Site Name:					
Investigator Site File – document version checklist Complete 'yes' or 'no' to confirm the presence or absence of each document specified.					
Document Name	**Version**	**Date**	**Present?**		**Comments**
1. TRIAL MANAGEMENT					
Contact List of CTC staff	2	28/09/2018	Y ☐	N ☐	
Trial/CTC Newsletters	N/A	N/A	Y ☐	N ☐	
Record/Minutes of (internal) trial related meetings at Site	Site specific	N/A	Y ☐	N ☐	
2. PROTOCOL AND TRIAL INFORMATION					
Protocol - Current	3.0	06/08/2018	Y ☐	N ☐	
Protocol – Superseded	2.0	03/01/2018	Y ☐	N ☐	
Protocol Version History Log *(updated with current protocol version)*	N/A	N/A	Y ☐	N ☐	
3. PATIENT INFORMATION					
Safety Run-in PIS - Current	4.0	06/08/2018	Y ☐	N ☐	
Safety Run-in PIS - Superseded	3.0	05/03/2018	Y ☐	N ☐	
Phase II PIS - Current	3.0	05/03/2018	Y ☐	N ☐	
Phase II PIS - Superseded	N/A	N/A	Y ☐	N ☐	
GDPR Transparency Statement	1.0	03/07/2018	Y ☐	N ☐	
Safety Run-in ICF - Current	5.0	04/02/2018	Y ☐	N ☐	
Safety Run-in ICF – Superseded	4.0	06/08/2018	Y ☐	N ☐	
Safety Run-in ICF – Superseded	3.0	05/03/2018	Y ☐	N ☐	
Phase II ICF - Current	3.0	05/03/2018	Y ☐	N ☐	
Phase II ICF - Superseded	N/A	N/A	Y ☐	N ☐	
Original Patient Signed ICFs	N/A	N/A	Y ☐	N ☐	
GP Letter – Safety Run-in	1.0	29/11/2017	Y ☐	N ☐	
GP Letter – Phase II	1.0	29/11/2017	Y ☐	N ☐	
Patient Contact Card – Safety Run-in	1.0	29/11/2017	Y ☐	N ☐	
Patient Contact Card – Phase II	1.0	29/11/2017	Y ☐	N ☐	
Patient Diary	1.0	29/11/2017	Y ☐	N ☐	
Pregnancy Monitoring PIS (Patient) - Current	2.0	06/08/2018	Y ☐	N ☐	
Pregnancy Monitoring PIS (Patient) - Superseded	1.0	29/11/2017	Y ☐	N ☐	
Pregnancy Monitoring PIS (Partner) - Current	2.0	06/08/2018	Y ☐	N ☐	
Pregnancy Monitoring PIS (Partner) - Superseded	1.0	29/11/2017	Y ☐	N ☐	
Pregnancy Monitoring Consent Form (Patient)- Current	2.0	06/08/2018	Y ☐	N ☐	
Pregnancy Monitoring Consent Form (Patient)- Superseded	1.0	29/11/2017	Y ☐	N ☐	
Pregnancy Monitoring Consent Form (Partner)- Current	2.0	06/08/2018	Y ☐	N ☐	

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Document Name	**Version**	**Date**	**Present?**		**Comments**
Pregnancy Monitoring Consent Form (Partner)- Superseded	1.0	29/11/2017	Y ☐	N ☐	
Version History Log *(updated with current versions)*	N/A	N/A	Y ☐	N ☐	
4.0 ETHICS & REGULATORY					
CTA Application Form	N/A	N/A	Y ☐	N ☐	
MHRA CTA Approval	N/A	09/01/2018	Y ☐	N ☐	
REC Favourable opinion on further information	N/A	16/03/2018	Y ☐	N ☐	
HRA Approval	N/A	26/03/2018	Y ☐	N ☐	
Sponsor Letter	N/A	01/11/2017	Y ☐	N ☐	
Insurance Letter	N/A	01/11/2017	Y ☐	N ☐	
Amendment Log	N/A	N/A	Y ☐	N ☐	Last updated 21/09/2018
Substantial Amendment 1	N/A	N/A	N/A	N/A	Non notifiable
Substantial Amendment 2 – MHRA Approval	N/A	07/09/2018	Y ☐	N ☐	
Substantial Amendment 2 – REC Approval (revised 20/09/2018)	N/A	20/09/2018	Y ☐	N ☐	
Substantial Amendment 2 – HRA Approval	N/A	20/09/2018	Y ☐	N ☐	
Substantial Amendment 3 – HRA Approval	N/A	08/02/2019	Y ☐	N ☐	Submitted to HRA only
Signed SSI Form *(non-English sites)*	N/A	Site specific	Y ☐	N ☐	
Site Approval R&D letter	Site specific	N/A	Y ☐	N ☐	
5. AGREEMENTS AND CONTRACTS					
Signed Clinical Trial Site Agreement (CTSA)	Site specific	Site specific	Y ☐	N ☐	
Completed Site Registration Form	1.0	09/03/2018	Y ☐	N ☐	
Site Activation Letter	N/A	20/07/2018	Y ☐	N ☐	
6. SITE INFORMATION/SITE STAFF INFORMATION					
Site Staff Delegation Log	2.0	19/07/2018	Y ☐	N ☐	
Site Contacts Form	1.0	25/05/2018	Y ☐	N ☐	
Site Staff CVs and GCPs	Site specific	N/A	Y ☐	N ☐	
Source Data Form	1.0	16/04/2018	Y ☐	N ☐	
7. PATIENT SCREENING & RECRUITMENT					
Patient Screening Log (or file note if kept as an Excel spreadsheet)	1.0	18/06/2018	Y ☐	N ☐	
Master Subject List	1.0	09/04/2018	Y ☐	N ☐	

Site Name:					
Investigator Site File – document version checklist Complete 'yes' or 'no' to confirm the presence or absence of each document specified.					
Document Name	**Version**	**Date**	**Present?**		**Comments**
Confirmation of Safety Run-in Registration Emails / Phase II randomisation Emails	Site specific	N/A	Y ☐	N ☐	
8. LABORATORY					
Laboratory Normal Ranges	1.0	07/06/2018	Y ☐	N ☐	
Accreditation Documents	N/A	Site Specific	Y ☐	N ☐	
Laboratory Manual - Current	3.0	01/10/2018	Y ☐	N ☐	
Laboratory Manual – Superseded	2.0	25/09/2018	Y ☐	N ☐	
Laboratory Manual – Superseded	1.0	09/07/2018	Y ☐	N ☐	
Archival FFPE Processing & Shipping Form	2.0	04/10/2018	Y ☐	N ☐	
New Biopsy FFPE Processing & Shipping Form	2.0	04/10/2018	Y ☐	N ☐	
New Biopsy in RPMI Processing & Shipping Form	2.0	04/10/2018	Y ☐	N ☐	
PBMC Sample Processing and Shipping Form	3.0	04/10/2018	Y ☐	N ☐	
Exosomes Sample Processing form	3.0	04/10/2018	Y ☐	N ☐	
ctDNA Sample Processing form	2.0	04/10/2018	Y ☐	N ☐	
Dry Ice Sample Shipping Form	2.0	04/10/2018	Y ☐	N ☐	
Archival FFPE Processing & Shipping Form- Superseded	1.0	29/06/2018	Y ☐	N ☐	
New Biopsy FFPE Processing & Shipping Form- Superseded	1.0	29/06/2018	Y ☐	N ☐	
New Biopsy in RPMI Processing & Shipping Form- Superseded	1.0	29/06/2018	Y ☐	N ☐	
PBMC Sample Processing and Shipping Form- Superseded	2.0	25/09/2018	Y ☐	N ☐	
PBMC Sample Processing and Shipping Form- Superseded	1.0	29/06/2018	Y ☐	N ☐	
Exosomes Sample Processing form-Superseded	2.0	25/09/2018	Y ☐	N ☐	
Exosomes Sample Processing form-Superseded	1.0	29/06/2018	Y ☐	N ☐	
ctDNA Sample Processing form-Superseded	1.0	29/06/2018	Y ☐	N ☐	
Dry Ice Sample Shipping Form-Superseded	1.0	29/06/2018	Y ☐	N ☐	
Biological Sample Inventory Log	1.0	27/06/2018	Y ☐	N ☐	
Biological Sample Labels	N/A	N/A	Y ☐	N ☐	
9. INVESTIGATOR'S BROCHURE (IB)					
Current Investigator Brochure: Avelumab	7	31/03/17	Y ☐	N ☐	

Site Name:					
Investigator Site File – document version checklist Complete 'yes' or 'no' to confirm the presence or absence of each document specified.					
Document Name	**Version**	**Date**	**Present?**		**Comments**
Current Investigator Brochure: Cetuximab Addendum 1	23	Apr 2018	Y ☐	N ☐	
Current Investigator Brochure: Cetuximab	23	Apr 2018	Y ☐	N ☐	
Superseded SPC: Cetuximab	n/a	Jun 2014	Y ☐	N ☐	
10. TRIAL DRUG SUPPLIES/PHARMACY ARRANGEMENTS					
Summary of Drug Arrangements	2.0	22/08/2018	Y ☐	N ☐	
Summary of Drug Arrangements-superseded	1.0	28/03/2018	Y ☐	N ☐	
Master trial prescription	Site specific	N/A	Y ☐	N ☐	
11. DATA MANAGEMENT					
SRI Registration form	1.0	07/06/2018	Y ☐	N ☐	
Rolling Concomitant Medication form	1.0	07/06/2018	Y ☐	N ☐	
Rolling Adverse event form	1.0	07/06/2018	Y ☐	N ☐	
SRI Pre-treatment form	1.0	07/06/2018	Y ☐	N ☐	
SRI Treatment form (Cycle 1)	1.0	07/06/2018	Y ☐	N ☐	
SRI Treatment form (Cycle 2)	1.0	07/06/2018	Y ☐	N ☐	
SRI Treatment form (Cycle 3 onwards)	1.0	07/06/2018	Y ☐	N ☐	
SRI Disease Assessment form	1.0	07/06/2018	Y ☐	N ☐	
Completion of trial treatment form	1.0	07/06/2018	Y ☐	N ☐	
Treatment Summary form	1.0	07/06/2018	Y ☐	N ☐	
Change of status form	1.0	07/06/2018	Y ☐	N ☐	
Follow Up form	1.0	07/06/2018	Y ☐	N ☐	
Progression	1.0	07/06/2018	Y ☐	N ☐	
Death form	1.0	07/06/2018	Y ☐	N ☐	
Additional Haematology/ Biochemistry form	1.0	07/06/2018	Y ☐	N ☐	
Normal ranges form	1.0	07/06/2018	Y ☐	N ☐	
SAE Report	1.0	07/06/2018	Y ☐	N ☐	
Pregnancy Report	1.0	11/07/2018	Y ☐	N ☐	
SAE Fax Cover Sheet	1.0	26/07/2018	Y ☐	N ☐	
Pregnancy Fax cover sheet	1.0	26/07/2018	Y ☐	N ☐	
12. PHARMACOVIGILANCE					
Completed SAE reports *(with fax cover sheets and acknowledgements from CTC)*	N/A	N/A	Y ☐	N ☐	
SAE report correspondence	N/A	N/A	Y ☐	N ☐	
Completed pregnancy reports	N/A	N/A	Y ☐	N ☐	

Site Name:					
Investigator Site File – document version checklist Complete 'yes' or 'no' to confirm the presence or absence of each document specified.					
Document Name	**Version**	**Date**	**Present?**		**Comments**
(with fax cover sheets and acknowledgements from CTC)					
Pregnancy report correspondence	N/A	N/A	Y ☐	N ☐	
Correspondence relating to pharmacovigilance	N/A	N/A	Y ☐	N ☐	
13. INCIDENT REPORTING					
UCL CTC Incident Report Template	2.0	25/06/15	Y ☐	N ☐	
Completed Incident reports	N/A	N/A	Y ☐	N ☐	
14. SPONSOR MONITORING ACTIVITIES					
Site Initiation Slides	1.0	07/06/2018	Y ☐	N ☐	
Site Initiation Report	1.0	07/06/2018	Y ☐	N ☐	
Monitoring Plan	1.0	17/07/2018	Y ☐	N ☐	
On site monitoring visit letters	N/A	Site specific	Y ☐	N ☐	
On-site Monitoring visit log	1.0	12/09/2018	Y ☐	N ☐	
On site monitoring visit Actions	N/A	Site specific	Y ☐	N ☐	
16. CORRESPONDENCE					
All correspondence filed	N/A	N/A	Y ☐	N ☐	
Please provide the email address of the person to whom updated documents should be sent:					

The completed form can be returned to ctc.each@ucl.ac.uk or faxed to 020 7679 9871 .

This is intended to support site's own internal systems for maintaining the ISF, **therefore if the checklist is not returned to UCL CTC we will assume that documents contained within your ISF is up-to-date.**

The following are general reminders regarding maintenance of the Investigator/Pharmacy Site File:

The folder must be stored in a secure location with appropriate/restricted access.

The documents should be filed as per index.
(CTC index or site's own index is acceptable)

Documents generated locally (e.g. local approvals, lab normal ranges, correspondence, etc.) must be filed in the applicable sections.

Where documents are held in an alternative location, file notes should be present to indicate this.

Up-to-date CVs must be present for all site staff.
(CVs should be current at the time the trial is opened, be kept up to date and be signed and dated)

GCP certificates must be present (or details of course attended listed in the CV) for all site staff.
(All staff should have attended a course – frequency of repeat training may be dictated by the employing institution policy, or 2 yearly where the institution has no policy, and more frequently when there have been updates to the legal or regulatory requirements for conduct of clinical trials). CVs/GCP certificates stored in an alternative location must be made available when required and archived in the ISF at the end of the trial.