practice only.

Service Improvements: Assess a clinical service either against a standard, or without reference to a standard and propose alternatives/improvements to those services.

If you are unsure of whether your project is research or not, please call us on **+973 17286052** or email at **RTST@health.gov.bh**.

2. Research type

The version of the form applicable to your project will depend on your answers to these questions. Tick all options that apply. If you are unsure of your research type, please call us on **+973 17286052** or email at **RTST@health.gov.bh**.

1) Basic science study involving procedures with human participants

This option includes studies involving procedures with participants that are additional to any routine clinical care, but NOT testing a new clinical intervention or involving randomization between treatment groups or any other change in existing clinical care. For example, it would be suitable for studies involving:

- Imaging investigations (MRI, ultrasound, etc.)
- Physical examinations
- Physical tests
- Computer tests
- Filming or photography
- Blood/tissue sampling

If the study involves taking human samples but no other physical intervention or procedure, you may select either this option or *"Research limited to use of tissue, other human biological samples and/or data"*. The set of questions generated in the application form(s) in the MOH RAS will be the same in either case.

If the study involves questionnaires and interviews but no physical interventions or procedures, it would be more appropriate to select the option *"Research involving questionnaires or interviews for quantitative analysis or mixed quantitative/qualitative methodology".*

2) Study administering questionnaires/interviews for quantitative/mixed quantitative-qualitative analysis

Please select this option if your research:

- Involves administering a questionnaire, or conducting interviews or focus groups with participants;
- Will use quantitative analysis, or a mix of quantitative and qualitative analysis methods; and
- Involves no new clinical interventions or procedures *(otherwise, please select one of the clinical research categories)*.

3) Study involving qualitative methods only

Please select this option if your research:

- Will use only qualitative analysis methods;
- Involves no use of human tissue samples or other human biological materials; and
- Involves no clinical interventions or procedures *(otherwise, please select one of the clinical research categories)*.

If you select this option, questions in MOH RAS relating to statistical analysis will be disabled.

4) Study limited to working with human tissue samples and/or analysis of data

Research in this category is based entirely on the analysis of data and/or use of human tissue samples or other human biological material. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to collect samples and seek informed consent where appropriate.

This category applies to specific research projects using samples and/or data. If you select this option, supplementary questions will appear about the proposed use of data or human tissue samples in your study. Research involving data collection through questionnaires or other interventions with participants should select another option.

5) Study limited to working with data only

Research in this category is based entirely on the use of data from MOH patients, service users or other MOH participants. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to seek informed consent where appropriate.

This category applies to research involving data relating to the deceased, as well as to living data subjects. This category applies to **specific research projects** using data to investigate specific research question(s) described in a protocol. This category is suitable for specific projects which may involve only obtaining data from a database for their study.
If you select this option, a supplementary question will appear about the identifiability of the data to be used in your study.

Research involving questionnaires, interviews, focus groups or other intervention with participants should select another option.

Clinical Research studies

In case your research falls under any of these categories, your research is an **Interventional study** and must be approved by the **NHRA (National Health Regulatory Agency)**. If you plan to conduct your study in MOH facilities, your study will be directed to the central MOH Research Committee for review **after NHRA approval only**. If you are unsure of your research type, please call us on **+973 17286052** or email at **RTST@health.gov.bh**.

2a. Clinical procedures:

a) Ionising radiation:

You should answer "Yes" to this question if the research protocol includes any procedure involving exposure to diagnostic or therapeutic ionising radiation. For all studies where the answer to this question is "Yes", you will also have to answer **Part B** of the MOH RAS.

Procedures involving ionising radiation include:

- Diagnostic X-rays, CT scans or DXA scans
- Radiotherapy (including brachytherapy and therapy using unsealed sources)
- Radionuclide imaging (including diagnostic imaging and in vitro measurements).

Magnetic Resonance Imaging (MRI) or ultrasound investigations do not involve ionising radiation.

You should answer "Yes" even if the radiation exposures to be received under the protocol would be in accordance with normal clinical care. You should answer "Yes" if imaging investigations involving ionising radiation are required by the *screening procedures* for the study (for example, if the protocol requires a diagnostic X-ray to confirm suitability for inclusion).
However, you may answer "No" if the *selection criteria* includes normal clinical exposure to radiation received previously outside the study, but the study itself does not involve radiation exposure. For example, an epidemiological study of the long-term effects of radiotherapy might require that the participant had received radiotherapy of a particular type or within a particular period prior to inclusion in the research. However, it is not a research exposure and does not require approval as part of the ethical opinion.

For studies involving administration of radioactive materials, **prior NHRA (National Health Regulatory Agency)** approval is required.

b) Administration of radioactive materials:

Procedures involving the administration of radioactive materials include:

- PET-CT
- Nuclear Medicine Bone Scans
- MUGA

Diagnostic X-rays, CT scans and DXA do not involve the administration of radioactive materials.

You should answer "Yes" to this question if the research protocol includes any procedure involving the administration of radioactive materials. You should answer "Yes" even where the administration of radioactive materials to be received under protocol would be in accordance with normal clinical care outside the research setting. You should answer "Yes" even where the procedures involving administration of radioactive materials are required by the *screening procedures* for the study, for example where the protocol requires a MUGA scan to confirm suitability for inclusion.

For all studies where the answer to this question is "Yes", **prior NHRA (National Health Regulatory Agency)** approval is required.

However, you may answer "No" if the *selection criteria* include normal clinical exposures received outside the study but the study itself does not involve radiation exposure. For example, an epidemiological study of the long-term effects of ^{131}I radioiodine treatment for thyrotoxicosis might require that the participant had received ^{131}I radioiodine treatment prior to inclusion in the research. However, since no radioactive materials will be administered *during* the research, it does not require approval as part of the ethical opinion.

c) New human tissue samples (or other human biological samples):

Please answer "Yes" if the research will involve collecting samples prospectively from participants primarily for research purposes.

d) Existing human tissue samples (or other human biological samples):

Please answer "Yes" if the research will involve the use of residual samples left over from routine clinical or diagnostic procedures, or existing stored samples from an archived collection or tissue bank.

2a. Clinical procedures for Studies limited to Human tissue samples

a) Taking new samples for research: This option should be selected for research in which samples are collected prospectively from participants primarily for research purposes.

b) Research involving surplus or existing samples identifiable to the researcher: Select this option for research using residual tissue left over from routine clinical or diagnostic procedures or using existing samples from an archived collection or tissue bank, where it is likely that the researcher will be able to identify the donors.

c) Research involving surplus or existing samples not identifiable to the researcher: Select this option for research using residual tissue left over from routine clinical or diagnostic procedures using existing samples from an archived collection or tissue bank, where all the samples will be anonymised or pseudonymised and there is no possibility of the researcher being able to identify any donor.

d) Research involving identifiable data:

This option should be selected for research:

- Using identifiable patient data or service user data from databases or records which are not anonymised
- Observing treatment or care with *no intervention*.

Research involving data collection through questionnaires or other intervention with participants should select another option.

Answer "No" if your research will *only* use non-identifiable data, i.e. data that are "anonymised" or "pseudonymised" at the point of access by researchers.

> Anonymised data means data prepared from personal information but from which all identifiers have been removed so that it is no longer possible to identify the person concerned.
>
> Pseudonymised data is like anonymised data – it cannot reasonably be used by the holder to identify an individual. However, the data may be linked to codes or other unique references so that the data will only be identifiable to those who have access to the key or index.

3. MOH research sites

This application pertains to research to be conducted in **MOH facilities only**. These include MOH health centers, MOH hospitals and MOH departments. Answer "Yes" even if you are applying for a multicenter study with only one MOH study site.

For studies to be conducted only in other government hospitals, private clinics, or other organizations, MOH approval is not required. Please apply directly to the participating organization.

4. Data collection from MOH patients/employees/medical records

Answer "Yes" if your research involves collecting any form of data (information/tissue samples/access to medical records) from MOH patients or employees.

5. Directing your research application:

If your answer is "No" to all of these questions, your research may need to be directed to the MOH Primary or Secondary Healthcare Research Committee, or may not require MOH research approval at all.

If you are unsure of where your research should be directed, please call us on **+973 17286052** or email at **RTST@health.gov.bh**.

6. Research in children:

Please answer "Yes" if the research will include participants aged under 15 years, or make use of their samples or data. You should still answer "Yes" even if some or all of the participants will be able to consent for themselves. Further guidance about this is available in **Part B Section 5** of the MOH RAS, which covers issues in the inclusion of children in research.

7. Research in adults who are unable to consent for themselves:

Please answer "Yes" if it is possible that the research could *at any stage* include adults (aged 15 or over) who are unable to consent for themselves due to physical or mental incapacity (including temporary incapacity).

You should still answer "Yes" if the participants will be able to give consent initially but you plan to undertake further research procedures on or in relation to such participants (including collection of new samples or data) following loss of consciousness/ mental capacity to consent during the study. If participants would be withdrawn from the study following loss of capacity, you may answer "No". For guidance on retaining samples or data already collected at the point capacity is lost, please refer to the guidance on Question A29.

8. Research in prisoners:

A prisoner or young offender is defined as any inmate of the Bahrain prison system. It does not include patients detained at special mental hospitals or other psychiatric secure units. Health research involving prisoners or young offenders should relate directly to their health care and be of such a nature that it could only be conducted in this population.