Continuing Review Process

IRB Board Member Training
June 2018

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

When conducting CR, the IRB should:

- Start with the *working presumption* that the research, as previously approved, satisfies all of the above criteria.
- *Focus on new information* provided by the investigator, or otherwise available that would change the risk: benefit ratio or require a revision of the protocol and/or the informed consent document.

When conducting CR, the IRB should:

- Evaluate if the research continues to satisfy the criteria for IRB approval of research
- Pay particular attention to the following 4 aspects:
  - **Risk assessment and monitoring;**
  - **Adequacy of informed consent process;**
  - **Investigator and institutional issues; and**
  - **Research progress.* http://www.hhs.gov/ohrp/policy/continuingreview2010.html#section-b1)**

When conducting CR, the IRB should:

- Disapprove or require modifications in (to secure re-approval of) a research activity that does not meet the regulatory requirements.

OHRE Guidance: Primary Presenter's Summary

- Highlight any critical issues for consideration
- Identify any key changes being proposed
- Include recommendations for IRB action
- Typically, note the following:
  - No issues of concern since the prior IRB review
  - No changes are being proposed by the investigator,
  - Adverse events are of the type and frequency expected,
  - The research appears to satisfy all criteria required for approval under 45 CFR 46.111 (also, subparts B, C, and D),
  - Recommends approval without any stipulated changes.
  - Include the new approval period.

What's Changed in the Past Year?

Submissions for 16-2164

	Submission Type	Reference ID	Approval State	Date Routing Complete	Action Date	Expiration Date	Review Type
>>	Renewal (w/ Modification)	215122	Submitted	05/17/2018			Full Board

Submission Information Submission Status: Accepted for Review Reference ID: 215122

IRB: Biomedical Office Staff: Sonya H Bateman

Accepted By IRB: 05/18/2018 IRB Analyst: Cat Collins Assign Me Options

Submission Notes: by Kathy Seabolt on 05/18/2018 at 08:42 AM IRB Chair: Weber, David J.

Submission Reviews

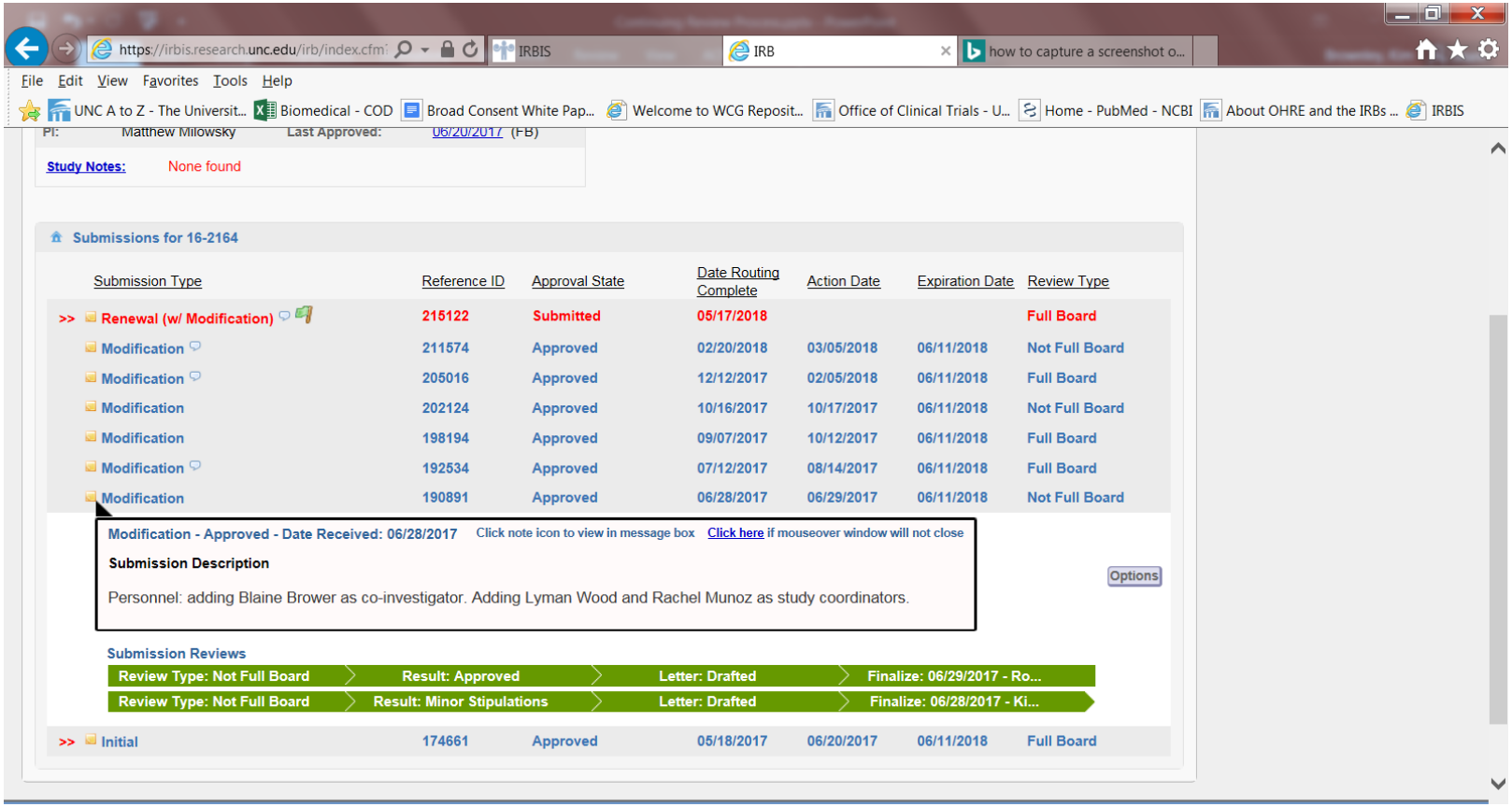
Review Type: Full Board | Result: TBD | Letter: TBD | Finalize: TBD

Navigate To : Application / Library Stipulations (0) Next Step : Record Result

	Modification	211574	Approved	02/20/2018	03/05/2018	06/11/2018	Not Full Board
	Modification	205016	Approved	12/12/2017	02/05/2018	06/11/2018	Full Board
	Modification	202124	Approved	10/16/2017	10/17/2017	06/11/2018	Not Full Board
	Modification	198194	Approved	09/07/2017	10/12/2017	06/11/2018	Full Board
	Modification	192534	Approved	07/12/2017	08/14/2017	06/11/2018	Full Board
	Modification	190891	Approved	06/28/2017	06/29/2017	06/11/2018	Not Full Board
>>	Initial	174661	Approved	05/18/2017	06/20/2017	06/11/2018	Full Board

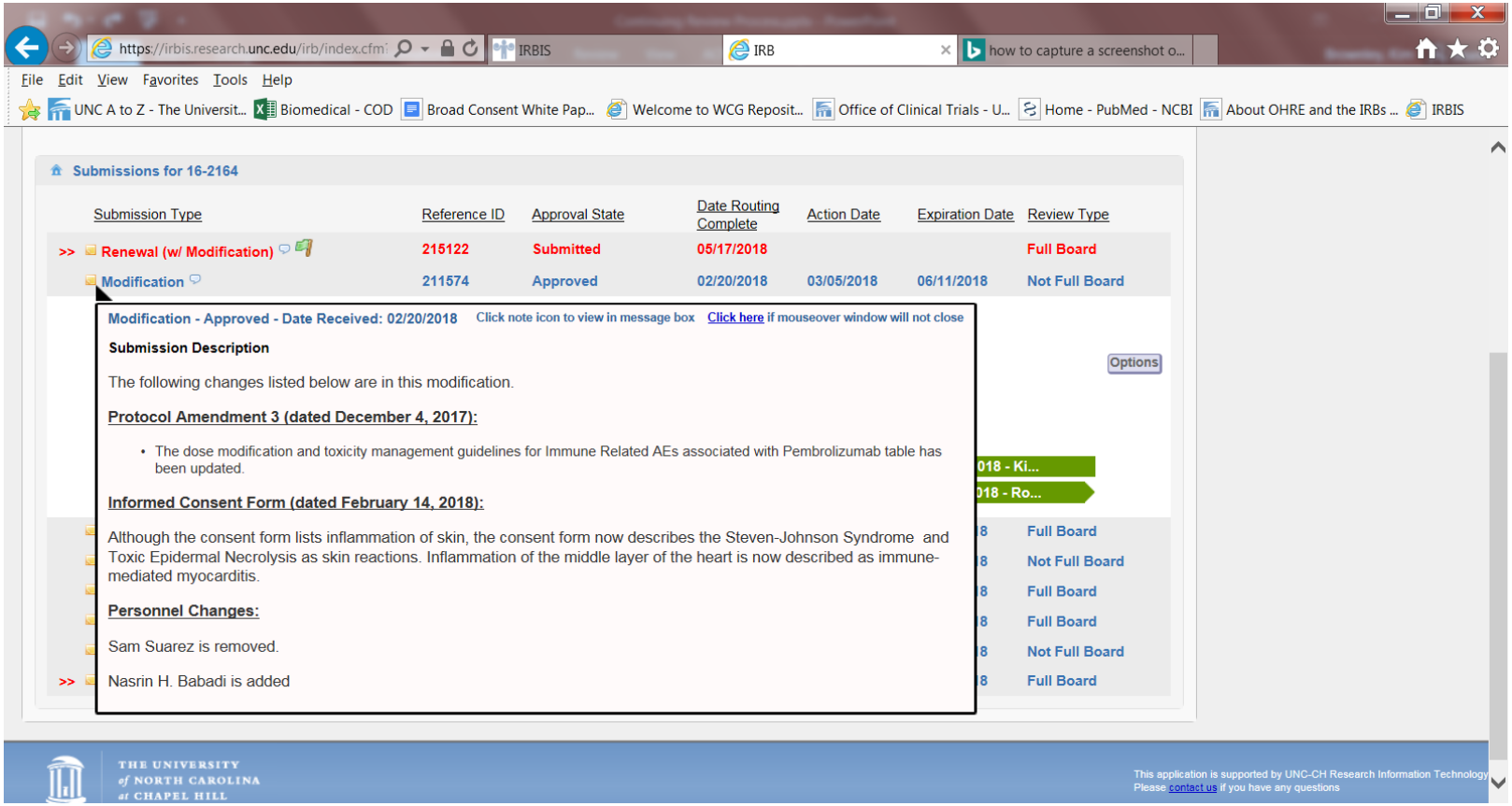
What's Changed in the Past Year?

i.e., personnel changes



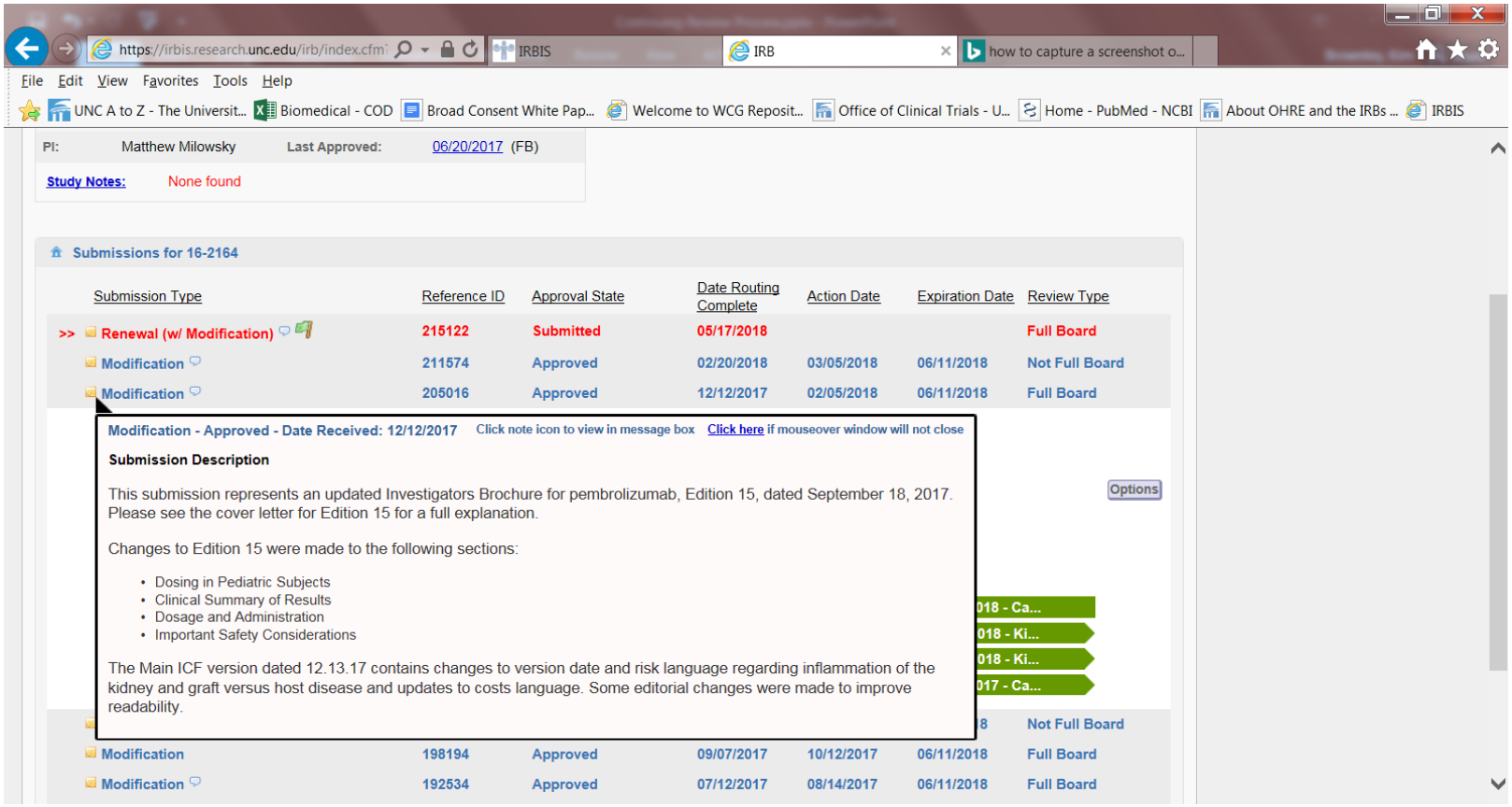
What's Changed in the Past Year?

i.e., "minor" ICD & protocol changes



What's Changed in the Past Year?

i.e., "major" ICD & protocol changes



What's Changed in the Past Year?

i.e., Outstanding or Resolved NSI

Submissions for 16-2412

	Submission Type	Reference ID	Approval State	Date Routing Complete	Action Date	Expiration Date	Review Type
>>	Renewal (w/ Modification)	217635	Submitted	05/15/2018			Full Board

Submission Information — Submission Status: Accepted for Review — Reference ID: 217635

IRB: Biomedical — Office Staff: Flora F Davidson

Accepted By IRB: 05/15/2018 — IRB Analyst: Cat Collins — Assign Me — Options

Submission Notes: None found — IRB Chair: Weber, David J.

Submission Reviews

Review Type: Full Board | Result: TBD | Letter: TBD | Finalize: TBD

Navigate To : Application / Library Stipulations (1) Next Step : Record Result

	Modification	217440	Approved	05/10/2018	05/14/2018	06/11/2018	Not Full Board
	Modification	215457	Approved	04/19/2018	04/24/2018	06/11/2018	Not Full Board
	Modification	214093	Approved	03/26/2018	04/11/2018	06/11/2018	Not Full Board
	Modification	209015	Approved	01/30/2018	02/19/2018	06/11/2018	Full Board
	Modification	202577	Approved	11/01/2017	11/20/2017	06/11/2018	Full Board
	Modification	194185	Approved	09/20/2017	09/29/2017	06/11/2018	Not Full Board
	New Safety Information (R)	8610	Noted	06/22/2017	08/28/2017		Full Board
	New Safety Information (NR)	8607	Noted	06/22/2017	08/28/2017		Full Board
>>	Initial	176029	Approved	04/11/2017	06/14/2017	06/11/2018	Full Board

At the Meeting: Brief Oral Overview

- Short description of study design, study objectives & progress of the study—is it going as planned?
- Identification of subjects & enrollment numbers
- Any changes to study design over the past year
- Is an amendment included with the renewal?
- Recommend stipulations, acceptance of IB changes, ICF changes, re-consenting of subjects if applicable, etc.
- Make the final motion, including period of approval based on level of risk.

Sample Oral Report

Sample Oral Report

Study title & IRB#:

Primary Objective:

Procedures:

Cohort, Numbers:

IND/IDE #:

Continuing Renewal Report:

 # Subjects Enrolled in the past year/within the total approved by the IRB initially:

 # Subjects Completed the study in the past year:

 # Subjects withdrawn from the study & why:

Summary of Unanticipated Events reported in the past year:

Summary of any Amendment included with renewal:

Where any complaints received about the study?

New information, published or unpublished, about study topic:

Recommendation:

Questions???