The Committee is an independent body that fulfills the HWCOM faculty needs for independent and unbiased content expertise evaluation and Methods and research design review to support PIs in response to requests for research protocols assistance.

The ORFS will help coordinate:
- Reviews by the Research Support Committee
- Pre-award process
- IRB and other regulatory clearance processes

The Committee:
- Standing members
- Will invite other experts as necessary

Faculty Research Support Structure

HWCOM Department of Medical and Population Health Sciences Research

Office of Research and Faculty Support (ORFS)

Provides Comments/Suggestions/Revisions/Technical assistance and support on research protocols to investigators
Investigator-initiated, external projects with FIU HWCOM faculty and multi-site research protocol

**Step I: project design**

- Research idea generated by an investigator or protocol received
  - Is there a need or desire for regulatory, methodological and (if relevant) human research regulations (IRB) support?
    - NO
      - Project design by investigator
      - Protocol Completed
    - YES
      - Project design supported through formal consultation to the Office of Research and Faculty Support within the Department for Medical and Health Sciences Research
        - Present to your department Chair (or follow your Department’s research policies)
        - Go to Step II: Protocol Review
Step II: Protocol Review and Research Pre-Award Review Process

Research Protocol completed by Investigator or by external partners

Unbiased scientific technical and human subjects research review is provided (HWCOM policy):
- Feasibility, quality
- Strategic Alignment with mission
- Budget
- Faculty effort allocation, etc.

Office of Research and Faculty Support (ORFS)
Department of Medical and Population HS Research

Department Chair Approves

Protocol reviewed and approved

Back to investigator

Comments/ Suggestions/ revisions

The ORFS will help coordinate:
- Evaluation by the Research and Faculty Support Committee
- Pre-award process
- IRB clearance process and other regulatory assessments as needed

Forward to IRB
Create ePRAF (if needed)
DOR Pre-award process (if needed)

Go to step III: Post-award project monitoring

Project approved/ funded
Step III Research Post Award or Post-Approval Monitoring Process

Monitoring during the life of the project (approval to closure)

- Adherence to Project Timeline
- Staffing levels
- Budget accountability
- Subject/Recruitment Goals
- Protocol violations
- Adverse events reporting

Auditing

- Data Management/Documentation
- Compliance
- Consent Procedures
- Reports to funders
- Certification/Training Records

These services are to be provided by the **Office of Research and Faculty Support** in coordination with the Research Committee. Time-lines and processes are to be defined, probably will vary on a project to project basis.