DFCI IRB – AMENDMENT SUBMISSION FORM

Use this form to request any change to an approved research protocol including changes to the protocol, consent form or other related documents. This includes revisions as a result of an Adverse Event, IND/IDE Safety Report, Deviation/Violation or a revised Investigator Brochure. This form is not to be used for responses to the IRB, SRC or PSRC.

Please note:

- Changes may not be initiated prior to IRB approval except as necessary to eliminate apparent immediate hazard to subjects [(45 CFR 46.103(b)(4)(iii) and 21 CFR 56.108(a)(4)]; Therefore, amendments *must* be approved by the IRB prior to implementation.
- This form may **NOT** be used for changes to study staff or the addition of new study sites. Such changes must be submitted on the **Research Team Update form**, **PI/Site PI Change form** or the **Request to Add New Site Form**.
- Submissions that are incomplete due to missing/inadequate documents, signatures or responses to the questions on this form may be returned to sender and will delay the review process.
- The **ENTIRE SUBMISSION MUST BE ELECTRONIC**. Each of the required revised documents MUST accompany the electronic submission.

DFCI Protocol Number: **06-172**	**Today's Date:** 4/27/07
Protocol Title: INTERNATIONAL COLLABORATIVE TREATMENT PROTOCOL FOR INFANTS UNDER ONE YEAR WITH ACUTE LYMPHOBLASTIC OR BIPHENOTYPIC LEUKEMIA	
Principal Investigator: Silverman, Lewis *First Name, Middle Initial, Last Name, Degree(s)*	**Sponsor/Source of Funding:**
Disease Program: Pediatric Oncology	**Email**: lewis_silverman@dfci.harvard.edu
Office Address: SW 360	**Phone/Pager**: 632-5285

Study Contact for Questions about this submission: **Jane O'Brien**	Email: **jane_obrien@dfci.harvard.edu**
Office Address: Dana 308	Phone/Pager: 632-3549
Sponsor Amendment Number (if applicable): **01**	

1. DOSE ESCALATION STUDIES ONLY: N/A ☒
Does this amendment apply only to a change in cohort which is included in the current approved protocol and which does not change the risk/benefit ratio? Yes ☐ **No** ☐

2. What is the justification/rationale for this amendment? (Required) There was a typo in the Low, Medium and High Risk Consent forms. On week 8 of Maintenance all patients get an LP with IT therapy which included Cytarabine and Hydrocortisone. The consents listed this IT as Methotrexate with Hydrocortisone.

3. Does this involve consent form revisions? Yes ☒ **No** ☐
If YES, specify all additions/deletions (e.g. Page 4, replaced "30 subjects" with "40 subjects") Low Risk (page 4), Medium Risk and High Risk (page 5 and page 7), item #4 Maintenance Phase: Read: "Methotrexate and Hydrocortisone" on Week 8 now reads: "Cytarabine (Ara-C) and Hydrocortisone".
Attach the following revised document(s):
☒ One copy of the revised document(s) with changes or additions underlined.
☐ For deletions, attach one hard copy of old pages with deletions crossed-out.
☐ One copy of the consent form (not underlined).

4. Does this involve protocol revisions? Yes ☐ **No** ☒ **(New Version Name/Date: _____)**
If YES, specify all additions/deletions (e.g. Page 4, replaced "30 subjects" with "40 subjects") _____
Attach the following revised document(s):.
☐ One copy of the revised pages(s) with changes underlined.
☐ For deletions, attach one hard copy of old pages with deletions crossed-out.
☐ One copy of the entire revised version of the protocol without changes underlined.
☐ One copy of the revised protocol (not underlined).

5. Does this involve revisions to other study documents (questionnaires, surveys, diaries)? Yes ☐ No ☒

If YES, specify all additions/deletions (e.g. Page 4, replaced "30 subjects" with "40 subjects") _____

Attach the following revised document(s):

☐ One copy of the revised pages(s) with changes underlined.
☐ For deletions, attach one hard copy of old pages with deletions crossed-out.
☐ One copy of the entire revised version without changes underlined.

6. Does this amendment add a front sheet or affect any information currently captured on the front sheet?
Yes ☐ No ☒

If YES, attach revised document. If an electronic copy does not exist, the study team is responsible for re-creating one, using the current DFCI IRB Protocol Front Sheet template posted on the OPRS website, which replicates what is currently on OncPro and incorporates the information being added/deleted through this amendment.

☐ One copy of revised front sheet with the changes underlined.
☐ One copy of the revised front sheet.

7. Will enrolled study subjects be informed of these changes? (Consider: Is it possible that the changes proposed would affect a subject's decision to continue participation?)

Yes ☒ If YES, how will this be accomplished? The only enrolled patient on the study was reconsented in Maine where they are being followed and the corrected version of the consents were used. **No** ☐ If NO, why not: _____

8. Does this amendment affect pharmacy orders including COE (chemotherapy order entry), drug preparation/administration, medication orders, treatment plan (including dose modifications)?
Yes ☐ No ☒

If YES, how: _____

9. Does this amendment either remove or modify an Alert Page currently posted on the Oncology Protocol System?

☐ Add or Modify. Specify changes and attach copy (or revised copy). _____
☐ Remove.
☒ N/A

10. Does this amendment modify the Eligibility Checklist?

☐ Yes
☒ No

11. Is this amendment being submitted as a result of an SAE, IND/IDE Safety Report or revised IDB?

☐ Yes – Include the SAE, IND/IDE Safety Report(s) and/or revised IDB for IRB Review.
☒ No

Assurance

The undersigned assures that the information provided in this application is complete and accurate, and that it is consistent with proposal(s) submitted to external funding agencies. The undersigned assures that modifications to the originally approved project will not take place without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and DFHCC IRB policies and procedures.

Lewis Silverman, MD _____
Overall Principal Investigator (Signature/Name) **Date**

Jane O'Brien _____
Prepared By (Signature/Name) **Date**

FOR OPRS USE ONLY	Overall Status: _____ No. of subjects enrolled per QACT/OPRS: _____ Date: _____

IRB MEMBER REVIEW	☐ Minor modifications acceptable for expedited review (Changes are minor, administrative changes, and/or they do not make the protocol more complex or risky) EXPEDITED per 45 CFR 46.110(b) (2)/25 CFR 56.110(b) (2) _____ Brief Description: _____ *Signature of IRB Member/Date:* _____ ☐ Major modifications that require full IRB review (changes are substantial enough to warrant full committee review, make the study more complex or potentially increase risk or decrease potential benefit)