

<b>ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY</b>	<b>CORRELATIVE SCIENCE PROCEDURE MANUAL</b> Biospecimen Collection for Randomized phase II/III study of venetoclax (ABT-199) plus chemoimmunotherapy for MYC/BCL2 double-hit and double expressing lymphomas Short Title- A051701	Version No: 2.0	Effective Date: 09/22/2020
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## CORRELATIVE SCIENCE PROCEDURE MANUAL

### 1. Purpose

This document describes the procedures required for the collection, shipping, and processing of biospecimens from all patients enrolled or registered on A051701. This document also describes the procedures that will be followed subsequent to the receipt of biospecimens by Cleveland Clinic or the Alliance Biorepository (i.e. Siteman Cancer Center Tissue Procurement Core at Washington University), prior to their use for protocol-specified and future, unspecified correlative science research studies. This document should be used by staff involved with any aspect of the A051701 biospecimen collection, processing, and submission, including staff at satellite institutions.

### 2. Scope

This document applies to all biospecimens collected specifically for A051701 only. Please refer to the trial protocol-specific language for additional details regarding eligibility, participant enrollment, data submission, and specific procurement procedures. **Please ensure that you are reading the most updated version of this document. This document may experience minor updates, revisions, and clarifications independent of a formal protocol amendment. The most recent version of this document may be found on the Alliance website and CTSU.**

### 3. Definitions

Term	Definition
ABWUSTL	Alliance Biorepository at Washington University in St. Louis
FFPE	Formalin fixed, paraffin embedded

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#### 4. Contact Information

- 4.1** For questions and problems related to protocol administration, eligibility, patient registration, and data submission, relevant contact information is listed on protocol pages 1 and 2.
- 4.2** For information on using the BiOMS system, please refer to the ‘Help’ links on the BiOMS webpage to access the online user manual, FAQs, and training videos. To report technical problems, such as login issues or application errors, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org). For assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).
- 4.3** For all other questions regarding biospecimen procurement and shipping procedures, please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu)

#### 5. Site Preparation

- 5.1** Please refer to A051701 protocol document for any specific requirements related to patient enrollment, registration, and regulatory compliance.
- 5.2** Please ensure that you have appropriate log on credentials and can successfully access the BiOMS application. The BiOMS application is used for both requesting biospecimen collection kits and for logging the collection and shipment of biospecimens to Cleveland Clinic or to the Alliance Biorepository at Washington University. For training and assistance in using the application or questions or problems related to specific specimen logging, please contact: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).
- 5.3** Prior to collection of whole blood specimens, a biospecimen collection kit must be at the collection site. Please see section 7 for requesting biospecimen collection kits. Please allow at least 10 working days to receive the collection kit.

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**5.4** Please confirm that your institutional pathology department is willing to submit original diagnostic slides and immunostains for histopathology review AND up to eight (8) unstained slides from diagnostic tumor tissue for additional confirmatory tests to be performed, if needed. Institutions whose pathology department is unwilling to comply with slide submission should not enroll patients to this study.

**6. Collection Schema**

The following biospecimens are to be collected at each of the time points. Please refer to individual collection kit instructions, biospecimen collection and processing methods, and specific shipping procedures below.

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Time Point	Kit (Y/N)	Biospecimen	Quantity	Collection / Processing Method	Shipping	Recipient Lab	Notes
<b>Mandatory for all patients registered to A051701</b>							
Registration	N	Original diagnostic slides and immunostains for histopathology review	Case dependent	Stained slide submission (9.2)	Ambient	Cleveland Clinic	1
Registration	N	8 unstained tumor tissue slides	8	Fixed tissue slides (9.3)	Ambient	Cleveland Clinic	2
<b>A051701 Biobanking</b>							
Registration	N	Fixed tissue block	1	Fixed tissue block (9.4)	Ambient	ABWUSTL	3, 4
Registration	N	Unstained slides	5	Fixed tissue slides (9.5)	Ambient	ABWUSTL	3, 4
Registration	N	Fixed tissue cores	2 x 4 mm	Fixed tissue cores (9.6)	Ambient	ABWUSTL	3, 4
Registration	Y	Whole blood ( Streck BCT tubes)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	ABWUSTL	3
Registration	Y	Whole blood ( EDTA tube)	1 x 10 ml	Whole blood- EDTA tube (10.2)	Ambient	ABWUSTL	3
<b>End of Cycle 1</b>							
End of Cycle 1	Y	Whole blood ( Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	ABWUSTL	3
<b>End of Cycle 2</b>							
End of Cycle 2	Y	Whole blood ( Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	ABWUSTL	3
<b>End of Treatment</b>							
End of Treatment	Y	Whole blood ( Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	ABWUSTL	3
<b>Every 3 Months</b>							
Every 3 Months	Y	Whole blood ( Streck BCT tube)	2 x 10 ml	Plasma for cfDNA (10.1)	Ambient	ABWUSTL	3, 5

**Notes:**

- To facilitate central review turnaround time for eligibility determination, submission of **original stained slides is highly encouraged**. Stained slides will be promptly returned. Submitted samples must include the stained slides of the diagnostic tumor biopsy including (but not limited to) H&E, CD20, BCL2, BCL6, MYC, CD10, MUM1, and Ki-67. Due to small biopsy size and extensive workup during diagnosis, unstained recut slides often do not represent tumor and can result in failure to confirm biomarker status.

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2. If unstained slides are not available, the stained slides must be of sufficient diagnostic quality for central confirmation of the diagnosis. Eight (8) unstained slides should be submitted. If tissue is limited, please submit as many slides as possible, up to 8. See section 9.3 for additional details.
3. Collection is optional for patients but requires all sites offer to patients to consent. Please see protocol-specific consent documents. Specimens should be collected only from patients who answer “yes” to model consent question #1.
4. A paraffin tissue block with adequate tumor **OR** 5 unstained slides (10 micron) **AND** 2 fixed tissue cores (4 mm) from such a block should be submitted for patients opting in for A051701 biobanking. If fewer than 5 unstained slides can be submitted, please submit as many as possible.
5. Collection will occur every 3 months until 24 months following the end of treatment.

## 7. Biospecimen Collection Kits

### 7.1 Blood Specimens

- 7.1.1** To facilitate the proper collection and shipping of whole blood specimens, biospecimen collection kits and materials will be provided. The cost of the kit and shipping the kit to the site will be paid for. The institution is expected to pay for return shipping of the kit with the biospecimens to the Alliance Biorepository at Washington University in St. Louis via priority overnight shipping.
- 7.1.2** Kits should be requested at least 10 working days in advance of the anticipated collection date. As many as 3 kits can be requested at one time. Since the collection materials (vacutainer tubes) have expiration dates, do not request kits more than 90 days prior to their anticipated use. All kits must be requested by using the BiOMS system.
- 7.1.3** Kit contents and specific instructions for use of the kit are provided in the kit box. Please return any used collection materials with the kit.
- 7.1.4** Once a kit is received, do not discard the outer cardboard overwrap. The kit, containing biospecimens, is to be shipped back in the same box.
- 7.1.5** Please return all components of the kit, regardless of whether they have been used or not. Kits and kit components are recycled when possible, minimizing the kit cost.

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- 7.1.6** Well in advance of collecting biospecimens, inspect the biospecimen collection kit to ensure that all components are present and not expired, particularly if the kit has been onsite for longer than 30 days.
- 7.1.7** Note that individual kit components that are expired, damaged, or missing cannot be replaced. The remedy is to order a complete, new kit (Please note in your request that you are replacing an expired or damaged kit).
- 7.1.8** Please return all kits that have expired or missing components. Return the ENTIRE kit using the cheapest possible shipping method at your expense. DO NOT DISCARD kits that have missing or expired components. Recycling kits keeps the cost of kit materials to a minimum. Please note that all out-going and in coming kits are tracked, and sites that have requested many more kits than they have returned will be charged for non-returned kits.
- 7.1.9** If a biospecimen collection component (e.g. vacutainer collection tube) is missing, damaged, or expired, the institution may substitute a like-kind collection tube from their own supply. However, note that some kit components are highly specialized (e.g. Streck BCT) and probably are not available at the institution.
- 7.1.10** Note that protocol requirements are based on blood volumes, not tube sizes. If the protocol requires the collection of 8 cc of whole blood, generally a 10 cc tube is provided in the kit for convenience. If desirable or necessary to collect 8 cc in 3 x 3 cc tubes (for example), that is permissible.

## **7.2 Tissue Specimens**

- 7.2.1** There is no independent “kit” for submission of paraffin blocks or slides.
- 7.2.2** Blocks and slides should be packaged to avoid breakage using a padded envelope or, preferably, a small Styrofoam container.
- 7.2.3** During warm weather months, paraffin blocks and slides should be shipped in an insulated container that contains a refrigerant pack, to avoid heat > 25 degrees C (77 degrees F) that may melt paraffin and damage the tissue specimens.

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**7.2.4** Please see **Section 11 – Biospecimen Shipping** for specific instructions on shipping.

## 8. Biospecimen Labeling and Tracking

- 8.1** All research biospecimens (vacutainer tubes and tissue bags) **MUST** be labeled with the participant study number, patient initials (Last, First, Middle), the date and time (if applicable) of collection and specimen type.
- 8.2** Surgical pathology tissue blocks should not be labeled in any manner. The institutional surgical pathology number (e.g. “S16-1234”) and the individual block identifier (e.g. “A3”) should be readable on the block. If tissue sections are being submitted instead of the block, each tissue section slide should be labeled with the patient study number, the institutional Surgical Pathology Number and block identifier. Provide **a de-identified copy of the surgical pathology report**, labeled with the patient study number, institutional Surgical Pathology Number and block identifier, corresponding to the blocks or slides submitted. **A copy of the “A051701 Central Review Submission Form” should accompany unstained slides submitted to the Cleveland Clinic for histopathology review.** See section 9 for additional details.
- 8.3** Label all containers and vials with an indelible, solvent-resistant marker when they are at ambient temperature.
- 8.4** Do not affix any labels to vials, slides or tubes. Label the collection containers directly with the marking pen.
- 8.5** All biospecimens that are collected and sent to the Alliance Biorepository or Cleveland Clinic must be **logged and tracked in BioMS**. The BioMS system is a web-based application that tracks the collection and shipping of biospecimens. Once individual biospecimens are logged and ‘shipped’ in the BioMS system, a packing manifest will be created by the system. Note that a different packing manifest will be generated for each shipment to Cleveland Clinic and to the Alliance Biorepository, respectively. This manifest must be printed out and must accompany all biospecimen shipments. To become familiar with the BioMS system and for further information about training, access, and use, please contact the BioMS Help desk at: 1-855-55-BIOMS or [bioms@alliancenctn.org](mailto:bioms@alliancenctn.org).

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**8.6** In the event that BioMS cannot be accessed, please complete a BioMS Specimen Log and Shipping Manifest form which can be found here- <http://tinyurl.com/alliance-bioms-contingency>.

## 9. Tissue Collection

### 9.1 Overview.

**9.1.1** Please refer to protocol-specific instructions for procedures related to actual tissue procurement from individual participants. The method for research tissue procurement (needle core biopsy, sampling of surgically resected tumor) is dependent upon the disease site and the individual patient.

**9.1.2** When procuring tissue biospecimens by any method, when possible, avoid tissue that is grossly necrotic, hemorrhagic, fatty, or fibrous. If in doubt, briefly (1 min or less) place the tissue segment in a sterile specimen cup containing physiologic (normal) saline to rinse the tissue. Necrotic, hemorrhagic, and fatty tissue will generally dissolve or float on the surface while tumor and parenchymal tissue will remain intact and sink to the bottom of the cup.

### 9.2 Submission of Stained Slides for Histopathology Review

**9.2.1** To facilitate central review turnaround time for eligibility determination, **submission of original stained slides is highly encouraged**. Due to small biopsy size and extensive workup during diagnosis, unstained recut slides often do not represent tumor and can result in failure to confirm biomarker status.

**9.2.2** Stained slides will be promptly returned after review. Submitted samples must include the stained slides of the diagnostic tumor biopsy including (but not limited to) H&E, CD20, BCL2, BCL6, MYC, CD10, MUM1, and Ki-67. All diagnostic slides should be submitted to Cleveland Clinic along with a de-identified copy of the corresponding pathology report and A051701 Central Review Submission Form which is available from the Alliance website or CTSU.



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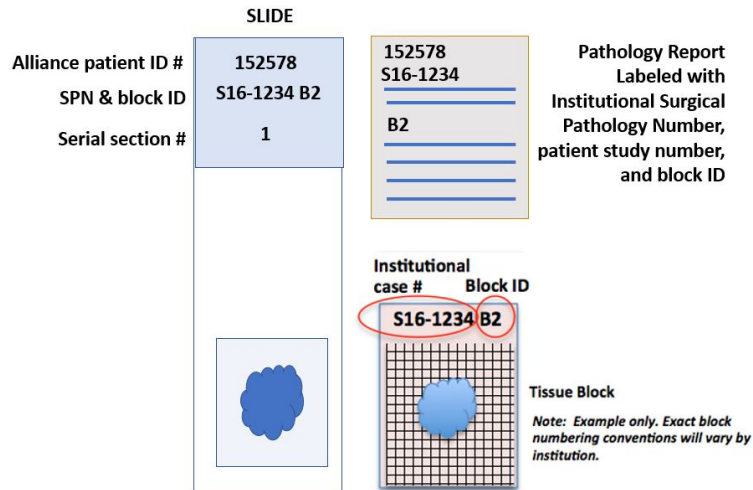
### 9.3 Submission of Unstained Slides for Histopathology Review

**9.3.1** Eight (8) unstained sections from a diagnostic tumor tissue block are required for additional confirmatory tests to be performed, if needed. If fewer than 8 slides can be submitted, please submit as many as possible. Please follow procedures below for submitting unstained slides.

# of slides	Section thickness	Slide type	Purpose
8	4-6 micron	Positively Charged	Additional tests to confirm diagnosis and biomarker status

- 9.3.2** Serial, tissue sections should be cut fresh from the appropriate formalin fixed, paraffin embedded tissue block.
- 9.3.3** Cut sections at 4-6 micron thickness as indicated onto charged slides.
- 9.3.4** Ensure that each slide is labeled with the patient study number, the institutional Surgical Pathology Number and block ID, and the slide serial section number (1, 2, 3, etc.).
- 9.3.5** Do not label slides with adhesive labels. Write or print information on the textured surface of the slide with indelible, solvent-resistant ink.
- 9.3.6** No adhesives or other additives should be used in the water bath.
- 9.3.7** Mount only one tissue section per slide. Make certain sections are placed on the painted / textured side of the slide.
- 9.3.8** When placing the sections onto the slides, ensure that the tissue is placed on the bottom third of the slide. Ensure that each serial section from the block is placed in the same orientation on each slide.
- 9.3.9** See figure below for proper mounting and labeling.

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**9.3.10** Air dry slides for 12-24 hours prior to shipping. Do not oven dry slides.

**9.3.11** Use slide mailers or a slide box to ship slides. Slides should not be touching each other. Ensure that slides from only one patient are placed in one slide mailer.

**9.3.12** Include a copy of the **de-identified pathology report and the “A051701 Central Review Submission Form”** with slides. This form is available for download on the Alliance website or from CTSU. Please include any ancillary immunophenotyping, flow cytometry, cytogenetic, or molecular genetic (FISH) reports related to the sample.

#### **9.4 Diagnostic Pathology Fixed Tissue Blocks for Biobanking**

**9.4.1** For patients who consent to A051701 biobanking for future research, a representative diagnostic block with adequate tumor should be submitted, if applicable.

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**9.4.2** Any clinical surgical pathology block that is submitted for research studies will not be exhausted or rendered unsuitable for future diagnostic use. Any clinical surgical pathology block that is submitted will be returned within ten working days of written request, when needed for clinical management or clinical trial enrollment for a specific patient. Otherwise, all blocks will be returned to the submitting institution when the trial and correlative science study end points have been met.

**9.4.3** In the event that an institution will not release a tumor tissue block, the institution may instead submit two (2), 4 mm cores **in addition to** five (5), 10 micron unstained slides.

## **9.5 Unstained Slides from Diagnostic Fixed Tissue Blocks for Biobanking**

**9.5.1** In cases where an institution is unwilling or unable to submit a tissue block for biobanking for future research, a set of 5 unstained slides with adequate tumor may be sent as an alternative. These slides are in addition to the required slides for histopathology review and diagnosis confirmation (section 9.3) If fewer than 5 unstained slides can be submitted, please submit as many as possible. Please follow the procedures below for submitting unstained slides. If your pathology department is unwilling or unable to follow these tissue-sectioning instructions, please consider submission of a tissue block, which can be cut at the biorepository and returned to your institution at a later date.

<b># of slides</b>	<b>Section thickness</b>	<b>Slide type</b>	<b>Purpose</b>
5	10 micron	Non Charged	DNA, RNA

**9.5.2** Serial, tissue sections should be cut fresh from the appropriate formalin fixed, paraffin embedded tissue block.

**9.5.3** Cut sections at 10 micron thickness as indicated onto non charged slides.

**9.5.4** Ensure that each slide is labeled following instructions in section 9.3.

**9.5.5** Use slide mailers or a slide box to ship slides. Slides should not be touching each other. Ensure that slides from only one patient are placed in one slide mailer.

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**9.5.6** Include a copy of a **de-identified pathology report**, labeled with patient study number, institutional Surgical Pathology Number and block identifier.

## **9.6 Tissue Cores from Diagnostic Fixed Tissue Blocks for Biobanking**

**9.6.1** In cases where an institution is unwilling or unable to submit a tissue block, two (2), 4 mm cores may be submitted **in addition to** the unstained tumor tissue slides.

**9.6.2** Place the tissue cores directly into a microcentrifuge tube or any other suitable container. Label the tube of tissue following the guidelines outlined in section 9.3.

## **10. Blood Collection Methods**

### **10.1 Plasma Nucleic Acid (Streck) Tube Processing**

**10.1.1** Collect 10 ml of blood into each of the Streck BCT tubes using standard venous phlebotomy. Invert tubes 10 times.

**10.1.2** Store Streck tubes with whole blood at room temperature. Do not freeze or refrigerate the tubes. The tubes may be stored for up to 72 hours at ambient temperature before shipment. Ensure that the Streck tubes are shipped at ambient temperature to avoid freezing.

### **10.2 Whole blood- EDTA tube (no processing)**

**10.2.1** Collect whole blood by standard venous phlebotomy technique into the EDTA tube. Invert tube 10 times.

**10.2.2** Store EDTA tube with whole blood at 4 degrees Celsius (i.e. refrigerated) until shipping. Do not freeze the tube. The tube must be received at the Biorepository within 24 hours of collection (e.g. Friday—Saturday or holiday collections are not allowed). Ensure that the EDTA tube is shipped at ambient temperature to avoid freezing.

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## 11. Biospecimen Shipping

### 11.1 Overview

- 11.1.1** Please see the Directions for Use (DFU) document that is included in each kit for specific directions on how to package and ship biospecimens.
- 11.1.2** Place the original, completed copy of the BioMS packing manifest in the shipment. If sending tissue or slides, include a **copy of the de-identified surgical pathology report**, labeled with the patient study number, institutional Surgical Pathology Number and block identifier. Mandatory tissue submission to Cleveland Clinic should also be accompanied by the A051701 Central Review Submission Form available for download on the Alliance website or CTSU. Do not send specimens without a completed BioMS Packing Manifest or substitute “BioMS Downtime Form.” Biospecimens cannot be accepted without this completed form.
- 11.1.3** Many biospecimens (e.g. unprocessed whole blood in EDTA tubes) should be shipped on the same day that they are collected (Monday – Thursday). Many biospecimens must be received by the recipient lab within 24 hours of collection. If collected biospecimens cannot be shipped on the same day that they are collected (e.g. Friday – Saturday or Holiday collections), please contact the Alliance Biorepository Program Manager: 1-314-747-4402 or [alliance@email.wustl.edu](mailto:alliance@email.wustl.edu) for further instructions, at least 24 hours prior to anticipated collection.
- 11.1.4** **Do not ship on Friday, Saturday, Sunday or the day before a nationally recognized holiday.**

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## **11.2 Shipping to ABWUSTL (Biobanking)**

**11.2.1** Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor. A blank FedEx Air Bill is provided with the kit for convenience.

Ship to:

**Alliance Biorepository  
c/o Siteman Cancer Center Tissue Procurement Core  
Washington Univ. School of Medicine  
425 S. Euclid Ave.  
Room 5120  
St. Louis, MO  
63110-1005  
Phone: 314-454-7615**

## **11.3 Shipping to Cleveland Clinic (Central Pathology Review)**

**11.3.1** Ship container for PRIORITY OVERNIGHT DELIVERY according to IATA guidelines and standard institutional policies and using the preferred vendor. A blank FedEx Air Bill is provided with the kit for convenience.

Ship to:

**Cleveland Clinic  
Pathology and Lab Medicine  
Attn: Eric Hsi/Joanne Chilton  
Alliance A051701  
2119 E 93<sup>rd</sup> St, L15  
Cleveland OH 44106  
Phone: (216) 636-0186**

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## 12. ABWUSTL Biospecimen Receipt and Quality Assurance Measures

- 12.1** Upon receipt, all biospecimens will be accessioned into the TPC informatics system, OpenSpecimen.
- 12.2** All biospecimens will be logged, associated, and tracked by the unique patient biopsy control number.
- 12.3** Each individual biospecimen will receive and be physically labeled with a unique biospecimen identifier, associated with the biopsy control number in the TPC informatics system.
- 12.4** Upon receipt, all physical biospecimens received will be reconciled with what is recorded on the BioMS packing manifest. Any discrepancies noted will be communicated to the Program Manager who will contact the submitting site for reconciliation.
- 12.5** Upon receipt, any biospecimen received that is not in appropriate physical condition (broken vials, frozen samples that are thawed, ambient samples that are frozen) will be reported to the Program Manager, who will contact the submitting site for reconciliation.
- 12.6** Frozen aliquoted biofluids will be stored under liquid nitrogen vapor.
- 12.7** Fixed tissue biospecimens will be processed and embedded into paraffin using TPC standard operating procedures.
- 12.8** All biospecimens will remain in storage until additional processing or review is requested in writing by the appropriate protocol PI.

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Version	Description and Justification of Change	Author	Effective Date
2.0	Removed instructions for scanning slides Other minor updates to align with template	PAA	09/22/2020
1.2	Removed signature page Corrected versioning Updated hyperlinks	PAA	07/09/2020
1.1	Update required slides, footnote 5 Updated submission of image files Other minor updates	GLS, MAW	06/01/2020
1.0	New	PAA	07/09/2019