UFHealth
PROTON THERAPY INSTITUTE

Research Department Overview

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Why Research?

- Research is important in all medical fields. It assists with the progress of treatment.
- It is especially vital for proton radiation since it is an **emerging technology** that is currently used in **limited supply**.
- Proton was FDA-approved in 1988
- It is our responsibility to create a strong research program to help further advances in the treatment of cancer.

What is a Protocol?

A protocol is the **plan** used to conduct the trial and answer a research question. It describes:

- Who may participate in the study
- What tests/procedures will be used and when
- The treatment or intervention involved
- The length of the study
- How many people will need to participate
- What the investigator hopes to learn from the study

What is an Investigator?

- **Principal Investigator** (PI): Takes direct responsibility for the study:
  - oversight of compliance, financial, and ethical considerations
  - management and integrity of the design, conduct, data collection, analysis, and interpretation and reporting of results
  - ensuring that all research team members have appropriate education, training, and qualifications
  - assure research is conducted in accordance with state and federal regulations and University and sponsoring agency's policies and procedures
  - ensuring informed consent is appropriately obtained from each participant and for appropriately maintaining study records

Types of Research at UFHPTI

- Outcomes Projects
  - Determine associations between specific interventions and outcomes
  - Patient treated per the standard of care/physician discretion
  - Includes surveys, case studies, chart reviews, registries, focus groups
  - Usually retrospective for medical record

Types of Research at UFHPTI

- Clinical Trials
  - Designed to answer a specific question
  - An intervention or modification in treatment
  - Patient treated per the protocol

Types of Clinical Trials at UFHPTI

- Investigator-initiated
  - UFHPTI physician writes the protocol and can modify as needed (with approval from IRB ethics committee)
  - Usually single institution but can be multi-site
  - UFHPTI is the primary sponsor; can obtain external funding if needed
  - E.g., PR07, PC04, LU03

Types of Clinical Trials at UFHPTI

- Collaborative
  - UFHPTI participates in trial but is not the sponsor
  - Multi-institutional
  - Protocol cannot be locally modified
  - E.g., Collaborations with St. Jude, Mass General, U Penn

Types of Clinical Trials at UFHPTI

- Cooperative Group
  - National/international, federally funded
  - Multi-institutional
  - Protocol cannot be locally modified
  - E.g., Children's Oncology Group (COG), Proton Collaborative Group (PCG), Radiation Therapy Oncology Group (RTOG)

What disease types do we treat via protocols?

- Clinical trials currently open to enrollment
  - Cancers of the prostate, breast, lung, pancreas

What disease types do we treat via protocols?

- Outcomes Projects
  - Cancers of the head and neck, breast, pancreas, prostate, brain/spine, lung, lymphoma, sarcoma, and dosimetry reviews

Outcomes Tracking Project (OTP)

- OTP is a registry offered to every eligible patient at UFHPTI and UF Health. Patients who consent to participate in this protocol agree to allow the investigator to collect/consolidate information from them and their medical records regarding their disease, treatment, side effects, etc. to see what effects the radiation has on them and their disease.
- Additionally, some patients will be asked to bank tumor tissue and/or blood for future research.
- They will never identify you in any way.

How many patients do we currently have enrolled on protocols at UFHPTI?

- Clinical Trials: 1,353 patients
- Outcomes Studies:
  - Prospective: 1,720
  - Retrospective OTP Registry: 8,821

  - As of 5/12/17

Financial Considerations

Insurance and Research

- Some insurance companies will *not* pay for services under a clinical trial; other insurance companies will *only* pay for proton radiation if patient is on a clinical trial
- Our billing department will obtain insurance clearance for you prior to beginning treatment

Financial Considerations

- Most items in a protocol are standard and are billed to insurance.
- If the sponsor is going to pay for anything, this will be very clearly stated in the consent form.

Clinical Research Coordinator

- Specialized research professional
- Supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study.
- Works with the PI, sponsor, and institution to provide guidance on the administration of the compliance, financial, personnel and other related aspects of the study.
- Can be RNs, or have bachelor's or master's degrees

Specifically….

- Protocol development, consent writing
- Staff credentialing and training
- Monitoring and compliance
- Regulations: FDA, ICH GCP, UF
- Committee approvals: IRB, RAC, SRMC, HURRC
- Invoices, payments, billing modifiers
- Advertising, websites
- ClinicalTrials.gov registration and results

Research Staff at UFHPTI

- Amanda- Research Director- Certified
- Chris- Biostatistician
- Robin- Lead Research Coordinator- Certified
- Ashley- Research Coordinator- Certified
- Jackie- Research Coordinator/Database Developer- Certified
- David- Research Coordinator- Certified
- Sam- Research Coordinator
- Linda- Research Coordinator
- Cathi- Research Coordinator
- Valerie- Research Monitor- Certified
- Brittany and Piper- Research Assistants

FAQs from patients

- Q: If I am in a research study, is my treatment free?
- A: Most likely not. The items that are usually provided for free, if any, are those items that are not standard of care *and* are not covered by Medicare et al. If anything in the study is provided, this will be clearly stated in the consent form.

FAQs from patients

- Q: What does UFPTI do with the research information/data?
- A: Physicians will develop retrospective outcomes studies. Working with the biostatistician, they will analyze the results and publish the de-identified data.
- floridaproton.org/about-us/research-portfolio
- floridaproton.org/about-us/physicians-staff (publications available through PubMed)

FAQs from patients

- Q: You have been open for 10 years, why do you not have 10 year data?
- A: Once a physician writes a clinical trial, it takes 4-6 months to obtain all needed approvals. Then it can take 2-4 years to accrue all of the patients needed to answer the research question. For example, if we want to look at what is going on with the patient at 2 years follow-up…….

FAQs continued

- …….then we have to wait until the last patient enrolled has hit that 2 year follow-up mark. Once that happens, data is collected, analyzed and submitted for publication. This latter process can take another 1-2 years as well.

FAQs from patients

Q: Why do insurance companies say that proton is experimental?

A: Great question…..

- Proton used in physics research in Berkeley since 1954 and Sweden since 1957
- Harvard treats first patient in 1961
- *Proton approved by FDA in 1988
- Clatterbridge, UK started treated eye patients in 1989
- Loma Linda, Calif started treating in 1990
- Mass General started treating in 2001
- UFHPTI started in 2006