Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) Application Form

Instructions:

Please fill in all white boxes. Please do not add anything to or change any blue boxes.

Please do not reformat the form in any way or change the footer.

Instructions are written in black, e.g. Please answer all questions as instructed in the white boxes

*Detailed guidance notes can be found in the '**Guidance for Applicants'** on the HSC-PBPP website. Please refer to this document when completing the form.*

https://www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/

Brief guidance for each question is written in blue: e.g. "this should be the person in charge".

***To fill in a tick box**, double-click on it and change "default value" from "checked / unchecked" as required.*

***To 'choose an item'**, click on the text and choose the appropriate item from the drop-down menu that should appear.*

Application Control			
Applicants should not complete the "submitted date" field			
Application Coordinator			
Application Number	2122-0999	Submitted Date	1st September 2021
Applicant Name and Title	Sugarplum		
Proposal Name	Evaluation of Tooth Fairy Services in the UK		
Proposed End Date	31st December 2025		
Which version of the Guidance for Applicants did you read?	v4.0		

Application History and Version Control					
HSC-PBPP use only					
Application *YYYY-1234 Surname*	Submitted date *dd/mm/yy*	Approval date *dd/mm/yy*	Approved version *V1.x*	PSD* version *if applicable* *V1.x*	End date *dd/mm/yy*
2122-0999 Sugarplum	01/09/21	08/09/21 with conditions	V1.0	V1.0	31/12/25
2122-0999 Sugarplum		28/09/21 full	V1.1	V1.0	31/12/25
Amendment No. *Amendment 1* *Amendment 2*	**Reason** *Addition of personnel* *Addition of data*	**Submitted date** *dd/mm/yy* *dd/mm/yy*	**Date of approval** *dd/mm/yy* *dd/mm/yy*	**Approved version** *V2.x* *V3.x*	**PSD* version** *if applicable* V1.x V2.x	**End date** *dd/mm/yy* *dd/mm/yy*

Add rows as required for subsequent amendments.

* PSD is the eDRIS Project Specification Document

For any amendments, the latest approved version of the application form is that which should be amended and sent to HSC-PBPP.

Pre-submission checklist *(to be completed by the eDRIS coordinator)*	
Applicants should not fill out this section	
Approved Information Governance Training	☒ Approved training complete and certificates received *Application should not be submitted until all training certificates have been received for **all** people in sections 1.1 – 1.5.*
Use of accredited Scottish Safe Haven	☐ Yes ☐ National Safe Haven ☐ NHS Research Scotland Regional Safe Haven (please specify which): ☐ Lothian Research Safe Haven (Edinburgh) ☐ North (DaSH, Aberdeen) ☐ West (Robertson Centre, Glasgow) ☐ East (HIC, Dundee) ☐ NRS SLS (Ladywell House) ☒ No
If applicant is using the National Safe Haven: Is the proposal covered by National Safe Haven generic ethics approval or other ethical opinion?	For this proposal, please confirm that the following statements are true: 1) Data held / accessed in National Safe Haven (Q3.4) ☐ Yes ☐ No 2) Research in field of Health or Social care (Q3.1.04) ☐ Yes ☐ No 3) There will be no contact with participants (Q4.6) ☐ Yes ☐ No 4) Study has undergone external scientific peer review (Q3.1.16) ☐ Yes ☐ No 5) Will be carried out by UK-based research team (Q2.1) ☐ Yes ☐ No ☐ Yes, covered by National Safe Haven generic ethics ☐ Covered by other ethical opinion or approval ☒ Ethical opinion is not required

NHS Central Register (NHSCR) Involvement	☐ Yes
	   Reference number:
	     ☐ Email confirmation of approval supplied
	☒ No

Has section 7 been signified by all signees?	☒ Yes ☐ No

Supporting Documents
*Please list only supporting documents which you have **clearly referenced in your application**, the **brief** name of each should clearly indicate the nature and content of the document*

Document no. e.g. SD1	Document type / description *e.g. protocol, DPIA*	Filename (please use short names) e.g. SD1 protocol YYYY-1234 Surname e.g. SD2 DPIA YYYY-1234 Surname
SD1	Project Support Document and Data variables list v1.0	SD1 PSD v1.0 2122-0999 Sugarplum
SD2	DPIA	SD2 DPIA 2122-0999 Sugarplum
SD3	Privacy notice	SD3 Privacy notice 2122-0999 Sugarplum
SD4	Public Engagement survey	SD4 PE Outcomes 2122-0999 Sugarplum
SD5	Contract between Puck Enterprises, Tooth Fairy Services and NHS Paediatric Happiness Services.	SD5 TFS & Puck Service Contract 2122-0999 Sugarplum
SD6	TFS Information Security Policy	SD6 TFS IS Policy 2122-0999 Sugarplum
SD7	TFS Data Protection and Confidentiality Policy	SD7 TFS DP Policy 2122-0999 Sugarplum
SD8	TFS Administrator Rights Policy	SD8 TFS Admin Rights Policy 2122-0999 Sugarplum
SD9	TFS Access Control Policy	SD9 TFS Access control Policy 2122-0999 Sugarplum
SD10	TFS Adverse Event Management Policy	SD10 TFS Adverse Event Policy 2122-0999 Sugarplum
SD11	TFS Password Policy	SD11 TFS Password Policy 2122-0999 Sugarplum
SD12	TFS Network Security Policy	SD12 TFS Network Security Policy 2122-0999 Sugarplum
SD13	TFS Information Sharing & Transfer Policy	SD13 TFS Info Sharing & Transfer Policy 2122-0999 Sugarplum
SD14	TFS Mobile Computing & Remote Access Policy	SD14 TFS Remote Access Policy 2122-0999 Sugarplum

Note to Applicants

Prior to completing your application form you should:

- Contact the eDRIS Team, who will assist you at phs.edris@phs.scot
- Read and understand the Guidance for Applicants *https://www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/*

Your application should be typed, not handwritten. Your eDRIS coordinator will inform you of how to submit your application form and any supporting evidence. Before submitting your completed application, you should ensure that:

- All relevant sections of the application are complete
- Relevant supporting evidence is attached
- Individuals named on the form have read and approved its submission, and signed and dated in section 7.

Please note that submitted applications may be circulated to panel members, administrative colleagues, NHSScotland information governance and information security colleagues, Caldicott Guardians, the CHI Advisory Group and, where appropriate, non-NHS Scotland colleagues from a variety of participating partner bodies, in the course of processing. You must make your eDRIS coordinator aware of any confidential or sensitive information contained in your application which you would consider inappropriate for circulation in such a manner. Your application could be subject to disclosure or partial disclosure under the Freedom of Information (Scotland) Act, and will be retained in line with NHSScotland information policy.

Please answer all questions in the form.

Section 1: Safe People

1.1	**Applicant**
	This should be the person who is the principal contact for the application and has operational or day-to-day responsibility for the project.
	For more details please read section 1.1 of Guidance for Applicants

1.1.01	Full Name	Sugarplum
1.1.02	Title	Fairy
1.1.03	Position	Lead Tooth Fairy
1.1.04	Organisation Name	Tooth Fairy Services
1.1.05	Address (incl. postcode)	Titania Way, Oberon Town, Nowhere, UK. NO15 9WH
1.1.06	Email	Sugarplum@toothfairy.service.uk
1.1.07	Professional Registration No. (organisation and number)	General Fairy Council (GFC) 84294521
1.1.08	Do you have an NHS contract?	Yes, Standard
1.1.09	Does this proposal form a part of an academic qualification? (If yes please also complete section 1.2)	No
1.1.10	Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years. *Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.* *A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the applicant will not personally access the data, IG training is required so they are aware of the standards required for processing the data by those for whom they are responsible. Access to data will not be given until evidence of HSC-PBPP-approved IG training has been provided.*	
	Name and institution of course	MRC Research GDPR and confidentiality course
	Date completed	May 2021

1.2	**Academic Supervisor** (*Do not fill in if you answered 'No' to Q1.1.09*)
	This should be the primary academic supervisor for the applicant undertaking the academic qualification, usually from the same organisation.
	For more details, please read section 1.2 of Guidance for Applicants

1.2.01	Full Name	
1.2.02	Title	
1.2.03	Position	
1.2.04	Organisation Name	
1.2.05	Address (incl. postcode)	
1.2.06	Email	
1.2.07	Professional Registration No. (organisation and number)	
1.2.08	Does this person have an NHS contract?	Choose an item.
1.2.09	Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years.	

	Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training. *A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the academic supervisor will not personally access the data, IG training is required so they are aware of the standards required for processing the data.*	
	Name and institution of course	
	Date completed	

1.3	**Clinical Lead** *This should be the person with clinical responsibility for the use of health data. This person cannot be someone also completing an academic qualification.* *For more details, please read section 1.3 of Guidance for Applicants*	
1.3.01	Full Name	Godmother
1.3.02	Title	Fairy
1.3.03	Position	Clinical Lead for Child Happiness
1.3.04	Organisation Name	Tooth Fairy Services
1.3.05	Address (incl. postcode)	Titania Way, Oberon Town, Nowhere, UK. NO15 9WH
1.3.06	Email	Fairy.godmother@toothfairy.service.uk
1.3.07	Professional Registration No. (organisation and number)	General Medical Fairy Council (GMFC) 39460167
1.3.08	Does this person have an NHS contract?	Yes, standard
1.3.09	Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years. *Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.* *A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the clinical lead will not personally access the data, the training is required so they are aware of the standards required for processing the data.*	
	Name and institution of course	MRC Research GDPR and Confidentiality course
	Date completed	April 2021

1.4	**Information/Data Custodian** *This should be a senior person responsible for safeguarding the confidentiality and security of the data throughout the application. This person cannot be someone also completing an academic qualification.* *For more details, please read section 1.4 of Guidance for Applicants*	
1.4.01	Full Name	Tinkerbell
1.4.02	Title	Fairy
1.4.03	Position	Head of Numbers
1.4.04	Organisation Name	Tooth Fairy Services
1.4.05	Address (incl. postcode)	Titania Way, Oberon Town, Nowhere, UK. NO15 9WH
1.4.06	Email	Tinkerbell@toothfairy.service.uk
1.4.07	Professional Registration No. (organisation and number)	GFC 83890273
1.4.08	Does this person have an NHS contract?	Yes, standard

1.4.09	Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years.
	Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.
	A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the information custodian will not personally access the data, the training is required so they are aware of the standards required for processing the data.
	Name and institution of course	MRC Research GDPR and Confidentiality course
	Date completed	May 2021

1.5 Others with access to identifiable or potentially identifiable data

Please give details of all additional people who will have access to identifiable, potentially identifiable, or pseudonymised individual-level data.
Please add lines for each additional person. Please do not use a separate list.
Pseudonymised data is where someone still holds the identifiers and can re-link the data back to the patients and still counts as personal data under data protection law. Combinations of data can make people potentially identifiable.
All researchers accessing data must have completed IG training within the last three years. Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training for each researcher.
For more details, please read section 1.5 of the Guidance for Applicants

Title and Name	Position	Organisation	Email	Professional Registration (organisation and number)	Does this person have an NHS contract?	Information governance (IG) training	
						Name and institution of course	Date completed
Fairy Moth	Data Collector / Analyst	Tooth Fairy Service	Moth@toothfairy.serv.uk	GFC 55293762	Yes	MRC Research GDPR & Confidentiality	May 2021
Fairy Cobweb	Data Collector / Analyst	Tooth Fairy Service	Cobweb@toothfairy.serv.uk	GFC 00636515	Yes	MRC Research GDPR & Confidentiality	May 2021
Fairy Mustardseed	Data Collector / Analyst	Tooth Fairy Service	Mustardseed@toothfairy.serv.uk	GFC 27184594	Yes	MRC Research GDPR & Confidentiality	June 2021
Fairy Peaseblossom	Data Collector / Analyst	Tooth Fairy Service	Peaseblossom@toothfairy.serv.uk	GFC 02192964	Yes	MRC Research GDPR & Confidentiality	July 2021

1.6 Others

*Please include here all people who are involved in the project (e.g. significant involvement in proposal design, content or outcomes), but who will **not** access the data for analysis.*
Please copy and complete box for each additional person. Please do not use a separate list.
For further information, please read section 1.6 of the guidance.

Title and Name	Organisation	Position	Involvement in Proposal
Robin Goodfellow	Puck Enterprises	Designer and Engineer	Designed and made the PilloWapp device used for collecting administrative data from Tooth Fairy visits.

			Will have access to aggregated data regarding the performance of the PilloWapp but will not have access to the individual-level data.
Fairy Ariel	Tooth Fairy Services	Service Improvement Manager	Will have access to aggregated results and outcomes to identify areas for service improvement but will not see the individual -level data.

Section 2: Safe Organisations & Bodies

2.1	**Organisation or Body Leading Proposal**	
	The lead organisation is usually the one by which applicant is employed, and which will be responsible for the data and will become the (joint) data controller. Where multiple organisations are collaborating to produce the proposal, this should be the organisation which has a lead in the operational delivery of the proposal and will therefore take responsibility for matters relating to the access to and processing of personal data.	
	For more details, please read section 2.1 of the Guidance for Applicants	
2.1.01	Organisation or Body Name	Tooth Fairy Services
2.1.02	What type of organisation is this?	NHS
2.1.02a	If this is a commercial organisation, please provide a full explanation of the organisation or body's activity and industry sector, including any previous experience of using NHSScotland data. Please append supporting documents as appropriate.	
	Tooth Fairy Services (TFS) is a specialist NHS service that works within NHS Paediatric Happiness Services in the UK to collect Baby Teeth as they naturally fall out.	
	It is now known that if a third party (in particular fairy-tale witches) obtains a child's baby teeth it will gain undue harmful influence over the happiness of that child. TFS safely collects and respectfully destroys these Baby Teeth, so that children are guarded against any such damaging influences. The Tooth Fairy on duty is notified of teeth requiring collection via the PilloWapp (which detects teeth placed under pillows, including ID and location of the child in question). The Duty Tooth Fairy collects the teeth, leaving behind a small gift or remuneration (usually a coin). TFS destroys the teeth soon after collection. Child-specific tooth data are pseudonymised and retained securely for up to 20 years, for collation of data for subsequent tooth collections. These data are stored separately from the child identifiers. Once a full set of baby teeth has been collected or the 20 years have passed, the child's data is fully anonymised and the child's identifiers are securely removed.	
	For further information regarding TFS, please see the website: fww.toothfairy.service.uk.	
2.1.03	Is this organisation or body wholly funding or paying for the costs of conducting the proposal? ==If wholly funding the proposal, you do not need to fill in Q 2.3.==	Partly funding

2.2	**Main Contact for Lead Organisation**	
	This should be the agreed senior person within the lead organisation who is aware of the proposal and accepts and assures the organisation's obligations and roles, for compliance with data protection law and GDPR, with respect to any processing of data. This person cannot be anyone who is also mentioned in section 1.	
	This is for the lead organisation to comply with the Data Protection Accountability principle.	
	For further information, please read section 2.2 of the Guidance for Applicants.	
2.2.01	Full Name	Nuff
2.2.02	Title	Fairy

2.2.03	Position in organisation	TFS Data Protection and Governance Officer
2.2.04	Email	Fairy.nuff@toothfairy.serv.uk

2.3	**Organisation or Body Funding Proposal**	
	<mark>*Complete the following section if you answered 'partially funding or not funding' to question 2.1.03. Otherwise please go to Q 2.4.*</mark>	
	Please read section 2.3 of the Guidance for Applicants.	
2.3.01	Who is funding this proposal? *Please give organisation or body name:*	This proposal is jointly funded by Tooth Fairy Services (NHS) and Puck Enterprises.
2.3.02	What type of organisation is this?	Commercial
2.3.02a	If this is a commercial organisation, please provide a full explanation of the organisation or body's activity and industry sector, including any previous experience of using NHSScotland data. *Please append supporting documents as appropriate*	
	Puck Enterprises is a not-for-profit commercial organisation that designs and tests interventions to improve the happiness of children, for NHS and other organisations. Puck Enterprises is registered with the ICO Z(F)945737 A contract between Puck Enterprises, NHS Paediatric Happiness Services and Tooth Fairy Services is attached as supporting document SD5.	

2.4	**Research Sponsor**	
	Please read section 2.4 of the Guidance for Applicants.	
	Any research that uses health and social care data requires a Research Sponsor according to the UK Policy Framework for Health and Social Care Research (2017). The Research Sponsor should be aware of all activity regarding the research study.	
2.4.01	Does this proposal require a research sponsor?	☐ Yes ☒ No
	<mark>*If no, please go to Q 2.5.*</mark> *If yes, please fill details of the Research Sponsor below*	
2.4.02	Full Name	
2.4.03	Title	
2.4.04	Position	
2.4.05	Organisation	
2.4.06	Email	
2.4.07	Sponsor's Reference number	

2.5	**Other Relevant Organisations or Bodies**	
	These are other organisations or bodies which have a significant involvement or interest in the proposal (design, content or outcomes, provision of services or who host or employ individuals mentioned in section 1). Any organisation mentioned elsewhere in this application should be added below.	
	<mark>*Complete this section if applicable.*</mark>	
	For more details, please read section 2.5 of the guidance	

Organisation Name	Nature of Business/Sector	Nature of interest in proposal

Puck Enterprises	Puck Enterprises is a not-for-profit company that designs and tests interventions to improve the happiness of children. The company has worked with NHS Paediatric Happiness Services over a number of years on different devices to try to improve the welfare and happiness of children. Puck Enterprises is registered with the ICO Z(F)945737	Designed and made the PilloWapp used for collecting administrative data from Tooth Fairy visits. Aggregated data regarding the performance of the PilloWapp will be provided but will not have access to the individual-level data.

Section 3: Safe Proposal Overview

<table>
<tr>
<td>3.1</td>
<td colspan="2">Proposal Essentials
This section must outline the need and nature of the proposal, how it will benefit the public, how it will use NHSS data and justify the data requests and data processing from patient to outputs.
For more details for each question, please read section 3.1 of the Guidance for Applicants.</td>
</tr>
<tr>
<td>3.1.01</td>
<td>Please specify the proposal end date.
Please note that requests for data from NHS Central Register (NHSCR) will be capped at five years.
To reduce the need for amendment requests for time extensions, this end date should reflect the entire duration of the proposal, including time for obtaining the data, data analysis and preparation of manuscripts or reports based on the outcomes.</td>
<td>31st December 2025</td>
</tr>
<tr>
<td>3.1.02</td>
<td colspan="2">Please indicate whether this application is:

☒ A new application <mark>Please go to Q 3.1.03</mark>
☐ An extension of an existing application (e.g. in terms of scope)
☐ A renewal of an existing approval (e.g. for NHSCR)
☐ Related to a previous application (approved or not)</td>
</tr>
<tr>
<td>3.1.02a</td>
<td colspan="2">If this is an extension, renewal or related to a previous or existing application, please provide details, including the HSC-PBPP reference number and a copy of the previous or existing application, and summarise the changes requested. Please explain how this updated application relates to any associated, currently ongoing application.

</td>
</tr>
<tr>
<td>3.1.03</td>
<td colspan="2">Does this proposal require updates of health information or to be repeated at regular intervals?
No

</td>
</tr>
<tr>
<td>3.1.03a</td>
<td colspan="2"><mark>If no, please go to 3.1.04</mark>
<mark>If yes,</mark> please advise of the frequency of these updates.

</td>
</tr>
<tr>
<td>3.1.04</td>
<td colspan="2">What is the substantive purpose of the proposal?
Please choose <u>one</u> option from below that best matches your proposal.
Please be clear and consistent about the purpose of this application, as this will affect the answers to other questions within this application form: e.g. the legal basis for processing data under data protection law (Q 3.2.02) should match the purpose of the application.</td>
</tr>
<tr>
<td></td>
<td colspan="2">

☒ Audit / Clinical Audit   ☐ Service Planning / Improvement

☐ Research   ☐ Research Resource

☐ Performance Monitoring / Management

☐ Health / Social Care Administration   ☐ Systems Implementation / Testing

☐ Training/Education

☐ Other <mark>(please specify below)</mark></td>
</tr>
<tr>
<td></td>
<td colspan="2">If 'other' clearly defined purpose, please give details:</td>
</tr>
</table>

3.1.05	Access is requested to data from which sources, covered by HSC-PBPP? *Please tick all that are relevant*	
	☐ NHS National Services Scotland (NHS NSS) ☒ Public Health Scotland (PHS) ☐ A single NHS Scotland Board (excluding NHS NSS or PHS) including any system / database ☐ More than one NHS Scotland Board including any system / database ☐ NRS births *Please tick, even if getting data from PHS* ☐ NRS deaths *Please tick, even if getting data from PHS* ☐ NHS Central Registry (NHSCR) *Please complete section 4.4. Please ensure NHSCR are aware of the request for their data.* ☐ Community Health Index (CHI) database *Please complete section 4.6. This refers to specific access to the CHI database, not the use of CHI numbers for data linkage.* ☐ Other (*please specify below*)	
	If other, please give details:	
3.1.05a	For this proposal, are you requesting access to data from any other sources, not covered by HSC-PBPP? *This is to give an idea of the full scope of the combined datasets and variables for this proposal, and the requirement for approvals from other data controllers.*	
	Yes	
3.1.05b	If no, please go to Q 3.1.06 If yes, please tick all that are relevant	
	☐ GP data via Albasoft ☐ Scottish Government (e.g. Education, Census) via Stats PBPP ☐ Local Authority ☒ Other (please specify):	
	Please give details of the requested data. *Please provide evidence of the data controller approval, as a supporting document.*	
	Data will be obtained from the PilloWapp system by Tooth Fairy Services for the audit and linked with the NHS dental data, to determine the efficiency of the system in detecting teeth for collection. NHS Dental data will be obtained from other parts of the UK to be combined with the data from Scotland.	
3.1.06	Provide a <u>clear and concise</u> ***lay*** outline of the proposal (max. 250 words). This will be published on the HSC-PBPP website. *This is a **stand-alone** lay summary of the whole proposal, from participants to outputs, to **inform the public** of the use of their confidential health data. This should include why this is required and how the outcomes will benefit them, and should be written in clear and concise language that the public will understand. <u>All</u> abbreviations should be explained.*	

| | Tooth Fairy Services (TFS) collects Baby Teeth from children, as part of their happiness-guarding role, providing a small remuneration or gift in return, the value of which is determined by the child's family. In January 2013, TFS introduced the PilloWapp developed by Puck Enterprises, which detects when a child puts a tooth under a pillow for the Tooth Fairy, the location of the tooth to be collected and coded child identifiers (name, TFS number ID and CHI or NHS number). Prior to 2013, Tooth Fairy Services used household fairies to convey the information. The data retained by the PilloWapp includes coded child identifiers, location information and the current family level of remuneration; these data are used only for the collection of teeth. The PilloWapp does not collect data regarding dental health of any children. The PIlloWapp data are protected by StrongMagic IT systems during TFS provision. Once the tooth has been collected, the PilloWapp data are transferred and stored in a child-specific data file and held securely at TFS headquarters, located in the middle of Nowhere.

This is a data linkage study, whereby data from TFS will be linked with NHS Dental data and analysed in a secure environment. This will enable us to determine the effectiveness of the PilloWapp, the influence of dental health on its performance and to identify areas for improvement. In addition, social or geographical factors that might affect the uptake or provision of the service among children will be analysed. Levels of remuneration will also be assessed to determine their consistency across the UK. |
|---|---|
| 3.1.07 | Provide the specific aims and objectives of the proposal outlined in this application. *This should be the bullet points of the goals of the proposal.* |
| | This application is an evaluation of the Tooth Fairy Service since 2007, comparing the 6 years before and after the introduction of the PilloWapp, up to February 2020, after which COVID19 interrupted the running of the NHS Paediatric Happiness Services.

The application will use data linkage to external Dental data to determine:
    1) The level of use of Tooth Fairy Services across Scotland, compared with the number of children registered with an NHS Dentist:
        a) whether introduction of the PilloWapp affected TFS uptake using a 'before and after' analysis;
        b) whether specific social and geographical factors, might affect service coverage or use of the PilloWapp;

    2) Whether the health of the teeth and/or any NHS dental intervention in its extraction affect the ability of the PilloWapp to detect teeth that should (or not) have been collected:
        a) As above, whether this is affected by specific social or geographical factors;

    3) The variations in monetary remuneration across the service:
        a) whether this is affected by specific social or geographical factors
        b) whether this has changed significantly over time.

Results from this audit will be used to identify areas where service improvement may be required and possible factors that might affect the uptake or efficiency of the services. Differences in levels of remuneration, and the influence of social or geographical factors, will inform the ease of standardisation and the possible remuneration level that could be used for this standardisation. |
| 3.1.08 | Provide a description of the envisaged **benefits** of this specific proposal to the public and / or patients. |

	It is now known that carelessly discarded Baby Teeth from humans can be obtained by third parties (in particular fairy-tale witches) who will gain damaging influences over the happiness of children. The Tooth Fairy service aims to guard children against the malign influence of such third parties by collecting, carefully storing and then destroying these Baby Teeth, to the benefit and happiness of children, as part of their role within NHS Paediatric Happiness Services. To try to improve the Tooth Fairy service, the PilloWapp was introduced in January 2013. More recently it has been hypothesised that dental decay may interfere with the PilloWapp but there is no direct evidence of this from preliminary field tests. Another possibility may be the material used for pillows (which would be harder to address remotely), but by investigating the dental data, this possibility can be tested. To determine the effects of the introduction of the PilloWapp and to determine whether inequalities in Tooth Fairy Service use or level of remuneration have arisen over the 6 years before and after introduction of the PilloWapp, in line with general changes in dental health, social or geographical factors. The results of the audit will be directly fed back to Service Planners at Tooth Fairy Services to identify possible service improvements.
3.1.09	Provide <u>concise</u> details of the proposal: background and reason for requesting data, sample size, inclusion and exclusion criteria, time period; data collection; data processing or other means required to achieve the aims of your proposal. Please justify the use of all the datasets requested.
	• Why is this proposal needed? Tooth Fairy Services (TFS) is a specialist, NHS service, within Paediatric Happiness Services in the UK to collect Baby Teeth as they naturally fall out. Tooth Fairy Services safely destroys these Baby Teeth, so that children are guarded against third-party damaging influences, as it is thought that if a third party (especially fairy-tale witches) obtains a child's baby teeth it can gain harmful influence over the happiness of that child. The Tooth Fairy destroys the teeth soon after collection. In 2013, TFS introduced the PilloWapp developed by Puck Enterprises, which detects when a child puts a tooth under a pillow for the Tooth Fairy, the location of the tooth to be collected and coded child identifiers (name, TFS number ID and CHI number). Prior to 2013, Tooth Fairy Services used household fairies to convey the information, which was fairy-intensive. TFS wish to audit the efficacy of the process, comparing before and after the introduction of the PilloWapp and determine whether there is scope for improvement of the service. • What is the background, design and methodology of your proposal? The audit will compare linked Tooth Fairy Services data prior and subsequent to the introduction of the use of PilloWapp. These data will be linked to the child dental data, held in the Management Information and Dental Accounting System (MIDAS), by personal identifiers which

will only be used for data linkage. Child-level study data will be given a specific study ID for analysis. Dental data from MIDAS, for children who have not used the Tooth Fairy Services will also be obtained and given a different study ID by eDRIS. These children will be used in all analyses as a comparator group. Inequalities within the service will be analysed according to age and sex of the child, social deprivation (SIMD), ethnicity, geography (postcode sector) and dental health (MIDAS data) to identify whether these have arisen in a systematic manner.

Population: All children aged 5-17 years known to Dental Services in Scotland between 2007 and February 2020, according to MIDAS data. This is between ~750,000 in 2007 and 968,000 children in 2019. All those who have used TFS will be linked with data from MIDAS. For those children who have not used TFS, the same variables will be extracted and given new ID numbers. Data from all children will be anonymised / pseudonymised before returning to Tooth Fairy services.

Intervention: The audit will compare the use of TFS before and after the introduction of the PilloWapp. As the PilloWapp was introduced in January 2013, data from January 2007–December 2012 and January 2013–February 2020 will be compared, as 6 years before and 7 years after an intervention. Variations in service use over time will also be analysed according to age and sex of the child, social deprivation (SIMD in Scotland), ethnicity, geography (at postcode sector level) and dental health (MIDAS data). Variations in remuneration over time will be analysed according to age of the child, social deprivation (SIMD in Scotland), ethnicity, geography (postcode sector) and dental health.

Comparators: Children who have not used Tooth Fairy Services but are within MIDAS data will be the comparator group: these will be children who don't believe in fairies, or who have declined the use of Tooth Fairy Services by not putting their teeth under their pillow. Once these data have been identified, extracted and checked by eDRIS, these data will be anonymised as TFS have no identifiers relating to these children and just need them as a comparator group. Differences between those who have and have not used TFS will be compared over time and according to age and sex of the child, social deprivation (SIMD), ethnicity, geography (postcode sector) and dental health. This will indicate whether TFS use is particular to any social, geographical or dental factors.

Outcomes will be population statistics between the groups.
All data will be anonymised (controls) or pseudonymised (TFS data) for analysis. All data will be analysed on secure TFS servers located in central Nowhere. These data will be compared with similar data to be obtained from other parts of the UK.

- How will the datasets and variables requested be able to answer the questions posed in your proposal?

We will determine whether any differences in dental treatment (e.g. type of filling) of the child affects the ability of the PilloWapp to detect teeth that have fallen out, compared with the network of household fairies that were used before, which was effective but fairy-intensive. The PiiloWapp works through 'Dentine resonance detection' but different dental treatments may affect its ability to detect the teeth. Using the codes for level of treatment in dental data, will indicate what the treatments were and whether these adversely affected the PilloWapp.

- How many individuals will be required for this proposal (approximation)? Why is this number required?

The number of children registered with dental services in Scotland has increased from ~750,000 in 2007 and 968,000 in 2019. As awareness of dental hygiene has risen, it would be helpful to know whether this has affected take up of the services provided by TFS and can only be done if all children known to dental services are included.

- What criteria will be used to define your cohort or population of interest?

All children aged 5-17 years known to Dental Services in Scotland between January 2007 and February 2020, according to MIDAS data.

- Are there any datasets that will only be used for the cohort creation and or linkage and therefore needs to be identified in the project but won't be released to the researcher?

No, but there are variables that will be for processing only. Please see variables list.

- Will you contact the individuals for this work?

No.

- Please define and justify the time-period of the data required?

Six / seven years before and after the introduction of the pillow is a good amount of time to evaluate the effectiveness of the intervention. The number of procedures done on these children is unknown. The level of dental caries may change with time and geography and the use of a larger dataset over this time may reduce some of the fluctuations and show how the PilloWapp has benefitted the service.

- How will the data be obtained and processed?

Patient identifiers (CHI, name, address) from TFS will be given new study ID numbers and sent to eDRIS. MIDAS data will be extracted by eDRIS, and linked via the TFS study numbers and returned to TFS for analysis. Data from control children will be extracted and given study numbers and sent to TFS. These data will be destroyed at eDRIS once they have been sense-checked by TFS.

- Will you require any data linkage to take place? If so, who will carry out the linkage?

Yes, eDRIS will carry out the data linkage.

- Will you be linking datasets from different sources?

Yes, data from TFS will be linked to MIDAS dental data from Public Health Scotland. There will be similar linkages to dental data from other parts of the UK.

- Do you require matched controls for your subjects?

No, matched controls are not required.

3.1.10	Provide a clear and concise outline of any statistical methods that will be used in the proposal. Is there a formal statistical plan in place? *This should be a brief and non-technical description of the statistical analysis, for people who may not have a background in statistics.*
	This is a largely descriptive and comparative study, so only basic population statistics will be used to compare between groups. Multifactorial analysis will be used to determine whether any specific factors have more influence on the outcomes.

3.1.11	Provide a diagram to illustrate the data flow or data linkage process envisaged.
	This data flow diagram should show the data sources where the data is accessed and stored at each point in the process from patient to outcomes, and by whom, so that roles and responsibilities are clear for data controller and / or processors and for transfers of data.
	If the data flow diagram is in a supporting document, please state where it can be found.
	Patient identifiers from TFS given new Study ID Nos.
	Identifiers and Study IDs
	Patient identifiers from MIDAS
	Data from MIDAS
	eDRIS
	•Data linkage for TFS children with MIDAS data under study ID Nos.
	•MIDAS data from non-TFS children extracted and given study ID Nos.
	Linked pseudonymised and anonymised data
	Tooth Fairy Services Secure servers for analysis
	Comparable Data from other parts of the UK
	Aggregated data to be used to identify possible service improvements
	Aggregated data to be used to identify possible improvements to the PilloWapp™ **Puck Enterprises**
3.1.12	Does the proposal focus on or include information from people who might be considered vulnerable?
	Definitions of vulnerable people are given in Table 5 of Appendix A of the Guidance for Applicants.
	Yes, focus on vulnerable people
3.1.12a	If vulnerable people are the focus of, or included in, your proposal, please give details.
	All children who have been visited by the Tooth Fairy between January 2007 and February 2020 will be included. Children as a group could be described as a vulnerable population. This may include especially vulnerable children, through illness or social circumstances, but such information will not be identifiable in the analysis and are not the focus of this application.
3.1.13	Does the proposal seek access to data that could be considered to be highly sensitive or request other (non-health) special category data in addition to health data?
	Under GDPR, all health data is classed as special category data. However, some variables are considered highly sensitive health data. In addition, some commonly requested variables are also special category data but not health data (e.g. ethnicity). Classes of special category data and highly sensitive data are given in section 6 of Appendix A of the Guidance for Applicants.
	Yes

3.1.13a	If highly sensitive data or non-health special category data are requested, please give details of the variables and why they are required.
	Ethnicity is requested.
3.1.14	Does the proposal seek to use information <u>exclusively</u> about deceased persons? Please give details. *Please note that while deceased people are not subject to data protection law, they are still subject to the Common Law Duty of Confidentiality and legislation governing access to their health records.*
	No
3.1.15	Describe how you have included input from the public / lay representatives / patient groups in the design or any other aspect of your proposal.
	This is an audit for Tooth Fairy Services, comparing outcomes before and after an intervention in a service, which aims to improve service uptake and outcomes. Engagement with mortals can be tricky, especially those who don't believe in fairies. We asked some dental students to carry out a questionnaire for us at various UK dental practices asking parents and children about their experience of Tooth Fairy Services. Feedback was that there was room for improvement: sometimes the Tooth Fairy forgot to come in some areas. In addition, some members of the public thought that the current remuneration rates should be standardised. The general feedback when we asked about use of their NHS data for analysis was that was acceptable if the data were not identifiable and could not be traced back to the patients or the dental practice.
3.1.15a	How did the public / lay / patient input change your proposal?
	The fact that the Tooth Fairy forgot to come and the request for standardisation of remuneration rates suggested that there may be geographical or social factors in the effectiveness of TFS, but also that some interference may have arisen. This was added to the study design. We have already verified that, technologically, PilloWapp coverage is good across the UK.
3.1.15b	How will you keep these patients and the public informed about the ongoing use of their health data for this application and its outcomes?
	It is hard to do direct interaction with mortals, but we will try to keep them informed of the progress and outcomes of this audit through the NHS dental services, via patient leaflets and posters to be displayed in waiting rooms of NHS Dental practices.
3.1.16	Describe any scientific peer review undertaken, with details (e.g. formal external scientific review by a peer organisation or funding body, informal internal review, or review by a third party). If no formal external review has been carried out, please explain why not.
	The audit proposal was reviewed by the Service Improvement Manager at Tooth Fairy Services and also by the Scientific Officer at Puck Enterprises. Both suggested changes to the study design which have been incorporated. As this is an internal audit, it has not been reviewed by any external parties.
3.1.17	*The Information Commissioner's Office (ICO) recommends that a Data Protection Impact Assessment (DPIA) should be carried out at the beginning of any proposal to assess the privacy risks raised by processing people's personal and special category (e.g. health) data. It is also good practice.*

	*The ICO has information and screening questions as to whether a DPIA is legally required here (https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/. If any of these screening questions are answered with a **Yes**, then a DPIA is mandatory as a **legal requirement** by the ICO and a DPIA **must** be provided, which should be signed off by a suitable senior person.* *Some organisations provide their own screening questions and / or require a DPIA anyway.* *If your organisation does not sign off DPIAs, please provide evidence that your organisation has seen and accepts the risks associated with this processing of personal data.* **Please read the guidance for 3.1.17.** Has a Data Protection Impact Assessment (DPIA) been carried out for this proposal and the risks accepted by your organisation?
	Yes
3.1.17a	If Yes, please provide the DPIA as a supporting document and go to Q 3.1.18. If No, a DPIA has not been done, have the ICO screening questions been answered and agreed by your organisation?
	Choose an item.
3.1.17b	If Yes, please provide the screening questions and your reasoning for the answers as a supporting document and go to Q 3.1.18. If neither a DPIA nor the ICO screening questions have been carried out, please justify your reasoning and explain how your proposal has undergone a suitable privacy risk assessment.
3.1.18	Is there *any* commercial aspect or commercial dimension to the proposal or its outcomes? *This could include involvement of a commercial organisation, commercialisation of the product or outcome for which the data is required, commercial access to data, outsourced services provided by a commercial company. This needs to be explained carefully. If the commercial organisation is based outside the European Economic Area (EEA), then special consideration has to be made as GDPR does not allow personal data to be transferred outside the EEA.*
	Yes
3.1.18a	If no, please go to section 3.2. If yes, please justify the requirement for the involvement of this commercial aspect, how it is necessary for the success of the proposal and what the company will gain from their involvement in this proposal. *Please read 3.1.18 of the Guidance for Applicants.*
	Puck Enterprises is a not-for-profit company that designs and tests interventions to improve the happiness of children. Puck Enterprises has worked with the NHS Paediatric Happiness services for a number of years on different projects. The PilloWapp was developed to improve the efficiency of the TFS and has no other commercial application. Puck Enterprises will have no access to any personal data and will only receive aggregated outputs relating to the performance of the PilloWapp and possible factors affecting its performance.
3.1.18b	Please list the partners involved in the commercialisation of this application, and particularly those from NHSScotland. How will NHSS directly benefit from such use of NHSS data? *Please provide the formal agreement between these partners so the panel can be assured that suitable arrangements are in place for the commercialisation of outcomes from the use of NHSS data.*

	NHS Paediatric Happiness Service works in partnership with Puck Enterprises. The PilloWapp device will not be used or sold for any commercial gain. There is a contact in place between NHS Paediatric Happiness Services and Puck Enterprises for the use of the PilloWapp by TFS (see supporting document SD5).
3.1.18c	How will the commercialisation of any product or outcome and its associated intellectual property be handled, and by whom? Please give details.
	As stated above, the PilloWapp device will not be used or sold for any commercial gain.

3.2	Statutory and Regulatory Context *Please read section 3.2 of the Guidance for Applicants.*
3.2.01	Does your proposal have a statutory or regulatory justification? i.e. is the proposal responding to a statutory or regulatory instruction, duty or order? *This should relate to **specific** statutory or regulatory obligations that are detailed in specific legislation.*
	No
3.2.01a	If No, please go to Q 3.2.02 If yes, please give details and citation of the specific statutory or regulatory basis involved.
3.2.02	Will both personal and special category data be processed (either by you or on your behalf) as part of this proposal? *Definitions of personal and special category data are given in section 3.2. of the Guidance for Applicants.*
	Both personal and special category data
3.2.02a	Please tick which legal basis you will use to process **personal data**, under Article 6(1) of GDPR. The most appropriate and commonly ones used for health and social care data are listed below. *Please indicate the lawful basis under current data protection law for processing personal data. If you are unsure which lawful basis is applicable to your proposal, then you may wish to consult your organisation's Information Governance team or Data Protection officer or lead for advice.* **Please read the information on legal bases provided in 3.2.02 of the Guidance for Applicants, including the issues concerning using consent as a legal basis for processing data.**
	☐ 6(1)(c) processing is necessary for compliance with a legal obligation to which the controller is subject. Please cite the specific legislation that applies:
	☒ 6(1)(e) processing is necessary for the performance of a task carried out in the public interest.
	☐ Other: if using another legal basis under article 6(1) please cite specific basis:
3.2.02b	Please tick which legal basis you will use to process **special category data**, under Article 9(2) of GDPR. The most commonly used appropriate bases for health and social care data are listed. A further condition from the Data Protection Act (DPA) 2018 Schedule 1 Part 1 is also required for some legal bases and must be provided.

Please see the table 5 in Appendix B of the Guidance for Applicants for details, the link below, or get advice from your local data protection team.
https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/special-category-data/what-are-the-conditions-for-processing/

☒ 9(2)(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services.

Please cite the appropriate condition from the DPA 2018 Schedule 1 Part 1 Paragraph 2

As this is an audit of the provision of an NHS service used to prevent harm to children:
Conditions used are:
2(a) Preventive or occupational medicine
2(d) Provision of health care or treatment.
Fairy Godmother is the clinical lead and has responsibility for this service.

☐ 9(2)(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care, and of medicinal products or medical devices.

Please cite the appropriate condition from the DPA 2018 Schedule 1 Part 1 Paragraph 3

☐ 9(2)(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1).

Please cite the appropriate condition from the DPA 2018 Schedule 1 Part 1 paragraph 4

If you are using another legal basis under GDPR article 9.2, please cite the specific basis and additional DPIA Schedule 1 part 1 conditions, if required.

☒ Other: Article 9(2)g:
Processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

As there is a child protection element of the TFS, this legal basis is used with the condition 18 below.

Schedule 1 part 2 condition:

Condition 18: Safeguarding of children and individuals at risk.
1(a) The processing is necessary for the purpose of protecting an individual from physical, mental or emotional harm <u>and</u>
1(b) the individual is aged under 18.

1(c) the processing is carried out without the consent of the data subject because of:
2(b) in the circumstances, the controller cannot reasonably expect to obtain the consent of the data subject to the processing.

3.2.02c	Please specify who will process the personal and / or special category data? e.g. eDRIS, trusted third party (CHILi /NRS), local analysts, you, research team, other (please specify)?
	eDRIS will process the personal data as part of the data linkage process.

3.2.03	Are there any existing information sharing agreements or contracts in place which support your proposal? *Please give details and provide as supporting documents* *This would include any contracts or agreements with other parties involved in your proposal, which can inform the panel about the bases for access, sharing and / or transfer of data or information, and reassure of the controls in place to reduce any privacy risks arising from these processes.*
	Contract between Puck Enterprises and Tooth Fairy Services (supporting document SD5).

3.2.04	Are other regulatory approvals pending or received, from within or outside Scotland? *Please give details and provide as supporting documents.* *This would include approvals from other regulatory bodies e.g. Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA).*
	As this is a UK-wide study, we have applied for access to NHS Dental data for the matching and audit, to the NHS Digital for England, to the Secure Anonymised Information and Linkage (SAIL) service in Wales and to the Northern Ireland Statistics Research Authority (NISRA) for Northern Ireland. We are applying to the Confidentiality Advisory Group of the Health Research Authority for unconsented access to confidential data and exemption under section 251 for identifiable data from England and Wales.

3.3	**Research Ethics Governance** *If you answered No to Q 2.4, please go to Q 3.4.* *Please read section 3.3 of the Guidance for Applicants and consult your Research Sponsor.* *All research projects potentially need an ethical review, whether by NHS REC or by another ethics body. It is the responsibility of the applicant and research sponsor to ensure that suitable ethical review has taken place.*	
3.3.01	Has your proposal sought NHS or university research / ethics approval?	No
3.3.01a	If yes, provide committee details, status of approval (i.e. pending, approved) and reference number, as supporting documents and go to Q 3.4	
3.3.01b	If no, is your application covered by the National Safe Haven generic ethical approval? *This only applies for applications that will use the National Safe Haven, if the specific conditions outlined in the pre-submission checklist are met.*	
	No	
	If no, explain why NHS or university research ethics approval is not sought	
	This is an audit, not a research project. Therefore ethical approval is not required.	

3.4	**Safe Havens**
	Please read section 3.4 of the Guidance for Applicants.
3.4.01	Do you intend to access the data requested <u>exclusively</u> through any Scottish Government-accredited safe haven?
	The Scottish Safe Havens are listed in Table 3 of Appendix A of the Guidance for Applicants.
	No
3.4.02	If yes, please go to Q 3.4.03.
	If No, please answer this question and then go to section 4.
	If you are applying to use national data from Public Health Scotland (PHS) or NHS National Services Scotland (NHS NSS) and you do not intend to access these data through the National Safe Haven, please explain why.
	If you are not obtaining national data, then that should be stated.
	We will be collating data from the rest of the UK; therefore the data will be stored on a secure server at Tooth Fairy Services HQ in the middle of Nowhere.
3.4.03	Is this the National Safe Haven or a regional safe haven?
	If you are using the National Safe Haven you do not need to complete sections 5.1 or 5.2.
	Choose an item.
3.4.03a	If you are using a Regional Safe Haven, please specify which one.
	*If you are using a regional Safe Haven you do not need to complete sections 5.1 or 5.2., **unless** you wish to include NHSCR data. Please see section 3.4 of the guidance.*
3.4.03b	If you are applying to use national data from Public Health Scotland (PHS) or NHS National Services Scotland (NHS NSS) and you do not intend to access this through the National Safe Haven, please explain why.
	If you are not obtaining national data, then that should be stated.
3.4.04	How and from what location will you access the safe haven specified above?
	E.g. remotely from on a university-provided laptop from a university office.
	E.g. using a safe setting from… (specify location)
3.4.05	Will the safe haven be accessed by anyone working from home?
	Choose an item.
3.4.05a	If no, please go to section 4.
	If yes, please provide your organisation's home working policy and / or outline any mitigation measures in place to ensure that the access to the safe haven will be secure.

Section 4: Safe Data, Data Subjects and Methodology

4.1	**New Data yet to be collected for this proposal**
	Please read section 4.1 of Guidance for Applicants
	<mark>If no new data is to be collected please go to Q 4.2</mark>

Dataset/source Name	Collection by whom?
	This is the organisation or individuals referenced within the proposal.

4.2	**All Other Existing Datasets or Sources**
	Please use a separate line for each dataset.
	Please read section 4.2 of the Guidance for Applicants.
	Contact should be established as early in the process as possible with NHS Scotland boards / data providers to discuss data provisioning requirements for any of the applicable sources listed below.

Dataset or source Name	Data Controller (Organisation)
	<mark>**For existing dataset/sources for which the data controller is not an NHSScotland board, please append evidence of the data controllers permission to use the data**</mark>
Tooth Fairy Database	**Tooth Fairy Services**
MIDAS data	**PHS**

Add rows as required.

4.2.01	How were individuals originally informed of the use of their data? Please ensure that you include an appropriate explanation for each of the data sources which you have listed above.
	Please see Guidance for Applicants on the use of privacy notices relevant to each dataset, which should be transparent about how people's data will be used and comply with current data protection legislation.
	Children show their awareness of Tooth Fairy visits by putting their teeth under their pillow. This information was detected and passed on by household fairies prior to the introduction of the PilloWapp, which is meant to detect this information using Dentine Resonance detection. Privacy Notices regarding the use of child data obtained by Tooth Fairy Services are available on our website: fww.toothfairy.service.uk/privacy notices.
	The PHS privacy notice is provided here: https://www.publichealthscotland.scot/our-privacy-notice/
	For children who did not use the Tooth Fairy Services, only anonymised data will be obtained.
4.2.02	Please explain and justify how the principle of data minimisation has been applied to this application, and what measures have been followed to comply with it?
	*Data protection law requires that the use of potentially identifiable data is **minimised** to those variables, people and time-frame which are necessary and sufficient to achieve the stated purpose. This is known as the 'data minimisation' principle.(GDPR Article 5)*
	We have examined the variable list to ensure that only those data variables that are necessary and sufficient for our analysis have been requested. The time-frame is up to the end of February 2020, as we are aware that the introduction of COVID restrictions had a profound effect on paediatric

happiness and data obtained after that date could be influenced by factors not under investigation in this application.

Dates have been reduced to month and year; postcode sector will be returned for geographical analysis; deprivation measures will be derived from full postcode by the data processors but the full postcode will only be used for processing and for assigning deprivation scores and only the deprivation score will be provided.

4.3	**Data Variables**
	*Please justify the need for **all** of the variables included in your proposal.*
	Please read section 4.3 of the guidance, especially regarding the processing only variables.
	While a variable may not seem identifiable on its own, combinations of variables can make people identifiable, particularly for small populations or rare conditions.

Dataset Name	Variable	Dates required	Justification (i.e. why variable is required)	Please tick to show this item is for processing only and will not be part of the dataset used for analysis
Study ID	Study ID		This is a new study ID to be provided for this analysis.	☐
PilloWapp	TFS Database ID	Jan 2007–Feb 2020	For linkage with CHI number	☒
PilloWapp	CHI	Jan 2007–Feb 2020	For matching with MIDAS data	☒
PilloWapp	Name	Jan 2007–Feb 2020	For matching with MIDAS data	☒
PilloWapp	Address	Jan 2007–Feb 2020	For matching with MIDAS data	☒
PilloWapp	Date of Birth	Jan 2007–Feb 2020	For matching with MIDAS data	☒
PilloWapp	Postcode	Jan 2007–Feb 2020	For obtaining SIMD at time of tooth collection	☒
PilloWapp	Postcode sector	Jan 2007–Feb 2020	For geographical analysis	☐
PilloWapp	Ethnicity	Jan 2007–Feb 2020	For family / social analysis	☐
PilloWapp	Tooth collector ID	Jan 2007–Feb 2020	For internal QC analysis	☐
PilloWapp	Date first tooth	Jan 2007–Feb 2020	Temporal analysis	☐
PilloWapp	Date last tooth	Jan 2007–Feb 2020	Temporal analysis	☐
PilloWapp	Age at first tooth	Jan 2007–Feb 2020	Dental health analysis	☐
PilloWapp	Age at last tooth	Jan 2007–Feb 2020	Dental health analysis	☐
PilloWapp	No. Teeth collected overall	Jan 2007–Feb 2020	Dental health analysis	☐

PilloWapp	Is this the full set?	Jan 2007–Feb 2020	Dental health analysis	☐
PilloWapp	Price of first tooth	Jan 2007–Feb 2020	For remuneration analysis	☐
PilloWapp	Price of last tooth	Jan 2007–Feb 2020	For remuneration analysis	☐
PilloWapp	Average price per tooth	Jan 2007–Feb 2020	For remuneration analysis	☐
MIDAS	CHI	Jan 2007–Feb 2020	For linkage with MIDAS data. Data linkage will be processed primarily on CHI number as this should be unique and consistent for each child, if they change address or change name. Name, address and date of birth are requested for further matching should CHI not be available.	☒
MIDAS	Name	Jan 2007–Feb 2020	For linkage with MIDAS data	☒
MIDAS	Address	Jan 2007–Feb 2020	For linkage with MIDAS data	☒
MIDAS	Date of Birth	Jan 2007–Feb 2020	For derivation and provision of age at treatment	☒
MIDAS	Full Postcode	Jan 2007–Feb 2020	For obtaining and provision of SIMD at time of tooth collection	☒
MIDAS	Sex	Jan 2007–Feb 2020	For analysis of sex differences in use of service	☐
MIDAS	Postcode sector	Jan 2007–Feb 2020	For geographical analysis	☐
MIDAS	Ethnicity	Jan 2007–Feb 2020	For analysis of ethnic differences in use of service.	☐
MIDAS	Date of treatment start	Jan 2007–Feb 2020	Dates for dental treatment, to be used for temporal analysis. Full dates required as a child may lose more than one tooth in any month.	☐
MIDAS	Date of treatment stop	Jan 2007–Feb 2020	Dates for dental treatment, to be used for temporal analysis. Full dates required as a child may lose more than one tooth in any month.	☐
MIDAS	Age at start of treatment	Jan 2007–Feb 2020	Age (in months if under 3 and thereafter in years) at dental treatment, to be used for temporal analysis	☐

MIDAS	Treatment ID	Jan 2007–Feb 2020	Code for level of dental treatment	☐
MIDAS	Treatment Fee Code	Jan 2007–Feb 2020	Code for level of dental treatment	☐
MIDAS	Statutory Fee Code	Jan 2007 – Feb 2020	Code for level of dental treatment	☐
MIDAS	Item Code	Jan 2007 – Feb 2020	Code for level of dental treatment	☐
MIDAS	Item Description	Jan 2007 – Feb 2020	Code for level of dental treatment	☐

Add rows as required or provide the eDRIS Project Specification Document (including version number).

4.4	**National Records of Scotland (NRS) / NHS Central Register (NHSCR) Data**	
	Please read section 4.4 of the Guidance for Applicants	
	This is for access to NHSCR data and any access to NRS data, apart from the NRS births, stillbirths and deaths records (copies of which are held by PHS).	
4.4.01	Do you require access to NHSCR or any NRS involvement?	
	No	
4.4.02	If No, please go to Q 4.5.	
	If Yes, please provide the NHSCR Reference Number	
4.4.03	Does the proposal require access to NHSCR as a sampling frame for cohorts?	Choose an item.
	Does the proposal involve flagging of individuals on the NHSCR for long term follow up?	Choose an item.
4.4.04	If flagging is requested, please give reason below	
	☐ To contact individuals in Scotland	
	☐ To be informed of fact and cause of death	
	☐ To be informed of the incidence of on-going anonymised cancers registrations	
	☐ To be informed of emigrations prospectively and retrospectively	
4.4.05	Is any other NRS / NHSCR involvement required? Please provide details	

4.5	**Making Contact with Individuals**	
	Please read section 4.5 of the Guidance for Applicants.	
	This question is about contacting any people in relation to data collection or recruitment of participants.	
4.5.01	Is any direct contact with any group of individuals required as part of this proposal?	
	No	
4.5.01a	If no, please go to Q 4.6.	
	If Yes, please provide details below.	
	Contact Group and Method of contact.	

					Contact by whom
	Please note if communications are being sent electronically (via text or email) you need to ensure that they comply with Privacy and Electronic Communications Regulations (PECR). Please see Guidance for Applicants for further details.				
	☐ Hospital Consultants	☐ Letter / email	☐ Phone / text message	☐ Other (specify):	
	☐ Other NHSS Staff	☐ Letter / email	☐ Phone / text message	☐ Other (specify):	
	☐ General Practitioners	☐ Letter / email	☐ Phone / text message	☐ Other (specify):	
	☐ Patients / Public	☐ Letter / email	☐ Phone / text message	☐ Other (specify):	
	☐ Relatives of participants	☐ Letter / email	☐ Phone / text message	☐ Other (specify):	
	☐ Others (please specify):	☐ Letter / email	☐ Phone / text message	☐ Other (specify):	
4.5.02	Please justify and explain why contact is being made and append copies of any relevant correspondence as supporting evidence				

4.6	**Community Health Index (CHI) Database** *Please read section 4.7 of the Guidance for Applicants.* *This section does not apply to routine use of CHI for data linkage nor for obtaining matched controls.*
4.6.01	Do you require access to data from the live CHI database?
	No
4.6.02	<mark>If No, please go to Section 5.</mark> <mark>If Yes</mark>, what monitoring and audit of the use of CHI is planned? Please provide details.
4.6.03	What technical method will be used to access CHI (online read-only, download, other extract, anonymised extract)? Please provide details
4.6.04	Have any risks been identified in the proposal which relate specifically to CHI?

Section 5: Safe Data Processing and Security

5.1	**Access to data**
	Please read section 5.1 of the Guidance for Applicants. If data will be accessed from more than one environment during the proposal, this section must be completed for each one.
	*If you will access data <u>exclusively</u> via the National Safe Haven, or you are using a Regional Safe Haven and do not need to access NHSCR data, please go to **section 5.3**. Complete this section if you answered 'No' to question 3.4.01 i.e. data will not exclusively be accessed via a Safe Haven.*
	If you need to access NHSCR data through a regional Safe Haven, this section must be completed.
	Please provide concise answers from the relevant policies.
5.1.01	From what location will identifiable, pseudonymised, or potentially identifiable data be accessed?
	Potentially identifiable data includes the combinations of variables in such a way as to make individuals identifiable.
	All data will be accessed via secure servers within Tooth Fairy Services, based in Titania Way, Oberon Town, Nowhere, UK. NO15 9WH
5.1.02	Please provide details of the security policy and procedures governing access to this physical and technical environment.
	Please append supporting documents, referencing appropriate sections: e.g. Document no. / page no. / section no / excerpt.
	All data processing procedures are governed by the Tooth Fairy Services Information Governance and IT Security policies provided as supporting documents.
	SD 6 TFS Information Security Policy
	SD7 TFS Data Protection and Privacy Policy
	SD8 TFS Administrator Rights Policy
	SD9 TFS Access Control Policy
	SD10 TFS Information Security Incident Management Policy
	SD11 TFS Password Policy
	SD 12 TFS Network Security Policy
	SD13 TFS Information Sharing & Transfer Policy
	SD14 TFS Mobile Computing & Remote Access Policy
5.1.03	Please provide details of the policy and procedures that cover the use of passwords.
	Please provide details and append supporting documents referencing appropriate sections.
	Yes. All passwords have to be changed at the full moon, the dates of which are set as reminders in the system's calendar.
	SD11 TFS Password Policy, page 2 states:
	All passwords must be of at least 16 characters long and must contain at least one of each of the following: upper and lower case letters, numbers, runes and symbols. No password or one similar can be repeated within a year of use. The system records previous passwords for one year for each user to monitor compliance.

5.1.04	Please provide information on the processes for providing and removing user access to the data.
	Will access to the data be limited to the individual user accounts that require access, or will all users in the environment be able to access the data, even if they do not require to do so?
	This question is to try to understand how the principle of least privilege (PoLP) is applied in this system, whereby users can only access the information and resources that are necessary.
	Please provide details and append supporting documents, referencing appropriate sections
	SD9 TFS Access Control policy, p3 states:
	Access to all information systems will be controlled to ensure that only authorised users have access to the system and the information they are authorised to access. Tooth Fairy Services data systems have an audit functionality which records user access to confidential data items and keystroke use. Audit data will be used for review of actual or potential IG breaches or incidents. Routine audit of access will also be carried out.
	Where more than one user accesses an information system, each user of that system will have a unique and verifiable identity. All transactions on shared information systems will be attributed to the individual who initiated them.

5.1.05	Will individuals with access to data have individual or shared accounts?
	All individuals will have password-protected individual accounts, each of with a unique and verifiable identity.

5.1.06	Will the data be accessed by staff working off-site (e.g. staff working from home) at any time during the duration of the proposal?	Yes

5.1.06a	If No, please go to Q 5.1.07
	If Yes, what device will be used to access these data externally? Will this be an organisation-owned device or a personal device? If a personal device, is there a Bring Your Own Device (BYOD) policy, which complies with the organisations policies?
	Please provide details and append copies of the relevant policies as supporting documents, referencing appropriate sections
	This will use an organisation-issued laptop.

5.1.06b	For off-site working, will data be held in the same host environment, or taken off-site?
	☒ Data remain in the on-site host environment
	☐ Data will be taken off-site
	If the data remain on-site, will a VPN connection, or similar remote access technology be used to provide secure access to the data? Please give details.
	SD14 TRFS Remote Access Policy, p4 states:
	If required, members of staff have the facility to login to the servers using a virtual fairy network (VFN) with verification via a WisH key. The WisH key is only given to authorised users and only allows access to folders for which the user has authorised access for an approved purpose. Access is granted on a time limited basis. This process is monitored and audited as above. Permissions for remote access are renewed on the first day of each season.

	If the data are taken off-site, what measures are in place to maintain the security of the device and data (e.g. encryption of device and data?)
5.1.07	Will any moveable devices (e.g. laptops, iPads, USB drives) be used at any time as part of this application?
	Yes
5.1.07a	If No, please go to Q 5.1.08 If yes, is there a mobile device management (MDM) solution in place to manage such moveable devices? Does the MDM solution have a remote wipe capability to erase data in the event of theft or the device is lost?
	SD14 TFS Remote Access Policy, p8 states: In the event of misplacement of laptops, these can be wiped remotely. To ensure that, in the event of loss, confidential information cannot accessed by anyone, users are not allowed to keep confidential TFS information on the desktop of any device.
5.1.08	Does your organisation have a clear desk and / or clear screen policy when accessing data? *Please provide details and append copies of the relevant policies as supporting documents, referencing appropriate sections.*
	SD6 TFS IS policy, p16 states: Staff should not leave unsecured confidential or personal information in their work environment when unattended. In addition, staff should lock their screen whenever leaving their computer unattended and be aware if someone is looking over their shoulder or round corners. SD14 TFS Remote Access policy, p7 states: Staff should not access remotely any TFS systems while in a public environment, nor in any location where someone from outwith the organisation can easily read information on their screen.
5.1.09	Provide any additional detail of any mechanisms by which data will be protected from unauthorised access.
	Line Managers ensure fairies cannot gain unauthorised access to any Tooth Fairy Services systems or manual data which would compromise data integrity and confidentiality by only authorising access to data systems as is commensurate with the individual's job function.

5.2	**Storage & Use** *Please read section 5.2 of the Guidance for Applicants* *Please complete the following section if you answered 'No' to question 3.4.01.* *If you need to access NHSCR data through a regional Safe Haven, this section must be completed.*
5.2.01	Where will the data be stored and used? *(Location, organisation, address. Refer to addresses in previous sections if appropriate)*
	All data will be stored on secure servers based at Tooth Fairy Services, based in Titania Way, Oberon Town, Nowhere, UK. NO15 9WH. Access to these buildings is by ID card only.

	The servers are hosted in air-conditioned, locked rooms with access granted only to authorised IT staff. Access to the building is via ID card and is constantly monitored by Closed Circuit FairyVision (CCFV), intruder alarms and fire detection systems. Separate backup servers are situated in a separate building in the middle of Nowhere, a distance of about a league.
5.2.01a	If the data will be stored in a cloud, please state who will provide that cloud storage and in what country that cloud server is physically situated. Please provide the security information that covers such cloud storage and what access the provider will have to the data stored therein.
	There is no cloud storage for the data.
5.2.02	To what Cybersecurity standards does your organisation work (e.g. ISO 27001, Cyber Essentials, Cyber Essentials Plus, other of equivalent standard)? *Please give details and expiry dates, and provide certificates as supporting documents.*
	TFS complies with Network and Information Systems (NIS) Regulations (2018) and has been successfully audited and deemed compliant in March 2021.
5.2.03	Please provide details of policies and procedures governing storage and use of data within this physical and technical environment *Please provide details and append supporting documents, referencing appropriate sections.*

	The servers are hosted in air-conditioned, locked rooms with access granted only to authorised IT staff. Access to the building is via ID card and is constantly monitored by Closed Circuit FairyVision (CCFV), intruder alarms and fire detection systems. Separate backup servers are situated in a separate building on the other side of the Tooth Fairy Services campus, a distance of about half a league.
	
	 The use and processing of data is covered within the TFS policies:
	 • SD6 TFS Information Security Policy
	     p5, Information Security Policy Principles
	     p7, Information Asset Management
	     p11, Access to IT Equipment and Services
	     p14, Data Storage
	     p 15, Storing Records
	
	 • SD7 TFS DP & Confidentiality Policy
	     p10, Secure storage of data
	     p11, Building security
	     p14, Data Retention

5.2.04	What policies and procedures are in place to cover the implementation of up-to-date controls for the detection and prevention of malware? *Please provide details and append supporting documents, referencing appropriate sections*
	Tooth Fairy Services servers undergo daily updates of software to guard against known and newly released viruses and malware; this also includes a Spell Check function.
5.2.05	What policies and procedures are in place to cover access control and auditing of user and / or system administrator activity? *Please provide details and append supporting documents, referencing appropriate sections*

	The servers record all access to the systems for all personnel, including system administrators. Audit logs are configured to record any actions undertaken using administrator or elevated privileges. All audit logs are secured to protect from unauthorised modification. Any unauthorised access to servers at this level can be detected and the account and user are automatically frozen.
5.2.06	What policies and procedures are in place to cover the production and control of backup copies of the data? *Please provide details and append supporting documents, referencing appropriate sections.*
	Servers are backed up daily and the back-ups retained for one month, after which they are routinely and securely written over.
5.2.07	What policies and procedures are in place to ensure business continuity, contingency planning and system restoration in the event of a critical system failure? *Please provide details and append supporting documents, referencing appropriate sections.*
	Servers and systems are backed up daily and held in a separate and distant location to ensure restoration of data in the event of a system failure or fire. SD10 TFS Adverse Event Policy, p15 states: Adverse events may be either events for which TFS has full or partial responsibility or external events which are the responsibility of another organisation. Staff must report all adverse events that originate within TFS and for which TFS has direct responsibility. On occasion an error made in another organisation reaches TFS. Where TFS has no responsibility for causing the error, these are defined as 'external' adverse events. Staff must report these as external adverse events and take action to: (i) make the originating organisation aware of the error and (ii) minimise the impact of the error. An example is when person identifiable information has been sent in error to TFS by another organisation. All clinical and information governance adverse events or near misses must be reported by staff using the electronic adverse event reporting form available on the staff intranet.
5.2.08	What policies and procedures describe the controls in place to prohibit unauthorised copying of data? *Please provide details and append supporting documents, referencing appropriate sections*
	The TFS servers can be set to prevent unauthorised electronic copying of data. If this is attempted access accounts and user are automatically frozen. All users sign a confidentiality user agreement which prohibits copying of data using any other means without authorisation.
5.2.09	What policies and procedure describe physical and site controls? *Please provide details and append supporting documents, referencing appropriate sections.*
	The servers are hosted in air-conditioned, locked rooms with access granted only to authorised IT staff. Access to the building is via ID card and is constantly monitored by Closed Circuit FairyVision (CCFV), intruder alarms and fire detection systems. Separate backup servers are situated in a separate building in the middle of Nowhere, a distance of about a league.
5.2.10	What policies and procedures cover hardware repair, replacement or disposal of data, and protection of data from inappropriate access during such procedures? *Please provide details and append supporting documents, referencing appropriate sections.*

	Disposal of hardware that is no longer in use is carried out under contract by an approved external contractor. All electronic information is securely erased or rendered inaccessible prior to leaving the TFS site.
5.2.11	Describe the systems, software and security used to store and use data. *Please provide details and append supporting documents, referencing appropriate sections.* *Some examples of what information is required:* *Is the host environment infrastructure actively vulnerability scanned and penetration tested? If so, is there a policy that covers this?* *Is the data suitably encrypted, where possible?* *Does the policy describe the organisations patch management policy? Are security updates installed within a suitable timeframe? This is applicable to both server environment hosting the data, as well as the device used to access the data.*
	All data stored and analysed on the Tooth Fairy Services servers are encrypted. All files are required to be password-protected and, as described above, all access to the servers is monitored.
5.2.12	Is outsourced IT in use? If yes, please give details of the provider and the IT security measures in place.
	Outsourcing is only used for disposal of hardware no longer in use by Tooth Fairy Services servers.
Please repeat section 5.2 above for each relevant location in the proposal – see guidance	

5.3	**Transfer** *Please read section 5.3 of the Guidance for Applicants.*	
5.3.01	Please provide details of the security policies and procedures to ensure that data will be transferred in such a way that it is protected from inappropriate or unauthorised access (e.g. email encryption, secure file transfer protocols SFTP, device encryption, physical controls.) *Please provide details and append supporting documents, referencing appropriate sections.* *This should reflect what is in the data flow diagram for Q 3.1.11 and describe the transfer processes in the data flow from the patient to its final destination, including any intermediary stages.*	
	Patient data will be transferred to eDRIS for linkage and the linked data transferred back to Tooth Fairy Services servers using Secure File Transfer Protocols.	
5.3.02	At what intervals/ trigger points will data transfer take place? E.g. one off transfer, monthly intervals.	
	One off transfer.	
5.3.03	Will any personal (identifiable, pseudonymised or potentially identifiable) data be shared with or transferred to any organisation within or outside of the UK?	No
5.3.03a	If no, please go to Q 5.3.04 If yes, please specify the organisation and country of destination, and provide details of the method of transfer, the proposed location and method of storage at the destination, and details of the purpose of the data sharing and how the data will be handled and kept secure.	

5.3.04	Other than initial transfers from source systems, is there any copying of data required within the proposal? If no, please go to section 6 If yes, please give details.	No

Section 6: Safe Outputs and Review

6.1	Outputs and Dissemination
	Please read section 6.1 of the Guidance for Applicants.

6.1.01	What procedures will be used for disclosure control for the outcomes of the proposal? *Please outline or attach the policy that will be used.* *This is to ensure that tables and information from the findings does not include outputs from which any person could potentially be identified, e.g. through small numbers in specific groups.*
	Disclosure control will ensure that no groups containing <10 individuals will be released from the analysis. Any small groups containing numbers fewer than 10 will be further aggregated by combining with other groups (e.g. increase in an age range).

6.1.02	Will proposal outcomes be published or disseminated beyond those listed in Section 1? <mark>If 'No', please go to Section 6.2</mark> <mark>If Yes, please answer questions below</mark>	Yes

6.1.03	How will outcomes from the proposal be published or disseminated, to what audience and in what format, including to patients and the general public? *Please give details.* *How the outcomes from the use of their health data will be fed back to the patients and public needs to be described, as they do not read scientific literature nor attend conferences.*
	Aggregated results will be sent to those mentioned in section 1.6 for service improvement. Aggregated results will also be shared with NHS Paediatric Happiness Services for performance indicators. Performance indicators will be also be posted on the TFS website for public information. Outcomes and recommendations from this will form a patient leaflet which will be distributed in waiting rooms of NHS Dental practices.

6.1.04	What steps will be taken to ensure that persons cannot be identified in any outputs? *Please give details.*
	No identifiable information or outputs from groups of less than 10 will be made available to anyone outside Tooth Fairy Services.

6.1.05	Are there any circumstances where a living or dead individual would be cited? (E.g. where a person consented to their data being used as a case study)? *Please give details.*
	No.

6.1.06	Were any permissions to publish data required or sought (e.g. from data controllers)? *Please provide details*
	No.

6.2	Retention and Disposal of Data
	Please read section 6.2 of the Guidance for Applicants.
	Under data protection law, potentially identifiable, identifiable or pseudonymised data should only be retained for a limited time. Once it is no longer needed it should be fully

		anonymised or securely destroyed. This is known as the principle of storage limitation (GDPR Article 5).
6.2.01		Which information / data / records retention policy will you apply to the data obtained and used in this proposal? *Please provide details and append supporting documents, referencing appropriate sections.*
		Tooth Fairy Services will retain the pseudonymised and anonymised data for this audit for 20 years according to the SD7 TFS DP & Confidentiality policy (p14 Data Retention) for routine data. No identifiers will be retained for any of the audit dataset, which will itself be stored entirely separate from any data used for the ongoing Tooth Fairy service.
6.2.02		For how long do you intend to retain identifiable or potentially identifiable data after the conclusion of the proposal (including archive/backup copies)?
		Identifiers for the audit will only be used for the purposes of linkage and will not be retained.
6.2.03		Who will retain the data and where?
		Data will be retained on stored on secure servers based at Tooth Fairy Services, based in Titania Way, Oberon Town, Nowhere, UK. NO15 9WH.
6.2.04		What is the purpose for retaining the data for the specified time?
		The linked anonymised dataset will be retained for any further analysis and follow-up work associated with the audit.
6.2.05		What method of disposal or destruction will be used when this period has expired (including archive and backup copies)?
		All files will be destroyed according to the Tooth Fairy Services data erasure policies (see SD6 TFS IS Policy, p30 Erasure of data), as used for deletion of routine data from the Tooth Fairy Services servers.
6.2.06		What evidence will be obtained that destruction has occurred (e.g. IT supplier certificate of destruction)?
		Data erasure will be confirmed according to Tooth Fairy Services data erasure policies as used for deletion of routine data from its servers.

6.3	**Review** *Please read section 6.3 of the Guidance for Applicants.*
6.3.01	Describe how the mechanisms which safeguard data security will be audited and reviewed at regular intervals to ensure their continued efficacy.
	Audit logs of system use are checked by senior managers every full moon to assess the security of the data held on Tooth Fairy Services servers.
6.3.02	Describe any resource implications to any of the proposed measures for the protection of physical or technical security of information which are unresolved at the time of this application (e.g. encryption of devices is an intention not yet fulfilled, IT training is not yet undertaken etc.)
	None.
6.3.03	Describe the breach reporting mechanisms to be invoked in the event of any inappropriate access to data or other information security incident

	Within Tooth Fairy Services there are clear processes for reporting actual or potential breaches of confidential data. Access to all data is audited and unauthorised access can be identified. See SD10 TFS Adverse Event Policy.

Section 7: Declaration

- I DECLARE THAT this application is accurate, and that, should it be successful, any health data made accessible will be used for no other purpose, and in no other way than that described above.
- I UNDERTAKE TO notify the Public Benefit and Privacy Panel (PBPP) of any future changes to the purpose or manner in which data is processed in accordance with this application.
- I UNDERSTAND THAT any future applications by me, or my employing or sponsoring organisation, may be refused should any health data made accessible be used for any other purpose or in any other way than that described above.
- I AGREE TO abide by any conditions attached to the application by the HSC-PBPP during the approval process. I understand that failure to comply with these conditions may result in any future applications by me, or my employing or sponsoring organisation, may be refused.
- I CERTIFY THAT all those who have access to health data in this proposal are aware of the requirements of confidentiality and understand that any breach (e.g. disclosure of confidential information to a person not authorised to receive it) will be reported to the data controller.
- I CERTIFY THAT that only the persons named in the HSC-PBPP form (1.1-1.6) as requiring access to the data will be given access and that the data will not be transferred to anyone else.
- I GUARANTEE THAT no publication will appear in any form in which an individual may be identified without the written permission of that individual, and that I will apply appropriate disclosure control when planning publications involving the data requested.
- I UNDERSTAND THAT the Data Controller, and agents acting on its behalf, reserves the right to inspect the data on the sites where it is being processed.

To be signified by the APPLICANT

Name (in Capitals): SUGARPLUM	Date: 10 / 06/ 21

To be signified by the ACADEMIC SUPERVISOR (if applicable)

Name (in Capitals):	Date:

- I DECLARE THAT (the applicant named above) is a *bona fide* worker engaged in a reputable project and that the data they ask for can be entrusted to them in the knowledge that they will conscientiously discharge their obligations, including in regard to confidentiality of the data, as stated in the declaration above.

To be signified by the INFORMATION CUSTODIAN named in Section 1.4 above (where the Information Custodian is not the applicant).

| Name (in Capitals): TINKERBELL | Date: 11/06/21 |

- I ACCEPT the organisation's obligations and roles with respect to the processing of data for the purposes outlined in this application.

To be signified by the Main Contact for the Lead Organisation named in Section 2.2 above

| Name (in Capitals): FAIRY NUFF | Date: 11/06/21 |

To be signified by the Research Sponsor, if named in Section 2.4 above

| Name (in Capitals): | Date: |