



Review Checklist (FORM 2.5)

STUDY PROTOCOL INFORMATION

Reference Number:	
BUCM-IRB Code:	
Study Protocol Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date: <i>(to be accomplished by BUCM-IRB Staff)</i>	<dd/mm/yyyy>
Verified Complete by: <i>(to be accomplished by BUCM-IRB Staff)</i>	<Signature over Printed Name>
Classification of Review: <i>(to be accomplished by BUCM-IRB)</i>	<input type="checkbox"/> EXPEDITED <input type="checkbox"/> FULL BOARD
Classified by the: <input type="checkbox"/> BUCM-IRB CHAIR <input type="checkbox"/> BUCM-IRB COORDINATOR	<Signature over Printed Name>

Basic Documents (must submit)

- Review Checklist [BUCM-IRB-2.5]
- 8 Copies of Complete Research Protocol
- 8 Copies of Informed Consent Forms
- Accomplished Application Review Form [BUCM-IRB-2.1]
- Protocol Summary Sheet [BUCM-IRB-2.2]
- Protocol Evaluation Form [BUCM-IRB-2.3]
- Informed Consent Evaluation Form [BUCM-IRB-2.4]
- Study tools (all data tools)
- Study drug/medical device information (Investigative brochure and relevant literatures)
- CV of PI and study team members (include proof of relevant literatures)
- Electronic copy of study protocol & BUCM-IRB FORMS 2.1 to 2.5
- Information regarding fund, sponsor, institution application
- Study/protocol budget
- Contract of MOAs, MTAs, IPO, IDE and other relevant approval documents
- Previous IRB and approval result (if any)

Reviewed and verified by :

 IRB Secretariat

Classification :

- Expedited Review
- Full-committee Review