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