Navigating the Research Process at Carilion

Andrea Bidanset, MHA, CCRP, Director
Clinical Trials Office

CARILION CLINIC

Objectives:

- Participants will have clear understanding of research process at Carilion Clinic
- Participants will be aware of the resources available to support their research endeavors
- Participants will be aware of the different entities at Carilion that are responsible for research oversight

Agenda:

- Navigating the approval process
  - Research and Development
  - *Research Compliance: Conflict of Interest*
  - Institutional Review Board
- Research oversight at Carilion
- SOPs governing clinical research

Introduction:

- Carilion Clinic is an Academic Medical Center with over 400 active, human subjects research studies

- As we continue to grow our research footprint, our goal is to educate our current and future researchers to ensure that their research endeavors are successful

Research Approval Process at Carilion:

- Research projects at Carilion require specific approvals before project initiation
  - Research and Development (R&D)
  - *Research Compliance: Conflict of Interest (COI)*
  - Institutional Review Board (IRB)

- Additionally, research training is required by R&D, Organizational Integrity and Compliance (OIC), and the IRB (CITI Modules)

Required Training

- Human subjects research requires CITI training (www.citiprogram.org)
  - Basic Biomedical and Good Clinical Practice module
  - *GCP is required for FDA regulated research and NIH funded research*
  - *Conflict of Interest for externally supported projects*

- R&D Research Training
  - Essentials of Grant Proposal Development for grant-funded study teams
  - Essentials of Research Administration for all funded study teams
  - Individual research training is available by request from R&D representatives
    - Contact research@carilionclinic.org to request training.
  - Optional modules include: Clinical Trial Billing Compliance and Clinical Research Coordination

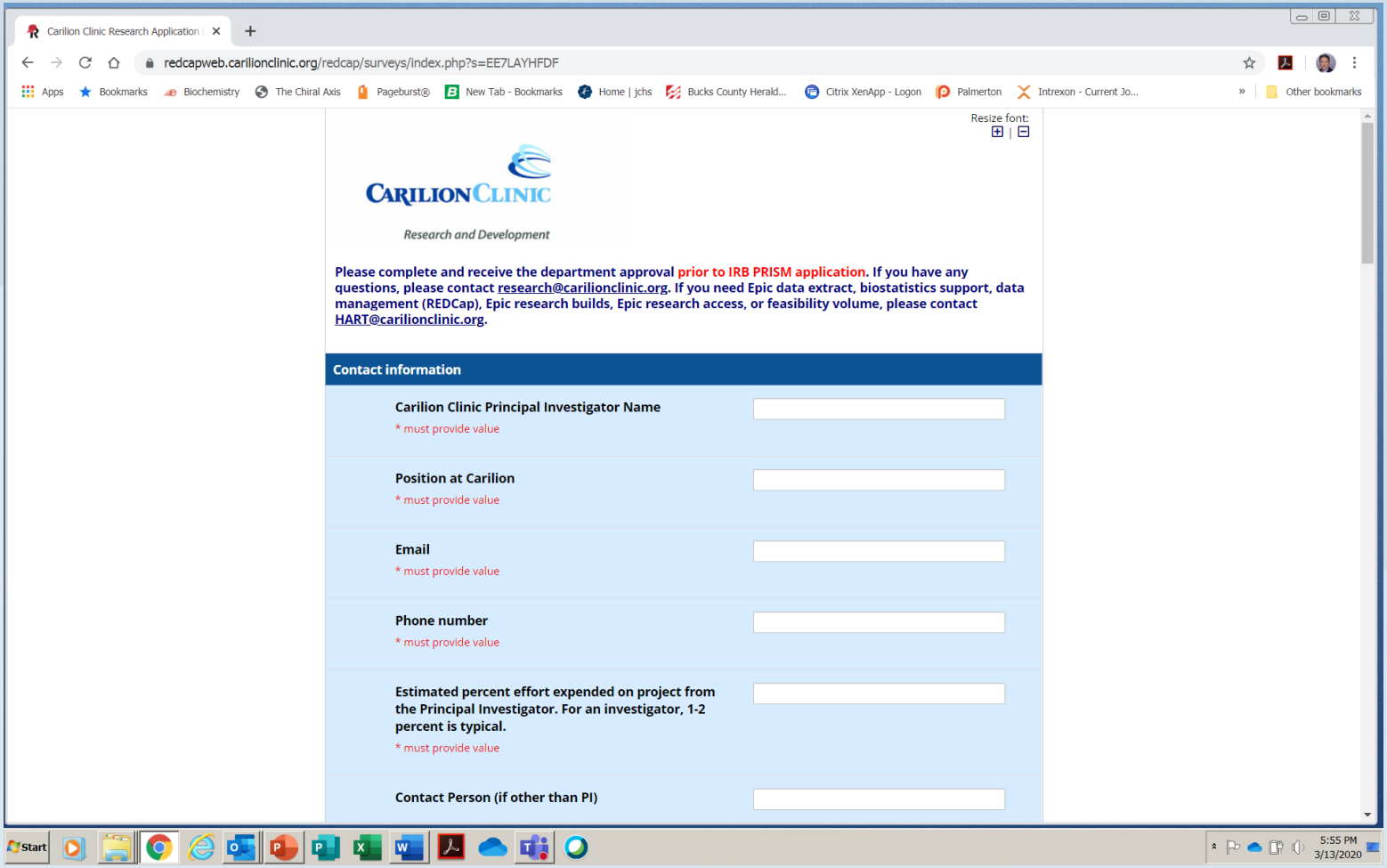
R&D Application

- When seeking approval for a new research project, the first step is to complete the Research and Development application. This is also known as the “Department Level Review” and requires a signature from the investigator’s department chair/leader.

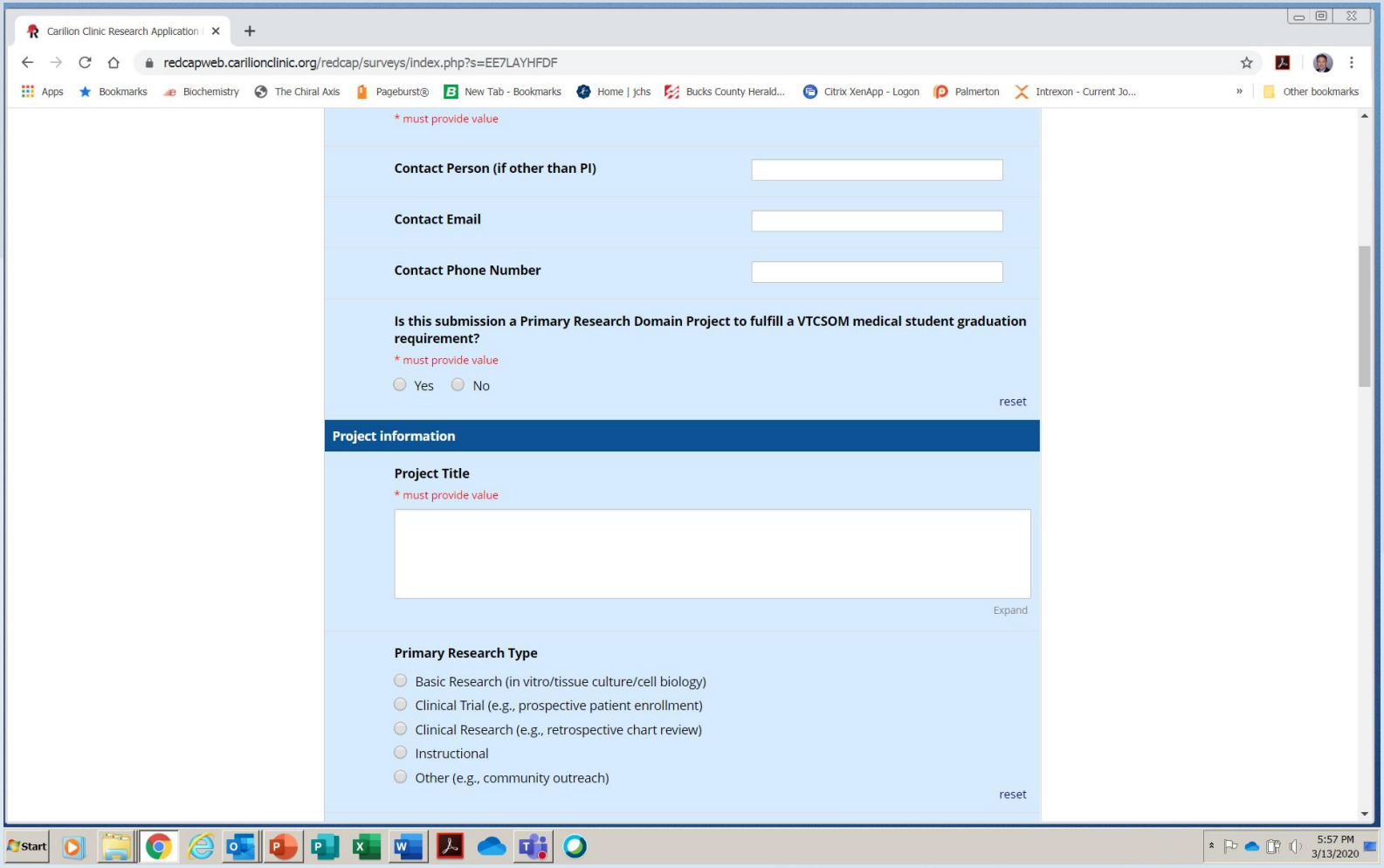
- **This application is available online at:**
  - https://is.gd/Research_Application
  - REDCap enabled application
  - 10-15 minutes to complete
  - eSignature
  - Automatic Routing for Approvals

- The R&D application provides department level approval for study personnel assignments and also serves as a trigger point for R&D to schedule a feasibility review meeting and begin contracting/budgeting, if needed.

R&D Application Step by Step



R&D Application Step by Step



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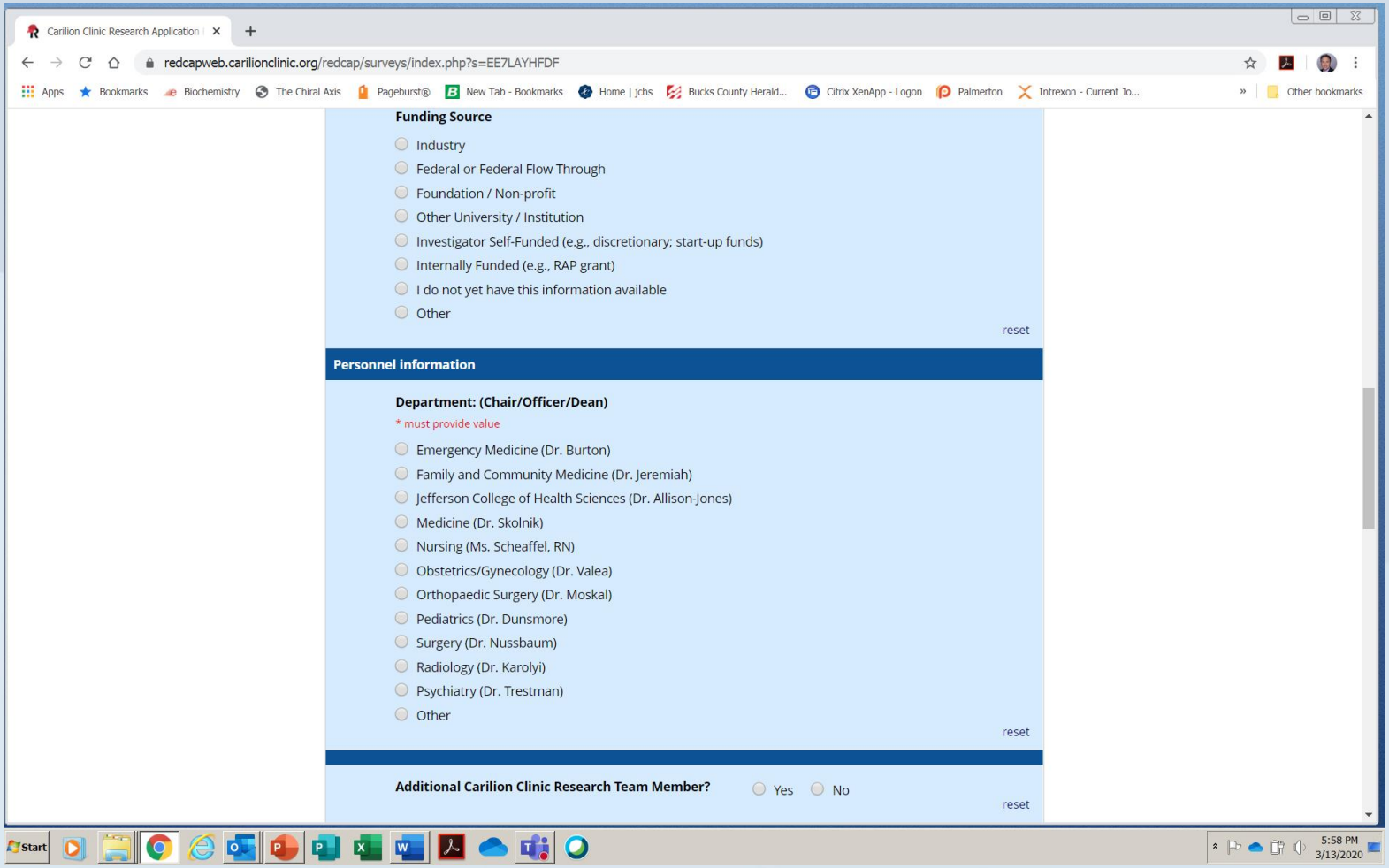

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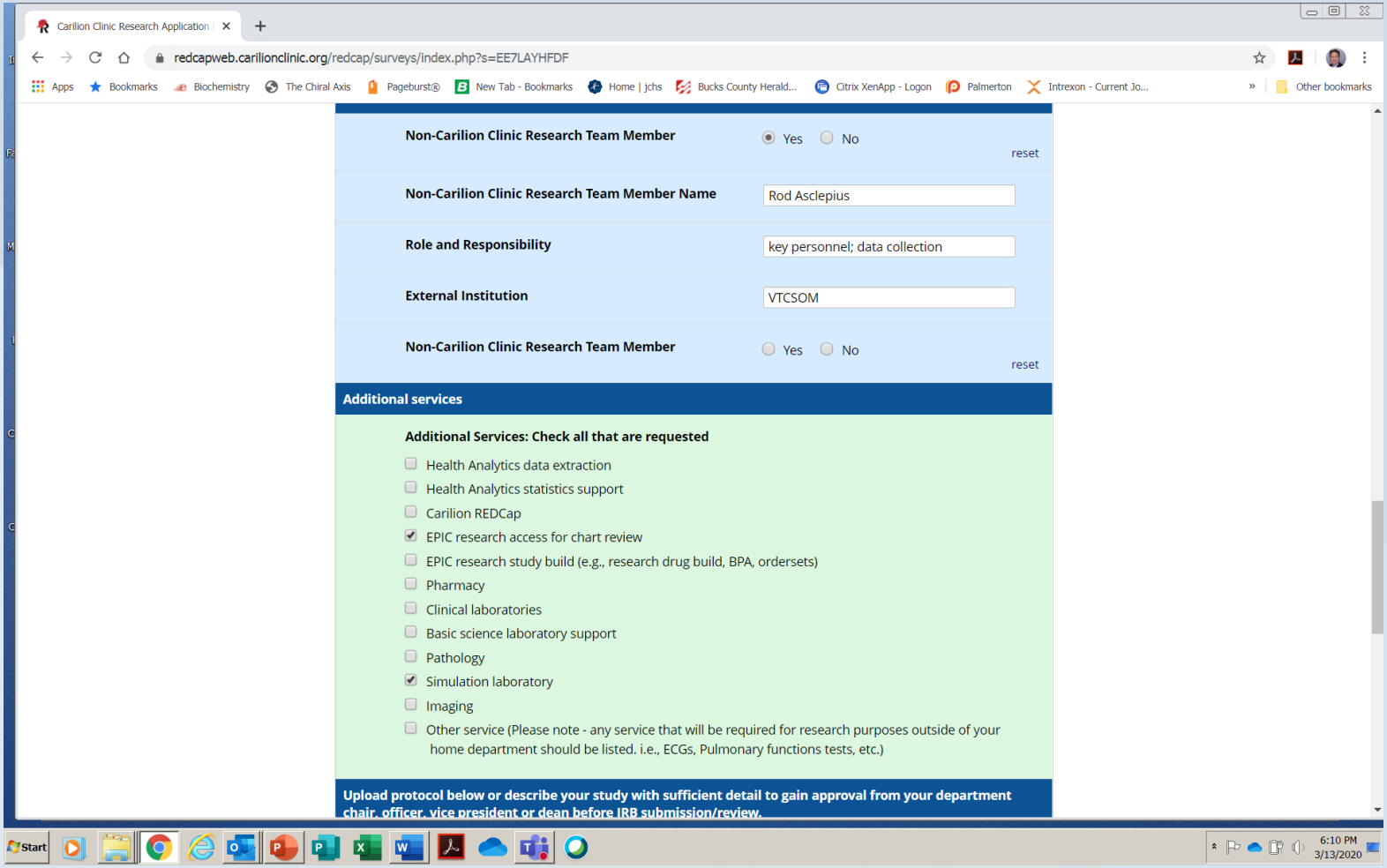

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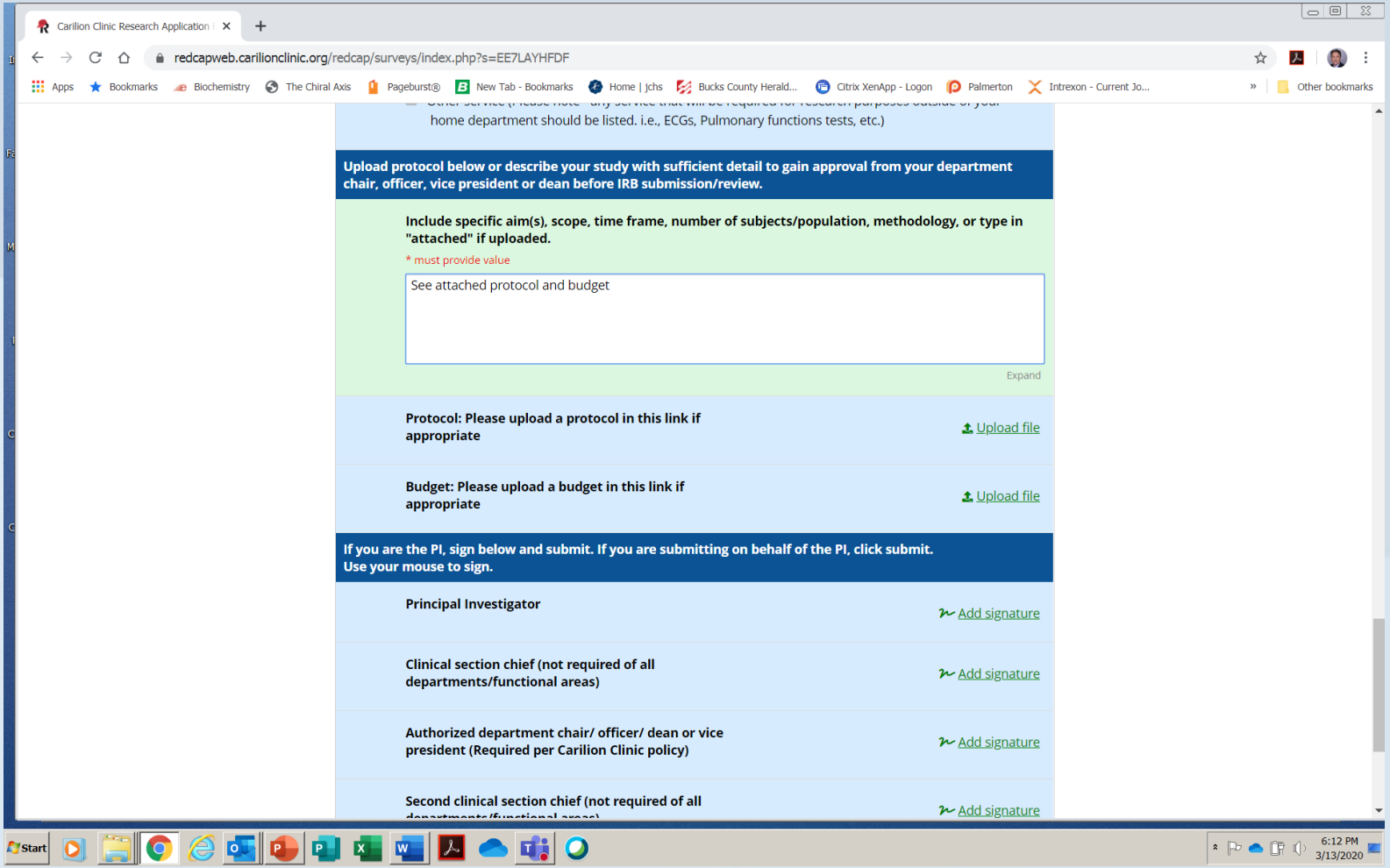

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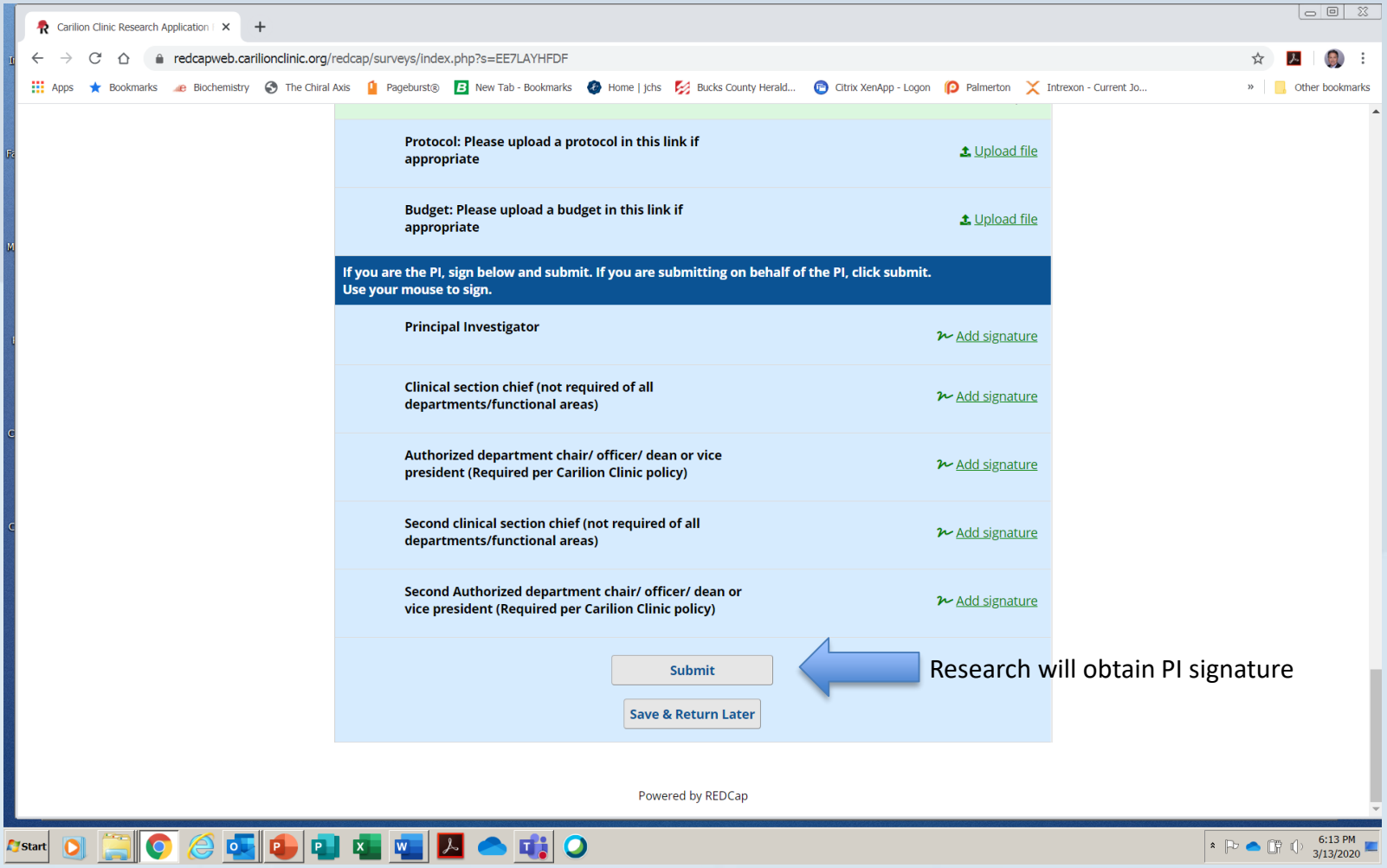

R&D Approval

- R&D will provide feedback within 5 business days for studies that require revisions
- Industry funded studies are reviewed by Director of Clinical Trials
- Grant funded studies are reviewed by Grants Administrator
- Once study is deemed satisfactory by R&D, Director of Clinical Trials, Grants Administrator, or Senior Director of R&D provides approval letter.
- **The IRB will not approve a project without R&D letter of approval. This should be uploaded to your IRB application prior to submission.**

Conflict of Interest (COI)

- Non-externally supported studies do not require COI disclosure or training
  - Studies with a Carilion Clinic Physician utilizing internal research funds do not require a COI disclosure
  - If VTCSOM student research funds are the only external support, please note in applications but select "N/A" for completing COI process

- Externally supported studies require COI disclosure and training
  - Research COIs should be disclosed in your annual COI disclosure to Carilion.
  - For investigators and study team members with a conflict, OIC will work with you to create a management plan. If a plan cannot be created, the study may not be able to be completed.
  - The CITI Program COI training should be completed initially and then renewed every 4 years or if the COI process changes significantly
  - Contact Carilion OIC's Research Compliance for further assistance (researchcompliance@carilionclinic.org)

- **RECENT CHANGE to COI Process**
  - Only Carilion Clinic personnel and affiliates must complete the CC COI process
  - Transactional questionnaires are no longer required for individual protocols
  - All Research COIs should be disclosed on annual COI disclosure. If new potential conflicts arise, annual COI must be updated within 30 days to reflect changes
  - OIC will review annual disclosures and CITI COI training at the time of IRB submission to verify completion; however, COI disclosure and training can occur earlier in the research application process.
  - Updated CITI COI training will be available soon! Details to come

- **The IRB will not approve an externally supported study without COI clearance.**

IRB Approval

- Following R&D approval and COI clearance (externally supported studies only), the study team can submit to the IRB for the final step in the approval process.
- Carilion Clinic's IRB reviews all human subjects research and can provide QA/QI determinations for projects that do not meet criteria for HSR.
- Industry-funded clinical trials are reviewed by Carilion Clinic IRB for personnel and local safety issues but rely on Western IRB as the IRB of record.
- Other commercial IRBs may be considered for industry-sponsored trials on a per-project basis.

IRB Approval, Continued

- The Carilion Clinic IRB uses an online review system PRI3SM
  - https://carilionclinic.imedris.net
- The IRB will review your submission and provide feedback
- The study may meet criteria for expedited review and can be reviewed without convening the IRB full board review committee
- If the study meets criteria for full board review, it will be brought before the IRB review committee for discussion with the investigator and study team
  - Please visit the IRB's website for additional details regarding exempt, expedited, and full board criteria
  - https://www.carilionclinic.org/irb
- Once the review is completed and the application is determined to be acceptable, approval will be granted
- **Any changes to your study protocol, personnel, or study materials, such as the Informed Consent Form, require additional approval from the IRB!**

What is the difference between IRB approval and R&D approval? Why are both necessary?

- The IRB is responsible for protecting the rights and welfare of human subjects research participants.

- R&D is responsible for operational aspects of research such as billing compliance, contracting/budgeting, feasibility analysis, and personnel assignments.

In Summary

- IRB approves studies if they are safe and ethical.

- R&D approves studies if they are feasible for the organization and processes the necessary agreements for you to proceed
  - Ex) Research Collaborative Agreements, CTAs, CDAs, DUAs, MTAs, etc.

Which studies require a feasibility meeting?

- Any study that prospectively enrolls patients and involves an intervention.
  - I.e., a drug, device, or research procedure is being studied

- Survey studies, observational studies, and retrospective studies **do not** require feasibility meetings.

What is discussed at a feasibility meeting and why is that important?

- Approval from ancillary departments
- *Coverage analysis*
- *Budget development and review*
- *Contract review*
- Logistical flow of study schedule of events
- Appropriate patient population – TriNetX
- Any glaring issues that would keep you from being successful?

Grant Startup Process

- Please notify R&D as soon as you plan on submitting an extramural application.
- Grant Administrator works with study team to prepare budget, gather documentation (such as biosketches, institutional forms, etc), and determine requirements for submission.
- If external collaborators (sub-investigators) are involved, letter of commitment must be received to confirm participation.
- R&D Application must be completed and approved by Dept Chair prior to submitting application package

Grant Startup Process, Cont.

- Grants that involve prospective patient enrollment with research intervention will require feasibility meetings prior to submission.
- Depending on grant type, IRB approval also may be required for interventional studies prior to submission/award.
- If grant is awarded, the agreement/contract will be negotiated and study will be submitted to IRB, if not already done in pre-award.

Grant Submission Deadlines

- The PI/PD must submit the budget and budget justification for review and approval no later than **10 business days** prior to the sponsor submission deadline.
- All collaborative/subaward materials (letters of commitment, budget and budget justification, biosketches, statement of work, etc.) must be received at least **5 business days** prior to the sponsor submission deadline.
- With at least **3 business days** lead time prior to the sponsor submission deadline, R&D will perform a complete final proposal review.
- R&D will submit with no less than **1 business day** prior to the application deadline.

Contracts

- Carilion Clinic does not permit investigators to sign contracts on behalf of the organization.

- All contracts must be reviewed centrally by R&D and signed by our institutional official (Dr. Daniel Harrington)

Resources for Research

- Central Clinical Research Coordinator support
- Central budgeting for grants and clinical trials
- Central regulatory management for industry-funded clinical trials
- Central post-award financial management for grants and industry-funded clinical trials
- Central contracting – CDAs, CTAs, Grant Agreements, Non-funded agreements (DUAs, MTAs, RCAs, etc)
- Assistance with project development and protocol development
- Feasibility review

Research Oversight at Carilion

- R&D
- Organizational Integrity and Compliance (OIC)
- IRB

- R&D, OIC, and the IRB are all responsible for research oversight at Carilion.
  - Each of these departments can conduct quality reviews and/or study audits to ensure that researchers are following organizational policies/SOPs and federal regulations.
  - Additional education will be provided as needed to study teams.
  - When in doubt, reach out to these departments for guidance. It is better to ask questions than to make assumptions that can lead to mistakes.

Clinical Research SOPs

- Standard Operating Procedures provide specific guidance to our investigators for conducting clinical research at Carilion Clinic.
- Standardized procedures increase compliance, reduce errors, and allow new investigators to learn the proper way to conduct clinical research.
- Our SOPs are based on federal regulations, FDA guidance, and local best practices.
- https://www.insidecarilion.org/system/files/2018-11/Clinical%20Trial%20SOPs_2018.pdf

Questions

research@carilionclinic.org

albidanset@carilionclinic.org

fxfarrell@carilionclinic.org

mlrothrock@carilionclinic.org

vlhollen@carilionclinic.org

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