Activities that involve systematic investigation and are designed to develop or contribute to generalizable knowledge are considered research. When such activities involve human participants, they will require review and approval by CPHS. Some examples of research involving human subjects are clinical trials, epidemiological research, retrospective medical records review research, and genetic research. However, we do recognize that it is not always easy to determine whether an activity is research involving human participants. The purpose of this guidance is to give some examples to help make this determination.

When in doubt whether an activity requires CPHS review and approval, the Principal Investigator must write to the ORSC Director with a summary of the proposal. The ORSC Director or designated ORSC staff will review the information and make a determination whether or not the described activity meets the definition of research involving human subjects. The ORSC Director or designated staff will send a written notification to the researcher with the final determination.

Below are some examples of activities that may or may not require IRB review:

**Case Reports** – Case reports do not involve systematic investigation; however the intent is to contribute to generalizable knowledge. Case reports are not considered to be research involving human subjects and do not require prior CPHS review and approval. However, a series of 3 or more subjects qualifies as a research project and hence should be submitted for review and approval by CPHS prior to initiation.

**Retrospective Medical Records Review** - All retrospective medical record reviews to be conducted at LBJ Hospital, Harris County Psychiatric Hospital, Thomas Street Clinic, or at a hospital within the Memorial Hermann Healthcare System for the purposes of research must be approved by CPHS. This may be accomplished by submitting a request through the iRIS system, which will be reviewed and approved administratively. Retrospective medical chart reviews also require approval by the Memorial Hermann Research Office when using Memorial Hermann Hospital or one of the MHHS community hospitals.

**Tissue Repositories** - Operation of Human Tissue Repositories and data management centers are subject to oversight by CPHS. CPHS will review and approve protocols specifying the conditions under which data and specimens may be accepted and shared, and ensure adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. CPHS will also review and approve a biological sample collection protocol and consent document.

**Research involving biological materials** – Research involving biological materials or data from individually identifiable living persons must be reviewed by CPHS. Researchers who are uncertain whether an activity is human research must contact CPHS. Below is a list of human derived materials and whether they require CPHS approval:

- **Examples of material not needing CPHS approval, include but are not limited to:**
  - anonymized nucleic acid
  - human cells or cell lines from established external repositories and tissue banks (such as ATCC)
  - anonymized commercially available blood
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- anonymized commercially available macrophage cell lines
- anonymized cell lines, cell products, or material purified from cells, tumor cells or cultured cell lines

Examples of material that do require CPHS approval, include but are not limited to:
- embryonic or fetal tissue, including the placenta, amniotic fluid, umbilical cord blood and stem cells
- tumor tissue
- tissues from individual donors
- material from cadavers
- diagnostic specimens collected for or being used for research purposes
- deciduous teeth at time of exfoliation or permanent teeth extracted for clinical purposes
- saliva, supra-and subgingival dental plaque, and calculus
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

Research Involving Coded Data or Specimens – Research involving coded private information or biological specimens, that were not collected for the current research proposal do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. Note: At UTHSC-H, such projects may qualify for exemption. Investigators must submit an application to CPHS for review.

Publicly Available Data – Research involving publicly available data do not require IRB review. Examples: census data, labor statistics. Note: Investigators should contact the CPHS if they are not sure whether the data qualifies as “publicly available”.

Quality Assurance and Improvement Projects (QA / QI) – Activities designed to determine if aspects of any practice are in line with established standards are called quality assurance. When an activity is designed to improve the performance of any practice in relation to an established standard, it is called quality improvement. When these QA / QI Projects involve systematic investigation and contribute to generalizable knowledge they must be reviewed and approved by CPHS. Additionally, any QA or QI activity where participants are subjected to additional risks or burdens beyond standard practice must be reviewed and approved by CPHS. If there is uncertainty whether an activity is human subjects research, CPHS must be contacted.

Research involving deceased individuals – Research involving deceased individuals does not meet the DHHS definition of human subjects research, but at UTHSC-H, such research must be reviewed and approved by the CPHS.

Outbreak investigations – Outbreak investigations are important activities that benefit public health. Such activities are not considered to be research and do not require CPHS review. However any interventional studies conducted during an outbreak would require review and approval by CPHS. CPHS will make an effort to expedite the review and approval process for such protocols.

Infection control – Rapid investigations to reduce the current or future spread of disease or infection carried out as part of an infection control program are not considered as research and these do not
require review by CPHS. Planned research conducted by an Infection Control department requires review and approval by CPHS.

**Compassionate / Emergency Use of Investigational Drug** - When a physician wishes to use an investigational drug for treatment of an individual patient for a single use or a single course of treatment, and the use is not covered by an existing CPHS approved protocol, contact CPHS office with the request and justification. The Executive Chairperson will advise if the justification for such use is sufficient for approval. This is discussed in greater detail in the Policy and Procedure on Emergency Use of an Investigational Drug.

**Compassionate / Emergency Use of Unapproved Medical Device** - If an emergency arises where an unapproved medical device may offer the only possible life-saving alternative, but an Investigational Device Exemption (IDE) for the device does not exist, or the proposed use is not approved under an existing IDE, a physician may use the device if each of the following conditions exist: 1) the patient is in a life-threatening condition requiring immediate treatment; 2) no generally acceptable alternative is available; and 3) there is no time to use existing procedures to get FDA approval for the use. This is discussed in greater detail in Policy and Procedure on Emergency Use of an Unapproved Medical Device.

**Off-Label Use Of Marketed Drugs, Biologics, and Medical Devices** - Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB).

**Investigational Use of Marketed Drugs, Biologics and Medical Devices** - Investigational use suggests the use of an approved product in the context of a clinical study protocol. When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, submission of an IND or IDE may be required. All such activities require prior CPHS review and approval.

**APPLICABLE REGULATIONS**

1. 21 CFR 56.104
2. 21 CFR 312.3(b)

**REFERENCES TO OTHER SOP**

1. Research Requiring Review by CPHS

**ATTACHMENTS**

1. None