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

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| **HC Folder Structure** | **Printing** | **Office Folder** |
| **Module 1**:  1.0 Correspondence  1.0 .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 Forms  Attestation for e-documents  Summary of Additional Drugs Form |  | *SOAD form only* |
| 1.2.5 Compliance and Site Information  1.2.5.1 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 Protocol  Amended (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 & Assent  Sample assent for children > 7 yrs of age, YIS  Sample 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.* |

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

DRUGS:

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| NAME | STRENGTH/ROUTE  **PER PROTOCOL** | STRENGTH/ROUTE  **AVAIL on Cdn Mkt** | HC  SCHEDULE (D OR F) | MKTD IN CDA (Y/N) | SUPPLIER | DISTRIBUTOR | WITHIN INDICATION (Y/N) |
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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](mailto:PMBAfterhours@mail.nih.gov) (subject line: NOL) for trials with **NCI-supplied agents**.