PROTOCOL: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Directorate: \_\_\_\_\_\_\_\_\_\_\_\_ Amendment: \_\_\_\_\_\_\_

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| **HC Folder Structure** | **Printing** | **Office Folder** |
| **Module 1**:1.0 Correspondence1.0 .1 Cover Letter *(include sample size; n of Cdns; LOT #)* |  |  |
| 1.1 TOC |  |  |
| 1.2 Administrative Information | **---** | **---** |
|  1.2.1 Drug Submission Application Form HC-SC 3011 |  |  |
|  1.2.3 Certification and Attestation FormsAttestation for e-documentsSummary of Additional Drugs Form |  | *SOAD form only* |
|  1.2.5 Compliance and Site Information1.2.5.1 CTSI |  | **---** |
| 1.2.6 Authorization for Sharing Information - CRL; letter of attestation, authorization |  |  |
|  1.2.7 International Information |  | **---** |
| 1.2.9 Other Administrative Information (non-scientific)List of COG, DFCI, TACL Institutions in Canada (15 for COG, 6 for BMT, 3 for DFCI, 3 for TACL, 2 for old COG Phase 1, 1 for new COG Phase 1) |  |  |
| 1.3 Product Information  | **---** | **---** |
| 1.3.4 Investigator’s Brochure |  | Title page |
| 1.4 Health Canada Summaries | **---** | **---** |
| 1.4.1 PSEAT-CTA  **(Complete for BGTD only – provide activation memo and approval letter)** | **---** | **---** |
| 1.7 Clinical Trial Information  |  |  |
| 1.7.1 ProtocolAmended (Track Changes)Amended (Clean Copy) Include COG memo + CTEP approval here **(include here for TPD only)**Safety Reports (all since last submission) Study Progress Report (most current) DSMC Report (most current) |  | Title page of protocol, activation memo and approval memo |
|  1.7.2 Informed Consent Document(s)Memo (02Apr13) re ICF & AssentSample assent for children > 7 yrs of age, YISSample ICFs from cooperative group(Track Changes for CTA-As) | **---** | **---** |
|  | **---** |
|  | **---** |
|  | **---** |
|  1.7.3 Canadian REB Refusals |  | **---** |
| 1.7.4 Information on Prior-Related Applications  | **---** | **---** |
| **Module 2**:2.1 TOC of Module 2 |  |  |
| 2.3 Quality Overall Summary (COS) |  |  |
| **Module 3**:3.1 TOC of Module 3 |  |  |
| 3.2 Body of Data |  |  |
|  3.2.P Drug Product |  |  |
|  3.2.S Drug Substance |  |  |
| 3.3 Literature References |  |  |

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| ***BINDER***1. *Email:*
* *3011 to HC CONTACT 1 & HC CONTACT 2 for HC CONTACT 2’s signature to fax or scan back to us*
* *3011 w HC CONTACT 2’s signature to HC CONTACT 3 for signature (HC CONTACT 4 – Oct2012)*
1. *Labels:*
* *Spine = CTA (or CTA-A) and COG protocol*
* *Directorate Address*
* *COG protocol*
1. *Fedex:*
* *Prepare Shipment Online & Schedule P/U*
1. *SENT:*
 | ***BURN CD***1. *Label CD:*
* *Sponsor = COG (or DFCI, or TACL, or C17)*
* *HC Control # (or “New CTA” if no prior #)*
* *“Protected B”*
* *Microsoft Forefront Endpoint Protection2010, version date*
* *Month & Year*
* *Disc 1 of 1 (etc.)*

1. *Burn CD:*
* *See NAME’s instructions.*

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PROTOCOL: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Directorate: \_\_\_\_\_\_\_\_\_\_\_\_ Amendment: \_\_\_\_\_\_\_

DRUGS:

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| NAME | STRENGTH/ROUTE**PER PROTOCOL** | STRENGTH/ROUTE**AVAIL on Cdn Mkt** | HCSCHEDULE (D OR F) | MKTD IN CDA (Y/N) | SUPPLIER | DISTRIBUTOR | WITHIN INDICATION (Y/N) |
| Common: |  |  |  |  |  |  |  |
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* 18-FDG? Then add 18-FDG Control # to ***Prior related applications*** as well as in 3011.
* MIBG? Required or recommended? I-123 (not marketed) or I-131 (marketed)?
* IB? From NCI; co? Emailed on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* CRL letter? Emailed on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Lot #? From NCI; co? Emailed on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Biologics faxback approval set up – SMO office to submit or company to submit? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	+ - * Faxback approval received on: \_\_\_\_\_\_\_\_\_\_\_\_
* Email NOL for **Phase 1 trials**
* Email NOL to PMBAfterhours@mail.nih.gov (subject line: NOL) for trials with **NCI-supplied agents**.