Department Of
Veterans Affairs

Memorandum

In Reply Refer To: 523/151B

Continuing Review
Notice to Proceed with Research Study

Date: May 20, 2013

To: Hiroshi Mashimo, M.D., Ph.D.

From: Associate Chief of Staff/Research and Development

Title of Protocol: "Optical Biopsy using Optical Coherence Tomography"

Sponsor: NIH/NCI

Administrator: Harvard

Protocol Number(s): IRB# 1868

1. This memo is to inform you that your research study protocol has received continuing review approval by the VA Boston Healthcare System subcommittee(s) as outlined below:

VABHS Institutional Review Board (IRB)
Approval dates: 06/3/13 – 06/2/14

2. As a principal investigator you are responsible for the following:

a) Compliance with VABHS Research and Development, Medical Center and outside regulatory policies and procedures.

b) Submission in writing of changes to this project for review by the appropriate committees prior to initiation of any change.

c) Submission of annual progress reports.

d) Annual required training for you and your staff members.

3. If you have any questions regarding this continuing approval please direct them to the Project Coordinator at 857 364-5674. Please note that paperwork for continuing review should be submitted 60 days prior to the expiration date of the applicable subcommittee or the R&D Committee for R&D only protocols.

TERENCE M. KEANE, PHD

VA BOSTON HEALTHCARE SYSTEM

HUMAN STUDIES SUBCOMMITTEE (IRB)

REPORT OF COMMITTEE ACTION

Version December 1, 2004

Date of Action:	May 20, 2013
Principal Investigator:	Hiroshi Mashimo, M.D., Ph.D.
Title of Submission:	"Optical Biopsy using Optical Coherence Tomography"
Protocol Number:	IRB #1868
Type of Submission & Item Description:	Request for **Continued Approval** of Human Studies
Human Subject Enrollment:	**Yes: X No:**
Vulnerable Population:	**Yes: No: X Category:** **Entire Study: Sub-Population:**
Sponsor:	NIH/NCI
Administrator of Funding:	Harvard

X	**APPROVED** at IRB meeting
	APPROVED under procedures for expedited review by
	CHANGES REQUIRED: Based on Committee review, the changes or actions noted below are stipulated as required for approval. Compliance with these stipulations may be confirmed under Committee procedures for expedited review.
	DEFERRED: The item has been deferred pending changes or clarifications noted below. The proposal will be reconsidered at the next Committee meeting after the requested information or changes are submitted.
	DISAPPROVED: The proposal was disapproved for the reasons noted below. Please consult with the ACOS for Research or the Committee Chairperson before resubmitting.
	NOTED

Note: For 'Changes Required' and 'deferred', responses must be received from the principal investigator within 60 days. After 60 days a new submission and full review are required.

COMMENTS (2C):

Please Note: The following personnel are instructed to refrain from research related activities pertaining to this study until their credentialing portals in eRD are approved, and any expired items are updated. **Please verify, via email to IRB administrative staff,** that personnel listed below will not participate in research activities related to this study until all credentialing issues have been resolved.

Liang, Kaichen

The IRB made the following determinations:

1. The IRB determined that no conflict of interest for the PI or any other study personnel that may influence the conduct of the research existed previously for this protocol or arose since the last continuing review.

VA BOSTON HEALTHCARE SYSTEM

HUMAN STUDIES SUBCOMMITTEE (IRB)

REPORT OF COMMITTEE ACTION

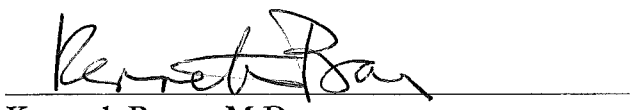
Version December 1, 2004

IRB #1868

2. There were 30 subjects consented within the most recent approval period (288 subjects for the entire study period). There were no subjects lost to follow-up and no withdrawals from the study.
3. This study continues to meet the criteria for partial waiver of HIPAA authorization for the purpose of accessing data collected under IRB#1653, under 45 CFR 164.512(i)(2)
4. This study continues to meet the criteria for a waiver of the requirement to post a clinical warning in the medical record.
5. This study has been designated as minimal risk and one year approval.
6. Approval period: 06/3/13 – 06/2/14.

PI registration of completed ICF documents is required within 72 hours of obtaining informed consent from each subject at the following link.

https://vaww.local.research.va.gov/SiteDirectory/523/_layouts/FormServer.aspx?XsnLocation=https://vaww.local.research.va.gov/SiteDirectory/523/RCOStudyRegistrationForm/Forms/template.xsn&SaveLocation=https%3A%2F%2Fvaww%2Elocal%2Eresearch%2Eva%2Egov%2FSiteDirectory%2F523%2FRCOStudyRegistrationForm&Source=&DefaultItemOpen=1



Kenneth Bauer, M.D.
Co-Chair, Human Studies Subcommittee

Department Of
Veterans Affairs

Memorandum

In Reply Refer To: 523/151B

Continuing Review
Notice to Proceed with Research Study

Date: May 19, 2014

To: Hiroshi Mashimo, M.D., Ph.D.

From: Associate Chief of Staff/Research and Development

Title of Protocol: 4K. Request for Continued Approval of Human Studies IRB # 1868 "Optical Biopsy Using Optical coherence Tomography (OCF)"

Sponsor: NIH

Administrator: HMS

Protocol Number(s): IRB #1868

1. This memo is to inform you that your research study protocol has received continuing review approval by the VA Boston Healthcare System subcommittee(s) as outlined below:

VABHS Institutional Review Board (IRB)
Approval dates: 06/03/14 – 06/02/15

2. As a principal investigator you are responsible for the following:

a) Compliance with VABHS Research and Development, Medical Center and outside regulatory policies and procedures.

b) Submission in writing of changes to this project for review by the appropriate committees prior to initiation of any change.

c) Submission of annual progress reports.

d) Annual required training for you and your staff members.

3. If you have any questions regarding this continuing approval please direct them to the Project Coordinator at 857 364-5674. Please note that paperwork for continuing review should be submitted 60 days prior to the expiration date of the applicable subcommittee or the R&D Committee for R&D only protocols.

TERENCE M. KEANE, PHD

VA BOSTON HEALTHCARE SYSTEM

HUMAN STUDIES SUBCOMMITTEE (IRB)

REPORT OF COMMITTEE ACTION

Version December 1, 2004

Date of Action:	May 19, 2014
Principal Investigator:	Hiroshi Mashimo, M.D., Ph.D.
Title of Submission:	"Optical Biopsy Using Optical coherence Tomography (OCT)"
Protocol Number:	IRB # 1868
Type of Submission & Item Description:	Continued Approval of Human Studies
Human Subject Enrollment:	**Yes:** X **No:**
Vulnerable Population:	**Yes:** **No:** X **Category:** **Entire Study:** **Sub-Population:**
Sponsor:	NIH
Administrator of Funding:	HMS

X	**APPROVED** at IRB meeting
	APPROVED under procedures for expedited review by
	CHANGES REQUIRED: Based on Committee review, the changes or actions noted below are stipulated as required for approval. Compliance with these stipulations may be confirmed under Committee procedures for expedited review.
	DEFERRED: The item has been deferred pending changes or clarifications noted below. The proposal will be reconsidered at the next Committee meeting after the requested information or changes are submitted.
	DISAPPROVED: The proposal was disapproved for the reasons noted below. Please consult with the ACOS for Research or the Committee Chairperson before resubmitting.
	NOTED

Note: For 'Changes Required' and 'deferred', responses must be received from the principal investigator within 60 days. After 60 days a new submission and full review are required.

COMMENTS (4K):

The IRB made the following determinations:

1. The IRB determined that no conflict of interest for the PI or any other study personnel that may influence the conduct of the research existed previously for this protocol or arose since the last continuing review.
2. There were 46 subjects consented within the most recent approval period 316 subjects for the entire study period). There were no subjects lost to follow-up and no withdrawals from the study.
3. This study continues to meet the criteria for a waiver of the requirement to post a clinical warning in the medical record.
4. The IRB reviewed and considered the most recent SRS committee action for approval of this protocol, along with a description of potential hazards and provisions for maintaining safety, and determined that there are no issues for concern regarding research safety at the time of continuing review. This research contains a protocol specific safety component involving Human or Non-Human cell or tissue samples, Flammable, explosive, or corrosive chemicals, Carcinogenic, mutagenic, or teratogenic chemicals, and Laser (Class 3b or Class 4). Approval period: 05/07/14 – 05/06/15.
5. The IRB has reviewed the HIPAA Authorization (version date 9/10/13), and endorses its use.
6. IRB approves the Informed Consent form (version date 9/10/13).
7. This study has been designated as minimal risk and one year approval. Approval period: 06/03/14 – 06/02/15.
8. PI registration of completed ICF documents is required within 72 hours of obtaining informed consent from each subject at the following link.

https://vaww.local.research.va.gov/SiteDirectory/523/_layouts/FormServer.aspx?XsnLocation=https://vaww.local.research.va.gov/SiteDirectory/523/RCOStudyRegistrationForm/Forms/template.xsn&SaveLocation=https%3A%2F%2Fvaww%2Elocal%2Eresearch%2Eva%2Egov%2FSiteDirectory%2F523%2FRCOStudyRegistrationForm&Source=https%3A%2F%2Fvaww%2Elocal%2Eresearch%2Eva%2Egov%2FSiteDirectory%2F523%2FRCOStudyRegistrationForm%2FForms%2FRCOView%2Easpx&DefaultItemOpen=1

Carole Palumbo, Ph.D.
Co-Chair, Human Studies Subcommittee

VA Boston Healthcare System

Human Studies Subcommittee (IRB)

Report of Committee Action

Version December 1, 2004

Date of Action:	June 01, 2015
Principal Investigator:	Hiroshi Mashimo, M.D., Ph.D.
Title of Submission:	"Optical Biopsy using Optical Coherence Tomography."
Protocol Number:	IRB #1868
Type of Submission & Item Description:	Continued Approval of Human Studies
Human Subject Enrollment:	**Yes: X No:**
Vulnerable Population:	**Yes: No: X Category:** **Entire Study: Sub-Population:**
Sponsor:	NIH / NCI
Administrator of Funding:	Harvard

X	**APPROVED** at IRB meeting
	APPROVED under procedures for expedited review by
	CHANGES REQUIRED: Based on Committee review, the changes or actions noted below are stipulated as required for approval. Compliance with these stipulations may be confirmed under Committee procedures for expedited review.
	DEFERRED: The item has been deferred pending changes or clarifications noted below. The proposal will be reconsidered at the next Committee meeting after the requested information or changes are submitted.
	DISAPPROVED: The proposal was disapproved for the reasons noted below. Please consult with the ACOS for Research or the Committee Chairperson before resubmitting.
	NOTED

Note: For 'Changes Required' and 'deferred', responses must be received from the principal investigator within 60 days. After 60 days a new submission and full review are required.

COMMENTS (4K): (Page 1 of 2)

The IRB made the following determinations:

1. The IRB determined that no conflict of interest for the PI or any other study personnel that may influence the conduct of the research existed previously for this protocol or arose since the last continuing review.

2. There were 34 subjects consented within the most recent approval period (350 subjects for the entire study period). There were no subjects lost to follow-up and no withdrawals from the study.

3. The IRB has reviewed the HIPAA Authorization (VHA Form 10-0493), and endorses its use.

4. IRB approves the Informed Consent form (version date 9/10/13).

5. The IRB reviewed and considered the most recent SRS committee action for approval of this protocol, along with a description of potential hazards and provisions for maintaining safety, and determined that there are no issues for concern regarding research safety at the time of continuing review. This research contains a protocol specific safety component involving Human or Non-Human cell or tissue samples, Flammable, explosive, or corrosive chemicals, Carcinogenic, mutagenic, or teratogenic chemicals, and Lasers. Approval period: 05/07/15 – 05/05/16.

6. This study has been designated as minimal risk and one year approval. Approval period: 06/03/15 – 06/02/16.

VA Boston Healthcare System

Human Studies Subcommittee (IRB)

Report of Committee Action

Version December 1, 2004

7. PI registration of completed ICF documents is required within 72 hours of obtaining informed consent from each subject at the following link.

https://vaww.local.research.va.gov/SiteDirectory/523/_layouts/FormServer.aspx?XsnLocation=https://vaww.local.research.va.gov/SiteDirectory/523/RCOStudyRegistrationForm/Forms/template.xsn&SaveLocation=https%3A%2F%2Fvaww%2Elocal%2Eresearch%2Eva%2Egov%2FSiteDirectory%2F523%2FRCOStudyRegistrationForm&Source=https%3A%2F%2Fvaww%2Elocal%2Eresearch%2Eva%2Egov%2FSiteDirectory%2F523%2FRCOStudyRegistrationForm%2FForms%2FRCOView%2Easpx&DefaultItemOpen=1

Antoun Houranieh, R.Ph., M.S., Ph.D.
Co-Chair, Human Studies Subcommittee

Department Of
Veterans Affairs

Memorandum

In Reply Refer To: 523/151B

Continuing Review
Notice to Proceed with Research Study

Date: May 16, 2016

To: Hiroshi Mashimo, MD, Ph.D.

From: Deputy Associate Chief of Staff/Research and Development

Title of Protocol: 4H. Request for Continued Approval of Human Studies "Optical Biopsy using Optical Coherence Tomography"

Sponsor: NIH / NCI

Administrator: HMS

Protocol Number(s): IRB # 1868

1. This memo is to inform you that your research study protocol has received continuing review approval by the VA Boston Healthcare System subcommittee(s) as outlined below:

VABHS Institutional Review Board (IRB)
Approval dates: 06/03/16 – 06/02/17

2. As a principal investigator you are responsible for the following:

a) Compliance with VABHS Research and Development, Medical Center and outside regulatory policies and procedures.

b) Submission in writing of changes to this project for review by the appropriate committees prior to initiation of any change.

c) Submission of annual progress reports.

d) Annual required training for you and your staff members.

3. If you have any questions regarding this continuing approval please direct them to the Project Coordinator at 857 364-5674. Please note that paperwork for continuing review should be submitted 60 days prior to the expiration date of the applicable subcommittee or the R&D Committee for R&D only protocols.

TERENCE M. KEANE, PH.D.

VA Boston Healthcare System

Human Studies Subcommittee (IRB)

Report of Committee Action

Version December 1, 2004

Date of Action:	May 16, 2016
Principal Investigator:	Hiroshi Mashimo, MD, Ph.D.
Title of Submission:	"Optical Biopsy using Optical Coherence Tomography"
Protocol Number:	IRB #1868
Type of Submission & Item Description:	Continued Approval of Human Studies
Human Subject Enrollment:	**Yes: X No:**
Vulnerable Population:	**Yes: No: X Category:** **Entire Study: Sub-Population:**
Sponsor:	NIH / NCI
Administrator of Funding:	HMS

X	**APPROVED** at IRB meeting
	APPROVED under procedures for expedited review by
	CHANGES REQUIRED: Based on Committee review, the changes or actions noted below are stipulated as required for approval. Compliance with these stipulations may be confirmed under Committee procedures for expedited review.
	DEFERRED: The item has been deferred pending changes or clarifications noted below. The proposal will be reconsidered at the next Committee meeting after the requested information or changes are submitted.
	DISAPPROVED: The proposal was disapproved for the reasons noted below. Please consult with the ACOS for Research or the Committee Chairperson before resubmitting.
	NOTED

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COMMENTS (4H): (Page 1 of 2)

The IRB made the following determinations:

1. The IRB determined that no conflict of interest for the PI or any other study personnel that may influence the conduct of the research existed previously for this protocol or arose since the last continuing review.

2. There were 61 subjects consented within the most recent approval period (411 subjects for the entire study period). There were no subjects lost to follow-up and no withdrawals from the study.

3. The IRB has reviewed the HIPAA Authorization (VHA Form 10-0493, September 2015), and endorses its use.

4. IRB approves the Informed Consent form (version date 9/10/13).

The IRB reviewed and considered the most recent SRS committee action for approval of this protocol, along with a description of potential hazards and provisions for maintaining safety, and determined that there are no issues for concern regarding research safety at the time of continuing review. This research contains a protocol specific safety component involving Human or Non-Human cell or tissue samples, chemicals (Flammable, explosive, or corrosive and Carcinogenic, mutagenic, or teratogenic), and Non Ionizing Radiation (Lasers (Class 3b or Class 4). Approval period: 05/07/16 – 05/06/17.

VA Boston Healthcare System

Human Studies Subcommittee (IRB)

Report of Committee Action

Version December 1, 2004

5. This study has been designated as minimal risk and one year approval. Approval period: 06/03/16 – 06/02/17.

6. PI registration of completed ICF documents is required within 72 hours of obtaining informed consent from each subject at the following link.

https://vaww.portal2.va.gov/sites/localresearch/Boston/_layouts/FormServer.aspx?XsnLocation=https://vaww.portal2.va.gov/sites/localresearch/Boston/RCOStudyRegistrationForm/Forms/template.xsn&SaveLocation=https%3A%2F%2Fvaww%2Eportal2%2Eva%2Egov%2Fsites%2Flocalresearch%2FBoston%2FRCOStudyRegistrationForm&ClientInstalled=true&Source=https%3A%2F%2Fvaww%2Eportal2%2Eva%2Egov%2Fsites%2Flocalresearch%2FBoston%2FRCOStudyRegistrationForm%2FForms%2FAllItems%2Easpx%3FGroupString%3D%253B%25232165%253B%2523%26IsGroupRender%3DTRUE&DefaultItemOpen=1

Avron Spiro, III, Ph.D.
Co-Chair, Human Studies Subcommittee