

## Co-Site Visit Report

Run By:

Date:

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<b>Audit Date:</b>	<b>Group Name:</b>	<b>Audit Category:</b>	<b>Audit Type:</b>
<b>Institution Code:</b>	<b>Name:</b>		<b>Member Study type?</b>
<i>Institution NCI Code Tier1:</i>	<i>Name:</i>		
<b>Audit Location:</b>			

**Number of Cases Audited:**

**Principal Investigator:**

**Number of Protocols Reviewed:**

### Auditor Information

**Audit Team Leader**

**Title**

**Affiliation**

**Co-Site Auditor**

**Title**

**Affiliation**

### Audit Outcome Summary

**Component**

**Assessment**

**IRB and Informed Consent Content Assessment**

Acceptable

**Accountability of Investigational Agents and Pharmacy Operations Assessment**

Acceptable

**Review of Patient Case Records Assessment**

Acceptable

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Audit Date:  
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Member Study type:

*Institution NCI Code Tier1:*

*Name:*

Audit Location:

### I. IRB and Informed Consent Content Review:

#### A. IRB Review

Yes/No

Comments

1. Were each of the selected protocols and informed consent documents available at the site?
2. Was the most up-to-date version of each protocol and informed consent document available?
3. Did the auditors review IRB documentation on-site or off-site?
4. Were the Protocols reviewed for initial IRB approval?
5. Were all annual re-approvals reviewed by the IRB in a timely manner?
6. Were all amendments and safety reports submitted and/or approved by the IRB in a timely manner?
7. Did the auditors conduct an adequate IRB review?

### B. Informed Consent Content (ICC) Review

1. Were locally used informed consent documents reviewed?
2. How many informed consent documents were reviewed for content?
3. Were local informed consent documents reviewed on-site or off-site? If off-site, did auditors relay the audit findings?
4. Did the auditors conduct an adequate informed consent content review?

### C. IRB and Informed Consent Content Assessment

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Audit Location:

### II. Accountability of Investigational Agents and Pharmacy Operations Review:

Yes/No      Comments

1. Were INDs and/or NCI supplied agents used at this site during the time period covered by this audit?

2. Was the pharmacy visited?

3. Are NCI DARFs in routine use?

4. Are NCI DARFs correctly and completely filled out?

5. Were satellite NCI DARFs reviewed?

6. Were NCI DARFs reviewed on-site or off-site?

7. Were drugs returned and/or destroyed appropriately and in a timely manner?

8. Were INDs and/or NCI supplied agents stored by protocol?

9. Was there adequate security?

10. Did the auditors conduct an adequate pharmacy/DARF review?

11. Was there any incidence of unauthorized personnel prescribing IND and/or NCI supplied agents?

Accountability of Investigational Agents and Pharmacy Operations  
Assessment

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**Audit Type:**  
**Member Study type:**

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*Name:*

**Audit Location:**

### III. Patient Case Review:

Yes/No

Comments

1. Were patient informed consent documents reviewed?
2. Were any major concerns or deficiencies for informed consent review noted?
3. Was each audited case reviewed for eligibility?
4. Were any major concerns and/or deficiencies for eligibility review noted?
5. Were any major treatment concerns and/or deficiencies noted?
6. Were any major disease outcome/response concerns and/or deficiencies noted?
7. Were any major adverse event concerns and/or reporting deficiencies noted?
8. Were any major general data management quality concerns and/or deficiencies noted?
9. Were the materials available for the audit adequate?
10. Did the auditors conduct an adequate patient case review?

Patient Case Review Assessment

Acceptable

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**Member Study type:**

*Institution NCI Code Tier1:*

*Name:*

**Audit Location:**

### Exit Interview

Yes/No

Comments

1. Was the exit interview attended by the PI?

2. Were the audit findings presented?

3. Were Group recommendations made? If "Yes", summarize:

4. Did the auditors conduct an adequate review?

Exit Interview Comments

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Member Study type:

*Institution NCI Code Tier1:*

*Name:*

Audit Location:

### General Comments:

1. Was the audit conducted according to current CTMB guidelines?

Comments and/or recommendations for auditor(s)

Prepared By

Date

Approved By

Date