Appendix Name: Version History	**Appendix:** A
Section: Appendices	**Date Revised:** November 7, 2013

Appendix A - Version history

1. Introduction

Date Revised	Description of Change
November 7, 2013	Section 1.2: Add Sequencing and Biorepository committees to Table 1-1.
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

2. Institutional Membership

Date Revised	Description of Change
November 7, 2013	Section 2.8.7.2.1: Clarify that major IRB deficiency for initial approval by expedited review is specific to protocols requiring full board review per OHRP guidelines.
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013. Section 2.5.4.1: Specify that approval of institutional cytogeneticist is from the PI for cytogenetic studies and the chair of the Karyotype Committee.

3. Participants

Date Revised	Description of Change
March 15, 2013	Remaining sections 3.1, 3.2, 3.3, and 3.4: Submitted to Board of Directors for review on February 12, 2013.
June 29, 2012	Section 3.5 – Conflict of Interest: Approved by the Board of Directors on June 29, 2012.

4. Committees

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

5. Meetings

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

6. Study Protocol

Date Revised	Description of Change
November 7, 2013	6.4.1: Add Cancer Care Delivery Research to tables 6-1 and 6-2.
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

7. Patient Registration

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

8. Data Management

Date Revised	Description of Change
November 7, 2013	Section 8.1.2.3: Remove outdated name for CTSU's patient transfer form.
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

9. Information Systems

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013. Section 9.1.7: Update help desk name to Alliance Service Center. Extend availability by half an hour to 5:30 PM Eastern Time.

10. Publications

Date Revised	Description of Change
November 7, 2013	Approved by the Board of Directors on November 7, 2013. • Section 10.2: Add Group Review members, including new table. • Section 10.3: Add reference to ICMJE, emphasize Group Review, and redefine authorship guidelines. • Section 10.4: Clarify processes related to timelines. • Section 10.5: Add approval step for co-authors. • Section 10.6: Add PDF of printed manuscript must be sent to the publications coordinator. • Section 10.8: Update study results to include treatment phase 3 or randomized phase 2. Add template for public summary will be sent to author. • Section 10.9: Add new section with NIH Public Access Policy. • Section 10.10: Update timelines in table 10-3 to match above changes.
March 15, 2013	Initial draft approved by the Board of Directors on June 29, 2012. Resubmitted to Board of Directors for review on February 12, 2013. • Section 10.3.3: Add new content specific to correlative studies. • Section 10.4.3 Add new section describing timelines for submission of manuscripts to publications coordinator. • Section 10.9: Add new section regarding compliance with NIH Public Access Policy. • Throughout: Update email address for publications coordinator.

11. Translational Research

Date Revised	Description of Change
November 7, 2013	Section 11.1: Update name of HEME biorepository.
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013. Section 11.1: Update biorepository names. Section 11.4.1: Add new subsection detailing process for approved concepts.

12. Investigational Agents

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

13. Industry Relations

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013. Section 13.4: Remove incorrect reference to NIH data sharing policy. Clarify that data will be available to industry collaborators within six months of data maturity for primary endpoint.

14. Public Relations

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

15. Data Sharing

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

16. Study Monitoring

Date Revised	Description of Change
March 15, 2013	Submitted to Board of Directors for review on February 12, 2013.

Appendix Name: Abbreviations	**Appendix:** B
Section: Appendices	**Date Revised:** November 7, 2013

Appendix B - Abbreviations

Abbreviation	Full Term
1572	Statement of Investigator (Form FDA 1572)
AACR	American Association for Cancer Research
ACOSOG	American College of Surgeons Oncology Group
ACS CRP	American College of Surgeons Clinical Research Program
AdEERS	Adverse Event Expedited Reporting System
AER	Adverse Event Report
AIS	Audit Information System
Alliance	Alliance for Clinical Trials in Oncology
ANFU	Acceptable needs follow-up
ASCII	American Standard Code for Information Interchange
ASCO	American Society of Clinical Oncology
ASTRO	American Society for Radiation Oncology
BioMS	Biospecimen Management System
BIQSFP	Biomarker, Imaging and Quality of Life Studies Funding Program
BLA	Biologic License Application
CALGB	Cancer and Leukemia Group B
CAO	Chief administrative officer
CAP	College of American Pathologists
CAPA	Corrective and Preventive Action
CCOP	Community Clinical Oncology Program
CFO	Chief financial officer
CFR	Code of Federal Regulations
CIRB	Central Institutional Review Board
CLIA	Clinical Laboratory Improvement Amendments
CoC	Commission on Cancer
COI	Conflict of Interest
COPRTRG	Community Oncology and Prevention Trials Research Group
CPOP	Central Protocol Operations Program
CR	Complete Response

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Abbreviation	**Full Term**
CRA	Clinical research associate
CRADAs	Cooperative Research and Development Agreements
CRFs	Case report forms
CRP	Clinical research professional
CSA	Clinical Supply Agreement
CT	Central Time
CTA	Clinical Trial Application
CTAs	Clinical Trial Agreements
CTCAE	Common Terminology Criteria for Adverse Events
CTEP	Cancer Therapy Evaluation Program
CTMB	Clinical Trials Monitoring Branch
CTSU	Cancer Trials Support Unit
CV	Curriculum Vitae
DARF	Drug Accountability Record Form
dbGaP	Database of Genotypes and Phenotypes
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DNA	Deoxyribonucleic acid
DSMB	Data Safety and Monitoring Board
ET	East Coast Time
EU	European Union
FCOI	Financial conflict of interest
FDA	Food and Drug Administration
FFPE	Formalin-Fixed, Paraffin-Embedded (tissue)
FWA	Federalwide Assurance
GBC	Group Banking Committee
GCP	Good Clinical Practice
HEME	Alliance Hematologic Malignancy Biorepository
HHS	Department of Health and Human Services
HIPPA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health

Appendix Name: Abbreviations	**Appendix:** B
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Abbreviation	**Full Term**
IAM	Identity and Access Management
ICC	Informed Consent Content
ID	Identification
IDE	Investigational Device Exemption
IND	Investigational New Drug
IOM	Institute of Medicine
IPEC	Institutional Performance Evaluation Committee
IRB	Institutional Review Board
IRS	Internal Revenue Service
IS	Information Systems
ISU	Information Systems Unit
IT	Information Technology
LCTB	Alliance Lung Cancer Tissue Bank
LOI	Letter of Intent
MAYO	Alliance Biorepository at Mayo Clinic
MedDRA	Medical Dictionary for Regulatory Activities
MS	Microsoft
NCCTG	North Central Cancer Treatment Group
NCDB	National Cancer Data Base
NCI	National Cancer Institute
NCORP	NCI Community Oncology Research Program
NCTN	National Clinical Trials Network
NDA	New Drug Application
NIH	National Institutes of Health
OAOP	Online Agent Order Processing
OEWG	Operational Efficiency Working Group
OHRP	Office for Human Research Protections
OPEN	Oncology Patient Enrollment Network
ORI	Office of Research Integrity
OSU	Alliance Biorepository at The Ohio State University
PDF	Portable Document Format

Abbreviation	**Full Term**
PHI	Protected Health Information
PI	Principal investigator
PMB	Pharmaceutical Management Branch
PPP	Pharmacogenomics and Population Pharmacology
PR	Partial Response
QA	Quality assurance
QARC	Quality Assurance Review Center
QOL	Quality of life
RECIST	Response Evaluation Criteria In Solid Tumors
RNA	Ribonucleic acid
RRA	Request for Rapid Amendment
RSS	Regulatory Support System
RT	Radiologic Technology
SAE	Serious adverse event
SAS	Statistical Analysis System
SCRC	Study Concept Review Committee
SDC	Statistics and Data Center
SEI	Sensitive Electronic Information
SMU	Systems Management Unit
SPOREs	Specialized Programs of Research Excellence
TRP	Translational Research Program
U10	Cooperative Multicenter Reproductive Medicine Network
W-9	Request for Taxpayer Identification Number and Certification (Form W-9)
WUSTL	Alliance Biorepository at Washington University

Appendix C - Summary of figures and tables

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