

## Defining Research – Research Type

### Medical Research Center, HMC Doha-Qatar

The following definitions provide descriptions for each type of research study listed as a selection option for the 'Research Type' question on the application and submission forms used for research at HMC.

For example, Make the selection that best represents WHAT you are doing in the research.

The types are in the order as they appear on the forms and only one choice can be selected in the dropdown menu. As a result, make the selection that best describes the nature or type of research activities taking place. If the research can be represented by more than one selection, choose the type that represents the HIGHEST CATEGORY OF RISK or activities that exposes the research subjects and controls to more risk of harm or injury than people not participating in the research.

#### 1.1. Investigational Product Clinical Trial

A clinical trial that enrolls humans as a test subject or control in order to determine the safety and efficacy of a non-approved drug/device that is investigational, these are defined as PRODUCTS THAT DO NOT HAVE MARKET APPROVAL AND ARE NOT COMMERCIALY DISTRIBUTED. These are usually multi-site, international, randomized, blinded, placebo controlled studies.

Outcomes are unknown. This type of research is typically sponsored, funded and the protocol created by the product manufacturer. These studies are highly regulated human subjects research requiring extensive scientific, ethical, safety review and data monitoring. This is research likely regulated by the US-Food and Drug Administration (FDA), The European Medicines Agency (EMA), World Health Organization (WHO) or national Medicines Control Council(s) that regulate the manufacture and use of drugs/devices in their country.

#### 1.2. Investigational Use Clinical Trial

A clinical trial that enrolls humans as a test subject or control in order to CLINICALLY EVALUATE a legally marketed drug or device for a NEW INTENDED USE or for a new indication for use. This includes a product that is used or assembled in a way that is different from the approved form, or used for an unapproved indication (off-label).

The primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The distinction is that the use in research is NOT intended to make a determination about the safety and effectiveness of the drug or medical device, rather to evaluate the treatment or procedural regimen. Outcomes and risks are unknown. This type of research is usually sponsored by the manufacturer; the research protocol may be created by the sponsor or investigator. These studies are regulated human subjects research.

#### 1.3. Comparative Clinical Trial

A clinical trial enrolls humans as a test subject or control in order to CLINICALLY COMPARE and evaluate the effectiveness of accepted diagnostic (standard of care) tests, treatments, procedures or health care services with the intention of improving patient outcomes.

Outcomes are unknown but treatment risks are generally known. Oversight requirements may vary depending on the setting and nature of the research, but are generally defined as human subjects' research. The research protocol is usually created by the investigator.

#### 1.4. Therapeutic Clinical Research

An INTERVENTIONAL PROSPECTIVE STUDY that enrolls patients in order to provide a specific therapeutic treatment to patients to study its impact and effectiveness on a specific disease or health condition of a patient diagnosed with the particular disease or health condition in question. These include the testing of new approaches to prevention, screening, diagnosis, treatment and patient education (supportive care) methods to improve outcomes of a particular disease state.

Outcomes are unknown. May also be a type of clinical trial research indicated above; oversight requirements may vary depending on the setting and nature of the research, but are generally defined as human subjects' research; the research protocol is created by the investigator.

#### 1.5. Non-Therapeutic Clinical Research

A non-interventional prospective study that does not provide a treatment to patients, but instead studies factors which may help advance the understanding of a particular disease, condition or progression of disease. Non-therapeutic clinical research is commonly the precursor to therapeutic clinical research and clinical trial studies. These include bio-specimen collection to examine or track biomarkers, DNA and RNA as predictors or identifiers of a particular disease state, surveillance studies to monitor the long-term health effects of a treatment or therapy, and post approval monitoring of patients or participants from clinical trial research.

# Help Guidance: Types of Research

## 1.6. **Translational Research**

Research referred to as 'Bench To Bed'; this begins as laboratory based scientific research that leads to or may include clinical research that enrolls humans as test subjects or controls in order to conduct genetic testing (DNA/RNA) or identify biomarkers to facilitate diagnosis or prevention/ treatment of a particular condition/ disease. Translational research may be the precursor to therapeutic clinical research.

## 1.7. **Population/ Epidemiologic Research**

Research that is intended to establish incidence, prevalence and mortality rates of a condition or disease in the general population or in a specific target group. These are generally surveillance studies that do not interfere or modify patient care, but may collect bio-specimens or perform diagnostic or genetic testing in order to establish baseline data. This population based research may include analysis of banked bio-specimens, registry data, etc. Data resources may or may not contain identifiable information (PHI) about the source. There may be indirect or direct contact with human subjects. This can be either prospective or retrospective in nature.

## 1.8. **Behavioral Research**

Research that uses diagnostic tools, surveys, interviews, focus groups, or other means to gather qualitative data or information on behaviors, attitudes, opinions, etc. Behavioral research may occur as a component for other research to support or enhance quantitative findings. There may be indirect/direct contact with human subjects.

## 1.9. **Retrospective Data Review**

An activity that involves the review and analysis of pre-existing data obtained from medical records or previously conducted research, and may include bio-specimens collected and banked from previous research activities or left over or discarded from non-research related medical procedures. These resources may or may not contain identifiable information (PHI) about the source of the materials. There is no direct contact with human subjects in this kind of research.

## 1.10. **Systematic Review**

A literature review focused on a research question that tries to identify, appraise, select and synthesize all high quality research evidence relevant to the research question. Also referred to as a systematic literature review or structured literature review (SLR).

Systematic reviews may be comprised of a review of clinical tests, diagnostics, public health and social interventions, adverse outcomes and economic evaluations where published data is collected and methodology assessed to contribute to evidence-based medicine and to determine if and how to implement a standard practice into the delivery of health care services.

## 1.11. **Quality/Performance Evaluations**

An activity that involves the collection of information, either quantitative or qualitative in nature, which may include surveys or interaction with individuals for the objective of improving processes, policy, performance or quality of service. This generally does not meet the definition of human subjects' research.

## 1.12. **Case Study Report**

A review or investigation of an individual or group that queries a particular topic or context, such as patient experience or discussions on medical care, scientific advances or discussion of health care topics; target audiences are usually physicians, faculty and members of the health care community. This generally does not meet the definition of human subjects' research.

## 1.13. **Article for Publication**

A written piece on a particular subject that is intended for a journal, magazine, or intended for public distribution, may include a literature review. This generally does not meet the definition of human subjects' research.

## 1.14. **Course Related Activities**

This is any activity that is part of a curriculum requirement, a learning objective or educational exercise at a learning or academic institution. This generally does not meet the definition for research.

## 1.15. **PhD Dissertation / Research**

This is any activity that is part of a PhD dissertation requirement from an academic institution. The dissertation is a technical work used to document and set forth proof of one's thesis.

## 1.16. **Other** - Any other activity that does not meet any of the above descriptions.