This protocol has regard for the HRA guidance and order of content.
Surgical patients' experience of being managed in ambulatory care

FULL/LONG TITLE OF THE STUDY
Patient experience of ambulatory emergency care on the Surgical Admissions Unit (SAU)

SHORT STUDY TITLE / ACRONYM
Surgical patients' experience of being managed in ambulatory care

PROTOCOL VERSION NUMBER AND DATE
Version 0.4 10.04.18

RESEARCH REFERENCE NUMBERS

IRAS Number: 232776

SPONSORS Number: 1718/01
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: ................................................................................................................. Date: ..../...../......

Name (please print): ........................................................................................................

Position: .....................................................................................................................

Chief Investigator:

Signature: ................................................................................................................. Date: ..../...../......

Name: (please print): .....................................................................................................
**LIST of CONTENTS**

<table>
<thead>
<tr>
<th>GENERAL INFORMATION</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRA PROTOCOL COMPLIANCE DECLARATION</td>
<td>i</td>
</tr>
<tr>
<td>TITLE PAGE</td>
<td>ii</td>
</tr>
<tr>
<td>RESEARCH REFERENCE NUMBERS</td>
<td>ii</td>
</tr>
<tr>
<td>SIGNATURE PAGE</td>
<td>iii</td>
</tr>
<tr>
<td>LIST OF CONTENTS</td>
<td>iv</td>
</tr>
<tr>
<td>KEY STUDY CONTACTS</td>
<td>v</td>
</tr>
<tr>
<td>STUDY SUMMARY</td>
<td>vi</td>
</tr>
<tr>
<td>ROLE OF SPONSOR</td>
<td>vi</td>
</tr>
<tr>
<td>ROLES &amp; RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS</td>
<td>vi</td>
</tr>
<tr>
<td>STUDY FLOW CHART</td>
<td>vii</td>
</tr>
<tr>
<td>SECTION</td>
<td></td>
</tr>
<tr>
<td>1. BACKGROUND</td>
<td>1</td>
</tr>
<tr>
<td>2. RATIONALE</td>
<td>1-2</td>
</tr>
<tr>
<td>3. THEORETICAL FRAMEWORK</td>
<td>2</td>
</tr>
<tr>
<td>4. RESEARCH QUESTION/AIM(S)</td>
<td>2</td>
</tr>
<tr>
<td>5. STUDY DESIGN/METHODS</td>
<td>2-3</td>
</tr>
<tr>
<td>6. STUDY SETTING</td>
<td>3</td>
</tr>
<tr>
<td>7. SAMPLE AND RECRUITMENT</td>
<td>4-5</td>
</tr>
<tr>
<td>8. ETHICAL AND REGULATORY COMPLIANCE</td>
<td>5-8</td>
</tr>
<tr>
<td>9. DISSEMINATION POLICY</td>
<td>8-9</td>
</tr>
<tr>
<td>10. REFERENCES</td>
<td>9</td>
</tr>
<tr>
<td>11. APPENDICES</td>
<td>9-10</td>
</tr>
</tbody>
</table>
**KEY STUDY CONTACTS**

<table>
<thead>
<tr>
<th>Role</th>
<th>Contact Person</th>
<th>Address</th>
<th>Email Address</th>
<th>Telephone</th>
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**STUDY SUMMARY**

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Surgical patients’ experience of being managed in ambulatory care on the Surgical Admissions Unit (SAU)</th>
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<tbody>
<tr>
<td>Internal ref. no. (or short title)</td>
<td>Surgical patients’ experience of being managed in ambulatory care</td>
</tr>
<tr>
<td>Study Design</td>
<td>Qualitative semi-structured interviews of patient experience</td>
</tr>
<tr>
<td>Study Participants</td>
<td>General surgical patients who have received ambulatory emergency care at the surgical assessment unit.</td>
</tr>
<tr>
<td>Planned Size of Sample (if applicable)</td>
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<td>Follow up duration (if applicable)</td>
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<td>Planned Study Period</td>
<td>June – December 2018</td>
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<tr>
<td>Research Question/Aim(s)</td>
<td>What are patients’ experience of being managed in an ambulatory manner when they are referred to emergency general surgery? Why does this method of care work better for some people than others?</td>
</tr>
</tbody>
</table>

**ROLE OF STUDY SPONSOR**

The sponsor is Exeter University as this research is being undertaken as part of a MbyRes degree thesis. The sponsor is and has been involved in all stages of the study in particular the design and will oversee the conduct of the study. The research thesis containing the results of the study will be freely available publicly from the sponsor. The sponsor controls the final decision for all aspects of the study.

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS**

**Study Steering Groups**

**Patient and public involvement group**

The overall design of this study and participant and potential participant information sheets and study literature has been discussed with members of the Royal Devon and Exeter hospital volunteer PPI group. Individuals that responded to a request for help with this research were consulted and changes were made to study documents including the introduction of a more detailed study information sheet as a result. Any changes made to the study as a result of e.g. low recruitment will be discussed with those volunteers.

The volunteer PPI group contact list is held by Jane Homan, Clinical Research Officer at the Royal Devon and Exeter Hospital, email: janehoman@nhs.net.
PROTOCOL CONTRIBUTORS

As described previously the sponsor is and has been involved in all stages of the study in particular the design and will oversee the conduct of the study. The research thesis containing the results of the study will be freely available publicly from the sponsor. The sponsor controls the final decision for all aspects of the study.

Data collection, data analysis and writing of the manuscript will be undertaken by Lisa Massey with input from Rob Bethune and Iain Lang as educational supervisors. Corrections to the manuscript may be suggested by the sponsor in their role.

As described previously individuals from the Royal Devon and Exeter volunteer PPI group have been involved in the design of the study, in particular the layout and wording of the information sheets. These are a mix of members of the public and previous service users.

KEY WORDS:  
Emergency general surgery
Ambulatory care
Patient experience
Surgical patients’ experience of being managed in ambulatory care

STUDY FLOW CHART

General surgical patients attend the admissions unit (SAU).

Not eligible:
- Inpatient admission
- Referred to other specialty

Ambulatory care – given information leaflet.

Potential participants give contact details. Attempt telephone contact within 2 weeks by study team.

Further information given out and questions answered. Ability to give consent assessed.

Arrangements made for interview either at same conversation or separate appointment. Verbal consent statement taken and recorded.

Potential participants contact study team at a later date after reading participant information sheet.

Do not make contact to provide further details after information leaflet.

- Potential participants do not wish to proceed further.
- Do not have capacity to consent.
Contact details removed.

Unable to make contact after a maximum of 3 attempts. Contact details removed.

Withdrawal of consent after interview. Data deleted.

Proceed to telephone interview

Included in study.
STUDY PROTOCOL
Patient experience of ambulatory emergency care on the Surgical Admissions Unit (SAU)

1 BACKGROUND
Abdominal pain is a common reason for people to attend hospital as an emergency. It makes up a considerable proportion of the patients being admitted under the care of general surgeons. Other common reasons for people attending include infections such as abscesses and problems following previous surgery.

A Surgical Assessment Unit (SAU) is an ambulatory area with a waiting room and assessment cubicles. It is staffed by a triage nurse or healthcare assistant and doctors from the surgical team. Patients can be assessed and have investigations including blood tests and radiology procedures including x-rays, ultrasound and CT. After assessment they are either admitted to the ward, discharged home or have their care continued in an ambulatory manner returning in the next few days for further or repeat assessment.

Previously patients were either discharged or admitted for observation, investigation and treatment such as intravenous antibiotics. Many of these patients could be managed safely in a "day case" manner. This pathway allows for re-attendance should it be required.

Emergency ambulatory care is well-established in medicine for conditions such as suspected deep vein thrombosis (DVT) and transient ischaemic attack (TIA) but has not yet been widely adopted in surgery. (Commissioning guide: Emergency general surgery (acute abdominal pain) Commissioning guide 2014) There is uncertainty surrounding the best way of looking after these patients as the diagnosis is often uncertain and it can be difficult to judge which patients require admission.

Pilot studies have shown that up to 30% of emergency general surgical patients could be managed in this way. (Tierney GM, Tou S, Hender J, 2014) These studies also report a high patient satisfaction score but do not inform us what works, why and for whom. These would be important considerations for organisations looking to expand their emergency general surgical ambulatory service.

This study aims to expand upon previous work in this area (Improving the Patient Experience of Ambulatory Care in the Surgical Assessment Unit, 2014) by conducting semi-structured interviews with patients who have experienced emergency general surgical ambulatory care. We aim to achieve a representative sample of participants by age, attending condition and satisfaction score. We hope to identify themes that influence patient experience of emergency ambulatory care and whether this might vary depending on patient factors such as age, social support/responsibilities and attending condition.

2 RATIONALE
Emergency ambulatory general surgical care is a new area that is set to expand in the next few years. (Commissioning guide: Emergency general surgery (acute abdominal pain) Commissioning guide 2014) There will be economic implications to this expansion. Reduction in inpatient stays will reduce healthcare costs but pilot studies have used additional resources such as a separate consultant allocated to the assessment unit and dedicated imaging slots.
Patient experience is an important factor in the quality of the care delivered and will influence how people interact and engage with the service. Within this study we are interested in discovering what factors in the delivery of this care are important for the patient experience, and how this varies amongst patients. This will allow individual clinicians to make better-informed decisions about which patients may not be suitable for ambulatory care, or may need support to enable it to be delivered in a way that works for them. It will also inform organisations looking to expand their ambulatory services about which components of the service are important from a perspective of patient experience.

We are not gathering data on clinical outcomes or undertaking an economic evaluation. These are also important factors to consider when expanding an ambulatory service but are outside the scope of this study methodology.

3 THEORETICAL FRAMEWORK

Data will be analyzed using the method of thematic analysis. We have chosen this method because we are interested in individual themes that are important influences on the patient experience. These themes may be quite separate from one another and not related to an encompassing theory, which suits this method of analysis as opposed to e.g. a grounded theory method. (Braun V, 2006)

4 RESEARCH QUESTION/AIM(S)

To explore general surgical patients’ experiences of being managed in an ambulatory manner.

4.1 Objectives

To establish why this method of care works better for some people than for others.

4.2 Outcome

To identify which groups of patients are most likely to be able to engage well with this method of care and for whom it would not be appropriate or may need more support. To identify parts of the process specific to ambulatory care that most affects patient experience.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

This is a qualitative study of patient experience. Data will be collected by semi-structured telephone interviews.

Participants will be recruited to the study by the clinical team by means of short verbal explanation and the provision of an information sheet. Potential participants will give their contact details to be passed to the study team or will make contact themselves at a later stage. They will then be contacted by the study team and given further information over the telephone. Those wishing to proceed will have arrangements made for a telephone interview. A recording of consent will be made prior to the start of the interview and will be stored as a separate audio file.

The interview schedule has been drawn up based on areas that have emerged from work in the past using patient diaries. (Improving the Patient Experience of Ambulatory Care in the Surgical
Assessment Unit, 2014) The PPI work done has included review of these questions for acceptability and ease of understanding and minor changes have been made to the wording of questions as a result. The prompts used are mainly to encourage explanations of why participants have answered the way they have.

The interviews will last 20-40mins and will be recorded using digital recording software. They will be conducted by the study co-ordinator. No potentially identifiable information will be recorded and participants will be advised not to divulge identifiable information prior to the interview. If this occurs inadvertently it will be deleted prior to transcription. These audio recordings will be given an anonymous identification number and then be transcribed into text documents using a paid transcription service within the UK. Once the transcription has been completed the recording will be deleted.

The transcribed data will be stored on a NHS server. It will be available for access to the study team by password protection and on request in an anonymised form by the university sponsor. Once the study is complete it will be stored on a university repository for the period required for archive and deleted from the NHS server.

The transcribed data will be coded and then undergo thematic analysis using NVIVO software. Coding will be done by the principal investigator and a proportion of the data will be separately coded by the 2 senior members of the study team. Interim analysis will be conducted after each 5 patients and the interview schedule may undergo some change to explore in more detail areas of interest that emerge.

If groups are underrepresented in the interim analysis then there may be targeted recruitment to the underrepresented group. This may include the characteristics of patient age and overall satisfaction with care given.

6 STUDY SETTING

This is a single centre study based at the Royal Devon and Exeter Hospital. This hospital has a frequently-accessed surgical assessment unit but has not previously undertaken any other studies of ambulatory emergency care. It can therefore be considered to be a “typical” unit for a hospital of this size and suitable for this study.

Potential participants will be approached by members of the clinical team after having their details screened from the existing admission list on the surgical assessment unit. They will be given a brief description of the study and those that are interested are given an information sheet and the option to either give contact details (telephone number) immediately or to contact the research team themselves. Those that give contact details will have these written on a paper form that will be stored on a locked drawer on the surgical assessment unit. They will later be collected by the study team and stored on an encrypted password-protected database that will be stored on an NHS computer in a locked research office.

The interview data will be collected on site at the Royal Devon and Exeter Hospital. The telephone interview with audio recordings will be carried out from a secure office on the NHS site. Audio files of the participant consent procedure and the interviews will be downloaded from the recording device onto a secure hard drive and will be allocated a unique participant ID number with the ID key kept in a separate location. Prior to sending for transcription the interviews will be fully anonymised and the transcribed audio files will be securely destroyed.
7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

English-speaking adult patients of any gender over the age of 18 undergoing emergency ambulatory care via the surgical assessment unit for a general surgical condition will be included.

7.1.2 Exclusion criteria

The following are exclusion criteria:

- Children under the age of 18
- Adults without capacity to consent as participants for the study
- Those who have primarily presented with a condition that is not within the remit of general surgeons
- Those who had their care continued as an inpatient immediately following their initial presentation.
- Unable to understand or speak English to the level required to understand the information sheet or conduct the interview

7.2 Sampling

Sampling will occur any time the surgical assessment unit is open and receiving patients – generally 0800-2200 7 days a week. It is possible that there will be targeted recruitment later in the study if certain groups are overrepresented using random sampling.

7.2.1 Size of sample

The sample size of 20 has been estimated from other similar studies that use a similar technique of semi-structured interviews and thematic analysis. We believe this is a valid estimate as this is a single centre study looking at people attending the same unit with similar conditions. We will conduct interim analysis after each 5 patients to allow ongoing estimates of the number needed to reach thematic saturation.

7.2.2 Sampling technique

Potential participants are identified from the admission list on the surgical assessment unit by the clinical team.

Patients will initially be approached at random but purposive sampling may be used later in the study if demographic groups e.g. by age are under-represented. This strategy has been used as we believe different groups may have different attitudes and difficulties with aspects of emergency ambulatory care. However, many patient characteristics are difficult to select for at the point of sampling so this will not be possible for most characteristics other than age.
Surgical patients’ experience of being managed in ambulatory care

7.3 Recruitment

7.3.1 Sample identification
Potential participants will be identified by the clinical team. There exists an admissions list on the surgical assessment unit that has basic patient details (name, date of birth and hospital number) and presenting problem listed. This is regularly consulted by the clinical team as part of their clinical work. Eligible patients will be given basic information about the study by the clinical team at the point at which they are being discharged from their ambulatory stay on the surgical admissions unit. Patients interested in finding out more about the study will be given an information sheet and given the option of either leaving their telephone number for the study team to make contact or contacting the study team themselves using contact information given on the information sheet.

Participants will not receive any payment for participation in this study.

7.3.2 Consent
Potential participants who are interested in finding out more about the study will be given a participant information sheet. This includes details of the study including the purpose of the study and method of data collection and details of how confidentiality will be ensured. They will be given the opportunity to ask for clarification and further questions at the first telephone contact meeting.

Capacity will be assessed at the initial telephone contact and again prior to the interview if this is scheduled for a separate conversation. This will be done by exploring with potential participants their understanding of the purpose and nature of the research, the potential benefits (which will likely be to others rather than them as an individual) and risks. This will include how the data will be handled and confidentiality ensured. We will also ask participants if they have discussed their decision to participate with others and establish whether there has been any element of coercion to take part. Individuals deemed not competent to consent will not proceed to recorded interview.

A statement of consent will be taken at the start of the telephone interview and stored as a separate file. This will include the following statements:

- that they have read and understood the information sheet
- participation is voluntary and there will be a period immediately after the interview for up to 2wks when they can change their mind about participating
- they understand that their care will not be affected by the decision to participate
- interviews will be recorded and then transcribed using an external transcription service. This will not include any sensitive information and they should take care not to mention sensitive information including their name and address in the interview.
- direct quotes may be taken from their interview to be published in the final research but will not contain any potentially identifiable information
- if any concerns about the participants ongoing health arise during the interview we are obliged to disclose these to their GP
8 ETHICAL AND REGULATORY CONSIDERATIONS

There is no intervention in this study and it will not affect any care that patients receive in the future. The main potential risks to the participant are considered to be potential distress from discussing upsetting episodes of care they received and risk to their confidentiality by the use of direct quotes.

This study does not aim to explore particularly sensitive or personal aspects of a patient’s care. The interview schedule has been reviewed by volunteers interested in helping with research design to check that the questions are deemed to be acceptable. Despite this, it is not possible to predict what each individual may find upsetting and sensitive to discuss. Participants who become distressed during the interview will be given the option to halt or terminate the discussion. Some participants may wish to share their experience although they find it upsetting because they believe it is important for the purpose of the research and will be given the opportunity to do this if they wish to.

Participants will be made aware during the consent process that direct quotations from their interview may be used but that they will be anonymised and great care will be taken that they do not include any potentially identifiable information. Participants who inadvertently identify themselves during the interview will be reminded by the interviewer to avoid revealing identifiable information. In this event this section of the recording will be erased and the participant prompted to try to express their statement again without the identifiable information.

The potential benefits of this study are to foster a greater understanding amongst healthcare professionals of how patients experience emergency ambulatory general surgical care which may help them deliver this care in a way that is deemed more acceptable to patients. It may also help those planning an expansion in this service to identify those most likely to engage well with this method of care delivery. It is possible that these benefits may be seen by patients undergoing similar care again in the future but it is likely that this will be a small number of participants.

Telephone interview has been selected as the method of data collection for this study as it is thought to be a method which minimises inconvenience and intrusion to the participants. The timing of the interviews is planned to be 1-2 weeks after the ambulatory attendance episode to give potential participants time to reflect on their experience and time to consider whether they would be willing to take part in the study and feel free from any sense of obligation to the staff who may have initially approached them regarding the study.

The study is subject to NHS ethical review and HRA approval.

8.1 Assessment and management of risk

The interview questions have not been written to explore specifically the mental well-being of the participant but it is possible that participants may bring this up when discussing their experience at a time of ill-health. If the participant makes statements describing thoughts or intentions of self-harm then the interviewer will act on this as a safeguarding concern.

The participant will be asked if they have shared this information with any of their healthcare team, in particular their mental health team (if applicable) or GP. If not they will be encouraged to do so. The interviewer will then inform the participant that they are obliged to pass this information on to the participant’s GP for them to arrange further support and care as needed.
Any issues that arise describing potential harm to others will need to be disclosed to the appropriate authority. This may include social service and the child safeguarding team at the Royal Devon and Exeter Hospital if the concerns relate to children. Any expression of intention to harm others will need to be disclosed to the police. The intention to disclose information will be declared to the participant unless it is thought this declaration risks endangering any other person.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports
Prior to the start of the study NHS ethical review will be sought via the HRA. Any substantial amendments that require review will not be implemented until that review is in place. The chief investigator is responsible for keeping all correspondence with the RECs, producing annual reports, notifying the REC at the end of the study and producing final reports.

Regulatory Review & Compliance
This is a single site study. All appropriate governance and compliance approvals will be gained prior to the start of the study and a copy of the approved study documents will be submitted to the site.

Amendments
The chief investigator will make the decision to request an amendment. The sponsor’s protocols for amendments will be adhered to and the sponsor will determine what constitutes a substantial amendment. Following sponsor approval the amendment will be submitted for NHS REC approval following published HRA guidelines. This will include submitting a Notice of Substantial Amendment form in IRAS.

History of amendments will be detailed within the protocol and previous versions of the protocol will be retained for reference.

8.3 Peer review
The proposal for the study has been internally peer-reviewed by experts in the field chosen by the sponsor that do not have any association with the study. Comments from this peer-review process were acted upon in the development of this protocol.

8.4 Patient & Public Involvement
A volunteer patient and public involvement in research (PPI) group associated with the Royal Devon and Exeter Hospital were involved in the design of the study including the acceptability of the interview schedule questions and the content, layout and readability of the study literature. This included detailed feedback from a small number of individuals who had had some experience of emergency surgical care.
8.5 Protocol compliance

Accidental protocol deviations will be documented and reported to the chief investigator and sponsor. There will follow a discussion amongst the study team about how future similar breaches can be avoided and an action plan documented.

8.6 Data protection and patient confidentiality

All investigators will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

All personal data collected during the course of the study will be either stored electronically on an encrypted, password-protected NHS computer hard drive or as paper files which will be stored in a locked drawer in a locked office with limited access.

The participant interviews will be recording using a digital recording device by the principle investigator. Audio files of the participant consent procedure and the interviews will be downloaded from the recording device onto a secure hard drive and will be allocated a unique participant ID sequence with the ID key kept in a separate location. Prior to sending for transcription the interviews will be fully anonymised and the transcribed audio files will be securely destroyed. This file will be stored in a secure password-protected encrypted file on an NHS server in a different location to the database containing the key.

A database linking the ID code to other information about the participants including sensitive data such as age, telephone number, presenting problem and distance from hospital will be stored separately in a secure password-protected encrypted file on an NHS server. This database will not be transferred elsewhere. It will be accessible only by the core members of the study team. It will be made available on request to the sponsor for the purposes of auditing but will then have sensitive data such as telephone number removed. The sponsor will store the data on secure servers according to their protocols.

The study data will be transferred to the University of Exeter repository and stored securely an in anonymised form by the sponsor for a minimum of 5 years after the end of the study as per the sponsor’s research data policy.

Lisa Massey will be the data custodian.

8.7 Indemnity

The sponsor (University of Exeter) is responsible for potential legal liability arising from the design and management of the research. Indemnity insurance is in place to cover this liability.

The NHS indemnity scheme will cover potential legal liability arising from the conduct of the research as this will be conducted on site at the Royal Devon and Exeter Hospital.
8.8 Access to the final study dataset
The full dataset will be accessible by the 3 named investigators only and on request by individuals nominated by the sponsor for the purpose of monitoring. No secondary analysis is planned for the dataset.

9 DISSEMINATION POLICY
9.1 Dissemination policy
The data arising from the study is owned by the investigators. On completion of the study the data will be analysed, tabulated and a final study report compiled. The Chief Investigator has ultimate responsibility for preparing this. The full study report and protocol will be accessible via the sponsor’s server within 12mths of the completion of the study.

The study team have rights to publish the study data via peer-reviewed scientific journals, conference presentations and internal report.

The sponsor’s role will be acknowledged within the publications. There is no funding body.

Participants who have given consent to be contacted further with the results of the study will be sent a participants’ report following the conclusion of the study and the compilation of the final study report.

9.2 Authorship eligibility guidelines and any intended use of professional writers
Lisa Massey will write any publications with support from the other study team members who will review the manuscripts and both be named authors.

10 REFERENCES


Darzi 2008 high quality care for all. (n.d.).


Improving the Patient Experience of Ambulatory Care in the Surgical Assessment Unit. (2014).


Surgical patients’ experience of being managed in ambulatory care

11. APPENDICIES

11.1 Appendix 1- Required documentation
CVS for Lisa Massey, Rob Bethune and Iain Lang.
Participant information sheet
Interview schedule

11.2 Appendix 2 – Schedule of Procedures

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Visits</th>
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<td>Screening</td>
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<td>telephone</td>
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<tr>
<td></td>
<td>contact</td>
</tr>
<tr>
<td></td>
<td>Interview</td>
</tr>
<tr>
<td>Participant information sheet given</td>
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</tr>
<tr>
<td>Further information given and questions answered</td>
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<tr>
<td>Capacity assessed</td>
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<td>Recorded consent</td>
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<td>Interview</td>
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11.3 Appendix 3 – Amendment History

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<th>Amendment No.</th>
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<th>Date issued</th>
<th>Author(s) of changes</th>
<th>Details of changes made</th>
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