PeRiOperaTivE mediCine plaTform (PROTECT) trial

Study IRAS Number: 353122

Chief Investigator: Tom Abbott

DATA COLLECTION SUPPORT TOOL

Version: 2.0

Date: 15/01/2026

SECTION 1: ELIGIBILITY				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	

Inclusion criteria	**YES**	**NO**
Adult (≥18 years) being treated within a surgical care pathway	☐	☐
Exclusion criteria		
Inability or refusal to provide informed consent	☐	☐

IF ALL ANSWERS ARE 'YES' TO THE INCLUSION CRITERIA AND 'NO' TO THE EXCLUSION CRITERIA THE PATIENT IS ELIGIBLE. PLEASE SEE PROTOCOL FOR MORE INFORMATION ON INCLUSION CRITERIA

SECTION 1: CONSENT				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

CONSENT		
Mode of consent	Paper ☐	Electronic ☐
Date of consent	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**	
Informed consent form and survey preferred language		
English		☐
Welsh		☐
Polish		☐
Romanian		☐
Panjabi		☐
Urdu		☐
Portuguese		☐

SECTION 2: PARTICIPANT DEMOGRAPHICS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

DEMOGRAPHICS					
Given name	|__|__|__|__|__|__|__|__|__|__|__|__|				
Family name	|__|__|__|__|__|__|__|__|__|__|__|__|				
Date of birth	|__|__|/|__|__|/|__|__|__|__| **(DD/MM/YYYY)**				
Age	|__|__|__| years				
Sex at birth	Female ☐	Male ☐			
National Health service (NHS) number	|__|__|__|__|__|__|__|__|__|__|__|__|				
Post code	|__|__|__|__| |__|__|__|				
Height (cm)	|__|__|__|	Weight (kg)	|__|__|__|	BMI	|__|__|

ETHNICITY *What is your ethnic group? Please select all the options that best describe your ethnicity or background E.g. you could select Black African and White British if this best reflects your identity.*	
Asian/ Asian British *If Yes, please give details*	☐
Bangladeshi	☐
Chinese	☐
Indian	☐
Pakistani	☐
Other Asian background, *please describe:*	
Black/ African/ Caribbean/ Black British *If Yes, please give details*	☐
African	☐
Caribbean	☐
Other Black/ African/ Caribbean background, *please describe:*	
White *If Yes, please give details*	☐
English / Welsh / Scottish / Northern Irish / British	☐
Gypsy or Irish traveller	☐
Irish	☐
Roma	☐
Other White background, *please describe:*	

Other ethnic group *If Yes, please give details*	☐
Arab	☐
Hispanic	☐
Latina/ Latino/ Latinx	☐
Other ethnic group, *please describe:*	
Other Mixed/ Multiple ethnic background, *please describe:*	

SECTION 3: BASELINE DATA				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

CO-MORBID DISEASE	**YES**	**NO**
Chronic obstructive pulmonary disease (COPD)	☐	☐
Asthma	☐	☐
Interstitial lung disease or pulmonary fibrosis	☐	☐
Ischaemic heart disease	☐	☐
Heart failure	☐	☐
Hypertension	☐	☐
Diabetes mellitus	☐	☐
If yes – does the patient use insulin therapy?	☐	☐
Liver cirrhosis	☐	☐
Chronic kidney disease	☐	☐
Peripheral vascular disease	☐	☐
Dementia	☐	☐
Active cancer	☐	☐
If yes – is cancer the indication for surgery?	☐	☐
Is the surgery intended to be curative?	☐	☐
Previous stroke or transient ischaemic attack	☐	☐
Current smoker *(within the last 14 days)*	☐	☐
Current vape or e-cigarette use *(within the last 14 days)*	☐	☐
Preoperative immunosuppressant therapy within 30 days before surgery *please tick one box*		
Steroids	☐	
Chemotherapy	☐	
None	☐	
Other immunosuppressant	☐	

LABORATORY TESTS (*most recent within 30 days before surgery*)	
Haemoglobin	|__|__|__| g/L
Creatinine measurement	|__|__|__|__| µmol/L
eGFR measurement	|__|__|__|__| ml/min per 1.73 m^2

ASA PHYSICAL STATUS SCORE *(Please refer to the data collection and definitions SOP for more details on ASA grade)*				
Class I ☐	Class II ☐	Class III ☐	Class IV ☐	Class V ☐

SECTION 3: QUALITY OF LIFE AT BASELINE (EQ5D)				PROTECT Perioperative Platform Trial
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	

QUALITY OF LIFE ASSESSMENT AT BASELINE (EQ5D)	
Mobility *please tick one box*	
I have no problems in walking about	☐
I have slight problems in walking about	☐
I have moderate problems in walking about	☐
I have severe problems in walking about	☐
I am unable to walk about	☐
Self-care *please tick one box*	
I have no problems washing or dressing myself	☐
I have slight problems washing or dressing myself	☐
I have moderate problems washing or dressing myself	☐
I have severe problems washing or dressing myself	☐
I am unable to wash or dress myself	☐
Usual Activities (e.g. work, study, housework, family of leisure activities) *please tick one box*	
I have no problems with performing my usual activities	☐
I have slight problems with performing my usual activities	☐
I have moderate problems doing my usual activities	☐
I have severe problems doing my usual activities	☐
I am unable to perform my usual activities	☐
Pain / Discomfort *please tick one box*	
I have no pain or discomfort	☐
I have slight pain or discomfort	☐
I have moderate pain or discomfort	☐
I have severe pain or discomfort	☐
I have extreme pain or discomfort	☐
Anxiety / Depression *please tick one box*	
I am not anxious or depressed	☐
I am slightly anxious or depressed	☐
I am moderately anxious or depressed	☐
I am severely anxious or depressed	☐
I am extremely anxious or depressed	☐
We would like to know how good or bad your health is TODAY. • **This scale is numbered from 0 to 100.** • **100 means the best health you can imagine.** • **0 means the worst health you can imagine.** **YOUR HEALTH TODAY =**	|__|__|__|

SECTION 5: SURGERY DETAILS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

SURGERY TIMINGS			
Date of surgery	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**		
Urgency of surgery *(Elective is surgery is where the intervention planned or booked in advance of routine admission to hospital. Timing to suit patient, hospital and staff.)*	Elective ☐	Non-elective ☐	
Urgency of non-elective surgery *(Please see the data collection and definitions SOP for details).*	Immediate ☐	Urgent ☐	Expedited ☐
Duration of anaesthesia	TIME: |__|__|__| **(MINS)**		
Duration of surgery	TIME: |__|__|__| **(MINS)**		

SECTION 5: SURGERY DETAILS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

SURGICAL SPECIALITY FOR MAIN PROCEDURE *please tick one box*	
Breast	☐
Cardiac	☐
Dental	☐
Ear, nose and throat	☐
Gastro-intestinal *(lower)*	☐
Gastro-intestinal *(upper)*	☐
Gynaecology	☐
Head and neck (maxilla-facial, salivary, thyroid)	☐
Hepato-biliary	☐
Neurosurgery	☐
Obstetrics	☐
Orthopaedics	☐
Plastics	☐
Thoracic	☐
Spine	☐
Urology & kidney	☐
Vascular	☐
Other, *please specify:*	☐
SURGICAL TECHNIQUE *please tick one box*	
Open surgical technique	☐
Laparoscopic surgical technique	☐
Laparoscopic converted to open	☐
Robotic technique	☐
Robotic converted to open	☐
Other, *please specify:*	☐

SECTION 5: SURGERY DETAILS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

ANAESTHESIA & ANALGESIA TECHNIQUES	**YES**	**NO**
General anaesthesia	☐	☐
If yes, was a total intravenous technique used?	☐	☐
Neuraxial technique *(e.g. spinal, epidural etc), please specify:*	☐	☐
Spinal neuraxial technique	☐	
Epidural neuraxial technique	☐	
Combined spinal and epidural neuraxial technique	☐	
Sedation	☐	☐
Regional technique, p*lease specify:*	☐	☐
Single shot injection	☐	
Catheter technique (e.g. rectus sheath catheter)	☐	
Patient-controlled intravenous analgesia (PCA) immediately after surgery	☐	☐
Other anaesthesia or analgesia technique, *please specify:*	☐	☐

LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY *please tick one box*

(The level of care should be defined according to the care the participant received rather than the location. If a participant remains in a recovery or post-anaesthetic care area, please record as level 2, unless the patient was intubated. In this case, please recorded as level 3)

Critical care level 3	☐
Critical care level 2	☐
Surgical ward (level 0 or 1)	☐

SECTION 7: FOLLOW-UP AT 30 DAYS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

Date of follow-up	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	
PARTICIPANT STATUS		
Participant status at 30 days after surgery	☐ Alive	☐ Dead
If dead, Date of death	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	

Hospital discharge		
Was the participant discharged within 30 days after surgery?	Yes ☐	No ☐
If yes: Discharge date	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**	
Discharge destination		
Own home	☐	
Rehabilitation facility	☐	
Care home	☐	
Other, *describe other destination of discharge:*		
Re-admission to hospital within 30 days from surgery	Yes ☐	No ☐
Length of hospital stay		
Duration of primary hospital admission (in calendar days) up to 30 days after surgery *(Duration of primary hospital admission in calendar days. If discharged before midnight on the day of surgery, please record as 0 days)*	|__|__| days	
Total duration of hospital stay within 30 days after surgery *(This is the total duration of hospital stay, in calendar days including any readmissions, within 30 days after surgery)*	|__|__| days	
Days alive and at home within 30 days after surgery	|__|__| days	

SECTION 7: FOLLOW-UP AT 30 DAYS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

POSTOPERATIVE COMPLICATIONS

Please refer to the data collection SOP for specific definitions of complications.

Please grade complications using the Clavien-Dindo scale as follows:

I. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diuretics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course.
II. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I.
III. Requires surgical, endoscopic or radiological intervention.
IV. Life-threatening complication (including CNS complication, but excluding transient ischaemic attack) requiring critical care admission
V. Death

CARDIAC & VASCULAR EVENTS *(Graded according to the Clavien-Dindo system)*	**I**	**II**	**III**	**IV**	**V**	**NONE**
Atrial fibrillation (new onset)	☐	☐	☐	☐	☐	☐
Myocardial infarction	☐	☐	☐	☐	☐	☐
Myocardial injury	☐	☐	☐	☐	☐	☐
Non-fatal cardiac arrest				☐	☐	☐
Cardiac death					☐	☐
Coronary revascularisation			☐	☐	☐	☐
Pulmonary embolism	☐	☐	☐	☐	☐	☐
Deep vein thrombosis	☐	☐	☐	☐	☐	☐
Stroke	☐	☐	☐	☐	☐	☐
Heart failure	☐	☐	☐	☐	☐	☐
RESPIRATORY COMPLICATIONS *(Graded according to the Clavien-Dindo system)*						
Atelectasis	☐	☐	☐	☐	☐	☐
Pulmonary Aspiration	☐	☐	☐	☐	☐	☐
Acute Respiratory Distress Syndrome (ARDS)				☐	☐	☐

SECTION 7: FOLLOW-UP AT 30 DAYS				PROTECT Perioperative Platform Trial
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	

INFECTION COMPLICATIONS *(Graded according to the Clavien-Dindo system)*	**I**	**II**	**III**	**IV**	**V**	**NONE**
Surgical site infection *(superficial)*	☐	☐	☐	☐	☐	☐
Surgical site infection *(deep)*	☐	☐	☐	☐	☐	☐
Surgical site infection *(organ space)*	☐	☐	☐	☐	☐	☐
Pneumonia	☐	☐	☐	☐	☐	☐
Urinary system infection	☐	☐	☐	☐	☐	☐
Neurological infection	☐	☐	☐	☐	☐	☐
Clostridium difficile colitis/infection	☐	☐	☐	☐	☐	☐
Endometritis	☐	☐	☐	☐	☐	☐
Pathogenic organism from tissue or fluid	☐	☐	☐	☐	☐	☐
RENAL COMPLICATIONS *(Graded according to the Clavien-Dindo system)*						
Acute kidney injury	☐	☐	☐	☐	☐	☐
Renal replacement therapy		☐	☐	☐	☐	☐
BLEEDING COMPLICATIONS *(Graded according to the Clavien-Dindo system)*						
Gastro-intestinal bleed *(upper)*	☐	☐	☐	☐	☐	☐
Gastro-intestinal bleed *(lower)*	☐	☐	☐	☐	☐	☐
Other postoperative haemorrhage (not GI)	☐	☐	☐	☐	☐	☐
OTHER COMPLICATIONS *(Graded according to the Clavien-Dindo system)*						
Acute psychosis or delirium	☐	☐	☐	☐	☐	☐
Anaphylaxis	☐	☐	☐	☐	☐	☐
Anastomotic leak	☐	☐	☐	☐	☐	☐
Bowel infarction	☐	☐	☐	☐	☐	☐
Multi-organ dysfunction syndrome			☐	☐	☐	☐
Paralytic ileus	☐	☐	☐	☐	☐	☐
Perforated viscus (e.g. bowel, gall bladder)	☐	☐	☐	☐	☐	☐
Other, *please describe:*	☐	☐	☐	☐	☐	☐

SECTION 7: FOLLOW-UP AT 30 DAYS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

Respiratory failure	**YES**	**NO**
Participant remained intubated after surgery	☐	☐
If YES, what was the total duration of invasive mechanical ventilation?	|__|__|__| hours	
Tracheal re-intubation after initial postoperative extubation	☐	☐
If YES, what was the total duration of invasive mechanical ventilation?	|__|__|__| hours	
Treatment for postoperative complications		
Drug therapy	☐	☐
Red blood cell transfusion	☐	☐
Parenteral (intra-venous) nutrition	☐	☐
Endoscopic or radiological intervention	☐	☐
Repeat surgery	☐	☐
If YES, please indicate the reason for repeat surgery		
Infection	☐	☐
Bleeding	☐	☐
Anastomotic leak	☐	☐
Other, *please describe*:	☐	☐

Participants admitted to a critical care unit		
Unplanned critical care admission to treat a complication	Yes ☐	No ☐
Planned critical care admission prolonged to treat a complication	Yes ☐	No ☐
What was the total duration of the level 2 critical care stay within 30 days of surgery?	|__|__| days	
What was the total duration of the level 3 critical care stay within 30 days of surgery?	|__|__| days	

LABORATORY TESTS (*within 30 days after surgery*)	
Lowest haemoglobin measurement	|__|__|__| g/L
Highest creatinine measurement	|__|__|__|__| µmol/L
Lowest eGFR measurement	|__|__|__|__| ml/min per 1.73 m^2

SECTION 7: QUALITY OF LIFE AT 30 DAYS (EQ5D)				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

QUALITY OF LIFE ASSESSMENT AT 30 DAYS AFTER SURGERY (EQ5D)	
Mobility *please tick one box*	
I have no problems in walking about	☐
I have slight problems in walking about	☐
I have moderate problems in walking about	☐
I have severe problems in walking about	☐
I am unable to walk about	☐
Self-care *please tick one box*	
I have no problems washing or dressing myself	☐
I have slight problems washing or dressing myself	☐
I have moderate problems washing or dressing myself	☐
I have severe problems washing or dressing myself	☐
I am unable to wash or dress myself	☐
Usual Activities (e.g. work, study, housework, family of leisure activities) *please tick one box*	
I have no problems with performing my usual activities	☐
I have slight problems with performing my usual activities	☐
I have moderate problems doing my usual activities	☐
I have severe problems doing my usual activities	☐
I am unable to perform my usual activities	☐
Pain / Discomfort *please tick one box*	
I have no pain or discomfort	☐
I have slight pain or discomfort	☐
I have moderate pain or discomfort	☐
I have severe pain or discomfort	☐
I have extreme pain or discomfort	☐
Anxiety / Depression *please tick one box*	
I am not anxious or depressed	☐
I am slightly anxious or depressed	☐
I am moderately anxious or depressed	☐
I am severely anxious or depressed	☐
I am extremely anxious or depressed	☐
We would like to know how good or bad your health is TODAY. • **This scale is numbered from 0 to 100.** • **100 means the best health you can imagine.** • **0 means the worst health you can imagine.** **YOUR HEALTH TODAY =**	|__|__|__|

SECTION 8: FOLLOW-UP AT 90 DAYS				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

Date of follow-up	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	
PARTICIPANT STATUS		
Participant status at 90 days after surgery	☐ Alive	☐ Dead
If dead, Date of death	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	

Hospital discharge		
Was the participant discharged within 90 days after surgery?	Yes ☐	No ☐
If yes, Discharge date	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**	
Discharge destination		
Own home	☐	
Rehabilitation facility	☐	
Care home	☐	
Other, *describe other destination of discharge:*		
Re-admission to hospital within 90 days from surgery	Yes ☐	No ☐
Length of hospital stay		
Duration of <u>primary</u> hospital admission within 90 days after surgery *(Duration of primary hospital admission in calendar days. If discharged before midnight on the day of surgery, please record as 0 days.)*	|__|__| days	
Total duration of hospital stay within 90 days after surgery *(This is the total duration of hospital admission within 90 days after surgery, including any readmissions)*	|__|__| days	
Days alive and at home within 90 days after surgery	|__|__| days	

SECTION 8: QUALITY OF LIFE AT 90 DAYS (EQ5D)				PROTECT Perioperative Platform Trial
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	

QUALITY OF LIFE ASSESSMENT AT 90 DAYS AFTER SURGERY (EQ5D)	
Mobility *please tick one box*	
I have no problems in walking about	☐
I have slight problems in walking about	☐
I have moderate problems in walking about	☐
I have severe problems in walking about	☐
I am unable to walk about	☐
Self-care *please tick one box*	
I have no problems washing or dressing myself	☐
I have slight problems washing or dressing myself	☐
I have moderate problems washing or dressing myself	☐
I have severe problems washing or dressing myself	☐
I am unable to wash or dress myself	☐
Usual Activities (e.g. work, study, housework, family of leisure activities) *please tick one box*	
I have no problems with performing my usual activities	☐
I have slight problems with performing my usual activities	☐
I have moderate problems doing my usual activities	☐
I have severe problems doing my usual activities	☐
I am unable to perform my usual activities	☐
Pain / Discomfort *please tick one box*	
I have no pain or discomfort	☐
I have slight pain or discomfort	☐
I have moderate pain or discomfort	☐
I have severe pain or discomfort	☐
I have extreme pain or discomfort	☐
Anxiety / Depression *please tick one box*	
I am not anxious or depressed	☐
I am slightly anxious or depressed	☐
I am moderately anxious or depressed	☐
I am severely anxious or depressed	☐
I am extremely anxious or depressed	☐
We would like to know how good or bad your health is TODAY. • **This scale is numbered from 0 to 100.** • **100 means the best health you can imagine.** • **0 means the worst health you can imagine.** **YOUR HEALTH TODAY =**	|__|__|__|

SUPPLEMENTARY FORM: PROTOCOL DEVIATION				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

ONLY COMPLETE THIS FORM IF THERE IS A PROTOCOL DEVIATION

Date of deviation	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	
Details of the deviation		
Briefly describe the protocol deviation:		
Is this a serious breach?	Yes ☐	No ☐
If yes, date reported to QMUL JRMO	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	
Was this reported as a serious breach to MHRA/HRA and REC?	Yes ☐	No ☐
If yes, please state outcome:		
Name of the person completing this form		
Date reported to the trial office	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	

SUPPLEMENTARY FORM: ADVERSE EVENT				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

		YES	NO
Did the participant experience an adverse event?		☐	☐
If YES, please answer the following questions.			
Date and time of onset of adverse event	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**	|__|__|:|__|__| **(HR : MINS)**	
Please describe the adverse event, including any treatment or medication required			
ASSESSMENT OF TYPE OF EVENT			
Seriousness			
Death		☐	
Life threatening		☐	
Prolonged hospital stay or re-admission		☐	
Disability / incapacity		☐	
Other important event *(detail in box above)*		☐	
Not an SAE		☐	
Causality			
Unrelated to the trial procedures		☐	
Possibly related to the trial procedures		☐	
Definitely related to the trial procedures		☐	
Was the adverse event expected?		Yes ☐	No ☐
Severity			
Mild *(Some discomfort noted but without disruption of daily life)*		☐	
Moderate *(Discomfort enough to affect/reduce normal activity)*		☐	
Severe *(Complete inability to perform daily activities and lead a normal life)*		☐	
Type of event			
AE: if 'causality' is 'unrelated' and 'Seriousness' is 'Not an SAE'		☐	
AR: if 'causality' is 'possibly related' OR 'definitely related' AND Seriousness' is 'Not an SAE'		☐	
SAE: if 'causality' is 'unrelated' and 'Seriousness' is any of the categories 1-5		☐	
SAR: if 'causality' is 'possibly related' OR 'definitely related' AND Seriousness' is any of the categories 1-5		☐	
SUSAR: if 'causality' is 'possibly related' OR 'definitely related' AND Seriousness' is any of the categories 1-5 AND 'is unexpected'		☐	

SUPPLEMENTARY FORM: ADVERSE EVENT				PROTECT Perioperative Platform Trial
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	

RESPONSE TO EVENT			
Response			
No action taken			☐
Treatment discontinued			☐
Withdrawal			☐
Non-drug therapy			☐
Escalation to higher level of care			☐
Response- further details (as needed):			
Name of the reporting investigator			
PI or delegate, sign off: I confirm the data entered in the form is complete and accurate *(Must be completed by PI or delegate with PI-level access)*		Yes ☐	No ☐
PI or delegate name *(Must be completed by PI or delegate with PI-level access)*			
Date and time adverse event resolved *(Must be completed by PI or delegate with PI-level access)*	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**	|__|__|:|__|__| **(HR : MINS)**	

SUPPLEMENTARY FORM: PARTICIPANT WITHDRAWAL				
TRIAL ID	|__||__|__|__| -|__|__|__|__|	**Participant Initials**	|__|__|	PROTECT Perioperative Platform Trial

ONLY COMPLETE THIS FORM IF THE PARTICIPANT HAS PREMATURELY STOPPED THEIR PARTICIPATION IN THE PROTECT PLATFORM

IF A PARTICIPANT COULD NOT BE CONTACTED FOR FOLLOW-UP THEY ARE NOT AUTOMOMICALLY WITHDRAWN. ATTEMPTS SHOUD BE MADE TO FOLLOW-UP ALL PARTICIPANTS, EVEN IF THEY MISS A VISIT / EVENT / FORM

PROTECT platform *(master study)*	Withdraw ☐	Continue ☐
Date of withdrawal	|__|__|/|__|__|__|/|__|__|__|__| **(DD-MMM-YYYY)**	
Why has the participant been withdrawn? *Please tick one box*	☐ At the request of the participant ☐ Other reason at Principal Investigator's discretion ☐ Termination of the trial by the sponsor ☐ Other (please specify): _____	
Regarding continuing access to data, *please check:*	☐ The participant DID NOT request to stop collecting data from their medical/ hospital/ GP/ central-NHS records ☐ The participant DID request to stop collecting data from their medical/ hospital/ GP/ central-NHS records	

FORM COMPLETION		
Person completing this form		
Date and time form submitted	|__|__|/|__|__|__|/|__|__|__|__| **(DD/MMM/YYYY)**	|__|__|:|__|__| **(HR : MINS)**