Research & Quality Project Education

WVUMedicine

THOMAS HOSPITALS

Quality & Performance Improvement (QI/PI)

Quality & Performance Improvement

- Efforts to improve practice performance with the goal of improvement in healthcare services and the health status of targeted patient groups. This is to improve effectiveness and efficiency to enhance the ability of an organization or program to deliver.

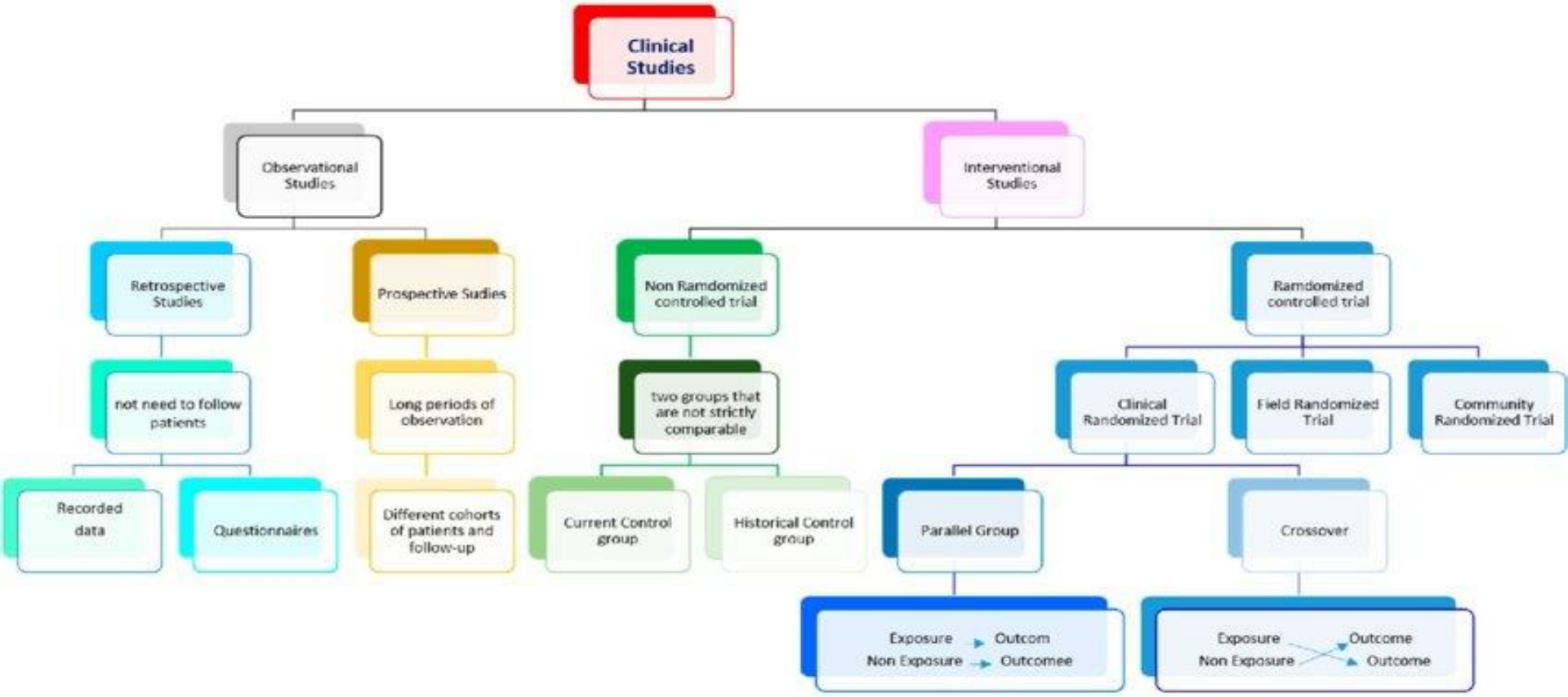
Research

Research

- Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This definition encompasses activities that use a scientifically accepted method to gather and analyze data, aiming to expand the knowledge base of a scientific discipline or other scholarly field.

Types of Clinical Studies

Observational vs. Interventional / Provider vs. Sponsor


Clinical Studies
Observational Studies
Interventional Studies
Retrospective Studies
Prospective Sudies
Non Ramdomized controlled trial
Ramdomized controlled trial
not need to follow patients
Long periods of observation
two groups that are not strictly comparable
Clinical Randomized Trial
Field Randomized Trial
Community Randomized Trial
Recorded data
Questionnaires
Different cohorts of patients and follow-up
Current Control group
Historical Control group
Parallel Group
Crossover
Exposure
Non Exposure
Outcom
Outcomee
Exposure
Non Exposure
Outcome
Outcome

Provider Initiated vs. Sponsor Initiated

Provider Initiated

- Provider-initiated studies (also known as investigator-initiated studies or IIS) are conceived and managed by the investigator.
- **Initiation:** The research question and study design originate with the investigator (a clinician, researcher, or academic group).
- **Sponsorship:** The investigator takes on the role of both sponsor and investigator, meaning they are responsible for all aspects of the study, including funding, regulatory compliance, and data management.
- **Funding:** IIS can be funded by various sources, including institutional grants, government funding, or industry support, but the investigator maintains control over the study's design and conduct.
- **Purpose:** IIS often focus on addressing specific clinical questions or exploring new uses for existing treatments, or independent research on disease states.
- **Examples:** Academic research, observational studies, or clinical trials exploring new indications for a marketed drug.

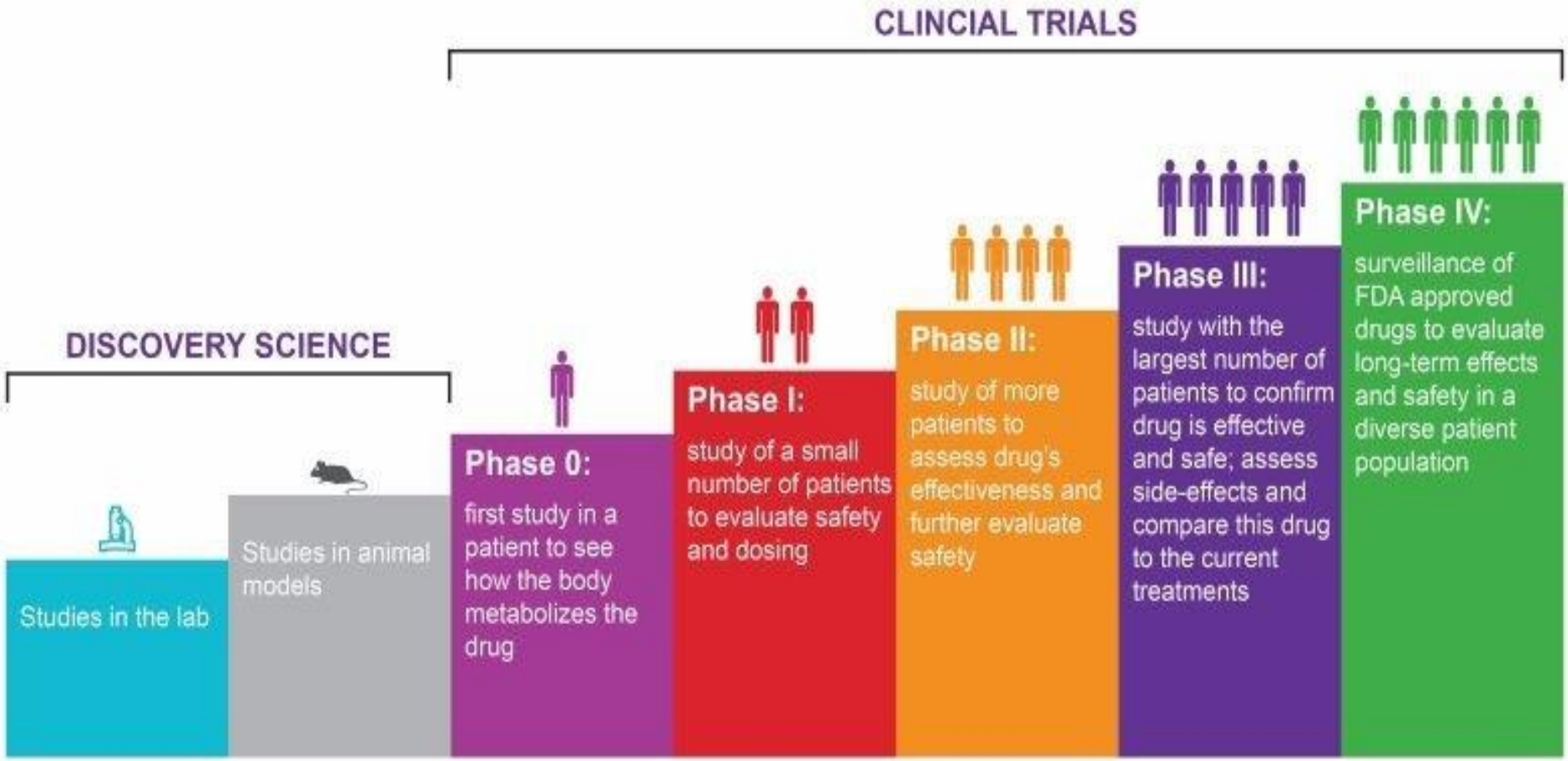
Sponsor Initiated

- Sponsor-initiated studies are led by an external entity (like a pharmaceutical company) that takes responsibility for the study's initiation, management, and financing.
- **Initiation**: The study is initiated and designed by an external entity (sponsor), such as a pharmaceutical company or a research organization.
- **Sponsorship**: The sponsor takes on the legal and financial responsibility for the study, including securing funding, regulatory approvals, and ensuring the study is conducted according to Good Clinical Practice (GCP) guidelines.
- **Funding**: Sponsors typically provide funding for the study, and they may also be involved in the study design, data analysis, and publication of results.
- **Purpose**: Sponsor-initiated studies often aim to support the development and approval of new drugs or medical devices.
- **Examples**: Clinical trials conducted by pharmaceutical companies to obtain regulatory approval for a new drug.

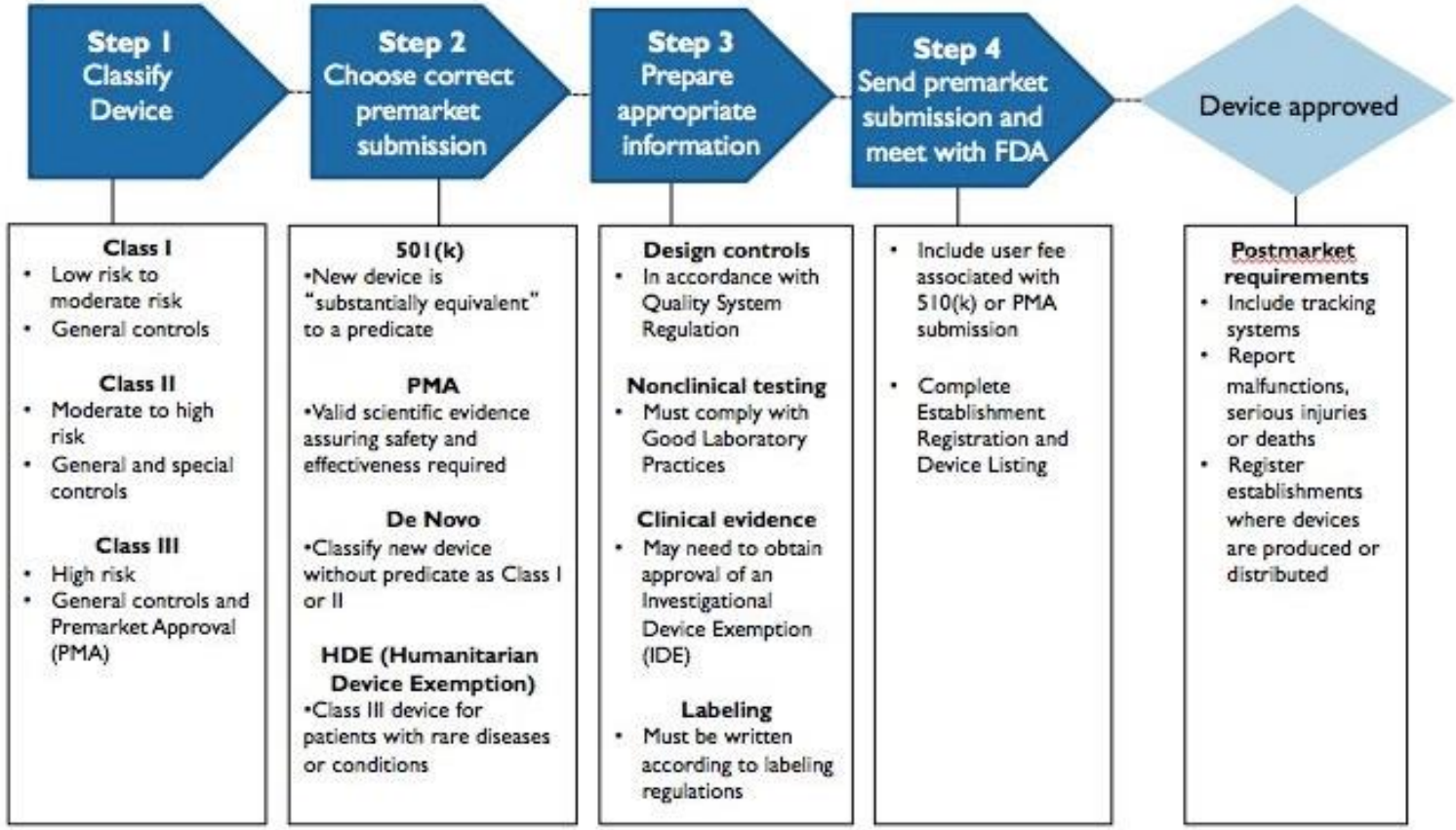
Phases of Clinical Trials

Drug vs. Device

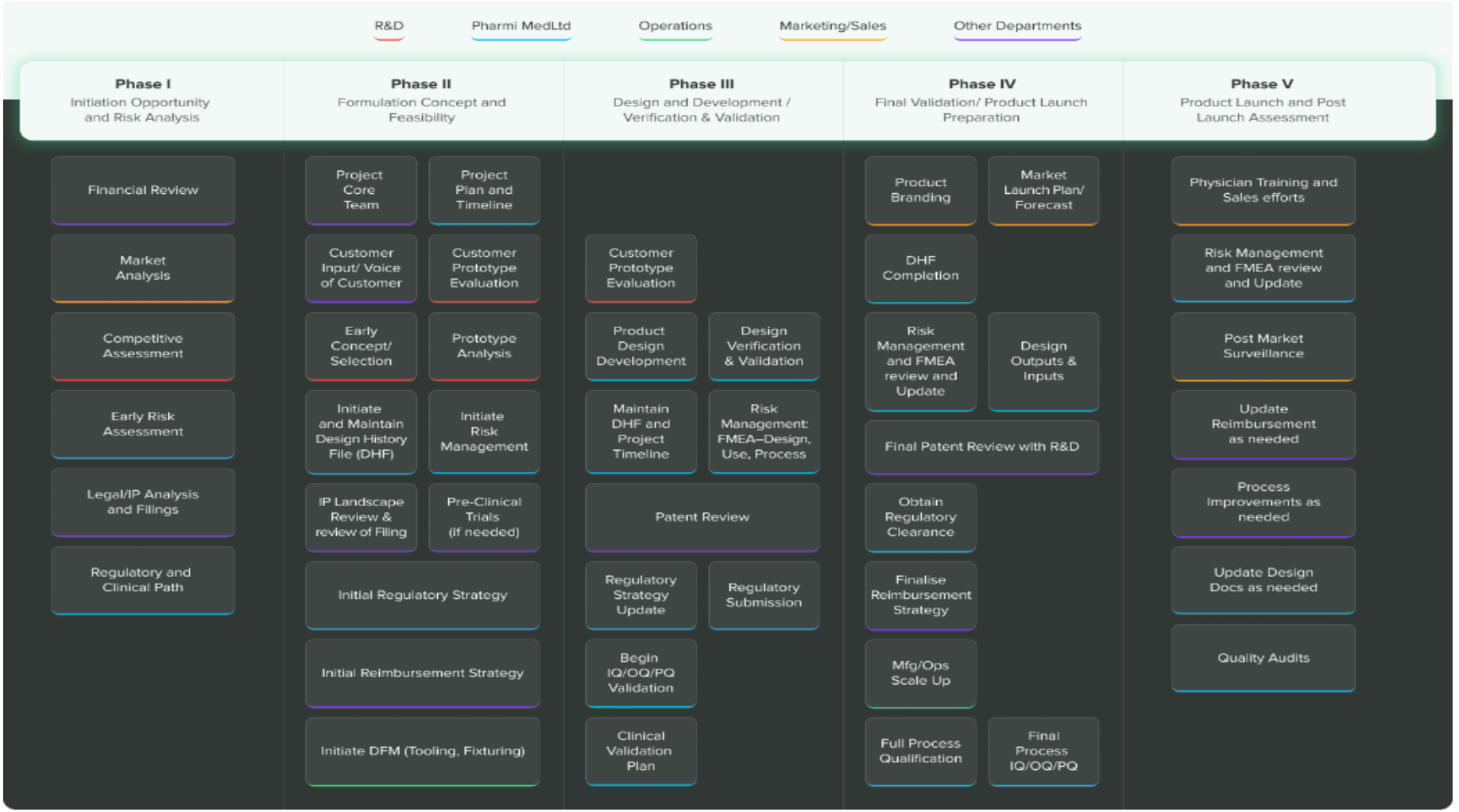
FDA Drug Approval Process


CLINCIAL TRIALS
DISCOVERY SCIENCE
Studies in the lab
Studies in animal models
Phase 0:
first study in a patient to see how the body metabolizes the drug
Phase I:
study of a small number of patients to evaluate safety and dosing
Phase II:
study of more patients to assess drug's effectiveness and further evaluate safety
Phase III:
study with the largest number of patients to confirm drug is effective and safe; assess side-effects and compare this drug to the current treatments
Phase IV:
surveillance of FDA approved drugs to evaluate long-term effects and safety in a diverse patient population

FDA Medical Device Approval Process



Development of a New Medical Device



Financing of Clinical Trials

Sponsor Billed vs. Insurance Billed and Grant Funding

Financing of Clinical Trials

Sponsor Billed

- All aspects of budget paid by Sponsor
- Typically on experimental/pre-FDA approved trials

Insurance Billed

- Standard of care (like office visits and procedures) billed to patient's insurance as normal
- Sponsor budget covers items required by study alone like staff time, paperwork/data collection, facility study fees
- Typically on post-approval studies

Financing of Clinical Trials

Grant Funding

- All or some aspects of budget paid by a Grant
- Available from various sources, including federal agencies like National Institutes of Health (NIH) and Department of Defense (DOD), as well as private and non-profit organizations such as the American Heart Association
- Federal funding can be found on the Grants.gov website

Governing/Regulatory Bodies

Who protects your project and your subjects?

Internal Review Boards (IRBs)

- Under FDA regulations, an IRB is a group of people who review research involving human subjects to ensure that it's ethical and safe. IRBs are also known as independent ethics committees or research ethics boards.

WVU IRB

- Morgantown

Central IRBs

- National
- Examples: WCG/WIRB, Sterling, Advarra

*WVU has contracts with WCG and Advarra**

IRBs continued

What do IRBs do?

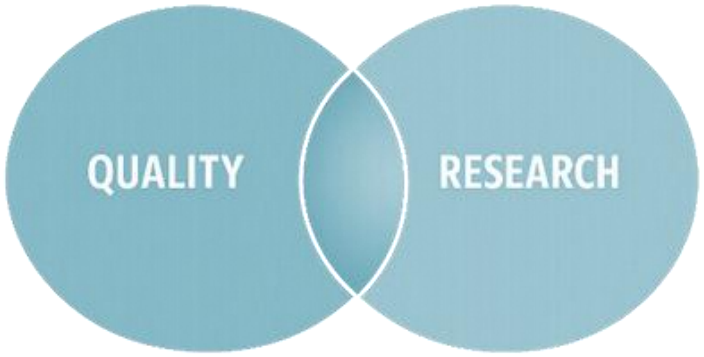
- Review research proposals to ensure they meet ethical standards
- Ensure research is legal and complies with regulations
- Protect research participants from risks
- Ensure research is well designed
- Ensure research includes a safety plan for participants

Who serves on an IRB?

- Scientists
- Doctors
- Clergy
- Patient advocates
- At least one member who is not affiliated with the institution
- At least one member who is not a scientist

Research vs Quality

There is often confusion as to whether a QI/PI project may meet the criteria for Research. Most QI/PI efforts do not require IRB review. However, in some cases Research vs. Quality will overlap. Our Office of Research would love to discuss more about what your goals and objectives are for your project requirements.



Thomas Project Initiation Steps

What to expect next…

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Clinical Research Project Process: Take Your Education from Interest to Impact

A STEP-BY-STEP GUIDE FROM INTEREST TO PROJECT COMPLETION

1. **Submit Project Interest Form**
   Complete the online project interest form indicating your interest in a QI/PI project or Research project/internship. This is located on the Thomas Hospitals home page under 'Research.'

2. **Research Team Review**
   Your interest survey will be reviewed by the research team.

3. **Initial Consultation**
   The research team will reach out regarding your interest survey submission. The research team will work with you to determine if you are working on a QI/PI project or a Research project.

4. **Facility & Department Onboarding**
   The research team will initiate the onboarding process at both a facility and department level.

5. **Project Planning / Mentor Assignment**
   The research team will reach out to you to discuss your goals/objectives, and your request details. If you do not have a physician mentor, the research team will work to provide you with one.

6. **Project Submission**
   Complete the online Project Submission Form for the department and Administration to formally review at a facility level.

7. **Onboarding Completion & Next Steps**
   Once onboarding tasks are complete, you will notify the research office and then complete IRB Protocol Template, Case Study Template, and/or Authorizations as required.

8. **IRB Submission**
   WVU IRB/CTSI Project Submission per Research Department.

9. **Time to Start!**
   The research team will alert you to IRB approval/project auth. Initiate case study abstracting and data mining for chart reviews while working with your mentor on your project.

10. **Data Completion and Dissemination**
    When complete, notify Research Dept to review data sheet, declassify, and submit to CTSI on your behalf for statistical analysis. (for retrospective chart reviews)

11. **Data Analysis and Project Write-Up**
    The research team will alert you when your stats are back. This can take several weeks. It is now time to work with your team to initiate your retrospective chart review abstracting.

12. **Poster Presentation Preparation**
    WVUM/Thomas Hospitals has a specific marketing approved poster template for research presentations. Please contact the research department when you are ready to start your draft.

13. **Project Finalization**
    When case study or retrospective study abstract and/or poster drafts are complete, contact the research department to set up a finalization and planning meeting with the team and your mentor.

14. **You Did It!**
    Congratulations!!!! Move ahead with journal submissions, poster presentations, etc. with the assistance of your mentor. Remember - it is necessary for the research team to receive final publication and/or presentation specifics.

15. **Exit Interview & Access Removal**
    An exit interview will be scheduled as the team would love to hear about your experience, and if there are any opportunities for us for improvement! Your access will now be removed from our electronic health record.

Throughout this process, you will receive guidance and support from your Physician Mentor and the Research Team. Just ask!

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Quality Improvement Project Process: Take Your Education from Interest to Impact

A STEP-BY-STEP GUIDE FROM INTEREST TO PROJECT COMPLETION

1. **Submit Project Interest Form**
   Complete the online project interest form indicating your interest in a QI/PI project, research project, or internship. This is located on the Thomas Hospitals home page under 'research.'

2. **Research Team Review**
   Your interest survey will be reviewed by the research team.

3. **Initial Consultation**
   The research team will reach out regarding your interest survey submission. The research team will work with you to determine if you are working on a QI/PI project or a research project.

4. **Referral to Quality Leadership**
   The research team will send your request to the quality lead for review.

5. **Project Planning / Mentor Assignment**
   The quality lead will reach out to you to discuss your goals/objectives and your request details. If you do not have a mentor, the quality lead will work to provide you with one.

6. **Research Office Onboarding**
   Once you established your quality project structure, you will be referred back to the research office for further on-boarding.

7. **Project Activation**
   Once your onboarding is completed by the research team, the quality team will be notified. You will then move forward with discussion with your quality representative.

8. **Start Project**
   Your quality project has now begun, and you are working with your quality representative and physician mentor.

9. **Data Analysis and Project Write-Up**
   Complete analysis, chart reviews, and work with your mentors on completing out your project.

10. **Project Completion and Dissemination**
    Finalize and present project results. Your physician mentor and quality representative will help you determine where your project will be reviewed.

11. **You Did It!**
    Now that you have finished your project, it is up to you to notify the research team. The team would love to hear about your experience and if there are any opportunities for us for improvement!

12. **Access Removed**
    Your access will now be removed from our electronic health record.

Throughout this process, you will receive guidance and support from your physician mentor, quality lead, research team, and the quality department. Just ask!

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Industry Project Initiation Steps

- Receive notice of new study from Physician or Sponsor
- Submit project proposal through link on facility webpage
- Ensure resources are available and no current conflicting studies (check NCT #s)
- Complete confidentiality/nondisclosure agreement rec'd from Sponsor and return (sent to Legal for review/execution)
- Complete sponsor feasibility assessment or other questionnaires if applicable and return to Sponsor
- Schedule and complete site qualification visit or questionnaire with Sponsor
- Receive start-up documents from Sponsor
  - Official study invitation letter/email
  - Protocol / CIP (Clinical Investigational Plan)
  - ICF (Informed Consent Form)
  - CTA (Clinical Trial Agreement) with included CTFA (Clinical Trial Financial Agreement)
  - Budget
- Review start-up documents for any errors or needed changes. If changes, note and return to sponsor for approval and fix prior to submission to facility personnel
- Provisional Acceptance Form following initial discussion during committee meeting to proceed with start-up process/review

Industry Project Initiation Steps

- Submit start-up documents to WVUM Administration
  - CIP
  - Budget
- Submit start-up documents to WVUM Legal
  - CIP
  - ICF
  - CTA
- Complete internal site documents
  - Financial Disclosures
  - CVs (signed and dated)
  - Licenses
  - Training
- Ensure all necessary departments outlined in the study protocol have a representative in negotiations/approval, i.e., Lab, Radiology, etc.
- Internal site meeting with WVUM Admin/Department Manager(s)/Research Director to review budget and negotiate with Sponsor if necessary
- Ensure Letter of Understanding completed by WVUM Admin and 3rd Party to allocate the breakdown of study related funds (If Necessary)

Industry Project Initiation Steps

- If separate contracts needed by Sponsor for other third parties like Anesthesia, etc., ensure delivery/submission
- Submit Project to Central IRB (WIRB-WCG, Advarra, Sterling, etc.)
- Submit Project to WVU IRB once Central IRB approved
- Complete FDA 1572 form from Sponsor (if applicable) and return
- If a pre-market/IDE Study, submit documents to CMS...
  - IDE (Investigational Device Exemption) Letter
  - IDE Form
  - CIP
  - ICF
  - IRB Approval Letter
- Submit request to WVUM EMR professionals to enter study billing status into EMR (currently EPIC)
- Enter study information into main WVU Study database, currently OnCore, which interfaces with EPIC EMR
- Confirm no needed tech support/oversight from facility for any study related devices, ie., Biotech, etc.

Industry Project Initiation Steps

- Ensure computer compatibility with EDC (Electronic Data Capture) program for training and study documentation, receipt of all binders, advertisements, brochures, and all other study related supplies
- Submit executed documents to Sponsor
  - Start-up
  - Internal docs
  - IRB
  - FDA or CMS
- Site initiation/training visit with Sponsor
- Receive official letter of activation from Sponsor

Educational Project Initiation Steps

- Receive new study/project interest form from Med Student or Resident (link on webpage)
- Meet with Department Head to assign Mentor and establish project for QI/PI, case study, or retrospective review (or approval to add to existing project)
- Submit project proposal through link on facility webpage
- Ensure Clinical Research CITI GCP and HRP trainings complete
- Ensure WVUM/TMH Onboarding documents/trainings complete
- Establish data collection needs/spreadsheet
- Establish access to appropriate databases with WVU/WVUM
- Submit start-up documents to WVU IRB/CTSI (Case Study Auth, Protocol Template, etc.)
- Initiate Project
- Submit completed declassified spreadsheet (data) to WVCTSI in Morgantown for statistical analysis
- Ensure appropriate WVU IRB/Facility approval for data release of work
- Work with Mentor for next steps (i.e. authorship of abstract or conference poster presentation, etc.)

Commonly Used Terms/Phrases

- IRB – Internal Review Board: A team of people who review studies to protect the rights and welfare of study participants
- CTA – Clinical Trial Agreement: A legally binding contract outlining the terms and obligations of all parties involved in a clinical trial
- CIP - Clinical Investigation Plan: A document that outlines everything needed to conduct a clinical trial
- ICF – Informed Consent Form: A document used to explain the planned research before a person decides whether to join a study
- CRF - Case Report Form: A printed, optical, or electronic (eCRF) document designed to capture all protocol-required information for a study
- Investigator: Responsible for the overall design, conduct, and reporting of a study, ensuring ethical conduct and data integrity, and may delegate tasks to qualified team members
- Sponsor: In a clinical trial, the sponsor holds the ultimate responsibility for the study's design, conduct, and outcome. They provide the necessary financial resources and oversee the entire process
- CRO - Contract Research Organization or Clinical Research Organization: Groups who specialize in providing support services to sponsors
- CRC – Clinical Research Coordinator: A research staff member who helps manage studies
- DMC/DSMB - Data Monitoring Committee/Data and Safety Monitoring Board: An independent group of experts that reviews study data to make sure that patient safety is protected
- IND – Investigational New Drug: An application to the United States Food & Drug Administration (FDA) to get permission to use a drug in a research study that enrolls people
- IDE - Investigational Device Exemption: A regulatory submission to the FDA that allows the use of an unapproved or approved device for a new purpose in a clinical study to determine safety and effectiveness
- QI/PI – Quality Improvement/Performance Improvement

Department Information

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