MRA Number:
Initiation Date:

Manufacturing Request Application (MRA)

SECTION 1: CONCEPT SUMMARY AND REVIEW

1A. PROPOSAL CONCEPT (PROJECT INITIATOR)				
Proposal Source	☐COH Client ☐External Client / In Collaboration with COH Investigator ☐External Client			
Project Name				
Product Name				
Initiator		**Phone**		
Principal Investigator		**Phone**		
Institute		**Project Code**		
Project GMP/OC Status	☐Previously Reviewed/Accepted ☐Previously Reviewed/Revision ☐Not Yet Reviewed			
Type of Request	☐New ☐Revised	☐Product New to COH Facility ☐Product Previously Manufactured in COH Facility		
Product Type	☐CGSF (Chemical) ☐CBG (Biologics) ☐CTPC (Cell Therapy)			
Intended Use of Product	**GLP** ☐Preclinical ☐Formulation ☐Toxicology ☐Initial Stability	**GMP** ☐Clinical Trial ☐Clinical Stability	**Other** (e.g., process development, etc., describe)	
If Clinical Product for Trial at COH	☐Proposed Trial ☐Ongoing Trial See Section 3. Disease Team Endorsement will be required.			
Funding for Manufacturing Request	☐Fully Funded ☐Partially Funded (%): ☐Not Yet Funded	☐Applied for Grant: Decision Date: % Funded:	Other (describe)	
Timing; Note any Timing Constraints (e.g., prior commitments to a grant, donor, clinical trial, etc.)				

Attach product description to this MRA, with header "SECTION 1"	**PRODUCT** I. Description of product to be manufactured II. Manufacturing steps III. Required quantity / Scale of manufacturing IV. Brief history of manufacture, including scale V. Additional development required (if known) VI. Include consideration of external manufacture, if applicable VII. Any other information deemed important to plan this manufacture
Initiator Name and Date	
MRA Routing	To Manufacturing Management Joe Gold jogold@coh.org OR David Horne dhorne@coh.org / James Simpson jasimpson@coh.org

1B. CONCEPT REVIEW AND RECOMMENDATION (BY MANUFACTURING MANAGEMENT)	
Insert or attach (if attach, use header "SECTION 1"	Attach review of Technical Readiness for Manufacturing/ Fit with COH Capabilities (1-2 paragraphs). Note any steps new to COH and assessment of risk to schedule and/or budget. Include consideration of external manufacture, if applicable.
Recommendation	☐Progress with MRA ☐Revise / Need more information (describe) ☐Do not progress
Manufacturing Management Name and Date	
MRA Routing	To GMP/OC Manager Lynne Smith lysmith@coh.org

STOP – DO NOT PROCEED UNTIL CONCEPT REVIEW IS SUCCESSFULLY COMPLETED

MRA Number:
Initiation Date:

SECTION 2: FULL PROJECT SUMMARY AND REVIEW

2A. PRODUCT / PROJECT DETAIL (BY PROJECT INITIATOR)	
Attach the described supplemental information to this MRA, with header "SECTION 2"	**For Internal Project or Collaboration** I. Product Mechanism and Key Proof of Concept Data (1-3 charts/brief description. List any related publications or pending publications.) II. Current Project Plan for Use of Material (brief description). Include disease area (1-2 paragraphs). III. COH Intellectual Property Status – Consult OTL for brief statement on COH IP IV. Budget (in consultation with Manufacturing Management) V. Time Requirements (in consultation with Manufacturing Management)
	For Contract Manufacturing I. Budget & ROI (in consultation with Manufacturing Management) II. Time Requirements (in consultation with Manufacturing Management)
Initiator Name and Date	
MRA Routing	To Manufacturing Management Joe Gold jogold@coh.org OR David Horne dhorne@coh.org / James Simpson jasimpson@coh.org

2B: PRODUCT / PROJECT DETAIL REVIEW (BY MANUFACTURING MANAGEMENT)	
Attach brief assessment of the project requirements to this MRA, with header "SECTION 2"	I. Requirements to complete (supplies, staff, capabilities) II. Manufacturing suite requirements III. Proposed scheduling IV. Line-item project costing V. Pricing (include subsidy, if any) VI. Any other information relevant to decision making
Manufacturing Management Name and Date	
MRA Routing	To GMP/OC Manager Lynne Smith lysmith@coh.org

MRA Number: Initiation Date:

SECTION 3: REVIEW BY GMP MANUFACTURING OVERSIGHT COMMITTEE (GMP/OC)

3: TO BE COMPLETED BY GMP/OC COMMITTEE MANAGER AND CHAIR			
GMP/OC Strategic Review Recommendation	☐Accepted – High Priority ☐Accepted – Mid to Low Priority ☐Do not recommend COH Manufacture ☐Investigate External Manufacture ☐Recommend Revision to Plan/Application	**Date**	
Approval by Chair, Signature		**Date**	
Comments (if any)			
MRA Routing	cc To Manufacturing Management Joe Gold jogold@coh.org OR David Horne dhorne@coh.org / James Simpson jasimpson@coh.org, Project initiator		

SECTION 4: ENDORSEMENT BY DISEASE TEAM (PRODUCT FOR PROPOSED COH CLINICAL TRIAL ONLY)

Date of Disease Team Endorsement	
MRA Routing	To Manufacturing Management Joe Gold jogold@coh.org OR David Horne dhorne@coh.org / James Simpson jasimpson@coh.org To GMP/OC Manager Lynne Smith lysmith@coh.org

Original file - Lynne Smith lysmith@coh.org