Health Research and Research Ethics Approval

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Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta

An Academic Partner of Trinity College Dublin

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What is Clinical Research?

- Is a branch of healthcare science that determines the safety and effectiveness (efficacy) of, or investigates outcomes related to medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for the prevention, treatment, diagnosis or for relieving symptoms of a disease.

- Clinical research also involves non-interventional studies involving patients and leads to the generation of new generalisable knowledge of importance to the national and international community – subject to Health Research Regulations.

- Involves a particular person or group of people or uses material or data from humans.

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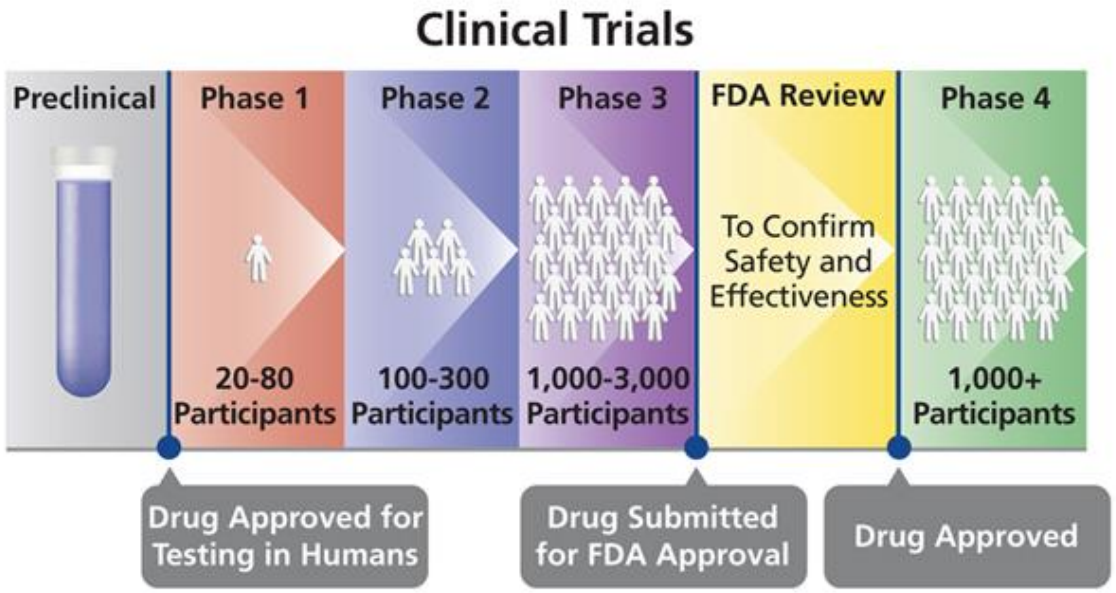
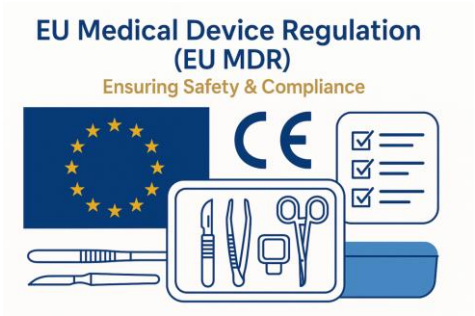
What are the Different Types of Clinical Research?

- **Clinical Trials and Device Trials** - Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational medicinal product(s) (IMP), and/or to identify any adverse reactions to an investigational products(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy





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What are the Different Types of Clinical Research?

- **Clinical Research –**
  - Retrospective Chart Review
  - Observational Research Study
  - Translational Research Study
  - Device Trials (fall outside scope of MDR)
  - Randomised Controlled Trial
  - Pilot Study
  - Feasibility Study
  - Staff or patient surveys
  - Staff or patient interviews or focus groups
  - Case Studies
  - Cohort study

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Why should we do Clinical Research?

- There are many reasons for doing Clinical Research, these include:

1. to explore the cause of a disease or a set of symptoms
2. to test if a treatment will help with a symptom or condition
3. to learn how a certain behaviour affects peoples health
4. satisfaction of answering important questions which will improve the health of our patients
5. status of Researchers
6. skills advancement
7. professional Advancement
8. **IMPROVE PATIENT OUTCOMES**

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The Ethical Principles of Clinical Research

- Clinical research is not just about discovering what works—it's about discovering what works safely, responsibly, and humanely.
- Ethics ensures that research doesn't merely push the boundaries of science but also respects the lives of those who make it possible: the participants.
- Ethics ensures:
    - Participants are protected
    - Maintains public trust in Science
    - Integrity of the data
    - Compliance with legislation and Regulatory bodies

- The Core Principles of Ethics:
    - Respect for Persons: Acknowledging that each participant is an autonomous individual and protecting those who cannot make independent decisions.
    - Beneficence: Maximizing potential benefits while minimizing possible harm. Every action in a trial must prioritize participant welfare.
    - Justice: Fair selection of participants, ensuring no group is exploited and benefits of research are shared equitably.
    - Transparency: Open communication about trial objectives, processes, and outcomes builds credibility and allows participants to make informed choices.

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The Ethical Challenges of Modern Clinical Research

- Medical advancement is based on clinical research, which makes it possible to develop novel cures, treatments, and preventative measures. **Ethical challenges in clinical research**, however, present significant issues alongside offering hope for innovation. The safety, dignity, and rights of participants must always come first.

- These ethical issues have grown increasingly complex in today's environment, where digital technology, international collaboration, and rapidly evolving methodologies are prevalent.

- How do we maintain Ethical Standards:

  1. Informed Consent

  One of the most important tenets of moral clinical research is informed consent. Before consenting to participate, participants must have a thorough understanding of the study's goals, methods, possible risks, and anticipated rewards.

  2. **Protecting Patient Privacy and Data Security**

  Data privacy has become a major concern with the increasing usage of wearable technology, digital health platforms, and electronic records. Strict laws like GDPR and in Ireland the Health Research Regulations must be followed by researchers

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How to Become Involved in Clinical Research

- Discuss with and get support from your hospital research support structure
    - TUH – TUH Research Office
    - SJH – Research and Innovation Office
    - Waterford - South/South West Research Manager
    - Roscommon - Clinical Research and Development Office (Saolta)
    - Connolly - TBC
- Decide how involved you want to be
- Complete all essential training
- Build your knowledge base
- Research the research taking place in your organisation, get involved in this
- Identify the area of interest
- Identify a physical space to conduct your research
- Identify your population
- Build a Research team lean on experienced researchers
- Design you study
- Design the privacy of your study
- Apply for Research Ethics Approval
- Put necessary contracts in place
- Recruit first participant

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“The Others”

Clinical Audit, Service Evaluation, Quality Improvement

Clinical Audit – Clinical audit is the systematic review and evaluation of current practice against **standard(s)** with a view to improving clinical care for service users.

Service evaluation – An internal evaluation of a service provided to a select set of patients for a given period of time in order to identify issues/good practice and implement appropriate changes if necessary.

Quality Improvement Initiative

- Improving quality is about making healthcare safe, effective, patient – centred, timely, efficient and equitable.
- Quality Improvement is the framework we use to systematically improve the ways care is delivered to our patients. Healthcare consists of thousands of interlinked processes that result in a very complex system. Processes are defined, measured, analysed, improvements implemented and then controlled.

Clinical Research	“The Others”
☑ GDPR ☑ HRR ☑ Research Ethics ☑ Consent	☑ GDPR

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Clinical Research and Data Protection

Legislation:

- GDPR
- Health Research Regulations

- GDPR details how personal data of individuals should be protected. Under the new definition of GDPR health data is now included under the definition of personal data.

- Under GDPR health data is considered a special category of personal data

- When designing your study you must select a legal basis for processing both personal data (Article 6) and Special Category of Personal Data (Article 9).
    - Article 6: **Processing necessary for the performance of a task carried out in the public interest**
    - Article 9: **Processing is necessary for the archiving purposes in the public interest, scientific or historical research purposes…**

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Privacy by Design

Planning & Design	Implementation	Data Collection	Analysis & Review	Publishing findings
Data Protection Impact Assessment (DPIA) Select lawful basis from GDPR Data Minimization	Data security / limit access Data sharing agreements Secure Storage Transparency HIQA Information standards	GDPR training for data collectors Pseudonymising the data Proportional processing Good record keeping	Data Quality – requirement under GDPR for data accuracy HIQA Data Quality Standards	Privacy of individuals Aggregated data - no individual identified Small numbers considered

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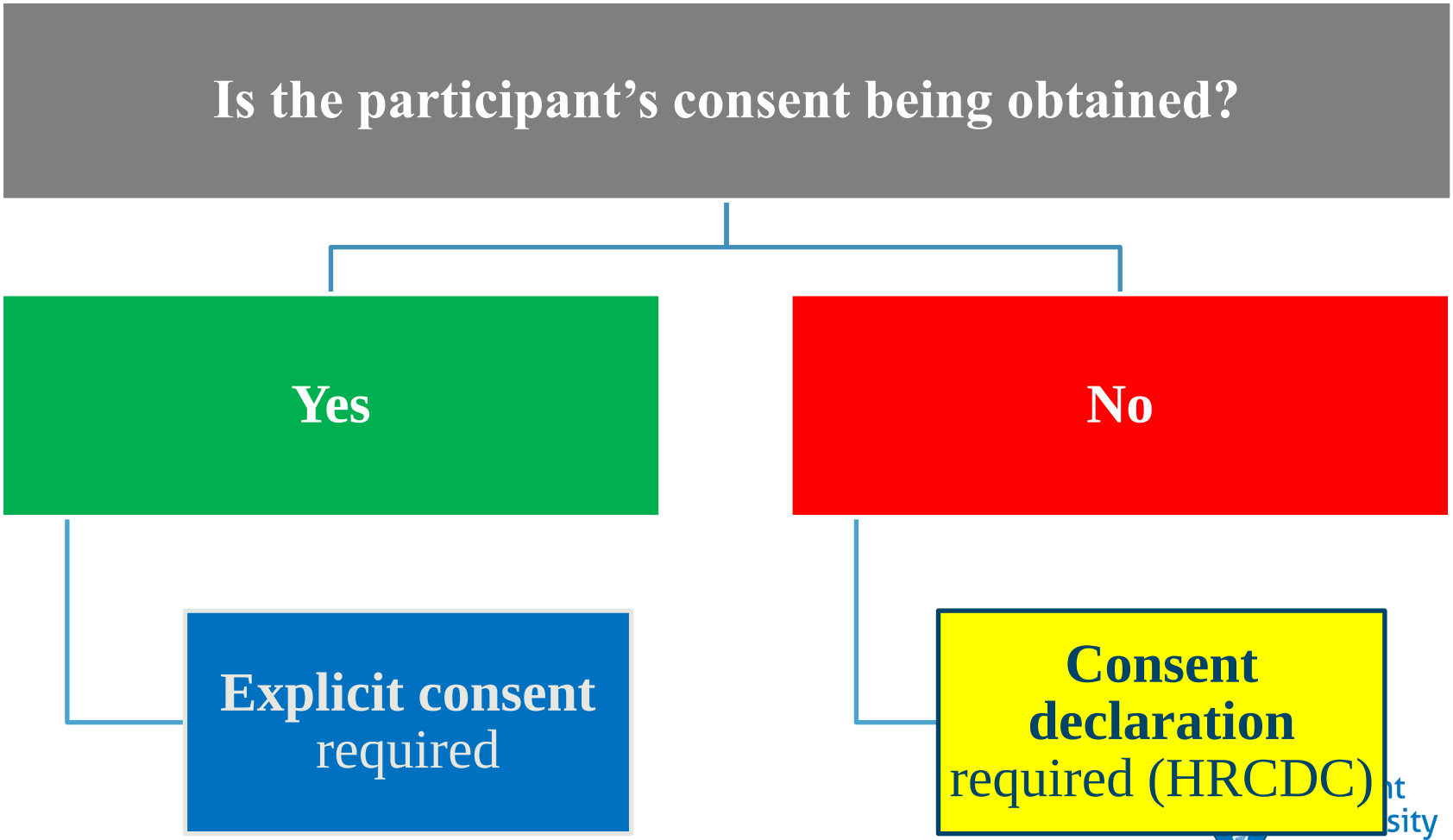
Participant's Lacking Capacity



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Health Research Consent Declaration Committee

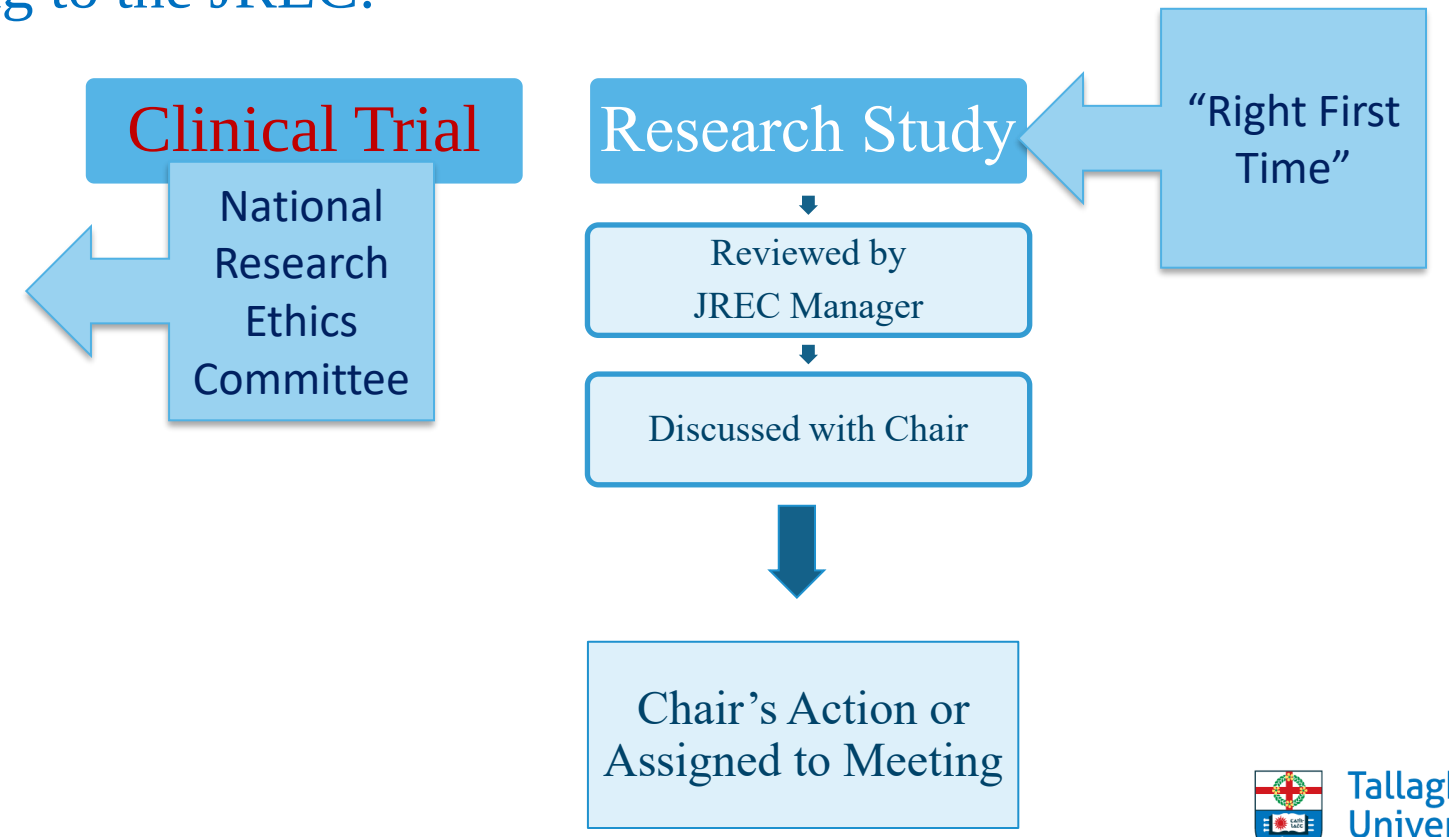
HRCDC
Health Research Consent Declaration Committee

Refer to HRCDC.ie

- National committee formed to assess situations where consent not being sought.
- Research Ethics Committee (REC) cannot issue consent ‘waivers’ .
- Must apply to the Health Research Consent Declaration Committee:
  - Single national committee
  - Separate to the REC application (may follow request by the REC/provisional approval)
- Must demonstrate, for example, that the public interest of the research significantly outweighs the public interest in requiring the explicit consent of the individual.

SJH/TUH Joint Research Ethics Committee

Applying to the JREC:



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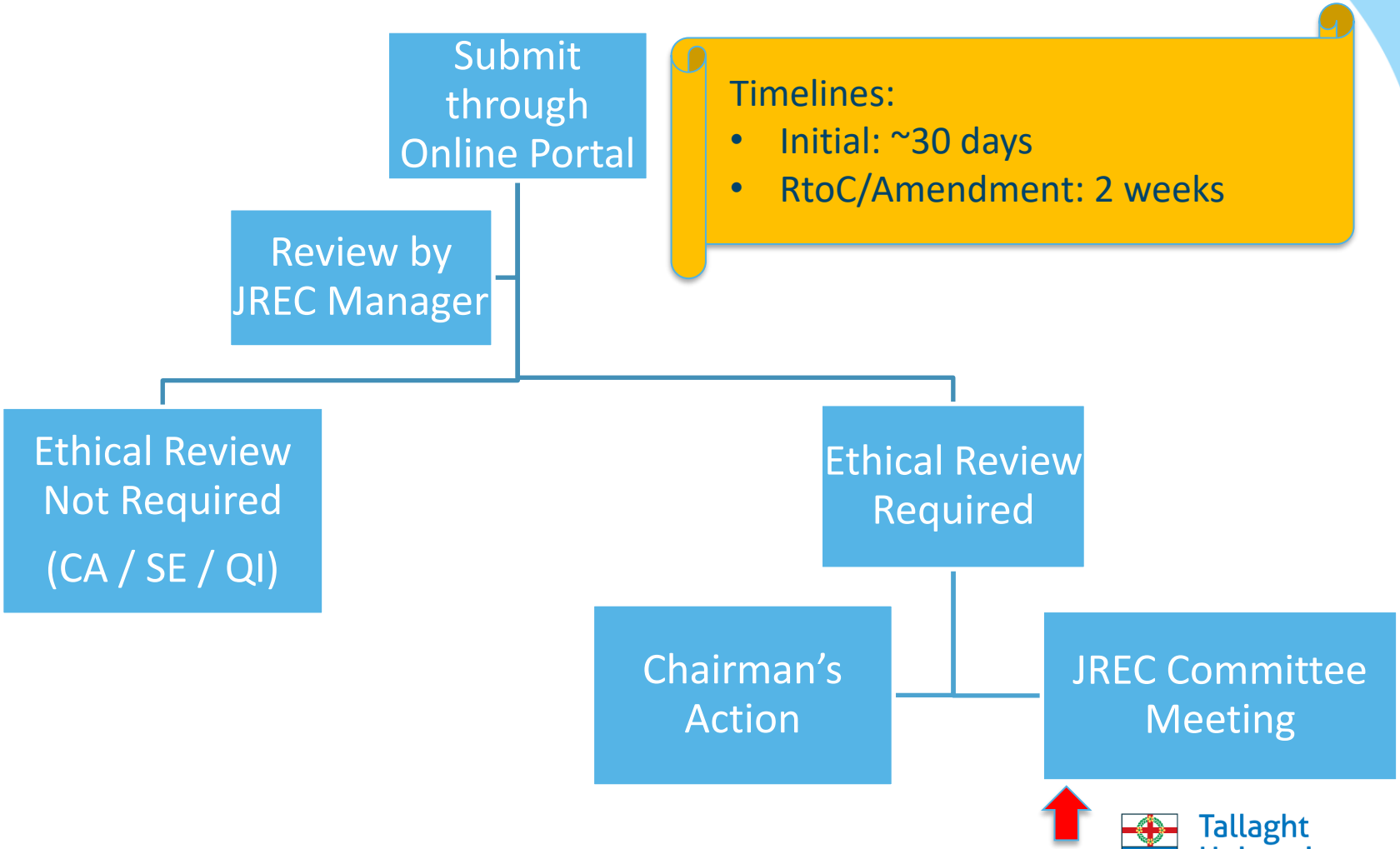
The Review/Approval Process



If there is a risk to patients or their data, or an application is being made to the HRCDC, a full committee review will be required.

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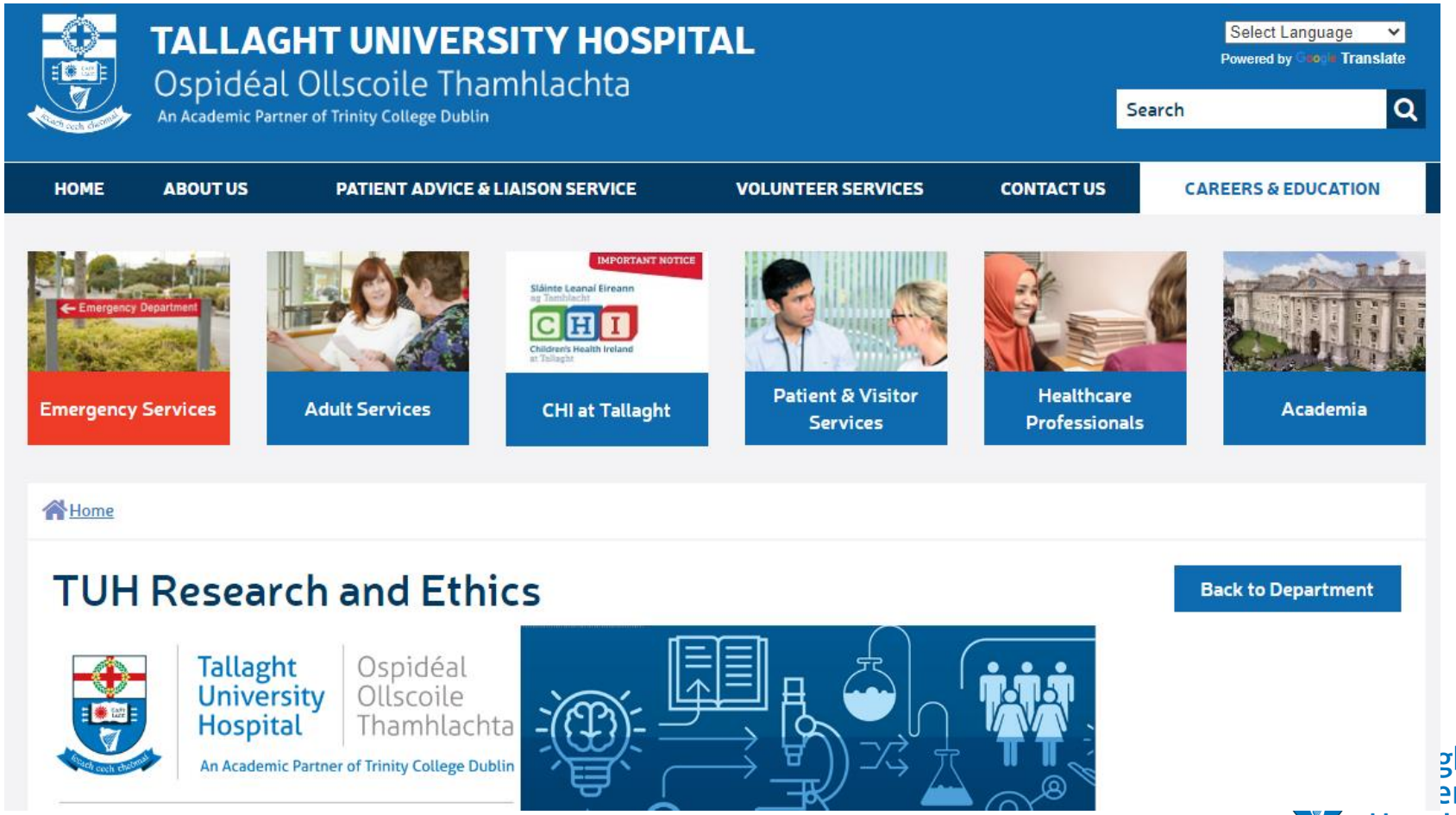
TUH Research Department - Website



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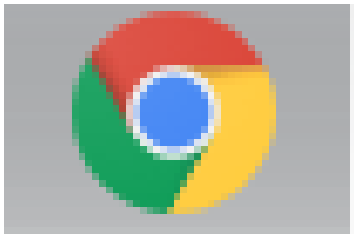
Research Ethics Application Submission Portal

Please only use Chrome to access the portal.



Research Ethics Applications Help Log in

Please read the following before proceeding:

Please only use the browser **Chrome** when using this review portal.

The system has the following functions:

1. Research Ethics review:
   - For new studies: select "Research-Main Application Form".
   - For previously reviewed studies: select "Research-Previously Reviewed Study-Research Registration Form".
   - Register the study and you will be able to submit an amendment or report.
2. Registration of research taking place in TUH:
   - For new studies: select "Research-Main Application Form".
   - For previously reviewed studies: select "Research-Previously Reviewed Study-Research Registration Form".
3. Clinical Audit/Service Evaluation/Quality Improvement Initiative:
   - Letter requests: select "Non-research: Clinical Audit/Service Evaluation/Quality Improvement Initiative registration"

Please use the login button to the right (top of page) when you are ready to proceed.

Select 'Create Project' to begin your application.

Thank You

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