

Continuing Review Process



IRB Board Member Training
June 2018



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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.



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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: Office Staff: [Sonya H Bateman](#)

Accepted By IRB: 05/18/2018 IRB Analyst:

[Submission Notes:](#) by Kathy Seabolt on 05/18/2018 at 08:42 AM IRB Chair:

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

PI: Matthew Milowsky Last Approved: 05/29/2017 (FB)

Study Notes: None found

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
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

Modification - Approved - Date Received: 06/28/2017 Click note icon to view in message box [Click here](#) if mouseover window will not close

Submission Description

Personnel: adding Blaine Brower as co-investigator. Adding Lyman Wood and Rachel Munoz as study coordinators.

Submission Reviews

- Review Type: Not Full Board > Result: Approved > Letter: Drafted > Finalize: 06/29/2017 - Ro...
- Review Type: Not Full Board > Result: Minor Stipulations > Letter: Drafted > Finalize: 06/28/2017 - Ki...

>> Initial 174661 Approved 05/18/2017 06/20/2017 06/11/2018 Full Board



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What's Changed in the Past Year?

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

The screenshot shows the IRBIS web application interface. The browser address bar displays <https://irbis.research.unc.edu/irb/index.cfm>. The page title is "Submissions for 16-2164". A table lists two submissions:

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
Modification	211574	Approved	02/20/2018	03/05/2018	06/11/2018	Not Full Board

The "Modification - Approved" entry is expanded, showing a modal window with the following details:

- Modification - Approved - Date Received: 02/20/2018**
- Submission Description:** The following changes listed below are in this modification.
- Protocol Amendment 3 (dated December 4, 2017):**
 - The dose modification and toxicity management guidelines for Immune Related AEs associated with Pembrolizumab table has been updated.
- Informed Consent Form (dated February 14, 2018):**
 - Although the consent form lists inflammation of skin, the consent form now describes the Steven-Johnson Syndrome and Toxic Epidermal Necrolysis as skin reactions. Inflammation of the middle layer of the heart is now described as immune-mediated myocarditis.
- Personnel Changes:**
 - Sam Suarez is removed.
 - Nasrin H. Babadi is added.

On the right side of the modal window, there is a list of "Options" with a "Full Board" button highlighted in green.



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This application is supported by UNC-CH Research Information Technology
Please [contact us](#) if you have any questions



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What's Changed in the Past Year?

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

PI: Matthew Milowsky Last Approved: 06/20/2017 (FB)

Study Notes: None found

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
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	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 - Approved - Date Received: 12/12/2017 Click note icon to view in message box [Click here](#) if mouseover window will not close

Submission Description

This submission represents an updated Investigators Brochure for pembrolizumab, Edition 15, dated September 18, 2017. Please see the cover letter for Edition 15 for a full explanation.

Changes to Edition 15 were made to the following sections:

- Dosing in Pediatric Subjects
- Clinical Summary of Results
- Dosage and Administration
- Important Safety Considerations

The Main ICF version dated 12.13.17 contains changes to version date and risk language regarding inflammation of the kidney and graft versus host disease and updates to costs language. Some editorial changes were made to improve readability.



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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: Office Staff: [Flora F Davidson](#)

Accepted By IRB: 05/15/2018 IRB Analyst:

Submission Notes: **None found** IRB Chair:

Submission Reviews

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

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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



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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:



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Questions???



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