Covid-19 impact On panNcreaTic cAncer Care paThway

A National, Pan-Specialty, Multi-Centre Study of the Impact of SARS-CoV-2 on New Diagnosed Pancreatic Cancer Treatment

Study Protocol

CONTACT Steering Committee

V1.3
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Contents

CONTACT Protocol

Background:

The SARS-CoV-2 pandemic has had an unprecedented impact on healthcare systems, with near-paralysis of non-COVID-related services during the peak of the pandemic. Pancreatic cancer is aggressive, often presenting late, with the majority of patients presenting with unresectable disease. With service disruption caused by the pandemic, there are concerns that patients with pancreatic cancer did not received optimal treatment. The impact is currently unknown, but may have led to delays in diagnosis, modified chemotherapy regimens, [more-rapid] disease progression, and some patients offered no treatment at all. It is essential to understand the impact of these alterations to diagnosis and treatment caused by the SARS-CoV-2 pandemic for this COVID-generation of patients in anticipation of a second-surge, or future pandemics.

Aim:

To assess the impact of the SARS-CoV-2 pandemic on newly diagnosed pancreatic cancer patients across the UK.

Primary objective:

To assess the rate of receipt of chemotherapy at 6 and 12 months from diagnosis during the peak of the SARS-CoV-2 pandemic, compared to pre-pandemic rates.

Secondary objective:

To assess 6 and 12 month outcomes for patients with newly diagnosed pancreatic cancer during the peak of the SARS-CoV-2 pandemic compared to pre-pandemic outcomes for: overall mortality, rate of disease progression, changes to treatment offered, receipt of chemotherapy/chemoradiotherapy regimens (neo-adjuvant, adjuvant and palliative), rates of surgery and unintended bypass, and time to diagnosis and treatment.

Methods:

CONTACT is a national, multi-centre, pan-specialty, retrospective review of the treatment and outcomes of patients with newly diagnosed pancreatic cancer during the SARS-CoV-2 pandemic.

This trainee-led initiative utilises an efficient study design to map the alterations of diagnostic and treatment pathways for pancreatic cancer patients caused by SARS-CoV-2 restrictions.

With an appreciation of time-constraints of clinicians caused by the ongoing impact of SARS-CoV-2 we have designed a study that reduces the workload on each centre, whilst providing data spanning the whole pancreatic cancer cohort of patients. It is important to map the impact not only in specialist pancreatic centres, but also in non-specialist pancreatic centres, where the majority of care is delivered for pancreatic cancer patients, as the majority are unresectable at presentation, and chemotherapy is delivered locally at the majority of institutions.

Patient Inclusion:

- All adult patients newly diagnosed with suspected pancreatic cancer (presenting during the '*patient entry period'* defined below) i.e. those discussed at MDT during the patient entry period as a new presentation/diagnosis of suspected pancreatic cancer.

Patient Exclusion:

- Patients presenting outside the *'patient entry period'.*
- Patients who initially presented to a different institution e.g. patient presents at St. Elsewhere Hospital, referred to Pancreatic Central Specialist Centre – patient will not be included at Pancreatic Central Specialist Centre as was not the site of initial presentation (the case will be captured and recorded for St. Elsewhere Hospital).

Patient Identification:

- From MDT records (and CNS lists where appropriate)
- Only patients presenting to the centre will be included, ***not those referred from other centres*** (to prevent duplication of records across centres, and reduce the workload to high-volume specialist centres).

Centre Inclusion:

- Any UK NHS hospital with a UGI/HPB MDT that manages pancreatic cancer patient treatment (including any of the following: operative, oncological, and palliative).

Patient Entry:

All patients fulfilling the inclusion criteria presenting within the following time periods:

Pre-pandemic cohort: **7th January 2019 to 3rd March 2019** (8 weeks).

Pandemic cohort: **16th March 2020 to 10th May 2020** (8 weeks).

Follow-up:

6-month and 12-month follow-up periods.

Data collection:

All data will be available from routinely collected patient records, and no patients will be contacted. Each site will need to register this as an audit. No identifiable data will be entered onto the centrally held REDCap database hosted at the University of Birmingham. The case report form (CRF) of data points is concise and limited to only key data points to ensure efficient data collection within a short timeframe. The 'paper version' of the CRF can be found on the CONTACT Pancreas website, and in Appendix 1 and 2.

The data is all added to REDCap, the secure online database. This uses branching logic, so you only asked relevant questions dependent on answers you provide throughout the form (e.g. will only be asked about adjuvant therapy IF that patient underwent surgery). We have provided 'paper' versions of the CRF in appendix 1 and 2, these look very long, but due to the online branching logic the number of questions the data collectors need to answer is considerably fewer online.

Data collection will cover the following elements:

- *Demographics:* Age, co-morbidity (Charlson Comorbidity Index), deprivation index etc.
- *Diagnosis:* Date of presentation, diagnostic investigations.
- *6- and 12-month follow-up:* Neo-adjuvant chemotherapy (type, number of cycles), surgery (resection or bypass), adjuvant chemotherapy (type, number of cycles), palliative chemotherapy (type, number of cycles), recurrence post-operatively (date, local/metastatic), survival, COVID status.

Governance:

All centres must register the study with their local governance departments as an audit prior to commencement. This qualifies as an audit and does not require formal ethics as no identifiable information will be shared outside the local trust. All data will be collected on REDCap, a secure online database, hosted by Birmingham University. Each local team is responsible for securely storing a local list of patients entered into the study with their name, hospital number, and corresponding 'REDCap ID' for the duration of the study (as these patients are not identifiable outside the local trust) (see Appendix 7). Please see Appendix 3-6 for MRC NHS REC Review tool showing NHS REC review not required for sites in England, Scotland, Wales, and Northern Ireland, which may be helpful for local governance department registration.

Data validation/verification:

A small number of datapoints will undergo a process of validation/verification after follow-up is complete. This will be voluntary, but we encourage all centres to participate.

Centre Survey:

All centres will complete a short centre survey on registration of their site to confirm site-specific characteristics.

Registering your centre:

Each member of the local team is required to complete a registration form for central governance purposes, and to ensure we have all details for authorship for publication of the study. The form can be found here:

http://bit.ly/CONTACT-registration

As soon as the site has registered and gained local governance approval, then data collection can commence immediately. Data collection will be complete after 12 month follow-up of the last patient entered (10th May 2021). The follow-up window will remain open until 10th June 2021 to enable entry of all follow-up data.

Authorship:

Authorship of all publications that result from the project will be under a collaborative authorship policy, this will be ***'The CONTACT study group'***. We will use a collaborative authorship model. All collaborators will be acknowledged according to their input to the study. There will be a writing group, steering committee, meta-coordinators, local leads and local collaborators. There may be other groups listed as appropriate. Collaborators will be listed according to hospital and then alphabetically, with local leads highlighted within this. This authorship policy is subject to alterations depending on journal requirements. All names will be PubMed citable.

Further details:

Please visit our website for the most up to date versions of documents

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Steering committee

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Demographics and Diagnosis

Unique REDCap ID

_____
(Please keep a record of the linked hospital-level patient identifier on a password-encrypted spreadsheet, or paper form in a locked, secure location.)

CONTACT study eligibility

In order to contribute to CONTACT you should first secure local study approval.
Has local study approval been secured?

◯ Yes ◯ No

Approvals are required to enter data on REDCap
Please secure all necessary local approvals for CONTACT prior to entering data on to REDCap. Materials to help you secure approvals are available at the CONTACT website.
Prior to receiving formal local study approval, if permitted, you can prospectively collect data using the hard copy case report form (download here). No data should be uploaded to the REDCap database until study approval is confirmed.

Please confirm patient is an adult with suspected pancreatic cancer

◯ Yes
◯ No

The patient must have suspected or confirmed pancreatic cancer to be eligible for the CONTACT study.

Patient Demographics and diagnosis

Please input patient age (in years) at presentation.

_____

Please select patient sex

◯ Female
◯ Male

Index of Multiple Deprivation SCORE (calculated from patients postcode using link https://tools.npeu.ox.ac.uk/imd/

_____
(Please enter the score)

Index of Multiple Deprivation QUINTILE (calculated from patients postcode using link https://tools.npeu.ox.ac.uk/imd/

◯ 1st
◯ 2nd
◯ 3rd
◯ 4th
◯ 5th
(Please enter the quintile)

WHO/ECOG Performance Status	◯ 0 - Fully active, able to carry on all pre-disease activities ◯ 1 - Restricted in physical strenuous activity, able to perform light work ◯ 2 - Ambulatory and capable of all self-care, unable to work ◯ 3 - Capable of limited self-care only. ◯ 4 - Completely disabled. Confined to bed or chair. (Full definition available at: http://radiopaedia.org/articles/ecog-performance-status)
What was the patient's body mass index (BMI) at presentation?	◯ Underweight: BMI < 18.5 ◯ Normal (healthy weight): BMI 18.5-24.9 ◯ Overweight: BMI 25-29.9 ◯ Moderately obese: BMI 30-34.9 ◯ Severely obese: BMI 35-39.9 ◯ Very severely obese: BMI ?40 (Online calculator: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/t
Co-morbidity (tick all that apply)	☐ Current smoker ☐ Asthma ☐ Current cancer diagnosis ☐ Chronic kidney disease (moderate/severe) ☐ Chronic obstructive pulmonary disease (COPD) ☐ Congenital abnormality - cardiac ☐ Congenital abnormality - non-cardiac ☐ Congestive heart failure ☐ Dementia ☐ Diabetes mellitus ☐ Human immunodeficiency virus (HIV) infection ☐ Hypertension ☐ Myocardial infarction or ischemic heart disease ☐ Peripheral vascular disease ☐ Stroke/ TIA ☐ Other (including other lung disease)
Comorbidity - please enter free text	_____
Date of presentation (index CT)?	_____
Date of treatment decision (date of MDT)	_____
What was the recommended treatment by the MDT?	◯ Surgery ◯ Neoadjuvant therapy ◯ Palliative therapy (e.g. chemotherapy or chemoradiotherapy) ◯ Best supportive care

If unresectable, why?	☐ Metastatic disease ☐ Locally advanced disease ☐ Performance Status ☐ Patient Choice ☐ Unclear
Was an EUS performed?	◯ Yes ◯ No
Date of EUS	_____
Was an MRI liver performed?	◯ Yes ◯ No
Date of MRI liver	_____
Was a PET scan performed?	◯ Yes ◯ No
Date of PET scan	_____
Was a pre-op tissue diagnosis obtained?	◯ Yes ◯ No
Date of tissue diagnosis?	_____
Did the patient undergo biliary drainage i.e. ERCP or PTC	☐ Yes - ERCP ☐ Yes - PTC ☐ No - patient not jaundiced ☐ No- patient proceeded to surgery jaundiced
Date of successful biliary drainage	_____

Appendix 2 – 6 and 12 month follow-up Case Report Form (CRF)

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Follow Up: 6 and 12 Months

Unique REDCap ID	_____ (Please keep a record of the linked hospital-level patient identifier on a password-encrypted spreadsheet, or paper form in a locked, secure location.)
Please select the study period for this patient	◯ 2019 pre-COVID cohort (01/01/2019-28/02/2019) ◯ 2020 COVID cohort (16/03/2020-13/05/2020)
Date of 6 month follow-up from Date of MDT treatment decision - please refer to table below to confirm date.	_____
Date of 12 month follow-up from Date of MDT treatment decision - please refer to table below to confirm date.	_____

Reference table for follow-up dates

MDT Decision Date	6 month F/U date	12 month F/U date
01/01/2019	01/07/2019	01/01/2020
02/01/2019	02/07/2019	02/01/2020
03/01/2019	03/07/2019	03/01/2020
04/01/2019	04/07/2019	04/01/2020
05/01/2019	05/07/2019	05/01/2020
06/01/2019	06/07/2019	06/01/2020
07/01/2019	07/07/2019	07/01/2020
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15/01/2019	15/07/2019	15/01/2020
16/01/2019	16/07/2019	16/01/2020
17/01/2019	17/07/2019	17/01/2020
18/01/2019	18/07/2019	18/01/2020
19/01/2019	19/07/2019	19/01/2020
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23/02/2019	23/08/2019	23/02/2020
24/02/2019	24/08/2019	24/02/2020
25/02/2019	25/08/2019	25/02/2020
26/02/2019	26/08/2019	26/02/2020
27/02/2019	27/08/2019	27/02/2020
28/02/2019	28/08/2019	28/02/2020

MDT Decision Date	6 month F/U date	12 month F/U date
16/03/2020	16/09/2020	16/03/2021
17/03/2020	17/09/2020	17/03/2021
18/03/2020	18/09/2020	18/03/2021
19/03/2020	19/09/2020	19/03/2021
20/03/2020	20/09/2020	20/03/2021
21/03/2020	21/09/2020	21/03/2021
22/03/2020	22/09/2020	22/03/2021
23/03/2020	23/09/2020	23/03/2021
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15/04/2020	15/10/2020	15/04/2021
16/04/2020	16/10/2020	16/04/2021
17/04/2020	17/10/2020	17/04/2021
18/04/2020	18/10/2020	18/04/2021
19/04/2020	19/10/2020	19/04/2021
20/04/2020	20/10/2020	20/04/2021
21/04/2020	21/10/2020	21/04/2021
22/04/2020	22/10/2020	22/04/2021
23/04/2020	23/10/2020	23/04/2021
24/04/2020	24/10/2020	24/04/2021
25/04/2020	25/10/2020	25/04/2021
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09/05/2020	09/11/2020	09/05/2021
10/05/2020	10/11/2020	10/05/2021
11/05/2020	11/11/2020	11/05/2021
12/05/2020	12/11/2020	12/05/2021
13/05/2020	13/11/2020	13/05/2021

Surgery	
Did the patient undergo surgery in the first 6 months? (from |Date of MDT treatment decision to date of 6 month follow-up)	◯ Yes ◯ No
What was the date of operation?	_____
Was the tumour intra-operatively resectable?	◯ Yes ◯ No
What type of surgery was performed?	◯ Pancreaticoduodenectomy (Whipple OR PPPD) ◯ Distal pancreatectomy ◯ Total pancreatectomy ◯ Other
If other, what surgery was performed?	_____
Did they undergo a vascular resection?	◯ Yes ◯ No
Post-operative Histology: T stage	◯ T1 ◯ T2 ◯ T3 ◯ T4
Post-operative Histology: N stage	◯ NX ◯ N0 ◯ N1 ◯ N2
What operation was performed?	◯ Laparotomy OR laparoscopy (OPEN and CLOSE) ◯ Laparotomy OR laparoscopy AND bypass
Did the patient undergo surgery from 6 to 12 months? (from |date of 6 month follow-up to date of 12 month follow-up)	◯ Yes ◯ No
What was the date of operation?	_____
Was the tumour intra-operatively resectable?	◯ Yes ◯ No
What type of surgery was performed?	◯ Pancreaticoduodenectomy (Whipple OR PPPD) ◯ Distal pancreatectomy ◯ Total pancreatectomy ◯ Other
If other, what surgery was performed?	_____
Did they undergo a vascular resection?	◯ Yes ◯ No

Post-operative Histology: T stage	◯ T1 ◯ T2 ◯ T3 ◯ T4
Post-operative Histology: N stage	◯ NX ◯ N0 ◯ N1 ◯ N2
What operation was performed?	◯ Laparotomy OR laparoscopy (OPEN and CLOSE) ◯ Laparotomy OR laparoscopy AND bypass

Neo-adjuvant Treatment (treatment for potentially resectable cancer prior to surgery)

Did the patient receive neo-adjuvant treatment in the first 6 months? (from date of MDT decision to date of 6 month follow-up)	◯ Yes ◯ No
What date did the patient first receive neo-adjuvant treatment?	_____
Neo-adjuvant chemotherapy agent used (first-line)	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other Neo-adjuvant chemotherapy agent used - please specify:	_____
How many cycles of this neo-adjuvant agent did the patient complete?	_____
Was neo-adjuvant chemotherapy stopped?	◯ Yes ◯ No
Why was Neo-adjuvant chemotherapy stopped?	◯ Received all cycles ◯ Proceded to surgery ◯ Cancer Progression ◯ Complications ◯ Frailty ◯ COVID-19
Did they receive SECOND-LINE neo-adjuvant chemotherapy (chemotherapy before surgery)?	◯ Yes ◯ No

SECOND-LINE Neo-adjuvant chemotherapy agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other Neo-adjuvant chemotherapy agent used - please specify:	_____
How many cycles of this second line neo-adjuvant agent did the patient complete?	_____
Did they receive THIRD-LINE neo-adjuvant chemotherapy (chemotherapy before surgery)?	◯ Yes ◯ No
THIRD-LINE Neo-adjuvant chemotherapy agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other Neo-adjuvant chemotherapy agent used - please specify:	_____
How many cycles of this second line neo-adjuvant agent did the patient complete?	_____
Why did the patient not receive neo-adjuvant chemotherapy?	◯ Frailty ◯ Patient choice ◯ Early recurrence ◯ Death ◯ not applicable (unresectable disease, no operation, straight to surgery) ◯ Other
If other, please specify.	_____
Did the patient receive neo-adjuvant treatment between 6 and 12 months?	◯ Yes ◯ No
Neo-adjuvant chemotherapy agent used between 6 and 12 months?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other

Other Neo-adjuvant chemotherapy agent used - please specify:	_____
Did they receive an additional neo-adjuvant chemotherapy agent?	◯ Yes ◯ No
Additional agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Was neo-adjuvant chemotherapy stopped between 6 and 12 months?	◯ Yes ◯ No
Why was Neo-adjuvant chemotherapy stopped?	◯ Received all cycles ◯ Proceded to surgery ◯ Cancer Progression ◯ Complications ◯ Frailty ◯ COVID-19
Why did the patient not receive neo-adjuvant chemotherapy?	◯ Frailty ◯ Patient choice ◯ Early recurrence ◯ COVID ◯ Death ◯ not applicable (unresectable disease, no operation, already completed) ◯ Other
If other, please specify.	_____
At 12 months , how many cycles of neo-adjuvant FOLFIRINOX has this patient completed? i.e. TOTAL number of cycles received in whole 12 months (please include all treatment within the first 6 months)	_____
At 12 months how many cycles of Neo-adjuvant Gemcitabine and Capecitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months f , how many cycles of Neo-adjuvant Gemcitabine and Cisplatin has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____

At 12 months , how many cycles of Neo-adjuvant Gemcitabine and Abraxane has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months , how many cycles of Neo-adjuvant Gemcitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months , how many cycles of Neo-adjuvant Capecitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____

Adjuvant treatment (chemotherapy given after a potentially curative resection - if surgery was non-curative, i.e bypass, please record as palliative chemotherapy later in questions)

Did the patient receive adjuvant chemotherapy in the first 6 months?	◯ Yes ◯ No
What date did the patient first receive adjuvant chemotherapy?	_____
Adjuvant chemotherapy agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other- please specify:	_____
How many cycles were used?	_____
Was adjuvant chemotherapy stopped?	◯ Yes ◯ No
Why was adjuvant chemotherapy stopped?	◯ Received all cycles ◯ Patient Choice ◯ Cancer Progression ◯ Complications ◯ Frailty ◯ COVID-19 ◯ Death
Did the patient receive SECOND-LINE adjuvant chemotherapy in the first 6 months?	◯ Yes ◯ No

What date did the patient first receive SECOND-LINE adjuvant chemotherapy?	_____
SECOND-LINE adjuvant chemotherapy agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other- please specify:	_____
How many cycles did the patient complete in the first 6 months?	_____
Did the patient receive THIRD-LINE adjuvant chemotherapy in the first 6 months?	◯ Yes ◯ No
What date did the patient first receive THIRD-LINE adjuvant chemotherapy?	_____
THIRD-LINE adjuvant chemotherapy agent used in the first 6 months?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other- please specify:	_____
How many cycles did the patient receive in the first 6 months?	_____
	Text
Why did the patient not receive adjuvant chemotherapy?	◯ Frailty ◯ Post-operative complications ◯ Patient choice ◯ Early recurrence ◯ Death ◯ not applicable (unresectable disease, no operation) ◯ Other
If other, please specify:	_____

Did the patient receive adjuvant treatment from 6 to 12 months?	◯ Yes ◯ No
Adjuvant chemotherapy agent used from 6 to 12 months?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other adjuvant chemotherapy agent used - please specify:	_____
Did they receive an additional adjuvant chemotherapy agent?	◯ Yes ◯ No
Additional agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Was adjuvant chemotherapy stopped between 6 and 12 months?	◯ Yes ◯ No
Why was adjuvant chemotherapy stopped?	☐ Received all cycles ☐ Patient choice ☐ Cancer Progression ☐ Complications ☐ Frailty ☐ COVID-19
Why did the patient not receive adjuvant chemotherapy?	◯ Frailty ◯ Patient choice ◯ Early recurrence ◯ COVID ◯ Death ◯ not applicable (unresectable disease, no operation, already completed) ◯ Other
If other, please specify.	_____
At 12 months _ _ _ how many cycles of adjuvant FOLFIRINOX has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____

At 12 months _ _ _ how many cycles of adjuvant Gemcitabine and Capecitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months _ _ _ how many cycles of adjuvant Gemcitabine and Cisplatin has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months _ _ _ how many cycles of adjuvant Gemcitabine and Abraxane has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months _ _ _ how many cycles of adjuvant Gemcitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months _ _ _ how many cycles of adjuvant Capecitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____

Palliative Treatment

Did the patient receive palliative chemotherapy in the first 6 months?	◯ Yes ◯ No
Why did the patient not receive palliative chemotherapy?	◯ Frailty ◯ Patient choice ◯ Not applicable (e.g. disease-free) ◯ Death ◯ Other
If other, please specify	_____
What date did they first receive palliative chemotherapy?	_____
Which palliative chemotherapy agent did they receive in the first 6 months?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other

If other- please specify.	_____
How many cycles did the receive in the first 6 months?	_____
Was palliative chemotherapy stopped?	◯ Yes ◯ No
Why was palliative chemotherapy stopped?	☐ Received all cycles ☐ Patient Choice ☐ Cancer Progression ☐ Complications ☐ Frailty ☐ COVID-19 ☐ Death
Did the patient receive SECOND-LINE palliative chemotherapy in the first 6 months?	◯ Yes ◯ No
What date did the patient first receive SECOND-LINE palliative chemotherapy?	_____
Which SECOND-LINE palliative chemotherapy agent did they receive in the first 6 months?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
If other- please specify.	_____
How many cycles were used in the first 6 months?	_____
Did the patient receive THIRD-LINE palliative chemotherapy in the first 6 months?	◯ Yes ◯ No
What date did the patient first receive THIRD-LINE palliative chemotherapy?	_____

Which THIRD-LINE palliative chemotherapy agent did they receive in the first 6 months?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
If other- please specify.	_____
How many cycles did they receive in the first 6 months?	_____
Did the patient receive palliative treatment between 6 and 12 months?	◯ Yes ◯ No
Palliative chemotherapy agent used?	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Other palliative chemotherapy agent used - please specify:	_____
Did they receive an additional palliative chemotherapy agent?	◯ Yes ◯ No
Additional agent used	◯ FOLFIRINOX ◯ Gemcitabine and Capecitabine ◯ Gemcitabine and Cisplatin ◯ Gemcitabine and Abraxane ◯ Gemcitabine ◯ Capecitabine ◯ Chemoradiotherapy ◯ Other
Was palliative chemotherapy stopped between 6 and 12 months?	◯ Yes ◯ No

Why was palliative chemotherapy stopped?	◯ Received all cycles ◯ Patient choice ◯ Cancer Progression ◯ Complications ◯ Frailty ◯ COVID-19
Why did the patient not receive palliative chemotherapy?	◯ Frailty ◯ Patient choice ◯ Early recurrence ◯ COVID ◯ Death ◯ not applicable (unresectable disease, no operation, already completed) ◯ Other
If other, please specify.	_____
At 12 months how many cycles of palliative FOLFIRINOX has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months how many cycles of palliative Gemcitabine and Capecitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months how many cycles of palliative Gemcitabine and Cisplatin has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months how many cycles of palliative Gemcitabine and Abraxane has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months how many cycles of palliative Gemcitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____
At 12 months how many cycles of palliative Capecitabine has this patient completed? i.e. TOTAL number of cycles received in whole 12 months	_____

Recurrence	
Has the patient experienced recurrence postoperatively (in the first 6 months)?	◯ Yes ◯ No
What date was the recurrence diagnosed?	_____
Where was the recurrence?	◯ Local ◯ Metastatic
Has the patient experienced recurrence post-operatively (between 6 month and 12 month follow-up)?	◯ Yes ◯ No
What date was the recurrence diagnosed?	_____
Where was the recurrence?	◯ Local ◯ Metastatic
Best supportive care	
You've selected that this patient received no treatment in the first 6 months i.e. received best supportive care - is this correct?	◯ Yes ◯ No
You've selected that this patient received no treatment between 6 and 12 months i.e. received best supportive care - is this correct?	◯ Yes ◯ No
COVID-19 Infection	
Did the patient contract COVID in the first 6 months?	◯ Yes ◯ No
When was COVID-19 diagnosed in the first 6 months?	_____
Was the patient admitted to an intensive care unit (ITU)/ high dependency unit (HDU) for their COVID-19 infection, in the first 6 months?	◯ Yes ◯ No
Did the patient contract COVID from 6 to 12 months	◯ Yes ◯ No
When was COVID-19 diagnosed from 6 to 12 months	_____

Was the patient admitted to an intensive care unit (ITU)/ high dependency unit (HDU) for their COVID-19 infection	◯ Yes ◯ No

Death

Did the patient die in the first 6 months?	◯ Yes ◯ No
Which week did they die?	_____

Appendix 3: MRC NHS REC Review tool: NHS REC review not required for sites in England

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Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

CONTACT (Covid-19 impact On panNcreaTic cAncer Care paThway)

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC review for sites in England.**

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check what other approvals are required for your research.

You have answered **'YES'** to: Is your study research?

You answered **'NO'** to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study one or more of the following: A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

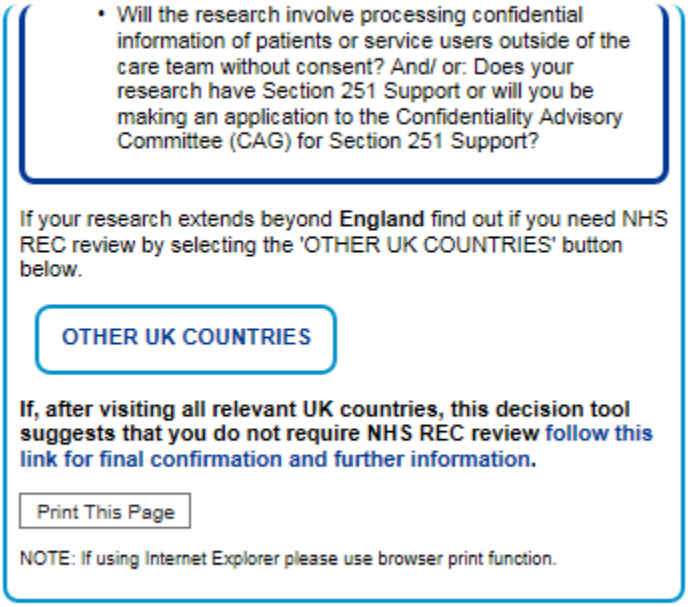
- Will your study involve potential research participants identified in the context of, or in connection with, their past or present use of services (NHS and adult social care), including participants recruited through these services as healthy controls?
- Will your research involve prospective collection of tissue (i.e. any material consisting of or including human cells) from any past or present users of these services (NHS and adult social care)?
- Will your research involve prospective collection of information from any past or present users of these services (NHS and adult social care)?
- Will your research involve the use of previously collected tissue and/or information from which individual past or present users of these services (NHS and adult social care), are likely to be identified by the researchers either directly from that tissue or information, or from its combination with other tissue or information likely to come into their possession?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (NHS and adult social care)?

Question Set 3

- Will your research involve the storage of relevant material from the living or the deceased on premises in England, Wales or Northern Ireland without a storage licence from the Human Tissue Authority (HTA)?
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent for research from the donors?
- Will your research involve the analysis of human DNA in cellular material (relevant material), collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor? And/or: Will your research involve the analysis of human DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage procedures (including use of identifiable tissue samples or personal information) involving adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Is your research health-related and involving offenders?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?



- Will the research involve processing confidential information of patients or service users outside of the care team without consent? And/ or: Does your research have Section 251 Support or will you be making an application to the Confidentiality Advisory Committee (CAG) for Section 251 Support?

If your research extends beyond **England** find out if you need NHS REC review by selecting the 'OTHER UK COUNTRIES' button below.

OTHER UK COUNTRIES

If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC review follow this link for final confirmation and further information.

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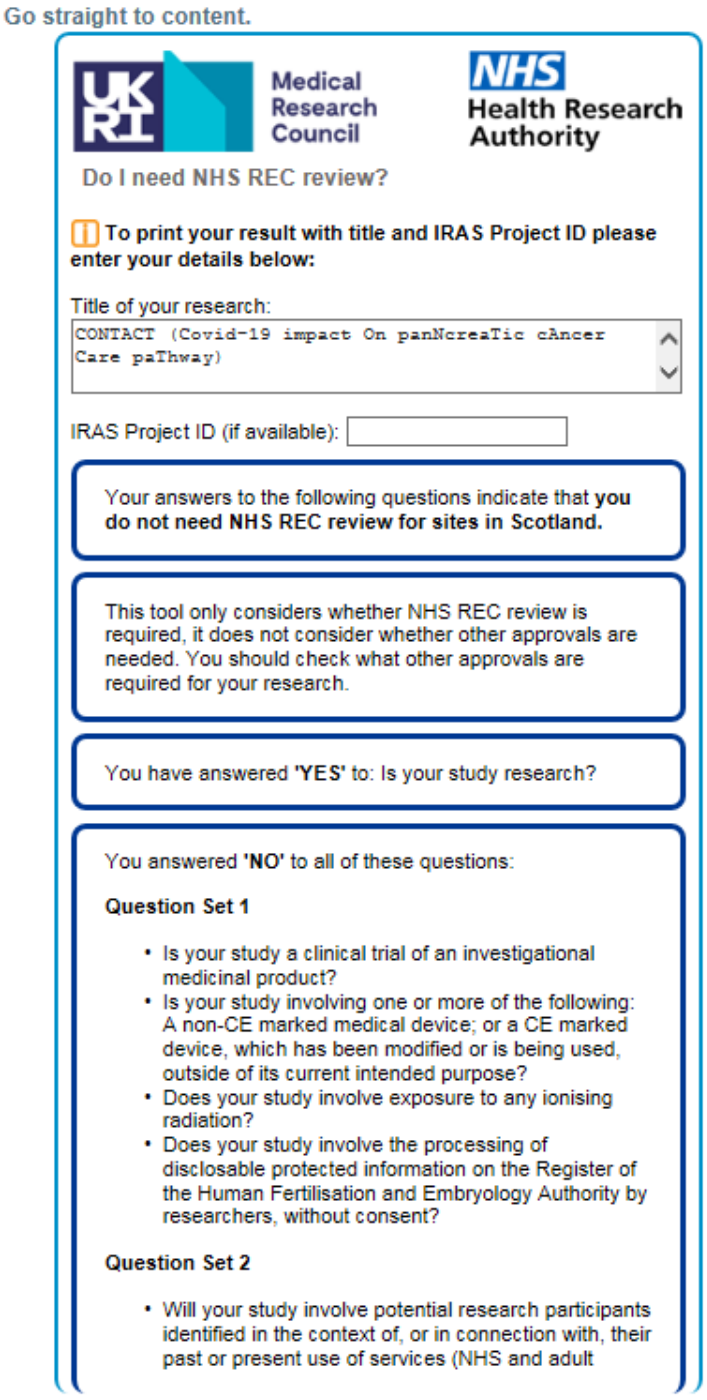
Appendix 4: MRC NHS REC Review tool: NHS REC review not required for sites in Scotland



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Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

CONTACT (Covid-19 impact On panNcreaTic cAncer Care paThway)

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC review for sites in Scotland.**

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check what other approvals are required for your research.

You have answered **'YES'** to: Is your study research?

You answered **'NO'** to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study involving one or more of the following: A non-CE marked medical device; or a CE marked device, which has been modified or is being used, outside of its current intended purpose?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

- Will your study involve potential research participants identified in the context of, or in connection with, their past or present use of services (NHS and adult

social care), including participants recruited through these services as healthy controls?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (NHS and adult social care)?
- Will your research involve prospective collection of tissue (i.e. any material consisting of or including human cells) from any past or present users of these services (NHS and adult social care), including participants recruited as healthy controls?
- Will your research involve prospective collection of information from any past or present users of these services (NHS and adult social care)?
- Will your research involve the use of previously collected tissue and/or information from which individual past or present users of these services (NHS and adult care), are likely to be identified by the researchers, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, their possession?

Question Set 3

- Does your research involve recruiting adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Will your research involve either of the following: a. organs retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal?; b. organs, tissue blocks or slides retained from a hospital post-mortem examination, or tissue blocks or slides retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal?
- Will your research involve the analysis of human DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Is your research health-related and involving offenders?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?

If your research extends beyond **Scotland** find out if you need NHS REC review by selecting the 'OTHER UK COUNTRIES' button below.

OTHER UK COUNTRIES

If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC review follow this link for final confirmation and further information.

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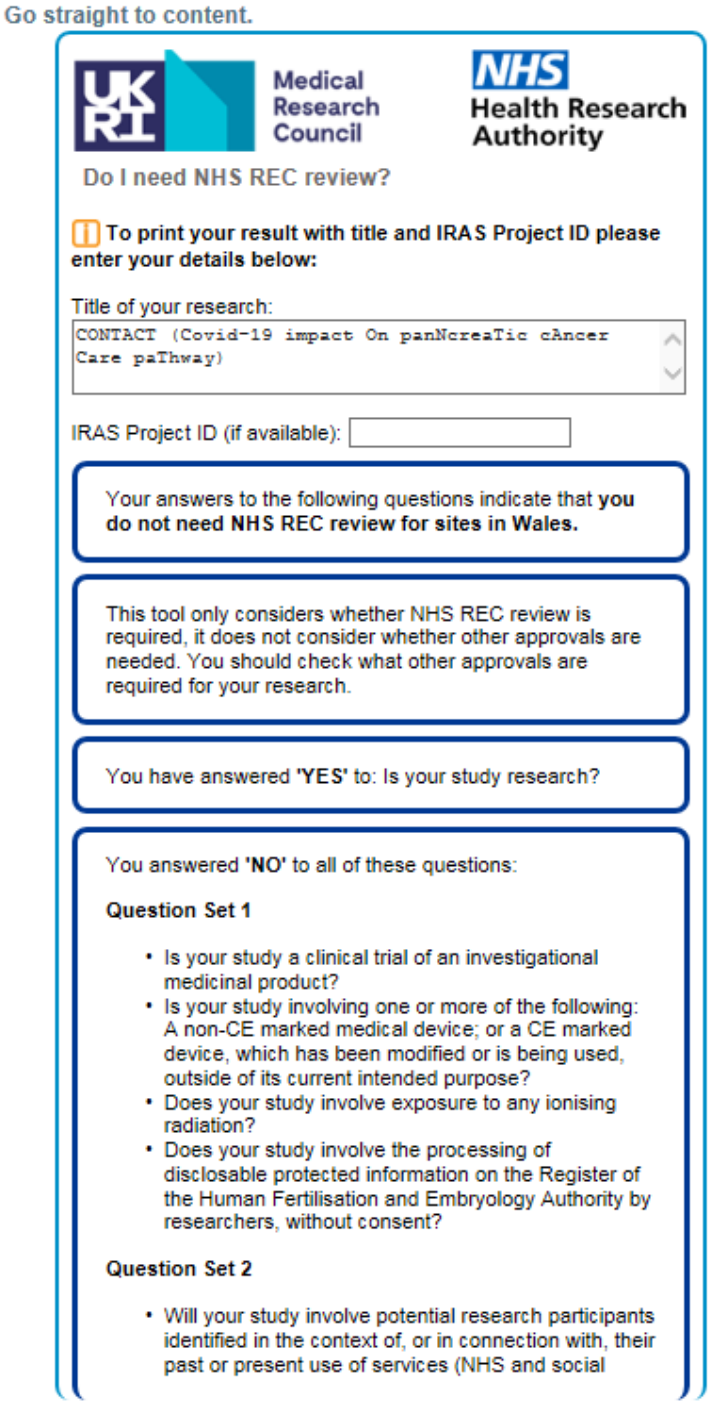
Appendix 5: MRC NHS REC Review tool: NHS REC review not required for sites in Wales



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Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

CONTACT (Covid-19 impact On panNcreaTic cAncer Care paThway)

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC review for sites in Wales.**

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check what other approvals are required for your research.

You have answered **'YES'** to: Is your study research?

You answered **'NO'** to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study involving one or more of the following: A non-CE marked medical device; or a CE marked device, which has been modified or is being used, outside of its current intended purpose?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

- Will your study involve potential research participants identified in the context of, or in connection with, their past or present use of services (NHS and social

care), including participants recruited through these services as healthy controls?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (NHS and social care)?
- Will your research involve prospective collection of tissue (i.e. any material consisting of or including human cells) from any past or present users of these services (NHS and social care), including participants recruited as healthy controls?
- Will your research involve prospective collection of information from any past or present users of these services (NHS and social care)?
- Will your research involve the use of previously collected tissue and/or information from which individual past or present users of these services (NHS and adult care), are likely to be identified by the researchers, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, their possession?
- Will your study involve patients (or tissue or information relating to patients) receiving treatment in an independent establishment in Wales or for the purposes of an independent establishment in Wales?

Question Set 3

- Will your research involve the storage of relevant material from the living or the deceased on premises in England, Wales or Northern Ireland without a storage licence from the Human Tissue Authority (HTA)?
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent for research from the donors?
- Will your research involve the analysis of human DNA in cellular material (relevant material), collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor? And/or: Will your research involve the analysis of human DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage procedures (including use of identifiable tissue samples or personal information) involving adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Is your research health-related and involving offenders?

- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?
- Will the research involve processing confidential information of patients or service users outside of the care team without consent? And/ or: Does your research have Section 251 Support or will you be making an application to the Confidentiality Advisory Committee (CAG) for Section 251 Support?

If your research extends beyond **Wales** find out if you need NHS REC review by selecting the 'OTHER UK COUNTRIES' button below.

OTHER UK COUNTRIES

If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC review follow this link for final confirmation and further information.

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Appendix 6: MRC NHS REC Review tool: NHS REC review not required for sites in Northern Ireland

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Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

CONTACT (Covid-19 impact On panNcreaTic cAncer Care paThway)

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC review for sites in Northern Ireland.**

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check what other approvals are required for your research.

You have answered **'YES'** to: Is your study research?

You answered **'NO'** to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study involving one or more of the following: A non-CE marked medical device; or a CE marked device, which has been modified or is being used, outside of its current intended purpose?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

- Will your study involve potential research participants identified in the context of, or in connection with, their

past or present use of services (Health and Social Care (HSC)), including participants recruited through these services as healthy controls?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (Health and Social Care (HSC))?
- Will your research involve prospective collection of tissue from any past or present users of these services (Health and Social Care (HSC)), including participants recruited as healthy controls?
- Will your research involve prospective collection of information from any past or present users of these services (Health and Social Care (HSC))?
- Will your research involve the use of previously collected tissue and/or information from which individual past or present users of these services (Health and Social Care (HSC)), are likely to be identified by the researchers, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, their possession?
- Will your study involve patients (or information about patients) in or for the purposes of an independent establishment or independent agency in Northern Ireland?
- Will your research involve residents or patients (or information about them) in or for the purpose of residential care homes or nursing homes in Northern Ireland?

Question Set 3

- Will your research involve the storage of relevant material from the living or the deceased on premises in England, Wales or Northern Ireland without a storage licence from the Human Tissue Authority (HTA)?
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent for research from the donors?
- Will your research involve the analysis of human DNA in cellular material (relevant material), collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor? And/or: Will your research involve the analysis of human DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage procedures (including use of identifiable tissue samples or personal information) involving adults who lack capacity to consent for themselves, including

participants retained in study following the loss of capacity?
- Is your research health-related and involving offenders?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?

If your research extends beyond **Northern Ireland** find out if you need NHS REC review by selecting the 'OTHER UK COUNTRIES' button below.

OTHER UK COUNTRIES

If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC review follow this link for final confirmation and further information.

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Appendix 7: Local Patient Database (to be securely stored at site for duration of the study)