



Intestinal Specimen Collection CRF

General Information			
CHAIN ID <small>(Write CHAIN ID #. Upon receipt in CHAIN lab, affix barcode here)</small>	[3] [0] [0] [0] [1] [] [] [] []		
Specimen Kit ID #			
Date of death	___ / ___ / ___ DD / MM / YYYY	Time of death	___ : ___ 24 hour
Date body received in mortuary	___ / ___ / ___ DD / MM / YYYY	Time received in mortuary	___ : ___ 24 hour
Date body placed in refrigerator	___ / ___ / ___ DD / MM / YYYY	Time body in refrigerator	___ : ___ 24 hour
Date body goes out of refrigerator	___ / ___ / ___ DD / MM / YYYY	Time body goes out of refrigerator	___ : ___ 24 hour
Were there circumstances that prevented the MITS intestinal sampling from being performed?			
<input type="checkbox"/> No <input type="checkbox"/> Yes, please explain circumstances _____ _____ _____ _____			
Upper Endoscopy			
Oral Mucosa (01)	Oral MUCOSA 10 mL Cryovial 01-A1 <input type="checkbox"/> Yes <input type="checkbox"/> No	Cut Copan oral swab tip with sterile scissors <i>N2</i>	
Date endoscope inserted	___ / ___ / ___ DD / MM / YYYY	Time endoscope inserted	___ : ___ 24 hour
Gastric Fluid			
Gastric Fluid (02) 20mL syringe needed and PBS if lavaging	GASTRIC FL 10 mL Cryovial 02-A1 <input type="checkbox"/> Yes <input type="checkbox"/> No Ambient <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, _____ . _____ (mL) Lavage <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, _____ . _____ (mL)	GASTRIC FL 10 mL Cryovial 02-A2 <input type="checkbox"/> Yes <input type="checkbox"/> No Ambient <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, _____ . _____ (mL) Lavage <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, _____ . _____ (mL)	
	1.5 mL PBS added (after pH if ambient) <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Cool</i>		1.5 mL PBS added (after pH if ambient) <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Cool</i>
If <5mL ambient fluid in each vial, check pH, add 1.5mL PBS, & later lavage to fill each vial to 5-7mL. If vials filled with 5-7mL ambient fluid each, check pH, add 1.5mL PBS, & no lavage needed later. Add PBS as soon as possible, and always before 30 min, then gently invert the vial twice.			

Gastric Aspirate pH <i>Ambient fluid only</i>	Broad range pH paper result: ____ . ____ <input type="checkbox"/> Not done	Photo of pH strip and interpretation panel <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Narrow range pH paper used (tick one): <input type="checkbox"/> Not done <input type="checkbox"/> 1.8 - 3.8 <input type="checkbox"/> 3.8 - 5.5 <input type="checkbox"/> 5.2 - 6.8 <input type="checkbox"/> 6.0 - 8.1 <input type="checkbox"/> 8.0 - 9.7		
	Narrow range pH paper result: ____ . ____ <input type="checkbox"/> Not readable	Photo of narrow range pH strip and interpretation panel <input type="checkbox"/> Yes <input type="checkbox"/> No	
Stomach Contents	<input type="checkbox"/> None	Clear stomach secretions, easy to aspirate <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Milk contents <input type="checkbox"/> Yes <input type="checkbox"/> No	Food contents <input type="checkbox"/> Yes <input type="checkbox"/> No	
Duodenal Fluid			
Duodenal Fluid (03) If <1.5 mL ambient fluid is aspirated, the lavage after the D3/D4/Jej biopsies & before the D2 biopsies. Priority order of vials: 03-V1, 03-V2, 03-H1-H3, 03-V3. If <3 mL ambient fluid is aspirated, skip 03-V3 cryovial (can return to refill with lavaged aspirate if lavage instilled). 10 mL syringe needed and PBS if lavaging	Total amount ambient fluid obtained: ____ . ____ (mL) <i>If >=1.5 mL ambient fluid collected, no need to lavage with PBS.</i>		
	PBS added for lavage: <input type="checkbox"/> No (>=1.5 mL ambient fluid collected) <input type="checkbox"/> Yes (<1.5 ml ambient fluid collected) <i>If yes, ____ . ____ (mL) PBS was infused</i> <i>If yes, ____ . ____ (mL) fluid obtained</i>		
	DUOD FL cryovial 03-V1 (1st priority) <input type="checkbox"/> Ambient <input type="checkbox"/> Lavage <input type="checkbox"/> None <i>If obtained, amount aliquoted:</i> <input type="checkbox"/> 0.5 mL <input type="checkbox"/> Other: ____ . ____ (mL) <i>N2</i>	DUOD FL BHI/CYS/GLY 03-H1 (3rd priority) <input type="checkbox"/> Ambient <input type="checkbox"/> Lavage <input type="checkbox"/> None <i>If obtained, amount aliquoted:</i> <input type="checkbox"/> 0.5 mL <input type="checkbox"/> Other: ____ . ____ (mL) <i>N2</i>	
	DUOD FL cryovial 03-V2 (2nd priority) <input type="checkbox"/> Ambient <input type="checkbox"/> Lavage <input type="checkbox"/> None <i>If obtained, amount aliquoted:</i> <input type="checkbox"/> 0.5 mL <input type="checkbox"/> Other: ____ . ____ (mL) <i>N2</i>	DUOD FL BHI/CYS/GLY 03-H2 (4th priority) <input type="checkbox"/> Ambient <input type="checkbox"/> Lavage <input type="checkbox"/> None <i>If obtained, amount aliquoted:</i> <input type="checkbox"/> 0.5 mL <input type="checkbox"/> Other: ____ . ____ (mL) <i>N2</i>	
	DUOD FL cryovial 03-V3 (6th priority) <input type="checkbox"/> Ambient <input type="checkbox"/> Lavage <input type="checkbox"/> None <i>If obtained, amount aliquoted:</i> <input type="checkbox"/> 0.5 mL <input type="checkbox"/> Other: ____ . ____ (mL) <i>N2</i>	DUOD FL BHI/CYS/GLY 03-H3 (5th priority) <input type="checkbox"/> Ambient <input type="checkbox"/> Lavage <input type="checkbox"/> None <i>If obtained, amount aliquoted:</i> <input type="checkbox"/> 0.5 mL <input type="checkbox"/> Other: ____ . ____ (mL) <i>N2</i>	
Approx. location <input type="checkbox"/> D1 <input type="checkbox"/> D2 <input type="checkbox"/> D3/D4/Jejunum <i>Tick one</i>			

Small Intestine			
Distal Duodenum/Proximal Jejunum (04)	D3/D4/JEJ cryovial 04-V1 (1+ bx) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____ N2	D3/D4/JEJ RNAlater cryovial 04-R1 (1+ bx) <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input checked="" type="checkbox"/> No # bx: _____ N2	D3/D4/JEJ formalin jar 04-J1 (2+ bx) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____
	D2 cryovial 05-V1 (1+ bx) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____ N2	D2 RNAlater cryovial 05-R1 (1+ bx) <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input checked="" type="checkbox"/> No # bx: _____ N2	D2 formalin jar 05-J1 (2+ bx) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____
D2 (05)	DUOD BR cryovial 06-V1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____ N2		DUOD BR BHI/CYS/GLY 06-H1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <i>Cool</i>
	D2 Mucosal Brushings (06) <i>Cut brush in 2 pieces with sterile wire cutters</i>		
D1/duodenal bulb (07)	D1 cryovial 07-V1 (1+ bx) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____ N2	D1 RNAlater cryovial 07-R1 (1+ bx) <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input checked="" type="checkbox"/> No # bx: _____ N2	D1 formalin jar 07-J1 (2+ bx) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No # bx: _____
	Date EM fixative prepared ____ / ____ / ____ DD / MM / YYYY		
Stomach			
Stomach (08)	STOMACH cryovial 08-V1 (1+ bx) <input type="checkbox"/> Yes <input type="checkbox"/> No # bx: _____ N2	Rapid urease test (CLOtest) (1 bx) <input type="checkbox"/> Yes <input type="checkbox"/> No	STOMACH formalin jar 08-J1 (1+ bx) <input type="checkbox"/> Yes <input type="checkbox"/> No # bx: _____
Upper Endoscopy Conclusion			
Date endoscope removed	____ / ____ / ____ DD / MM / YYYY	Time endoscope removed	____ : ____ 24 hour
If any of the upper endoscopy specimens were not collected, specify which and why they were not collected:			
<hr/> <hr/> <hr/> <hr/>			
Additional comments regarding the procedure and visual appearance of upper gastrointestinal tissues:			
<hr/> <hr/> <hr/> <hr/>			

Stool Collection			
Stool (MC 03)	STOOL in 10 mL cryovial Copan rectal swab MC-03-A0	STOOL in 10 mL cryovial Cervical swab MC-03-A1	STOOL in 10 mL cryovial Cervical swab MC-03-A2
	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>N2</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>N2</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>N2</i>

Lower Endoscopy			
Date endoscope inserted	___ / ___ / ___ DD / MM / YYYY	Time endoscope inserted	___ : ___ 24 hour

Rectal Biopsy			
Rectum (09)	RECTUM cryovial 09-V1 (1+ bx)	RECTUM RNAlater cryovial 09-R1 (1+ bx)	RECTUM formalin jar 09-J1 (2+ bx)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	# bx: _____ <i>N2</i>	# bx: _____ <i>N2</i>	# bx: _____
	RECTUM cryovial 09-V2 (1+ bx)	RECTUM EM jar 09-E1 (1+ bx)	Date EM fixative prepared
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	___ / ___ / ___ DD / MM / YYYY	
# bx: _____ <i>N2</i>	# bx: _____ <i>Cool</i>		

Lower Intestine			
Ileum/Colon (10)	TI/COLON cryovial 10- V1 (1+ bx)	TI/COLON RNAlater cryovial 10-R1 (1+ bx)	TI/COLON formalin jar 10-J1 (2+ bx)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	# bx: _____ <i>N2</i>	# bx: _____ <i>N2</i>	# bx: _____
Ileum/Colon <i>Tick one</i>	Scope advanced to and biopsies taken from:		
	<input type="checkbox"/> Sigmoid colon	<input type="checkbox"/> Splenic flexure	<input type="checkbox"/> Ascending colon
	<input type="checkbox"/> Descending colon	<input type="checkbox"/> Transverse colon	<input type="checkbox"/> Caecum
		<input type="checkbox"/> Hepatic flexure	<input type="checkbox"/> Terminal ileum
Stool Quality <i>Tick one</i>	<input type="checkbox"/> None	<input type="checkbox"/> Liquid, easy to aspirate	<input type="checkbox"/> Semisolid <input type="checkbox"/> Solid

If most proximal lower intestinal biopsy was distal to TI, tick reason(s) for failure to sample more proximally:		
Too much stool	Anatomic difficulties	Timed out
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other, if yes please specify :		
<input type="checkbox"/> Yes <input type="checkbox"/> No	_____	

Lower Endoscopy Conclusion			
Date endoscope removed	___ / ___ / ___ DD / MM / YYYY	Time endoscope removed	___ : ___ 24 hour
Media Contamination Control (11)	MEDIA CONTAM BHI/CYS/GLY 11-H1 <input type="checkbox"/> Yes <input type="checkbox"/> No <i>N2</i>		
Appearance after procedure	Bruising/swelling of lips <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a (no teeth) Oozing blood from rectum <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No		
If any lower endoscopy specimens were not collected, specify which and why they were not collected: <hr/> <hr/> <hr/>			
Additional comments regarding the procedure and visual appearance of lower gastrointestinal tissues: <hr/> <hr/> <hr/>			

Grossly Abnormal Tissues			
Grossly abnormal intestinal tissue (upper or lower) or esophagus	Location #1	Cryovial GC-21 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____ <i>N2</i>	Cryovial with RNAlater GC-21 <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input type="checkbox"/> No
		Formalin jar GC-21 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____	If collected, # bx _____ <i>N2</i>
		Location (tick one) :	
		<input type="checkbox"/> Rectum <input type="checkbox"/> Transverse Colon <input type="checkbox"/> D3/D4/Jej <input type="checkbox"/> Sigmoid Colon <input type="checkbox"/> Hepatic flexure <input type="checkbox"/> D2 <input type="checkbox"/> Descending Colon <input type="checkbox"/> Ascending Colon <input type="checkbox"/> D1 <input type="checkbox"/> Splenic Flexure <input type="checkbox"/> Caecum <input type="checkbox"/> Esophagus	
Description: <hr/> <hr/> <hr/>			

Extra Specimen GC-21

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Extra Specimen GC-21

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Extra Specimen GC-21

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Grossly abnormal intestinal tissue (upper or lower) or esophagus	Location #2	Cryovial GC-22 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____ <i>N2</i>	Cryovial with RNAlater GC-22 <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input type="checkbox"/> No
		Formalin jar GC-22 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____	If collected, # bx _____ <i>N2</i>
		Location (tick one) : <input type="checkbox"/> Rectum <input type="checkbox"/> Transverse Colon <input type="checkbox"/> D3/D4/Jej <input type="checkbox"/> Sigmoid Colon <input type="checkbox"/> Hepatic flexure <input type="checkbox"/> D2 <input type="checkbox"/> Descending Colon <input type="checkbox"/> Ascending Colon <input type="checkbox"/> D1 <input type="checkbox"/> Splenic Flexure <input type="checkbox"/> Caecum <input type="checkbox"/> Esophagus	
Description: _____ _____			

Extra Specimen GC-22

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Extra Specimen GC-22

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Grossly abnormal intestinal tissue (upper or lower) or esophagus	Location #3	Cryovial GC-23 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____ <i>N2</i>	Cryovial with RNAlater GC-23 <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input type="checkbox"/> No
		Formalin jar GC-23 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____	If collected, # bx _____ <i>N2</i>
		Location (tick one) : <input type="checkbox"/> Rectum <input type="checkbox"/> Transverse Colon <input type="checkbox"/> D3/D4/Jej <input type="checkbox"/> Sigmoid Colon <input type="checkbox"/> Hepatic flexure <input type="checkbox"/> D2 <input type="checkbox"/> Descending Colon <input type="checkbox"/> Ascending Colon <input type="checkbox"/> D1 <input type="checkbox"/> Splenic Flexure <input type="checkbox"/> Caecum <input type="checkbox"/> Esophagus	
Description: _____ _____			

Extra Specimen GC-23

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Grossly abnormal intestinal tissue (upper or lower) or esophagus	Location #4	Cryovial GC-23 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____ <i>N2</i>	Cryovial with RNAlater GC-23 <input type="checkbox"/> With RNAlater <input type="checkbox"/> Without RNAlater <input type="checkbox"/> No
		Formalin jar GC-23 <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # bx _____	If collected, # bx _____ <i>N2</i>
		Location (tick one) :	
		<input type="checkbox"/> Rectum <input type="checkbox"/> Transverse Colon <input type="checkbox"/> T1 <input type="checkbox"/> Sigmoid Colon <input type="checkbox"/> Hepatic flexure <input type="checkbox"/> D3/D4/Jej <input type="checkbox"/> Descending Colon <input type="checkbox"/> Ascending Colon <input type="checkbox"/> D2 <input type="checkbox"/> Splenic Flexure <input type="checkbox"/> Caecum <input type="checkbox"/> D1 <input type="checkbox"/> Esophagus	
Description: _____ _____ _____			

Extra Specimen GC-24

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Extra Specimen GC-24

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Extra Specimen GC-24

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Personnel Performing MITS	
Name of endoscopist	_____
Name(s) of all assistant(s) present for specimen collection	_____ _____ _____ Please separate names with a semi-colon
Scope Used <i>Tick one</i>	<input type="checkbox"/> GIF-160 <input type="checkbox"/> GIF-XP 160 <input type="checkbox"/> GIF-P140 <input type="checkbox"/> Other, specify: _____
Forceps Used <i>Tick one</i>	<input type="checkbox"/> 2.0 mm <input type="checkbox"/> 2.8 mm <input type="checkbox"/> Other, size: _____

Comments on Procedure (Optional)
_____ _____ _____ _____

Document History		
Version	Change Log	Date
V.1 GI Sampling CRF	Original Version	28-Jun-18
	<ol style="list-style-type: none"> 1. Upper Endoscopy: Oral Mucosa: Clarify oral swab is Copan oral swab 2. Gastric Aspirate pH: New pH measurements 3. Duodenal Fluid: lavage/PBS amount clarification 4. Duodenum, D2, D1, stomach, esophagus, rectum, ileum/colon/sigmoid: Updated the number of GI biopsies collected, added places to record number of biopsies 5. Duodenum, D2, D1, stomach: Removed scope distances 6. D2, Rectum: Added places to record dates of EM fixative preparation 7. Stool sample: Add rectal swab instruction 8. Stool sample: Added 3rd rectal swab (03-A0) 9. Rectal biopsy: Added a 2nd frozen rectal biopsy for Taq (09-V2) 10. Lower Intestine, Grossly Abnormal tissue: Updated locations of the ileum/colon 11. Lower endoscopy conclusion: Added checkbox for n/a (no teeth) 	21-Nov-18
V.2 GI Sampling CRF		

