SCHOOL OF DESIGN
THE GLASGOW SCHOOL OF ART

18th June, 2014

Dear Sir/Madam,

Thank you for taking the time to read this information letter. Before you give your written consent for me to use my observations that include you from today's Education Day, it is my duty to ensure you understand how the data will be used and the wider context of my study. Please feel free to contact me if there is anything you would like to discuss.

Background information
I am working under the supervision of Professor Alastair Macdonald in the School of Design at The Glasgow School of Art. Professor Macdonald and several of his colleagues have a history of working within the healthcare context, so I am very much looking forward to this collaboration and I am appreciative of the rare opportunity to work so closely with the QENSIU community.

This project follows on from the "Design and Rehabilitation" workshops initiated by the Royal Society of Art in 2011. These workshops were facilitated by partnering three of the leading spinal injury units in the UK with their with local universities, including a collaboration between QENSIU and The Glasgow School of Art. I was also involved in this project as a workshop facilitator through Sheffield Hallam University, in partnership with the Princess Royal Spinal Injuries Centre.

During this first part of my study, I aim to develop an understanding of how a spinal injury unit operates. I hope to gain an insight into how the many and varied roles within QENSIU work together to support a patient's development, including the perspectives and experiences of everyone involved – from patients to staff, carers, support groups, etc. In working towards this I have been conducting staff interviews, shadowing nursing staff on day/night shifts, observing gym sessions, attending the patient education sessions and spending time at the Spinal Injuries Scotland offices.

My role in the Relatives Education Day
I will be continuing my passive observations through today's session primarily to understand how the day is run and the types of information that are conveyed. However, if I would like to record a specific observation of a particular patient or relative, I will first ask for their permission to store and use this information in my work.

Participant and data protection
Your permission for me to use any observations that you are included in is completely voluntary. You are free to withdraw this permission at any time without giving any reason and without any negative consequences. You are also free to decline answering any question or questions.

With your permission, I would like to take handwritten notes of these observations. Any and all data will be kept strictly confidential and

anonymised. The data will be securely stored and you will not be identifiable from the notes, the report or reports that result from this data.

With your permission, I would like disclose your status as a patient or relative in my work, as this is relevant to the data content. However, you are free to decline this specific permission.

I am supervised by qualified staff who are obliged to ensure that I am working within the appropriate data collection protocols. This includes ensuring that all materials collected are subject to ethical policies and processes of safeguarding and anonymising of data.

Contact
Thank you for taking the time to read this letter. If you have any questions please feel free to contact me on:

Email: [redacted]
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

Or my primary supervisor, Professor Alastair Macdonald, on:

Email: [redacted]
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

Or my co-supervisor, Dr Mariel Purcell, on:

Email: [redacted]
Address: The Queen Elizabeth National Spinal Injuries Unit, Scotland South Glasgow University Hospitals Division, Southern General Hospital, 1345 Govan Road, Glasgow, G51 4TF

Thank you again.

Kind regards,
Gemma Wheeler
PhD Candidate, The Glasgow School of Art

SCHOOL OF DESIGN
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Preliminary Observations Consent Form

Project Title: "Developing an understanding of how a spinal injury unit operates and approaches to rehabilitation from multiple perspectives."

Observer: Gemma Wheeler

Please initial box

1. I confirm that I have had the opportunity to ask questions about the project. ☐
2. I understand that my participation in the project is voluntary and that I am free to withdraw at any time without giving any reason and without disadvantage to myself. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐
3. I understand that my responses and any observations made will be kept strictly confidential. My personal details will be anonymised. I give permission for members of the project team to have access to my anonymised responses and any observations made. I understand that my name will not be linked with the project materials, and I will not be identified or identifiable in the reports or presentations that result from the project. ☐
4. I agree for the data collected from me to be used in future reports or presentations. I understand that I have the right to withdraw permission to use the data collected from me at any time, without giving any reason and without disadvantage to myself. ☐
5. I agree to take part in the above project. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Witness (If appropriate)	Date	Signature
_____	_____	_____
Name of Observer	Date	Signature

Observer contact email: [redacted]

Observer contact address: The Glasgow School of Art, 167 Renfrew Street, (Rose Street 2nd floor), Glasgow, G3 6RQ

NHS
Greater Glasgow and Clyde

WoSRES

West of Scotland Research Ethics Service

Dr Mariel Purcell
Consultant in Spinal Injuries
Queen Elizabeth National Spinal Injuries Unit

West of Scotland Research Ethics Service
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT

Date 4th June 2015
Our Ref WoS ASD 991
Direct line 0141 211 2126
Fax 0141 211 1847
E-mail [redacted]@ggc.scot.nhs.uk

Dear Dr Purcell

Full title of project: **Review of current Goal Planning Meeting (GPM) behaviours/protocols**

You have sought advice from the West of Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that based on the submitted documentation (email correspondence 19 May 2015) it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition). This advice is based on the following.

- The project involves an opinion survey seeking the views of patients and their PIP on a service delivery.
- The project also includes further developing the service and then getting an opinion on the new service development.
- Recruitment is invitational and the transcripts from face to face interviews will be irreversibly anonymised so that the respondent's identity is fully protected.

Note that this advice is issued on behalf of the West of Scotland Research Ethics Service and does **not** constitute a favourable opinion from a REC. It is intended to satisfy journal editors and conference organisers and others who may require evidence of consideration of the need for ethical review prior to publication or presentation of your results.

However, if you, your sponsor/funder or any NHS organisation feels that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further.

Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS.

Kind regards

Judith Godden

Dr Judith Godden, WoSRES Scientific Officer/Manager

Form 1: Preliminary Ethical Assessment Form

Introduction Glasgow School of Art must ensure that all its research and knowledge exchange projects undergo appropriate ethical review before commencement. This covers both internally and externally funded projects executed by GSA staff and postgraduate research students. In addition to basic institutional requirements, main research funders (e.g. Research Councils) now require assurances that projects have been through an appropriate ethical review and that the research will be conducted within a research governance framework embedded within the institution.

Procedure Glasgow School of Art has a two stage ethical review process. Stage 1 at the point of:

i) obtaining sign off for a proposed research project;
ii) beginning a new piece of research;
iii) uncovering an ethical issue in an on going piece of work,

this preliminary ethical assessment form should be completed and sent to the Research Developer [redacted]@gsa.ac.uk) for review. The outcome of stage 1 will be communicated to researchers within a month of sign off being obtained. If the preliminary ethical assessment raises issues that require further consideration, researchers must complete stage 2, full ethical approval – you will be advised on this by your Research Developer and so please wait for instruction. Full ethical approval must be obtained from the Research Ethics Committee and well in advance of your project commencing. Note, requiring full ethical approval does not mean you cannot do the research, only that further consideration and sign off is required.

Governance All researchers must abide by the GSA Research Ethics Policy and Code of Practice. Research which commences in the absence of sign off may be subject to disciplinary procedures.

Researchers will find a variety of resources to help them on the VLE, Research and Knowledge Exchange Course (e.g. our GSA Ethics Toolkit and the Library's InfoSmart resource) and are encouraged to speak with a member of the Research Development Team as early as possible.

How to complete this form

1. Sections 1 – 3 and 10 – 14 are compulsory for all researchers and must be answered;

2. All questions highlighted in yellow are compulsory and must be answered;

3. If you answer YES to any of the questions highlighted in yellow, you must answer the remaining questions within that section.

4. Upon completion, this form, together with a research proposal outlining your work should be emailed to the Research Developer [redacted]@gsa.ac.uk).

Form 1: Preliminary Ethical Assessment Form

THE GLASGOW SCHOOL OF ART

SECTION 1: APPLICANT DETAILS

Name of Researcher (Applicant):	Gemma Wheeler
Email Address:	[redacted]@student.gsa.ac.uk
School:	The School of Design
Contact Address:	[redacted]
Telephone Number:	[redacted]
Project Title:	Using design methods to explore and enhance patient participation within spinal cord injury rehabilitation.
Proposed funder:	Arts and Humanities Research Council
Collaborators:	Primary Supervisor: Professor Alastair Macdonald, The Glasgow School of Art Co-Supervisor: Dr Mariel Purcell, The Queen Elizabeth National Spinal Injuries Unit, Southern General Hospital, Glasgow. Advisor: Mr David Allan, FRCS, previously Consultant in Orthopaedic Surgery, Southern General Hospital, Glasgow, and Clinical Director of QENSIU and the Scottish Centre for Innovation in Spinal Cord Injury (SCISCI).
*Project reference code:	

**Note: This will be administered to researchers by the Research Development Team. If you have a code, please enter. If not, one will be assigned to the project and you may leave blank.*

*Place an **X** in the appropriate box*

SECTION 2: VULNERABLE GROUPS

Does your research involve any of the following groups:	**YES**	**NO**
Children under 16	☐	☒
Adults unable to give consent under the Adults with Incapacity Act (2000) Scotland	☐	☒
Prisoners (incl those convicted under UK law, detainees or asylum seekers)	☐	☒
Individuals in dual relationships (e.g. familial or supervisory which may lead to a conflict of interest, or a positive or negative bias)	☐	☒

*If you answered **YES** to any of the above, full ethical approval is required and Disclosure Scotland checks may also need to be obtained. Please speak to a member of the Research Development Team.*

SECTION 3: SPECIAL PERMISSION

Does the research involve the use of animals of other organisms covered by the Animals (Scientific Procedures) Act?	**YES** ☐	**NO** ☒

Form 1: Preliminary Ethical Assessment Form

Will the research be conducted outside of the UK?	☐	☒
Does the research involve the use of human tissue?	☐	☒
Does the research involve the use of animal tissue?	☐	☒

*If you answered **YES** to any of the above, full ethical approval is required and legal permission from the relevant authorities may also need to be sought. Please speak to a member of the Research Development Team.*

If you answer **YES** to any of the questions highlighted in yellow in the following sections, you are required to complete the rest of the questions within that section.

If you answer **NO,** you may leave that section blank and move onto the next.

SECTION 4: INDIVIDUALS IN CLINICAL SETTING

Does the research involve any of the following?	**YES**	**NO**
Any individual for which the purpose of their involvement is a direct result of being within the NHS or in receipt of its care	☒	☐
Patients and users of the NHS	☒	☐
Relatives or carers of patients and users of the NHS	☒	☐
Foetal material and IVF involving NHS patients	☐	☒
The deceased on NHS premises	☐	☒
The use of, or potential access to, NHS premises or facilities	☒	☐
NHS staff recruited as research participants by virtue of their professional role	☒	☐
Participants aged 16 or over who are unable to give informed consent (e.g. people with learning disabilities; see Adults with Incapacity Act (2000) Scotland)	☐	☒

*If you answered **YES** to any of section 3, you need to submit an application for Full Ethical Review to the appropriate external health authority ethics committee through the National Research Ethics Service (NRES). Form 3 will also require completion – your Research Developer will work with you to develop both applications.*

SECTION 5: INDIVIDUALS IN NON-CLINICAL SETTING

Does the research involve any of the following?	**YES**	**NO**
Does the research involve individual participation (e.g. codesign of research question, use of questionnaires, focus groups or observation)?	☒	☐
Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited (e.g. students at school, members of a self-help group, and residents of a nursing home)?	☒	☐
Will it be necessary for participants to take part in the study without their	☐	☒

knowledge and consent at times (e.g. covert observation of people in non-public places)?		
Will this programme/project involve deliberately misleading participants in any way?	☐	☒
Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use)?	☒	☐
Are any drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?	☐	☒
Is pain or more than mild discomfort likely to result from the study?	☐	☒
Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?	☐	☒
Will the study involve prolonged or repetitive testing?	☐	☒
Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?	☐	☒
Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?	☐	☒
Will the research involve members of the public in a research capacity (i.e. participant research)?	☒	☐
Will research involve the sharing of data or confidential information beyond the initial consent given?	☐	☒

SECTION 6: ARCHIVAL RESEARCH

	YES	NO
Does your research involve use of archival material[1]	☐	☒
Is the material protected by copyright	☐	☐
Is the archive a public resource	☐	☐
Is the archive part of a private collection	☐	☐
Is the archive a personal collection (i.e the owner / holder of the archive material is related to the subject of the material)	☐	☐
Is the owner or holder of the archive known?	☐	☐
Does the use of the archive require the researcher to work in a non GSA location	☐	☐

[1] Archival research is defined as the systematic investigation of documents or records that are accumulated and maintained by individuals or organizations in order to provide answers to research questions.

Will archival material be destroyed, modified or defaced in any way as part of the research process	☐	☐
Will the material from the archive be reproduced as part of research dissemination activities:	☐	☐
If the answer to the above question is **YES**, please tick which of the following be reproduced: Photographs (people) ☐ Photographs (general) ☐ Letters ☐ Drawings ☐ Paintings ☐ Other (state):		

SECTION 7: ORAL HISTORIES

	YES	NO
Does your research involve taking oral histories[2]	☒	☐
If yes, will the history be directly obtained from a member of the public	☒	☐
If yes, will the history be taken from a professional or peer in a similar capacity to the researcher	☐	☒
Will you be making use of an oral history obtained by a third party	☐	☒
Will the participant be required to be identified as part of the research activities or subsequent dissemination	☐	☒
Will the history taken be modified in any way without the knowledge of the participant	☐	☒
Will the method of recording the history obtained be: Written / text ☒ Voice recording ☒ Video ☐ Other (state):		

SECTION 8: VISUAL RESEARCH

	YES	NO
Do you intend to utilise images in the course of your research (photo, video, painting etc)	☒	☐
Will your research involve the use of researcher generated images	☒	☐
Will your research involve the use of participant generated images	☒	☐
Will your research involve the use of images collected from the internet	☒	☐

[2] Oral histories defined as '*the collection and study of historical information using sound recordings of interviews with people having personal knowledge of past events*'.

Form 1: Preliminary Ethical Assessment Form

THE GLASGOW SCHOOL OF ART

Will your research involve images protected by copyright	☐	☒
Will your research involve images where the original producer of the image or the owner of the image is not identifiable	☒	☐
Will human participants be recorded	☒	☐
Will deceased subjects be recorded	☐	☒
Will the image be altered in any way as part of the research activities and dissemination	☒	☐
Will the image be disseminated	☒	☐

SECTION 10: COLLABORATORS

If involved in a multi party project, do all the partners involved have an institutional ethics policy?	**YES** ☒	**NO** ☐	**N/A** ☐

*If answered **NO** to the above, full ethical approval may be required, the Research Development Team will advise.*

If your project is being led by another institution or organisation, please append a copy of their ethics policy to this form or insert URL if available online:

http://www.hra.nhs.uk/research-ethics-committee-members/guidance-on-ethical-review-for-members/

SECTION 11: DISSEMINATION

Please tick all methods of dissemination the project will use:

Peer reviewed journal	☒	Conference publication	☒
Internal report	☒	Website publication	☒
Technical report	☐	Exhibitions	☒
Book	☐	Other (please state): PhD Thesis	

SECTION 12: CONFLICT OF INTEREST

Please state any conflict of interest that is already in existence or that might arise during this work (e.g. holding positions with organisations sponsoring or conducting research at GSA, a staff member accepting gifts of value, grants and/or favours from persons or associates who would be seen to benefit from the making of these gifts etc). *Note this will not prohibit the work taking place, further consideration in the form of a full ethical review may be required however.*

N/A

Form 1: Preliminary Ethical Assessment Form

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SECTION 13: GSA POLICY OBLIGATIONS
Please confirm that you have read and will abide by following internal GSA policy documents:

Health and Safety ☒ Data Protection Policy ☒

SECTION 14: DECLARATION

I certify that the information contained in this application is accurate. I understand that should I commence research work in absence of ethical approval, such behaviour may be subject to disciplinary procedures.	
Name of Principal Investigator:	Gemma Wheeler
Signed:	G. Wheeler
Date:	07-07-15

You should send copies of this form to the Research Development Team, with your research proposal or bid documents attached. Your request for ethical approval will not be considered without the appropriate accompanying documents.

If you have any queries about this or any other ethical issue, please contact the Research Development Team.

Form 1: Preliminary Ethical Assessment Form

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For office use only:

Date received in Research Office:	Requires full approval: YES/NO
Signed by Research Developer:	Signed by Convenor of Research Ethics Sub Committee:

Comments:

Form 2: Full ethical approval form

Participants in non clinical setting

Please complete all sections unless instructed otherwise by your Research Developer. Questions highlighted in **bold** and *italicised* are particularly important and answers must be detailed or there will be a delay in obtaining ethical approval.

Upon completion, please email or send in internal mail for the attention of the Research Developer [redacted]@gsa.ac.uk). Your application will then be discussed at the next meeting of the GSA Research Ethics Committee and a decision will be communicated back to the applicant.

1. APPLICANT DETAILS

Name of researcher (Applicant):	Gemma Wheeler
School:	The School of Design
Project Title:	Using design methods to explore and enhance patient participation within spinal cord injury rehabilitation
Funder:	Arts and Humanities Research Council
Project Reference Code:	

2. RECRUITMENT

a)

Number of participants required:	**(Please see appendices B and C for full details of each activity)** **Please note: Participants from Phase 1 will be invited to continue their involvement into Phase 2, but this will not be mandatory. Participants will be able to take part in Phase 2 equally, whether they were involved in Phase 1 or not.** **Phase 1: Review of current Goal Planning Meeting (GPM) Procedures** *Activity 1.1: Visual mapping of GPM:* • Patients = 8 • PIP's = max. 8 • Rehabilitation Teams (consisting of 2 – 7 hospital staff members, depending on availability to attend the meeting) = 8 *Activity 1.2a: Questionnaire-led discussion* • Patients = 8 *Activity 1.2b: Questionnaire-led discussion* • Person(s) Important to the Patient (PIP) (may include spouse, family member, friend, legal advisor) = max. 8 (a PIP does not need to be present for the GPM to take place, so total number may be less.) *Activity 1.2c: Questionnaire-led discussion* • SIU staff n=8 **Phase 2: 'Co-Plan' workshops ('Co-plan' being the**

	name for this project within the SIU) *Activity 2.1a, 2.2a: Establishing Patient/PIP priorities* • Patients = minimum of 3, maximum of 6 (fatigue and illness may contribute to a high drop-out rate) • PIP's = minimum of 3, maximum of 6 *Activity 2.1b, 2.2b: Establishing staff priorities* • Spinal Injury Unit (SIU) staff members = minimum 6, however more staff members will be invited (maximum = 12) *Activity 2.3-2.5: Co-design workshops* • Patients = 3-6 • PIP's = 3-6 • Staff = 6-12 • Spinal Cord Injury (SCI) – related charity workers = 3 *Activity 2.6: Prototype development workshops* • Patients = 3 • PIP's = 3 • SIU staff = max. 21 (using each patient's Rehabilitation Team, which may have 7 members each, however some staff members may be involved in more than one patient's Rehabilitation Team) **Please note: Participants in Phase 3 will be new to the study, and will not have been involved in Phase 1 or Phase 2.** **Phase 3: Implementation and evaluation** • Patients = 3 • PIP's = 3 • SIU staff = max. 21 (as in 2.4 above)
Will recruitment be direct (led by the researcher) or indirect (led by an organisation / third party)?	DIRECT (in case of staff and volunteer organisations) and INDIRECT (in case of patients and PIP's)

b) If your study involves INDIRECT recruitment, please detail the recruitment plan covering: i) organisation / institution / individual in charge of identifying possible participants; ii) how they will recruit individuals (letters, phone calls etc); iii) any individual who has direct contact with participants; iv) any ethical protocols the third party has in place; v) level of permission that third party has to disseminate information on behalf of the participants (append any documents if necessary)

i) The co-supervisor of this PhD project, Dr Mariel Purcell, is a Consultant in Spinal Injuries at The Queen Elizabeth National Spinal Injury Unit (QENSIU), Southern General Hospital, Glasgow (the partner institution in this Collaborative Doctoral Award). Dr Purcell will act as a gatekeeper in this study, identifying possible participants from the inpatient population.

ii) [Please note, each phase of the study has tailored information letters and consent forms, please see appendices L-Y.]

Dr Purcell will initially identify and approach possible patient participants on her own, giving a brief overview of the project before asking permission to introduce the patient to the researcher. If permission is granted, Dr Purcell will introduce the patient to the researcher to discuss the project further and provide an information letter and copy of the study consent form to review in their own time. The researcher and the patient will arrange a time to meet again at the patient's convenience (3 working days), with details on how to contact the

researcher or her supervisory team beforehand if necessary. In the second meeting the researcher will answer any questions the patient may have about the study. If the patient agrees to take part in the study, the researcher and the patient will sign the consent forms together (a witness may be recruited from the hospital staff to sign on behalf of the patient if necessary, as the patient may have limited dexterity), leaving one copy with the patient and one for the researcher. A photocopy of the completed consent form will be left in the patient's medical notes, with contact details of the researcher to discuss this further if necessary. The patient will be given a letter with details on when and where they will meet with the researcher again.

PIP's will be recruited via introduction by the patient. As above, PIP's will be given an information letter, a copy of the appropriate consent forms and 3 working days to decide whether they wish to participate. Experience in the host SIU suggests that some PIP's of patients who do not wish to participate may hear about the project through word of mouth in communal areas. If PIP's in this situation approach the researcher (either directly or through staff introduction), they will be welcome to participate providing the patient they visit is comfortable with their PIP's involvement in the study.

iii) Other than the staff population that patients and PIP's will normally be in contact with, the named researcher, Gemma Wheeler, will have direct access to participants.

c) If your study involves DIRECT recruitment (i.e led by the applicant / research team):

Who is in charge of recruitment:

Gemma Wheeler, with assistance from the Gatekeeper, Dr Mariel Purcell.

What is the method of identifying participants:

The contextual review informing this study involved working with a large number of staff from the host spinal injury unit and with SCI-related charities (Spinal Injuries Scotland (SIS) and The BackUp Trust). As such, the researcher has established a key working group amongst senior staff. Invitation to participate will be extended to this group initially, whilst encouraging them to extend this invitation to their colleagues.

How will participants be invited to take part: (e.g. letters, phonecalls, door to door):

Email – As discussed above, the researcher has the means to contact many potential professional participants directly by email due to previous work in the host SIU.

In addition to this, the researcher aims to create a project mailing list to keep staff informed of progress and opportunities to take part in the study. Posters inviting staff to join this mailing list will be displayed in staff-only areas (such as staff offices and staff kitchen areas).

Due to the researcher's permanent office in the host spinal injury unit, key senior staff members can also be approached in person to extend the invitation further or to answer any questions about the project.

Regardless of method of contact, all participants will be given an information letter, a copy of the consent form that they will complete if they wish to take part and 3 working days to decide if they choose to do so.

d) Regardless of method of recruitment, what is your exclusion / inclusion criteria for this study:

Patients:

- Clinical diagnosis of having sustained a spinal cord injury (e.g. due to trauma, infection, stroke, etc.)

- Currently involved in post-acute rehabilitation in QENSIU
- Of either gender
- Age ≥ 16
- Have English as their first language
- Be able to give informed consent for themselves, with a witness to sign on behalf of the patient if necessary.

Please note: The level of injury, whether the injury is complete/incomplete and the patient's home town will be recorded but will not necessarily dictate inclusion or exclusion in the study. Although the range of participants may be dictated by the inpatient population at the time of this study, the researcher aims to reflect the typical patient population in the host SIU. According to a recent study within the host SIU (pending publication), the ratio of men:women is approximately 4:1 and approximately 75% of patients have tetraplegic injuries (affecting motion and/or sensation in all four limbs).

PIP's:

- Have involvement with a current patient within the QENSIU rehabilitation ward
- Of either gender
- Have English as their first language
- Be able to give informed consent for themselves

QENSIU, SIS and BackUp professionals:

- Have involvement with the patient community of the QENSIU rehabilitation ward
- Have English as their first language
- Be able to give informed consent for themselves

Please note: This study aims is to gather a group of QENSIU staff that is representative of the various departments involved in SCI rehabilitation, including nursing, physiotherapy, occupational therapy, psychology and staff relating to discharge/outpatients. Consultant staff will be invited but may be prevented from doing so due to high workloads.

In all cases, append a copy of i) information sheet for participants; ii) consent form; iii) copies of any other documents distributed to participants
Please see appendices L-Y.

3. CONSENT

a) Give a detailed account of the steps taken by the researcher to obtain informed consent from the participants (regardless of method of recruitment):

As described in section 2, all participants will be given an information letter about the study and a copy of the consent form following initial contact with the researcher. The information letter will describe the background to the study, the aims of the study and what the participant will be asked to do, plus how information will be recorded and stored. The letter will emphasise the participant's right to withdraw participation and/or information recorded about them at any time.

Each participant will be offered 3 working days to consider their invitation to take part, and given contact details of the researcher should they wish to ask any questions about the study during this time. The researcher and participant will arrange a mutually suitable time to meet again after the 3 working days.

The second meeting between the researcher and participant will provide another opportunity to answer any questions about the study and the participant's involvement in it. If the participant agrees to take part in the study, two copies of the consent form will be completed together (with a witness to sign on behalf of the patient if necessary). One copy will be left with the patient and one will be kept for the researcher's records. A photocopy of the completed consent form will be left in the patient's medical notes, with contact details of the researcher to discuss this further if necessary.

b) How will researchers ensure the participant has capacity to consent:

Patients who are unable to give informed consent are identified by the host SIU and do not go through the Goal Planning process that this study is investigating. As such, the researcher will liaise with the gatekeeper to ensure only appropriate patients are invited to participate.

PIP's who are involved in the Goal Planning process may do so for several reasons, commonly to ask questions, provide advice, support the patient or to prepare for their care-giving role post-discharge. As such, it is almost certain that they will have the capacity to give informed consent, although this will also be verified by liaising with the gatekeeper.

QENSIU and charity staff are recruited through their professional affiliation with the host SIU, and as such are able to give informed consent.

c) If your work requires participants belonging to vulnerable groups (children under 16, adults unable to give consent, prisoners, individuals in dual relationships), what additional steps will be taken to gain consent:

N/A

d) If your work requires the consent of a gatekeeper, please detail the steps you will take to ensure participants are not coerced by their gatekeeper. State also whether you plan to obtain additional signatures from participants and if not, why

The elected gatekeeper, Dr Mariel Purcell, has carried out this role in several clinical research projects within the host SIU over recent years and as such has experience in ethical conduct. She is fully aware of what her role involves and as a resident consultant in spinal injuries her main priority is the welfare of the patient community. As Dr Purcell is also the researcher's co-supervisor, she shares responsibility in ensuring all aspects of this study are conducted appropriately. Prior to her identifying and approaching any potential patient participants, the researcher will provide Dr Purcell with a brief overview of what will be asked of each participant in each activity, so that patients can be informed without being coerced.

The researcher will also ask each patient participant not to coerce their PIP when inviting them to participate in the study.

Each information letter will emphasise that participation in this study is completely optional.

The researcher will not be collecting any additional signatures other than in the consent forms discussed above, as all participants will be made aware at this point that they are free to withdraw their participation and contributions at any time without any negative effect to themselves.

e)

How much time will be given for the participant to decide whether or not to take part:	3 working days from their first meeting with/invitation from the researcher.

By what method will you seek to obtain consent (written, oral, video etc) and why: NB: please be aware of any Data Protection issues here	Participants will be asked to print their name, sign their name and provide the date on two copies of the study consent form. A witness will be recruited from QENSIU staff to sign on behalf of the participant if necessary (for example, due to limited dexterity resulting from a spinal cord injury). Written consent has been chosen as this allows participants to review the consent form in advance of agreeing to participate (or not). It is also a formal, standardised method of obtaining consent that is understood and upheld within the clinical context of the SIU.
Will copies of consent be given to participants:	YES
For how long will the copies of consent be retained by the researcher and where will the consent form be stored:	A photocopy of the completed consent form will be left in the patient's medical notes for the duration of the study, stored securely according to QENSIU policy. This consent form will remain in the patient's medical records permanently, but no participant data from this study will be stored alongside it. The researcher will securely store the signed consent forms for the duration of the study securely on NHS premises. Upon completion of the study, the consent forms will be stored by The Glasgow School of Art for a period of 10 years, according to institutional policy, after which they will be destroyed.

4. LOCATION

a) If the research activities take place in a third party location (i.e. not on GSA premises), please explain the choice with reference to the study. Append confirmation of permission to use location given by the owner and confirm that all researchers have been made aware of any local rules and regulations (append if necessary).

Research activities will take place within the host spinal injury unit to minimize impact on staff workload and to ensure the safety of patient participants. Given that all patient participants will be going through the rehabilitation process at the time of the study, it is important that they are able to return to their ward to rest at any time. It is also important to have access to clinical staff should patient participants feel unwell. The act of travelling to a study location outside of the spinal injury unit could be very problematic for some patient participants, and as such could lead to highly reduced rates of recruitment. The site of intervention (the Goal Planning Meeting) occurs in the SIU at regular intervals during a patient's rehabilitation stay, so conducting the study within the unit also has contextual significance. The host SIU is also a known location for participants who are recruited due to their relation to the patient or by their affiliation with SCI-related charities, and in both cases may not require any additional travel. Please see appendix K for the confirmation of permission to use the QENSIU location by Dr Alan McLean, Lead Clinician in Spinal Injuries and Head of Service at The Queen Elizabeth Nation Spinal Injury Unit for Scotland. The researcher has been made aware of any local rules and regulations.

b) If the research activities take place in the participants' home, please CLEARLY explain the choice with reference to the study and why no other location is possible. Detail all measures taken to minimise the risk to both participants and researchers entering the home.

N/A

5. INCENTIVES

a) Reasonable reimbursements for time and travel compensation are acceptable as incentives to participate in a research study. An acceptable level of reimbursement would be no more than £50 (approximately).

Do you plan any of the following:

Travel reimbursement only	NO
Small incentive only (e.g. gift voucher)	NO
Travel and small incentive	NO

b) If the incentive exceeds £50, please state the reasons why (note a large financial incentive, whilst appearing generous, could be deemed unethical on the grounds of coercion. See also, the Bribery Act 2010):

N/A

6. METHODOLOGY AND ACTIVITIES

a) Please state the methodology employed within the study and give references (literature or any previous work by the researcher) to support their use:

Prior to this study, an in-depth contextual review of the host SIU (conducted by the researcher over a period of 12 months) identified the Goal Planning Meeting (where a patient, their Rehabilitation Team and usually 1-2 People Important to the Patient meet regularly to review progress and set rehabilitation goals for the next few weeks) as a regular rehabilitation event that could be enhanced to support patient and/or PIP participation in collaborative decision-making.

This mixed methods study has three linked phases:

i) Phase 1 involves a review of the current Goal Planning Meeting (GPM) format. Aspects of phenomenography (Barnard et al., 1999) and experience-based design (Bate and Robert, 2007) will be used to inform the collection of patient, PIP and staff experiences, and their understanding of them, through survey-led discussions. Objective accounts of what happens in the GPM will be gathered through visual 'mapping' of the conversation between patients, PIP's and SIU staff. Both accounts will be used to inform the co-design workshops.

ii) Phase 2 involves a series of co-design workshops, bringing together patients, PIP's, SIU staff and SCI-related charity volunteers. Tools from the field of participatory design (Simonsen and Robertson, 2013, Sanders, Brandt and Binder, 2010, Brandt and Messeter, 2004) will be used to encourage democratic interaction between the groups, and to transform the information gathered in Phase 1 and insights from the medical literature (see Levack et al., 2006, for a review of the purposes and mechanisms of goal planning in rehabilitation) into tangible, equally accessible materials for the group to work with. Literature from Experience Goal-driven design (Wheeler et al, 2014) and Co-design (a field within participatory design, as described by Sanders and Stappers, 2008) will also inform the use of generative tools and techniques to guide participants to

co-develop the current GPM experience into their preferred experience. Iterative prototyping techniques (Coughlan et al., 2007) will facilitate the co-creation of the study intervention, such as a new material to be used in the GPM, a different meeting agenda, etc.

iii) Phase 3 involves the introduction of the co-designed material into the rehabilitation pathway of 3 patients, and the evaluation of its effects (if any).

b) For each activity employed please detail: i) its purpose; ii) direct correlation to the research outcomes; iii) how any analysis will be performed. **Copies of all material given to participants must be appended to this form wherever possible.**

ACTIVITY 1: (e.g. questionnaire, focus group, interview etc),

Please see appendices B and C for full details of research activities.

ACTIVITY 2: (e.g. questionnaire, focus group, interview etc),

Please see appendices B and C for full details of research activities.

If there are any further activities, please continue and append to this form.

c) State how harm, distress or anxiety to the participants will be minimised during the study

The following measures will be put into place to minimize risk of harm to participants:

- Initial introduction to patient participants facilitated by the gatekeeper.
- Ensuring all participants have read the information letter and consent form, have had the opportunity to ask questions and understand what their participation will involve, how data will be recorded and stored, how data will be used and how the data may be disseminated prior to giving consent.
- Conducting research activities with or in close proximity to SCI specialist healthcare staff.
- All participants and staff in the SIU (who will be conducting their normal duties in close proximity to the research activities) will be reminded to report any misconduct (by the researcher or by any of the participant group) to either:
  - The researcher's supervisory team, whose contact details can be found on the information letter given to each participant at the time of recruitment.
  - Dr Alan McLean, Lead Clinician in Spinal Injuries and Head of Service for QENSIU.
- For the patients, conducting research activities in close proximity to their wards,

should they need to take a break to rest.

- Patients will be visited earlier in the day when research activities are due to take place, to check they still feel well and motivated enough to take part. They will be given the option to postpone or cancel if they feel unwell or fatigued.
- SCI rehabilitation involves learning to manage all effects of the injury, including (but not limited to) mobility, skin care and bowel, bladder and sexual function. Clearly such topics can involve sensitive issues, but any discussions about these issues will be led by the patient(s) and not introduced by the researcher. Given her 1.5 years' experience in the host SIU, the researcher is able to discuss these issues in an informed and sensitive manner.
- Research activities that involve working with individual patients or PIPs (such as conducting surveys or collecting oral histories) will be conducted in the host SIU's conference room. This is a central location that provides privacy to speak candidly, but also has clear visibility by SIU staff due to many windows into the main corridor. As such, SIU staff are able to identify and report any misconduct if necessary.
- Participants will be offered the chance to review any data involving them or their contributions prior to its use in the study.
- Images generated by the participants (for example, during the co-design workshops) will be kept anonymous and not used for profit.
- Images including the participants will be altered to provide anonymity.
- All data will be anonymised and securely stored on NHS premises.

d) Please state the time commitment of the participants and whether you plan repetitive testing as part of the study

Phase 1: Max. 150 mins for patient and PIP participants, and max. 120 mins for SIU staff participants. However, each participant also will be informed of and invited to the co-design workshops at the end of their session.

All participants in Phase 2 will be invited to attend one or all of the planned sessions; if a participant choses to attend all of the sessions they are invited to, their maximum time commitment will be:
Patient participants: 510 mins over 6 weeks
PIP participants: 510 mins over 6 weeks
Charity Staff participants: 270 mins over 3 weeks
SIU Staff participants: 510 mins over 6 weeks

In Phase 3, over approximately 5 weeks, the maximum time commitment for patient and PIP participants is 255 mins, and maximum time commitment for staff participants is 300 mins. However, approx. 180 mins of each participant's time will be spent in existing rehabilitation activities that would occur without the presence of this study or its intervention. As such, the researcher will not be conducting repetitive testing as part of this study.

e) What is the statistical power of the study:

The majority of datasets gathered and used within this study will be qualitative in nature, and due to the limited time of the PhD format, this study does not it intend to be statistically representative. Efforts will be made to recruit groups of participants that are representative to the communities involved in the study, but actual recruited groups will be dictated by the finite inpatient population and/or staff availability at the time of recruitment.

If you plan to leave participants with information at the close of the study (e.g. leaflets with further information, details of support groups etc), please append to this form.
N/A

7. PARTICIPANT DATA

Participants in non clinical setting

All researchers must abide by the Data Protection Act 1998 and the GSA Data Protection Policy – it is the responsibility of the researcher to familiarise themselves with each.

Who is the custodian of the data:	**Gemma Wheeler**
Where will the data be stored:	**NHS and GSA premises**
Who has access to the data:	**Gemma Wheeler. Anonymised data will be accessible by primary supervisor Professor Alastair Macdonald and co-supervisor Dr Mariel Purcell.**
Will permission to identify the participants be sought as part of informed consent	NO – other than (with participants' permission) their age, gender and role as permission will also be asked to record the level of their spinal cord injury and whether their injury is 'complete' or 'incomplete'.
What methods will be undertaken to guarantee anonymity (e.g. coding, ID numbers, use of pseudonyms)	As this study focuses on the importance of different types of experience, each participant will be given an ID code that identifies their role but not their name, for example: Patients: Patient A, Patient B, Patient C, etc. PIP's: The PIP who attends by invitation of Patient A will be referred to as PIP A. QENSIU staff: Staff will be designated codes within their department, as follows: Nursing: Nurse A, Nurse B, etc. Physiotherapy: Physiotherapist A, Physiotherapist B, etc. Occupational Therapy: OT A, OT B, etc. Discharge Liaisons: Discharge Liaison A, Discharge Liaison B, etc. Chaplaincy: Chaplain A, Chaplain B, etc. QENSIU currently employs one Discharge Coordinator and one Clinical Psychologist, so they will be referred to as such without any additional letter designation. One member of the patient's rehabilitation team is also assigned to be their Key Worker. Key Workers will be invited to questionnaire-led discussions in activities [**1.2**] and [**3.5**], where both roles will be identified. For example, if a patient's Physiotherapist was also assigned to be their Key Worker, they would be designated the code 'K.W.Physiotherapist A', 'K.W.Physiotherapist B'. Related Charities: Spinal Injuries Scotland / The BackUp trust: Volunteer A, Volunteer B, etc. Although these designations could be perhaps shortened, it is felt that the full title will provide greater clarity in the thesis/reports generated from this study. Although a copy of the patient's consent form will be stored in their medical notes, no patient data will be stored alongside this.
How will the link be broken between participant details and	A paper-based document will link the designations to participants' names. 2 copies of this document will be

information given as part of study?	securely stored in a separate locked filing cabinet from the study data on QENSIU premises for the duration of the study, after which it will be destroyed. No information that can identify patients will leave QENSIU premises. Any data stored at GSA premises will be anonymised. All documents and study materials will be anonymised using the codes above.
How long will the data be stored for? (Participants must be made aware of this at point of consent).	All information will be held securely for a period of 10 years, as required by The Glasgow School of Art. However, any audio/video-recorded data gathered from participants during the study will be destroyed once the study is complete.
How will the security of the dataset in its entirety be secured?	All digital and physical files will be securely stored in locked drawers, in a locked office, in a locked research department within the host SIU. Digital files will be backed up regularly and password protected. The researcher will also lodge hard and password-protected digital copies with her primary supervisor, Professor Alastair Macdonald, who will store these files securely on GSA premises. Professor Alastair Macdonald must comply with the GSA Data Protection policy.
How will the data generated by analysed and used?	As described in section 6, each phase of the study aims to inform the next. As a mixed-methods study, the researcher will analyse a mixture of: • Quantitative data (from initial and evaluation surveys), using simple statistical analysis (i.e. percentage of patients giving particular fixed answers, etc) • Qualitative data (from surveys, observational notes and interviews), using thematic analysis in NVivo software, in a method similar to that described by Fereday et al. (2006) • Visual data (from Goal Planning Meeting 'maps') will be reviewed to identify 'design patterns' (Bate and Robert, 2007) but also given to the co-design workshop participants to create their own interpretations.
Who will have access to the data beyond the project (if the data is being retained, not destroyed)	The data will be held securely by the GSA for a period of 10 years. During this time, the researcher (Gemma Wheeler), her primary supervisor (Professor Alastair Macdonald, GSA) and her co-supervisor (Dr Mariel Purcell, QENSIU) will have access to the data. The IT department of The Glasgow School of Art will act as custodians of the data, who will be given instructions concerning anonymity and how the data can be used at the point of archiving the dataset.
Does the research funder require the participant data generated be lodged with them upon conclusion? If yes, give details	No.

8. SAFETY

All researchers must abide by the GSA Health and Safety Policy – it is the responsibility of the researcher to familiarise themselves with this.

a) How will the safety of the participants be ensured during this study?

All research activities will take place in non-clinical areas on a hospital site. This means that fully qualified staff will be present or close by in case of medical issues that may occur. The spaces themselves, being in a spinal injury unit, are designed with the needs and safety of patients in mind, and as such also pose little risk to PIP, staff or volunteer participants.

The materials used in the activities (such as paper, pens, scissors, IT equipment) also pose very little risk to safety. Medical equipment, other than the patient's own equipment, is not stored in the areas where research activities will take place.

b) If your work requires participants belonging to vulnerable groups (children under 16, adults unable to give consent, prisoners, individuals in dual relationships), what additional steps will be taken to ensure their safety:

N/A

c) If the study involves work on non-GSA premises, how will the safety of researchers working off site be ensured?

As this study is contributing to a Collaborative Doctoral Award between the GSA and QENSIU, the researcher has access her own office and access to her co-supervisor whilst on the premises. The research activities will take place in the SIU's conference room and 'Step Down Unit'; both are non-clinical spaces adjacent to the main rehabilitation ward. As such, the researcher will have constant and easy access to NHS staff at all times.

If activities must be arranged outside of normal working hours (i.e. 09.00-17.00) for the convenience of participants, the researcher will contact a family member via text message before and after the research activities take place, with an agreement of when to expect these messages and who to contact if they don't receive these confirmations. All activities, whether conducted inside or outside of normal working hours, will take place in non-clinical areas of a hospital site, and as such the researcher will be in close proximity to hospital staff at all times.

The supervisory team will be provided with details of the timing and location of all activities in advance, and be advised of their completion at the earliest opportunity.

The researcher has also familiarized herself with the Social Researcher Association's 'Code of Practice for the Safety of Social Researchers', and will adhere to the guidelines therein (please see appendix J).

9. DECLARATION

Please ensure you have answered all the questions herein and have appended the following documents:

Form 2: Full ethical approval form

THE GLASGOW SCHOOL OF ART

Participants in non clinical setting

Consent form YES Participant Information Sheet YES

Follow up information (N/A) Any other relevant documentation (please state): YES:

- Study overviews (text and diagrammatic formats)
- Questionnaire frameworks
- SRA Safety Code of Practice
- Letter granting permission to use NHS location

Please see appendix A, on the final page of this form, for full details of appendices.

I certify that the information contained in this application is accurate. I understand that should I commence research work in absence of ethical approval, such behaviour may be subject to disciplinary procedures.	
Name of Principal Investigator:	Gemma Wheeler
Signed:	G. Wheeler
Date:	30-06-15

Please email the completed form and associated documents to the Research Developer ([redacted]@gsa.ac.uk).

Form 2: Full ethical approval form

Participants in non clinical setting

For office use only:

Approved (Convenor of Research Ethics Committee) YES / NO	Declined (Convenor of Research Ethics Committee) YES / NO
Signature:	
Comments?	

Approved (Member of Research Ethics Committee) YES / NO	Declined (Member of Research Ethics Committee) YES / NO
Signature:	
Comments?	

Appendices List of Contents

Appendix A: Bibliography

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Appendix B: Overview of study plan.

Phase 1: Review of current Goal Planning Meeting (GPM) behaviours/protocols

1.1 Visual mapping of GPM

8 x GPM's (typically 25-90 mins) of different patients will be observed and audio recorded. Handwritten notes will be taken of behaviours that cannot be captured by audio (for example, when and how staff refer to their own records). Verbal interactions will be 'mapped' from the audio recording using Microsoft Excel (using 'topics discussed' along the y axis, 'time' along the x axis and different colours to denote who is speaking) - creating a visual, objective account of what happens in the GPM. The researcher will review these visual 'GPM maps' alongside qualitative notes to establish patterns of behaviour and the potential influence(s) of current GPM materials (such as the patient records). The 'GPM maps' and the researcher's interpretations will be used to inform the co-design workshops.

1.2a – 1.2c Initial Questionnaire-led Discussion

Individual, questionnaire-led discussions with the patient, the Person Important to the Patient (PIP) and the staff Key Worker (leader of the patient's rehabilitation team) from each observed GPM in activity 1.1 (patient n= 8, max. PIP n=8, staff n=8). The questionnaire framework contains both open-ended questions and Likert-scale evaluations, as shown in appendices D-F. The activity will take approx. 45-60 mins for patient and PIP participants, and approx. 15-30 mins for Key Worker participants. The researcher will complete the questionnaire with patients, PIP's and staff individually, as soon after the GPM as possible. Order of priority to do this will be PIP>Patient>Key worker, as many PIP's may have to leave the hospital site soon after the GPM. Where more than 1 PIP is present (the current GPM format accommodates 1-2 PIP's), the researcher will allow them to decide if they would both like to complete the activity together, or if 1 of the 2 will act as a spokesperson (only 1 PIP questionnaire-led discussion will take place). To avoid participants feeling that they are being 'tested' (given that the researcher will be asking questions about events she has just observed), they will be reminded that the purpose of this activity is to gather their experience of the event, and as such their answers cannot be wrong. The researcher will act as scribe using the questionnaire framework with all participants, to support those who may have limited dexterity and to give additional guidance with non-traditional question formats, if necessary. This session will be audio recorded for reference (to clarify handwritten notes, if necessary). Statistical analysis and NVivo coding will be used to establish patient and PIP 'types' and to identify common bridges or barriers to participation. Information collected in this activity will be used to inform the co-design workshops (see Phase 2).

An anonymised copy of the notes taken throughout activities 1.2 will be provided for the participants to verify the discussion has been recorded accurately (and to suggest changes if necessary). This will be sent via email for staff participants, and a hard copy provided for patient and PIP participants, if they wish. Participants will be reminded that they are responsible for the safe storage of these notes.

After activities 1.1 and 1.2, the researcher will have gathered objective (from the visual mapping) and subjective (from patient and PIP questionnaire-led discussions) accounts of 8 GPM's. Both accounts will be compared and contrasted by the researcher, and considered alongside subjective accounts from SIU staff during the contextual review (prior to this study) to inform Phase 2.

Phase 2: 'Co-Plan' workshops ('Co-plan' being the name for this project within the SIU)

Please note: Participants will be recruited on the understanding that they are welcome at any and all of the sessions outlined in phase 2, but are also welcome to vary their attendance as their health, fatigue or schedule allows. As participant attrition is a potential problem within this stage of the study, the researcher will take the following steps (all of which will take place on hospital premises) to minimize the risk posed to successful data collection:

- Allocate sufficient time with individual participants during recruitment to answer any questions participants may have and to build working relationships.
- Meet with each patient, and where possible, PIP participant 2-3 days before each workshop to remind them of the date, time and content of the upcoming session.
- Email SIU and charity staff 2-3 days before each workshop to remind them of the date, time and content of the upcoming session.

- Meet with each patient, and where possible, PIP participant on the day of each workshop to enquire into their wellbeing and willingness to attend the day's session.
- Keep in contact with the gatekeeper, and be prepared to recruit further patient and/or PIP participants throughout Phase 2, if necessary.
- Although each workshop will inform the next, each session will be planned to work as a stand-alone activity.
- Develop a different plan for each workshop if the maximum or minimum number of participants attend, and deliver it accordingly on the day to provide the best participant experience.

The activities throughout Phase 2 are planned as follows:

2.1a Establish Patient and PIP experience goals: Brainstorming Session

Patients (minimum n=3, maximum n=6) and PIP's (minimum n=3, maximum n=6) will be invited to attend 1 of 2 brainstorming sessions to establish their priorities, aims and intended experience of a new GPM format. Two opportunities to attend are provided to account for Patient and PIP rehabilitation/work schedules, however each participant will only attend one Brainstorming Session (60-90 mins each). Handwritten notes of the key discussion points will be taken by the researcher, and verified at the end of each session by reading them back to the group. Observed differences of opinion of what the GPM should achieve will be translated into an 'either/or' card game (details available on request). The aim of these sessions is to identify differences in opinion in the patient and PIP community on the role of the GPM, and discuss these together until the group reaches a consensus on what the new GPM experience goals should be. After both brainstorming sessions, the researcher will consolidate all of the points made into a single, cohesive list of goals, with notes of any points that still need to be resolved.

2.1b Establish staff experience goals: Brainstorming Session

Repeat of 2.1a with QENSIU staff (minimum n=6, maximum n=12). As above, staff members will be invited to attend 1 of 2 brainstorming sessions (max. group n=6 in each, 60-90 mins each) to account for work schedules.

2.2a Establish Patient and PIP experience goals: Feedback Session

All participants of [**2.1a**] (max. n=12) will be invited to attend the feedback session (approx. 60 mins), where the researcher will present the experience goals gathered from the brainstorming activities for verification or discussion. By the end of this session the patient and PIP group should be agreed on a final set of experience goals to take forward to guide the co-design sessions and to act as a set of evaluation criteria during Phase 3.

2.2b Establish staff experience goals: Feedback Session

Repeat of 2.2a with all participants from [**2.1b**] (approx. 60 mins, max. n=12). Results of this session will also be emailed to interested staff members (this is not offered to patient and PIP participants, as they will not own a professional email address, i.e. through the NHS, Spinal Injuries Scotland or The BackUp Trust).

2.3 – 2.5 Co-design sessions

Patients (n=3-6), PIP's (n=3-6), SIU staff (n=6-12) and SCI-related charity volunteers (n=3) will be brought together in co-design workshops (n≈3, approx. 60-90 mins each). The group will use goals from [**2.2a**] and [**2.2b**] as a guide to 'what we want', whilst the analysis from the questionnaires, GPM maps, and previous ethnographic notes will be used as tools to access and work with 'what is' from multiple perspectives. We will build rough paper models of ideas (prototypes) and develop them in quick iterations to address the gaps between 'what is' and 'what we want'. Methods such as 'scenarios', 'design games' and 'storyboarding' will aid the co-design process (see references in section 6a). By the end of these 3 workshops, the group will aim to have chosen a prototype intervention (such as a new material to be used in the GPM, a different meeting agenda, etc) to take forward to be tested and developed in mock use situations.

2.6 Prototype development workshops

3 patients from activities [**2.3-2.5**] will be invited to individually 'act out' a GPM (each patient committing to a single session of approx. 60 - 90 mins) with their PIP (n=3) and/or Rehabilitation Team (max. total n=21, n≈7 in each Rehabilitation Team) using the co-designed prototypes, with input from the researcher to develop the prototypes in use (see references in section 6a). Participants and the researcher will develop the prototypes into a new protocol to be tested, possibly supported by physical/digital materials. University staff may be consulted for technical advice. If more than 3 patients volunteer to continue into

activity [**2.6**], selection will be based on involving as wide a participant sample as possible (selection criteria of profession of patient's key worker, level of injury, whether the injury is complete/incomplete, gender and age).

Qualitative observational notes will be taken throughout the activities in Phase 2, focused on the benefits and limitations of using these methods with these groups. These notes will be thematically analysed using NVivo, as described in section 7, and used to inform the thesis discussion.

Experiential knowledge will also be embedded into the changes made to prototypes in each iteration at each stage. Although this will not be used to inform Phase 3, it will be discussed in the researcher's PhD thesis.

Sessions in 2.4 will be audio recorded, to reinforce the researcher's handwritten notes in the event that she is needed to make adjustments to the prototype in use.

Following the activities in 2.4, the researcher and participants aim to have co-created a material/protocol to be introduced into the rehabilitation pathway of patients. The researcher will make any necessary changes to format or content of the material/protocol (if suggested by participants) if time/resources do not allow this during the prototype development workshops, before moving on to Phase 3.

Phase 3: Implementation and Evaluation
3 SIU patients (and their associated PIP's) who have not been involved in the study to date, and who have not yet begun the GPM process, will be invited to use the co-designed material/protocol in place of the standard GPM process, for at least 2 monthly meetings (approx. 25-90 mins each, approx. 4-5 weeks apart).

3.1 Training
Prior to the meeting, the researcher will meet with the patients' Rehabilitation Team (max. n=21, as each Rehabilitation Team may have 7 members, however some staff members may be involved in more than one patient's Rehabilitation Team) to discuss the use of the material/protocol and provide training if necessary (approx. 30 mins).

3.2 - 3.3 Observing intervention in use
2 consecutive meetings (4-5 weeks apart) of each patient using the co-designed intervention (approx. 25-90 mins each) will be observed and 'mapped' as in [**1.1**]

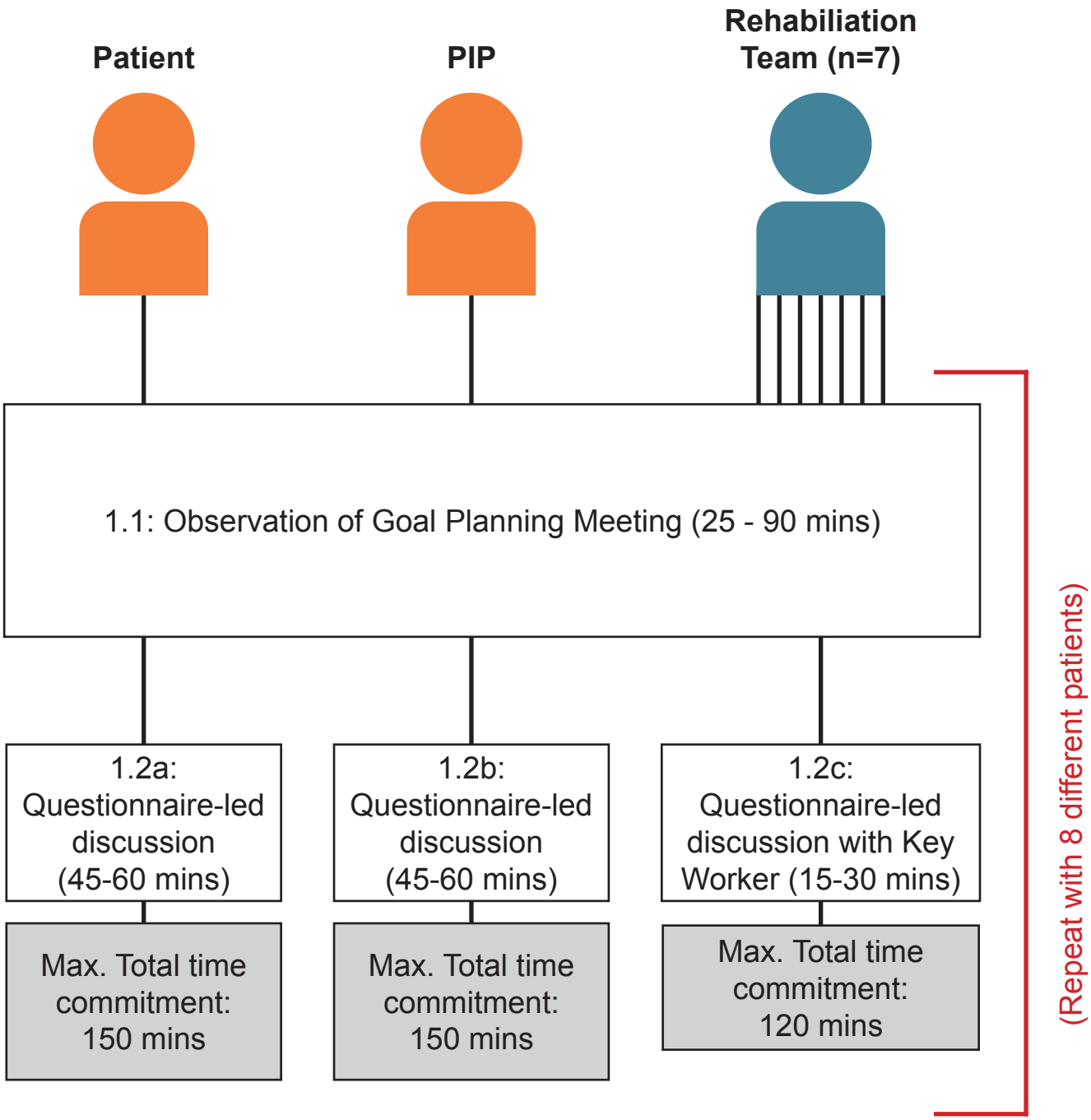
3.4a Evaluation questionnaire-led discussion: Patient
After each patient's second meeting, the patient (n=3) will be invited to an individual questionnaire-led discussion (approx. 45-75 mins), using a similar questionnaire framework to that used in [**1.2a**] (see appendix G). This activity will be audio recorded and open-ended questions will be transcribed verbatim.

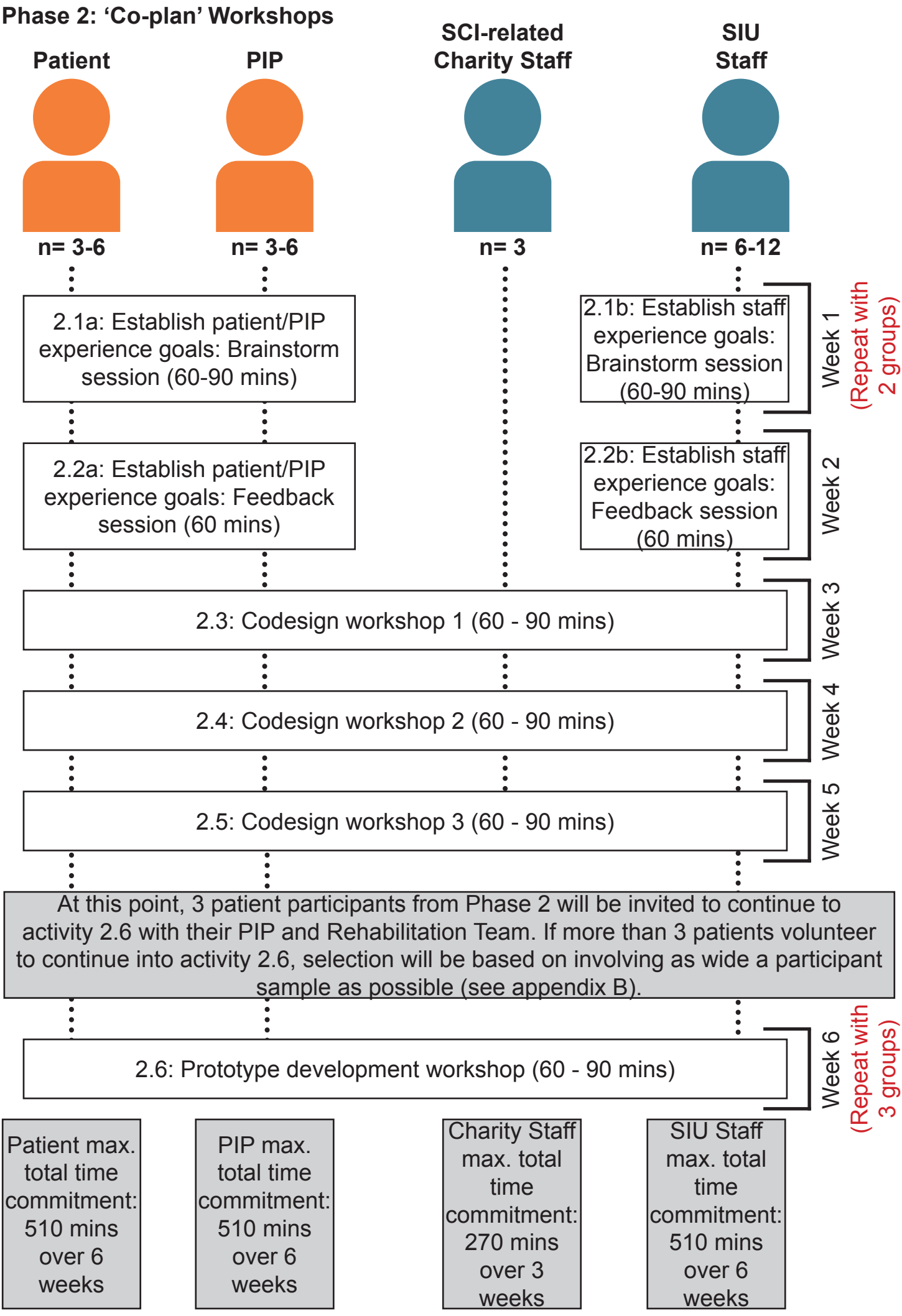
3.4b Evaluation questionnaire-led discussion: PIP
After each patient's second meeting, the PIP (n=3) will be invited to an individual questionnaire-led discussion (approx. 45-75 mins), using a similar questionnaire framework to that used in [**1.2b**] (see appendix H). This activity will be audio recorded and open-ended questions will be transcribed verbatim.

3.4c Evaluation interview: Key Worker and staff member
After each patient's second meeting, the key worker and one other staff member from each meeting (total n=6) will be invited in pairs to a semi-structured interview (total of 3 interviews, approx. 60-90 mins each). This interview will begin with a questionnaire-led discussion guided by a framework similar to that used in activity 1.2c, then move on to more open questions. See appendix I for a questionnaire framework and draft interview topic guide (may be subject to change following work conducted during the study). This activity will be audio recorded and open-ended questions will be transcribed verbatim.

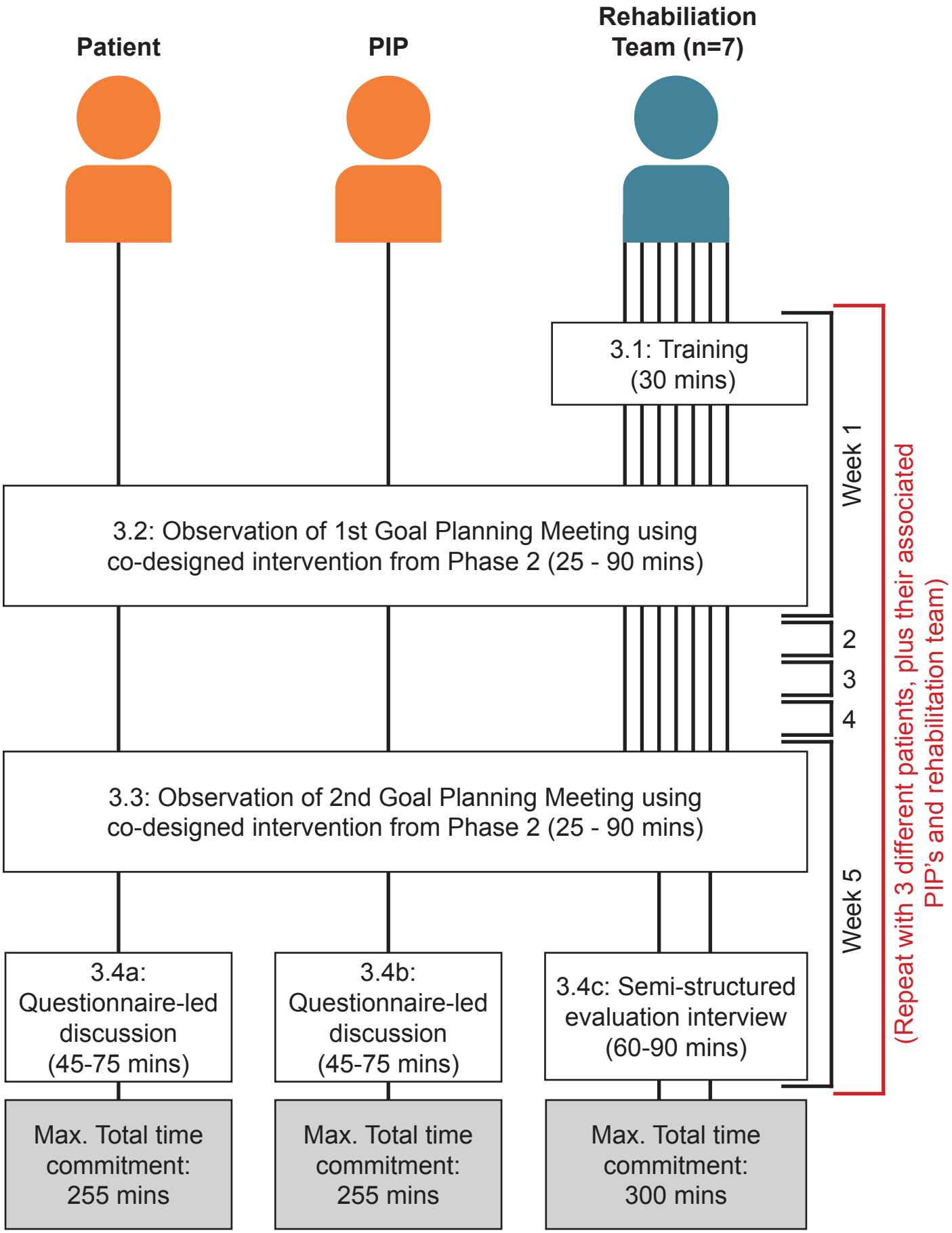
Phase 3 analysis: NVivo coding and statistical analysis of survey and interview data. Comparison of findings from initial and evaluation surveys, plus visual comparison of 'GPM maps' (from [**1.1**], [**3.2**] and [**3.3**]) will be used to establish and compare the observed behaviours and reported experiences of the GPM before and after intervention, and any changes therein, with a particular focus on the perceived patient and/or PIP participation within the GPM.

Appendix C
Study Plan Diagram
Phase 1: Review of current Goal Planning Meeting (GPM) behaviours/protocols




Phase 2: 'Co-plan' Workshops
Patient
PIP
SCI-related Charity Staff
SIU Staff
n= 3-6
n= 3-6
n= 3
n= 6-12
2.1a: Establish patient/PIP experience goals: Brainstorm session (60-90 mins)
2.1b: Establish staff experience goals: Brainstorm session (60-90 mins)
Week 1
(Repeat with 2 groups)
2.2a: Establish patient/PIP experience goals: Feedback session (60 mins)
2.2b: Establish staff experience goals: Feedback session (60 mins)
Week 2
2.3: Codesign workshop 1 (60 - 90 mins)
Week 3
2.4: Codesign workshop 2 (60 - 90 mins)
Week 4
2.5: Codesign workshop 3 (60 - 90 mins)
Week 5
At this point, 3 patient participants from Phase 2 will be invited to continue to activity 2.6 with their PIP and Rehabilitation Team. If more than 3 patients volunteer to continue into activity 2.6, selection will be based on involving as wide a participant sample as possible (see appendix B).
2.6: Prototype development workshop (60 - 90 mins)
Week 6
(Repeat with 3 groups)
Patient max. total time commitment: 510 mins over 6 weeks
PIP max. total time commitment: 510 mins over 6 weeks
Charity Staff max. total time commitment: 270 mins over 3 weeks
SIU Staff max. total time commitment: 510 mins over 6 weeks

Phase 3: Implementation and Evaluation



Acute Services Division

Regional Services Directorate

Southern General Hospital
1345 Govan Road
Glasgow G51 4TF
☎ 0141 201 [redacted]
🖷 0141 201 [redacted]

NHS
Greater Glasgow and Clyde

Queen Elizabeth
National Spinal Injuries Unit for Scotland

Administrative Enquiries to:- 0141 201 [redacted]
Direct Fax No. 0141 201 [redacted]

Email: [redacted]@ggc.scot.nhs.uk

Direct line: ** 0141 201 [redacted]
Liaison Sisters: 0141 201 [redacted]
Out-patient Clinic: 0141 201 [redacted]

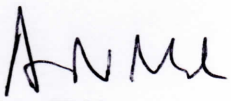
Our ref: AMcL/JI/
Date: 8th June 2015

Gemma Wheeler
PhD Candidate
The Glasgow School of Art
167 Renfrew Street
Glasgow
G3 6RQ

TO WHOM IT MAY CONCERN

I confirm that we are delighted to welcome Miss Wheeler as a Collaborative Researcher at the National Spinal Injuries Unit. As Head of Service, I give permission for her to use the location for her PhD studies.

Yours sincerely,



Dr A N McLean FRCP
Lead Clinician in Spinal Injuries
Queen Elizabeth National Spinal Injury Unit for Scotland

Dr M Purcell , Consultant in Spinal Injury

THE GLASGOW SCHOOL OF ART

14th July 2015

Dr Alison Hay;
[redacted]@gsa.ac.uk;
0141 566 [redacted]

Ethics Approval: Using design methods to explore and enhance patient participation within spinal cord injury rehabilitation

To Whom It May Concern;

Ms Gemma Wheeler is currently enrolled at The Glasgow School of Art as a doctoral candidate within the School of Design, under the supervision of Professor Alastair Macdonald. Her project is funded by the Arts and Humanities Research Council (AHRC, AH/L002906/1) as part of their Collaborative Doctoral Award (CDA) scheme.

The Glasgow School of Art places a great deal of importance on rigourous research which is conducted with both integrity and in an ethical manner. To that end we have a GSA Research Ethics Policy which doctoral students and research staff must comply with, a copy of this policy can be found here:

http://www.gsa.ac.uk/media/497492/gsa_research_ethics_policy.pdf

The research work planned and designed by Gemma must therefore comply with our research ethics policy, particularly as it concerns working with patients in receipt of on-going treatment. As this is a service intervention and not a clinical one, we are not required to go through the NHS research ethics service for clearance and so, our institutional GSA Research Ethics Policy prevails. Gemma has complied with all aspects of the policy, she applied for research clearance and she satisfied the requirements of the GSA Research Ethics Sub Committee. We are satisfied that her project meets our standards and she is cleared to begin work at her earliest convenience.

If you have any questions on the research ethics of this work, please do get in touch, contact details given within.

Yours sincerely,

Dr Alison Hay
RESEARCH DEVELOPER

PROF. TOM INNS
BEng(Hons) DIC MDes(RCA) PhD FRSA
Director

167 Renfrew Street
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United Kingdom
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www.gsa.ac.uk

Form 2: Full ethical approval form

Participants in non clinical setting

Please complete all sections unless instructed otherwise by your Research Developer. Questions highlighted in **bold** and *italicised* are particularly important and answers must be detailed or there will be a delay in obtaining ethical approval.

Upon completion, please email or send in internal mail for the attention of the Research Developer [redacted]@gsa.ac.uk). Your application will then be discussed at the next meeting of the GSA Research Ethics Committee and a decision will be communicated back to the applicant.

1. APPLICANT DETAILS

Name of researcher (Applicant):	Gemma Wheeler
School:	The School of Design
Project Title:	Using design methods to explore and enhance patient participation within spinal cord injury rehabilitation
Funder:	Arts and Humanities Research Council
Project Reference Code:	

2. RECRUITMENT

a)

Number of participants required:	**(Please see appendices B and C for full details of each activity)** **Please note: Participants from Phase 1 will be invited to continue their involvement into Phase 2, but this will not be mandatory. Participants will be able to take part in Phase 2 equally, whether they were involved in Phase 1 or not.** **Phase 1: Review of current Goal Planning Meeting (GPM) Procedures** *Activity 1.1: Visual mapping of GPM:* • Patients = 8 • PIP's = max. 8 • Rehabilitation Teams (consisting of 2 – 7 hospital staff members, depending on availability to attend the meeting) = 8 *Activity 1.2a: Questionnaire-led discussion* • Patients = 8 *Activity 1.2b: Questionnaire-led discussion* • Person(s) Important to the Patient (PIP) (may include spouse, family member, friend, legal advisor) = max. 8 (a PIP does not need to be present for the GPM to take place, so total number may be less.) *Activity 1.2c: Questionnaire-led discussion* • SIU staff n=8 **Phase 2: 'Co-Plan' workshops ('Co-plan' being the**

	name for this project within the SIU) *Activity 2.1a, 2.2a: Establishing Patient/PIP priorities* • Patients = minimum of 3, maximum of 6 (fatigue and illness may contribute to a high drop-out rate) • PIP's = minimum of 3, maximum of 6 *Activity 2.1b, 2.2b: Establishing staff priorities* • Spinal Injury Unit (SIU) staff members = minimum 6, however more staff members will be invited (maximum = 12) *Activity 2.3-2.5: Co-design workshops* • Patients = 3-6 • PIP's = 3-6 • Staff = 6-12 • Spinal Cord Injury (SCI) – related charity workers = 3 *Activity 2.6: Prototype development workshops* • Patients = 3 • PIP's = 3 • SIU staff = max. 21 (using each patient's Rehabilitation Team, which may have 7 members each, however some staff members may be involved in more than one patient's Rehabilitation Team) **Please note: Participants in Phase 3 will be new to the study, and will not have been involved in Phase 1 or Phase 2.** **Phase 3: Implementation and evaluation** • Patients = 3 • PIP's = 3 • SIU staff = max. 21 (as in 2.4 above)
Will recruitment be direct (led by the researcher) or indirect (led by an organisation / third party)?	DIRECT (in case of staff and volunteer organisations) and INDIRECT (in case of patients and PIP's)

b) If your study involves INDIRECT recruitment, please detail the recruitment plan covering: i) organisation / institution / individual in charge of identifying possible participants; ii) how they will recruit individuals (letters, phone calls etc); iii) any individual who has direct contact with participants; iv) any ethical protocols the third party has in place; v) level of permission that third party has to disseminate information on behalf of the participants (append any documents if necessary)

i) The co-supervisor of this PhD project, Dr Mariel Purcell, is a Consultant in Spinal Injuries at The Queen Elizabeth National Spinal Injury Unit (QENSIU), Southern General Hospital, Glasgow (the partner institution in this Collaborative Doctoral Award). Dr Purcell will act as a gatekeeper in this study, identifying possible participants from the inpatient population.

ii) [Please note, each phase of the study has tailored information letters and consent forms, please see appendices L-Y.]

Dr Purcell will initially identify and approach possible patient participants on her own, giving a brief overview of the project before asking permission to introduce the patient to the researcher. If permission is granted, Dr Purcell will introduce the patient to the researcher to discuss the project further and provide an information letter and copy of the study consent form to review in their own time. The researcher and the patient will arrange a time to meet again at the patient's convenience (3 working days), with details on how to contact the

researcher or her supervisory team beforehand if necessary. In the second meeting the researcher will answer any questions the patient may have about the study. If the patient agrees to take part in the study, the researcher and the patient will sign the consent forms together (a witness may be recruited from the hospital staff to sign on behalf of the patient if necessary, as the patient may have limited dexterity), leaving one copy with the patient and one for the researcher. A photocopy of the completed consent form will be left in the patient's medical notes, with contact details of the researcher to discuss this further if necessary. The patient will be given a letter with details on when and where they will meet with the researcher again.

PIP's will be recruited via introduction by the patient. As above, PIP's will be given an information letter, a copy of the appropriate consent forms and 3 working days to decide whether they wish to participate. Experience in the host SIU suggests that some PIP's of patients who do not wish to participate may hear about the project through word of mouth in communal areas. If PIP's in this situation approach the researcher (either directly or through staff introduction), they will be welcome to participate providing the patient they visit is comfortable with their PIP's involvement in the study.

iii) Other than the staff population that patients and PIP's will normally be in contact with, the named researcher, Gemma Wheeler, will have direct access to participants.

c) If your study involves DIRECT recruitment (i.e led by the applicant / research team):

Who is in charge of recruitment:

Gemma Wheeler, with assistance from the Gatekeeper, Dr Mariel Purcell.

What is the method of identifying participants:

The contextual review informing this study involved working with a large number of staff from the host spinal injury unit and with SCI-related charities (Spinal Injuries Scotland (SIS) and The BackUp Trust). As such, the researcher has established a key working group amongst senior staff. Invitation to participate will be extended to this group initially, whilst encouraging them to extend this invitation to their colleagues.

How will participants be invited to take part: (e.g. letters, phonecalls, door to door):

Email – As discussed above, the researcher has the means to contact many potential professional participants directly by email due to previous work in the host SIU.

In addition to this, the researcher aims to create a project mailing list to keep staff informed of progress and opportunities to take part in the study. Posters inviting staff to join this mailing list will be displayed in staff-only areas (such as staff offices and staff kitchen areas).

Due to the researcher's permanent office in the host spinal injury unit, key senior staff members can also be approached in person to extend the invitation further or to answer any questions about the project.

Regardless of method of contact, all participants will be given an information letter, a copy of the consent form that they will complete if they wish to take part and 3 working days to decide if they choose to do so.

d) Regardless of method of recruitment, what is your exclusion / inclusion criteria for this study:

Patients:

- Clinical diagnosis of having sustained a spinal cord injury (e.g. due to trauma, infection, stroke, etc.)

- Currently involved in post-acute rehabilitation in QENSIU
- Of either gender
- Age ≥ 16
- Have English as their first language
- Be able to give informed consent for themselves, with a witness to sign on behalf of the patient if necessary.

Please note: The level of injury, whether the injury is complete/incomplete and the patient's home town will be recorded but will not necessarily dictate inclusion or exclusion in the study. Although the range of participants may be dictated by the inpatient population at the time of this study, the researcher aims to reflect the typical patient population in the host SIU. According to a recent study within the host SIU (pending publication), the ratio of men:women is approximately 4:1 and approximately 75% of patients have tetraplegic injuries (affecting motion and/or sensation in all four limbs).

PIP's:

- Have involvement with a current patient within the QENSIU rehabilitation ward
- Of either gender
- Have English as their first language
- Be able to give informed consent for themselves

QENSIU, SIS and BackUp professionals:

- Have involvement with the patient community of the QENSIU rehabilitation ward
- Have English as their first language
- Be able to give informed consent for themselves

Please note: This study aims is to gather a group of QENSIU staff that is representative of the various departments involved in SCI rehabilitation, including nursing, physiotherapy, occupational therapy, psychology and staff relating to discharge/outpatients. Consultant staff will be invited but may be prevented from doing so due to high workloads.

In all cases, append a copy of i) information sheet for participants; ii) consent form; iii) copies of any other documents distributed to participants
Please see appendices L-Y.

3. CONSENT

a) Give a detailed account of the steps taken by the researcher to obtain informed consent from the participants (regardless of method of recruitment):

As described in section 2, all participants will be given an information letter about the study and a copy of the consent form following initial contact with the researcher. The information letter will describe the background to the study, the aims of the study and what the participant will be asked to do, plus how information will be recorded and stored. The letter will emphasise the participant's right to withdraw participation and/or information recorded about them at any time.

Each participant will be offered 3 working days to consider their invitation to take part, and given contact details of the researcher should they wish to ask any questions about the study during this time. The researcher and participant will arrange a mutually suitable time to meet again after the 3 working days.

The second meeting between the researcher and participant will provide another opportunity to answer any questions about the study and the participant's involvement in it. If the participant agrees to take part in the study, two copies of the consent form will be completed together (with a witness to sign on behalf of the patient if necessary). One copy will be left with the patient and one will be kept for the researcher's records. A photocopy of the completed consent form will be left in the patient's medical notes, with contact details of the researcher to discuss this further if necessary.

b) How will researchers ensure the participant has capacity to consent:

Patients who are unable to give informed consent are identified by the host SIU and do not go through the Goal Planning process that this study is investigating. As such, the researcher will liaise with the gatekeeper to ensure only appropriate patients are invited to participate.

PIP's who are involved in the Goal Planning process may do so for several reasons, commonly to ask questions, provide advice, support the patient or to prepare for their care-giving role post-discharge. As such, it is almost certain that they will have the capacity to give informed consent, although this will also be verified by liaising with the gatekeeper.

QENSIU and charity staff are recruited through their professional affiliation with the host SIU, and as such are able to give informed consent.

c) If your work requires participants belonging to vulnerable groups (children under 16, adults unable to give consent, prisoners, individuals in dual relationships), what additional steps will be taken to gain consent:

N/A

d) If your work requires the consent of a gatekeeper, please detail the steps you will take to ensure participants are not coerced by their gatekeeper. State also whether you plan to obtain additional signatures from participants and if not, why

The elected gatekeeper, Dr Mariel Purcell, has carried out this role in several clinical research projects within the host SIU over recent years and as such has experience in ethical conduct. She is fully aware of what her role involves and as a resident consultant in spinal injuries her main priority is the welfare of the patient community. As Dr Purcell is also the researcher's co-supervisor, she shares responsibility in ensuring all aspects of this study are conducted appropriately. Prior to her identifying and approaching any potential patient participants, the researcher will provide Dr Purcell with a brief overview of what will be asked of each participant in each activity, so that patients can be informed without being coerced.

The researcher will also ask each patient participant not to coerce their PIP when inviting them to participate in the study.

Each information letter will emphasise that participation in this study is completely optional.

The researcher will not be collecting any additional signatures other than in the consent forms discussed above, as all participants will be made aware at this point that they are free to withdraw their participation and contributions at any time without any negative effect to themselves.

e)

How much time will be given for the participant to decide whether or not to take part:	3 working days from their first meeting with/invitation from the researcher.

By what method will you seek to obtain consent (written, oral, video etc) and why: NB: please be aware of any Data Protection issues here	Participants will be asked to print their name, sign their name and provide the date on two copies of the study consent form. A witness will be recruited from QENSIU staff to sign on behalf of the participant if necessary (for example, due to limited dexterity resulting from a spinal cord injury). Written consent has been chosen as this allows participants to review the consent form in advance of agreeing to participate (or not). It is also a formal, standardised method of obtaining consent that is understood and upheld within the clinical context of the SIU.
Will copies of consent be given to participants:	YES
For how long will the copies of consent be retained by the researcher and where will the consent form be stored:	A photocopy of the completed consent form will be left in the patient's medical notes for the duration of the study, stored securely according to QENSIU policy. This consent form will remain in the patient's medical records permanently, but no participant data from this study will be stored alongside it. The researcher will securely store the signed consent forms for the duration of the study securely on NHS premises. Upon completion of the study, the consent forms will be stored by The Glasgow School of Art for a period of 10 years, according to institutional policy, after which they will be destroyed.

4. LOCATION

a) If the research activities take place in a third party location (i.e. not on GSA premises), please explain the choice with reference to the study. Append confirmation of permission to use location given by the owner and confirm that all researchers have been made aware of any local rules and regulations (append if necessary).

Research activities will take place within the host spinal injury unit to minimize impact on staff workload and to ensure the safety of patient participants. Given that all patient participants will be going through the rehabilitation process at the time of the study, it is important that they are able to return to their ward to rest at any time. It is also important to have access to clinical staff should patient participants feel unwell. The act of travelling to a study location outside of the spinal injury unit could be very problematic for some patient participants, and as such could lead to highly reduced rates of recruitment. The site of intervention (the Goal Planning Meeting) occurs in the SIU at regular intervals during a patient's rehabilitation stay, so conducting the study within the unit also has contextual significance. The host SIU is also a known location for participants who are recruited due to their relation to the patient or by their affiliation with SCI-related charities, and in both cases may not require any additional travel. Please see appendix K for the confirmation of permission to use the QENSIU location by Dr Alan McLean, Lead Clinician in Spinal Injuries and Head of Service at The Queen Elizabeth Nation Spinal Injury Unit for Scotland. The researcher has been made aware of any local rules and regulations.

b) If the research activities take place in the participants' home, please CLEARLY explain the choice with reference to the study and why no other location is possible. Detail all measures taken to minimise the risk to both participants and researchers entering the home.

N/A

5. INCENTIVES

a) Reasonable reimbursements for time and travel compensation are acceptable as incentives to participate in a research study. An acceptable level of reimbursement would be no more than £50 (approximately).

Do you plan any of the following:

Travel reimbursement only	NO
Small incentive only (e.g. gift voucher)	NO
Travel and small incentive	NO

b) If the incentive exceeds £50, please state the reasons why (note a large financial incentive, whilst appearing generous, could be deemed unethical on the grounds of coercion. See also, the Bribery Act 2010):

N/A

6. METHODOLOGY AND ACTIVITIES

a) Please state the methodology employed within the study and give references (literature or any previous work by the researcher) to support their use:

Prior to this study, an in-depth contextual review of the host SIU (conducted by the researcher over a period of 12 months) identified the Goal Planning Meeting (where a patient, their Rehabilitation Team and usually 1-2 People Important to the Patient meet regularly to review progress and set rehabilitation goals for the next few weeks) as a regular rehabilitation event that could be enhanced to support patient and/or PIP participation in collaborative decision-making.

This mixed methods study has three linked phases:

i) Phase 1 involves a review of the current Goal Planning Meeting (GPM) format. Aspects of phenomenography (Barnard et al., 1999) and experience-based design (Bate and Robert, 2007) will be used to inform the collection of patient, PIP and staff experiences, and their understanding of them, through survey-led discussions. Objective accounts of what happens in the GPM will be gathered through visual 'mapping' of the conversation between patients, PIP's and SIU staff. Both accounts will be used to inform the co-design workshops.

ii) Phase 2 involves a series of co-design workshops, bringing together patients, PIP's, SIU staff and SCI-related charity volunteers. Tools from the field of participatory design (Simonsen and Robertson, 2013, Sanders, Brandt and Binder, 2010, Brandt and Messeter, 2004) will be used to encourage democratic interaction between the groups, and to transform the information gathered in Phase 1 and insights from the medical literature (see Levack et al., 2006, for a review of the purposes and mechanisms of goal planning in rehabilitation) into tangible, equally accessible materials for the group to work with. Literature from Experience Goal-driven design (Wheeler et al, 2014) and Co-design (a field within participatory design, as described by Sanders and Stappers, 2008) will also inform the use of generative tools and techniques to guide participants to

co-develop the current GPM experience into their preferred experience. Iterative prototyping techniques (Coughlan et al., 2007) will facilitate the co-creation of the study intervention, such as a new material to be used in the GPM, a different meeting agenda, etc.

iii) Phase 3 involves the introduction of the co-designed material into the rehabilitation pathway of 3 patients, and the evaluation of its effects (if any).

b) For each activity employed please detail: i) its purpose; ii) direct correlation to the research outcomes; iii) how any analysis will be performed. **Copies of all material given to participants must be appended to this form wherever possible.**

ACTIVITY 1: (e.g. questionnaire, focus group, interview etc),

Please see appendices B and C for full details of research activities.

ACTIVITY 2: (e.g. questionnaire, focus group, interview etc),

Please see appendices B and C for full details of research activities.

If there are any further activities, please continue and append to this form.

c) State how harm, distress or anxiety to the participants will be minimised during the study

The following measures will be put into place to minimize risk of harm to participants:

- Initial introduction to patient participants facilitated by the gatekeeper.
- Ensuring all participants have read the information letter and consent form, have had the opportunity to ask questions and understand what their participation will involve, how data will be recorded and stored, how data will be used and how the data may be disseminated prior to giving consent.
- Conducting research activities with or in close proximity to SCI specialist healthcare staff.
- All participants and staff in the SIU (who will be conducting their normal duties in close proximity to the research activities) will be reminded to report any misconduct (by the researcher or by any of the participant group) to either:
  - The researcher's supervisory team, whose contact details can be found on the information letter given to each participant at the time of recruitment.
  - Dr Alan McLean, Lead Clinician in Spinal Injuries and Head of Service for QENSIU.
- For the patients, conducting research activities in close proximity to their wards,

should they need to take a break to rest.

- Patients will be visited earlier in the day when research activities are due to take place, to check they still feel well and motivated enough to take part. They will be given the option to postpone or cancel if they feel unwell or fatigued.
- SCI rehabilitation involves learning to manage all effects of the injury, including (but not limited to) mobility, skin care and bowel, bladder and sexual function. Clearly such topics can involve sensitive issues, but any discussions about these issues will be led by the patient(s) and not introduced by the researcher. Given her 1.5 years' experience in the host SIU, the researcher is able to discuss these issues in an informed and sensitive manner.
- Research activities that involve working with individual patients or PIPs (such as conducting surveys or collecting oral histories) will be conducted in the host SIU's conference room. This is a central location that provides privacy to speak candidly, but also has clear visibility by SIU staff due to many windows into the main corridor. As such, SIU staff are able to identify and report any misconduct if necessary.
- Participants will be offered the chance to review any data involving them or their contributions prior to its use in the study.
- Images generated by the participants (for example, during the co-design workshops) will be kept anonymous and not used for profit.
- Images including the participants will be altered to provide anonymity.
- All data will be anonymised and securely stored on NHS premises.

d) Please state the time commitment of the participants and whether you plan repetitive testing as part of the study

Phase 1: Max. 150 mins for patient and PIP participants, and max. 120 mins for SIU staff participants. However, each participant also will be informed of and invited to the co-design workshops at the end of their session.

All participants in Phase 2 will be invited to attend one or all of the planned sessions; if a participant choses to attend all of the sessions they are invited to, their maximum time commitment will be:
Patient participants: 510 mins over 6 weeks
PIP participants: 510 mins over 6 weeks
Charity Staff participants: 270 mins over 3 weeks
SIU Staff participants: 510 mins over 6 weeks

In Phase 3, over approximately 8 weeks, the maximum time commitment for patient and PIP participants is 345 mins, and maximum time commitment for staff participants is 450 mins. However, approx. 225 mins of each participant's time will be spent in existing rehabilitation activities that would occur without the presence of this study or its intervention. As such, the researcher will not be conducting repetitive testing as part of this study.

e) What is the statistical power of the study:

The majority of datasets gathered and used within this study will be qualitative in nature, and due to the limited time of the PhD format, this study does not it intend to be statistically representative. Efforts will be made to recruit groups of participants that are representative to the communities involved in the study, but actual recruited groups will be dictated by the finite inpatient population and/or staff availability at the time of recruitment.

If you plan to leave participants with information at the close of the study (e.g. leaflets with further information, details of support groups etc), please append to this form.
N/A

7. PARTICIPANT DATA

Participants in non clinical setting

All researchers must abide by the Data Protection Act 1998 and the GSA Data Protection Policy – it is the responsibility of the researcher to familiarise themselves with each.

Who is the custodian of the data:	**Gemma Wheeler**
Where will the data be stored:	**NHS and GSA premises**
Who has access to the data:	**Gemma Wheeler. Anonymised data will be accessible by primary supervisor Professor Alastair Macdonald and co-supervisor Dr Mariel Purcell.**
Will permission to identify the participants be sought as part of informed consent	NO – other than (with participants' permission) their age, gender and role as permission will also be asked to record the level of their spinal cord injury and whether their injury is 'complete' or 'incomplete'.
What methods will be undertaken to guarantee anonymity (e.g. coding, ID numbers, use of pseudonyms)	As this study focuses on the importance of different types of experience, each participant will be given an ID code that identifies their role but not their name, for example: Patients: Patient A, Patient B, Patient C, etc. PIP's: The PIP who attends by invitation of Patient A will be referred to as PIP A. QENSIU staff: Staff will be designated codes within their department, as follows: Nursing: Nurse A, Nurse B, etc. Physiotherapy: Physiotherapist A, Physiotherapist B, etc. Occupational Therapy: OT A, OT B, etc. Discharge Liaisons: Discharge Liaison A, Discharge Liaison B, etc. Chaplaincy: Chaplain A, Chaplain B, etc. QENSIU currently employs one Discharge Coordinator and one Clinical Psychologist, so they will be referred to as such without any additional letter designation. One member of the patient's rehabilitation team is also assigned to be their Key Worker. Key Workers will be invited to questionnaire-led discussions in activities [**1.2**] and [**3.5**], where both roles will be identified. For example, if a patient's Physiotherapist was also assigned to be their Key Worker, they would be designated the code 'K.W.Physiotherapist A', 'K.W.Physiotherapist B'. Related Charities: Spinal Injuries Scotland / The BackUp trust: Volunteer A, Volunteer B, etc. Although these designations could be perhaps shortened, it is felt that the full title will provide greater clarity in the thesis/reports generated from this study. Although a copy of the patient's consent form will be stored in their medical notes, no patient data will be stored alongside this.
How will the link be broken between participant details and	A paper-based document will link the designations to participants' names. 2 copies of this document will be

information given as part of study?	securely stored in a separate locked filing cabinet from the study data on QENSIU premises for the duration of the study, after which it will be destroyed. No information that can identify patients will leave QENSIU premises. Any data stored at GSA premises will be anonymised. All documents and study materials will be anonymised using the codes above.
How long will the data be stored for? (Participants must be made aware of this at point of consent).	All information will be held securely for a period of 10 years, as required by The Glasgow School of Art. However, any audio/video-recorded data gathered from participants during the study will be destroyed once the study is complete.
How will the security of the dataset in its entirety be secured?	All digital and physical files will be securely stored in locked drawers, in a locked office, in a locked research department within the host SIU. Digital files will be backed up regularly and password protected. The researcher will also lodge hard and password-protected digital copies with her primary supervisor, Professor Alastair Macdonald, who will store these files securely on GSA premises. Professor Alastair Macdonald must comply with the GSA Data Protection policy.
How will the data generated by analysed and used?	As described in section 6, each phase of the study aims to inform the next. As a mixed-methods study, the researcher will analyse a mixture of: • Quantitative data (from initial and evaluation surveys), using simple statistical analysis (i.e. percentage of patients giving particular fixed answers, etc) • Qualitative data (from surveys, observational notes and interviews), using thematic analysis in NVivo software, in a method similar to that described by Fereday et al. (2006) • Visual data (from Goal Planning Meeting 'maps') will be reviewed to identify 'design patterns' (Bate and Robert, 2007) but also given to the co-design workshop participants to create their own interpretations.
Who will have access to the data beyond the project (if the data is being retained, not destroyed)	The data will be held securely by the GSA for a period of 10 years. During this time, the researcher (Gemma Wheeler), her primary supervisor (Professor Alastair Macdonald, GSA) and her co-supervisor (Dr Mariel Purcell, QENSIU) will have access to the data. The IT department of The Glasgow School of Art will act as custodians of the data, who will be given instructions concerning anonymity and how the data can be used at the point of archiving the dataset.
Does the research funder require the participant data generated be lodged with them upon conclusion? If yes, give details	No.

8. SAFETY

All researchers must abide by the GSA Health and Safety Policy – it is the responsibility of the researcher to familiarise themselves with this.

a) How will the safety of the participants be ensured during this study?

All research activities will take place in non-clinical areas on a hospital site. This means that fully qualified staff will be present or close by in case of medical issues that may occur. The spaces themselves, being in a spinal injury unit, are designed with the needs and safety of patients in mind, and as such also pose little risk to PIP, staff or volunteer participants.

The materials used in the activities (such as paper, pens, scissors, IT equipment) also pose very little risk to safety. Medical equipment, other than the patient's own equipment, is not stored in the areas where research activities will take place.

b) If your work requires participants belonging to vulnerable groups (children under 16, adults unable to give consent, prisoners, individuals in dual relationships), what additional steps will be taken to ensure their safety:

N/A

c) If the study involves work on non-GSA premises, how will the safety of researchers working off site be ensured?

As this study is contributing to a Collaborative Doctoral Award between the GSA and QENSIU, the researcher has access her own office and access to her co-supervisor whilst on the premises. The research activities will take place in the SIU's conference room and 'Step Down Unit'; both are non-clinical spaces adjacent to the main rehabilitation ward. As such, the researcher will have constant and easy access to NHS staff at all times.

If activities must be arranged outside of normal working hours (i.e. 09.00-17.00) for the convenience of participants, the researcher will contact a family member via text message before and after the research activities take place, with an agreement of when to expect these messages and who to contact if they don't receive these confirmations. All activities, whether conducted inside or outside of normal working hours, will take place in non-clinical areas of a hospital site, and as such the researcher will be in close proximity to hospital staff at all times.

The supervisory team will be provided with details of the timing and location of all activities in advance, and be advised of their completion at the earliest opportunity.

The researcher has also familiarized herself with the Social Researcher Association's 'Code of Practice for the Safety of Social Researchers', and will adhere to the guidelines therein (please see appendix J).

9. DECLARATION

Please ensure you have answered all the questions herein and have appended the following documents:

Form 2: Full ethical approval form

THE GLASGOW SCHOOL OF ART

Participants in non clinical setting

Consent form YES Participant Information Sheet YES

Follow up information (N/A) Any other relevant documentation (please state): YES:

- Study overviews (text and diagrammatic formats)
- Questionnaire frameworks
- SRA Safety Code of Practice
- Letter granting permission to use NHS location

Please see appendix A, on the final page of this form, for full details of appendices.

I certify that the information contained in this application is accurate. I understand that should I commence research work in absence of ethical approval, such behaviour may be subject to disciplinary procedures.	
Name of Principal Investigator:	Gemma Wheeler
Signed:	G. Wheeler
Date:	30-06-15

Please email the completed form and associated documents to the Research Developer [redacted]@gsa.ac.uk).

Form 2: Full ethical approval form

Participants in non clinical setting

For office use only:

Approved (Convenor of Research Ethics Committee) YES / NO	Declined (Convenor of Research Ethics Committee) YES / NO
Signature:	
Comments?	

Approved (Member of Research Ethics Committee) YES / NO	Declined (Member of Research Ethics Committee) YES / NO
Signature:	
Comments?	

Appendices List of Contents

Appendix A: Bibliography

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Appendix B: Overview of study plan.

Phase 1: Review of current Goal Planning Meeting (GPM) behaviours/protocols

1.1 Visual mapping of GPM

8 x GPM's (typically 25-90 mins) of different patients will be observed and audio recorded. Handwritten notes will be taken of behaviours that cannot be captured by audio (for example, when and how staff refer to their own records). Verbal interactions will be 'mapped' from the audio recording using Microsoft Excel (using 'topics discussed' along the y axis, 'time' along the x axis and different colours to denote who is speaking) - creating a visual, objective account of what happens in the GPM. The researcher will review these visual 'GPM maps' alongside qualitative notes to establish patterns of behaviour and the potential influence(s) of current GPM materials (such as the patient records). The 'GPM maps' and the researcher's interpretations will be used to inform the co-design workshops.

1.2a – 1.2c Initial Questionnaire-led Discussion

Individual, questionnaire-led discussions with the patient, the Person Important to the Patient (PIP) and the staff Key Worker (leader of the patient's rehabilitation team) from each observed GPM in activity 1.1 (patient n= 8, max. PIP n=8, staff n=8). The questionnaire framework contains both open-ended questions and Likert-scale evaluations, as shown in appendices D-F. The activity will take approx. 45-60 mins for patient and PIP participants, and approx. 15-30 mins for Key Worker participants. The researcher will complete the questionnaire with patients, PIP's and staff individually, as soon after the GPM as possible. Order of priority to do this will be PIP>Patient>Key worker, as many PIP's may have to leave the hospital site soon after the GPM. Where more than 1 PIP is present (the current GPM format accommodates 1-2 PIP's), the researcher will allow them to decide if they would both like to complete the activity together, or if 1 of the 2 will act as a spokesperson (only 1 PIP questionnaire-led discussion will take place). To avoid participants feeling that they are being 'tested' (given that the researcher will be asking questions about events she has just observed), they will be reminded that the purpose of this activity is to gather their experience of the event, and as such their answers cannot be wrong. The researcher will act as scribe using the questionnaire framework with all participants, to support those who may have limited dexterity and to give additional guidance with non-traditional question formats, if necessary. This session will be audio recorded for reference (to clarify handwritten notes, if necessary). Statistical analysis and NVivo coding will be used to establish patient and PIP 'types' and to identify common bridges or barriers to participation. Information collected in this activity will be used to inform the co-design workshops (see Phase 2).

An anonymised copy of the notes taken throughout activities 1.2 will be provided for the participants to verify the discussion has been recorded accurately (and to suggest changes if necessary). This will be sent via email for staff participants, and a hard copy provided for patient and PIP participants, if they wish. Participants will be reminded that they are responsible for the safe storage of these notes.

After activities 1.1 and 1.2, the researcher will have gathered objective (from the visual mapping) and subjective (from patient and PIP questionnaire-led discussions) accounts of 8 GPM's. Both accounts will be compared and contrasted by the researcher, and considered alongside subjective accounts from SIU staff during the contextual review (prior to this study) to inform Phase 2.

Phase 2: 'Co-Plan' workshops ('Co-plan' being the name for this project within the SIU)

Please note: Participants will be recruited on the understanding that they are welcome at any and all of the sessions outlined in phase 2, but are also welcome to vary their attendance as their health, fatigue or schedule allows. As participant attrition is a potential problem within this stage of the study, the researcher will take the following steps (all of which will take place on hospital premises) to minimize the risk posed to successful data collection:

- Allocate sufficient time with individual participants during recruitment to answer any questions participants may have and to build working relationships.
- Meet with each patient, and where possible, PIP participant 2-3 days before each workshop to remind them of the date, time and content of the upcoming session.
- Email SIU and charity staff 2-3 days before each workshop to remind them of the date, time and content of the upcoming session.

- Meet with each patient, and where possible, PIP participant on the day of each workshop to enquire into their wellbeing and willingness to attend the day's session.
- Keep in contact with the gatekeeper, and be prepared to recruit further patient and/or PIP participants throughout Phase 2, if necessary.
- Although each workshop will inform the next, each session will be planned to work as a stand-alone activity.
- Develop a different plan for each workshop if the maximum or minimum number of participants attend, and deliver it accordingly on the day to provide the best participant experience.

The activities throughout Phase 2 are planned as follows:

2.1a Establish Patient and PIP experience goals: Brainstorming Session

Patients (minimum n=3, maximum n=6) and PIP's (minimum n=3, maximum n=6) will be invited to attend 1 of 2 brainstorming sessions to establish their priorities, aims and intended experience of a new GPM format. Two opportunities to attend are provided to account for Patient and PIP rehabilitation/work schedules, however each participant will only attend one Brainstorming Session (60-90 mins each). Handwritten notes of the key discussion points will be taken by the researcher, and verified at the end of each session by reading them back to the group. Observed differences of opinion of what the GPM should achieve will be translated into an 'either/or' card game (details available on request). The aim of these sessions is to identify differences in opinion in the patient and PIP community on the role of the GPM, and discuss these together until the group reaches a consensus on what the new GPM experience goals should be. After both brainstorming sessions, the researcher will consolidate all of the points made into a single, cohesive list of goals, with notes of any points that still need to be resolved.

2.1b Establish staff experience goals: Brainstorming Session

Repeat of 2.1a with QENSIU staff (minimum n=6, maximum n=12). As above, staff members will be invited to attend 1 of 2 brainstorming sessions (max. group n=6 in each, 60-90 mins each) to account for work schedules.

2.2a Establish Patient and PIP experience goals: Feedback Session

All participants of [**2.1a**] (max. n=12) will be invited to attend the feedback session (approx. 60 mins), where the researcher will present the experience goals gathered from the brainstorming activities for verification or discussion. By the end of this session the patient and PIP group should be agreed on a final set of experience goals to take forward to guide the co-design sessions and to act as a set of evaluation criteria during Phase 3.

2.2b Establish staff experience goals: Feedback Session

Repeat of 2.2a with all participants from [**2.1b**] (approx. 60 mins, max. n=12). Results of this session will also be emailed to interested staff members (this is not offered to patient and PIP participants, as they will not own a professional email address, i.e. through the NHS, Spinal Injuries Scotland or The BackUp Trust).

2.3 – 2.5 Co-design sessions

Patients (n=3-6), PIP's (n=3-6), SIU staff (n=6-12) and SCI-related charity volunteers (n=3) will be brought together in co-design workshops (n≈3, approx. 60-90 mins each). The group will use goals from [**2.2a**] and [**2.2b**] as a guide to 'what we want', whilst the analysis from the questionnaires, GPM maps, and previous ethnographic notes will be used as tools to access and work with 'what is' from multiple perspectives. We will build rough paper models of ideas (prototypes) and develop them in quick iterations to address the gaps between 'what is' and 'what we want'. Methods such as 'scenarios', 'design games' and 'storyboarding' will aid the co-design process (see references in section 6a). By the end of these 3 workshops, the group will aim to have chosen a prototype intervention (such as a new material to be used in the GPM, a different meeting agenda, etc) to take forward to be tested and developed in mock use situations.

2.6 Prototype development workshops

3 patients from activities [**2.3-2.5**] will be invited to individually 'act out' a GPM (each patient committing to a single session of approx. 60 - 90 mins) with their PIP (n=3) and/or Rehabilitation Team (max. total n=21, n≈7 in each Rehabilitation Team) using the co-designed prototypes, with input from the researcher to develop the prototypes in use (see references in section 6a). Participants and the researcher will develop the prototypes into a new protocol to be tested, possibly supported by physical/digital materials. University staff may be consulted for technical advice. If more than 3 patients volunteer to continue into

activity [**2.6**], selection will be based on involving as wide a participant sample as possible (selection criteria of profession of patient's key worker, level of injury, whether the injury is complete/incomplete, gender and age).

Qualitative observational notes will be taken throughout the activities in Phase 2, focused on the benefits and limitations of using these methods with these groups. These notes will be thematically analysed using NVivo, as described in section 7, and used to inform the thesis discussion.

Experiential knowledge will also be embedded into the changes made to prototypes in each iteration at each stage. Although this will not be used to inform Phase 3, it will be discussed in the researcher's PhD thesis.

Sessions in 2.4 will be audio recorded, to reinforce the researcher's handwritten notes in the event that she is needed to make adjustments to the prototype in use.

Following the activities in 2.4, the researcher and participants aim to have co-created a material/protocol to be introduced into the rehabilitation pathway of patients. The researcher will make any necessary changes to format or content of the material/protocol (if suggested by participants) if time/resources do not allow this during the prototype development workshops, before moving on to Phase 3.

Phase 3: Implementation and Evaluation

3 SIU patients (and their associated PIP's) who have not been involved in the study to date, and who have not yet begun the GPM process, will be invited to use the co-designed material/protocol in place of the standard GPM process, for at least 2 monthly meetings (approx. 25-90 mins each, approx. 4-5 weeks apart).

3.1a Patient Given Information Booklet

The patient will be given a short (approx. 4 page) booklet which explains the generic stages of a rehabilitation journey through the Spinal Injury Unit and who is involved (content contributed and approved by senior SIU staff). The patient's Consultant will deliver this booklet to the patient when arranging a time for the 'Projection Meeting' (see 3.2).

3.1b Staff Training

Prior to the meeting, the researcher will meet with the patients' Rehabilitation Team (max. n=21, as each Rehabilitation Team may have 7 members, however some staff members may be involved in more than one patient's Rehabilitation Team) to discuss the use of the material/protocol and provide training if necessary (approx. 30-90 mins).

3.2 Projection Meeting

The patient and their Consultant will meet to discuss their spinal cord injury and its effects (approx. 30-45 mins). In the current rehabilitation model, this already happens informally in several smaller meetings, but the Projection Meeting will use new supporting documentation, hospital-owned 3D models of the spine and (where possible) scans/x-rays of the patient's injury to aid discussion. The patient may invite a family or friend to the meeting, and another staff member will also be present to act as scribe.

3.3 Semi-Structured Evaluation Interview with the Consultant

Due to the sensitive nature of the discussion in 3.2, the researcher will not be present. As such, the researcher will meet with the patient's consultant after the meeting to gather their thoughts on the meeting and the effectiveness of the supporting documentation (approx. 30-60 mins). This interview will be audio recorded and handwritten notes will be taken. GW will later transcribe this interview verbatim to inform the discussion and evaluation of the intervention.

3.4 Key Worker Meeting

The patient and their Key Worker will meet to discuss and set long-term goals for their rehabilitation, with supporting materials (approx. 30-45 mins). In the current rehabilitation model the patient and Key Worker already meet prior to beginning the Goal Planning Meetings (see 3.5 and 3.6), but this conversation is currently more focused on protocol-driven needs, rather than a more personalized, goal-focused conversation as suggested by GW. Again, GW will not attend this meeting for sensitivity, but will gather feedback on this from the Key Worker in 3.7c.

3.5 - 3.6 Observing intervention in use

2 consecutive Goal Planning Meetings (4-5 weeks apart) of each patient using the co-designed supporting materials (approx. 25-90 mins each) will be observed and 'mapped' as in [**1.1**]

3.4a Evaluation questionnaire-led discussion: Patient

After each patient's second meeting, the patient (n=3) will be invited to an individual questionnaire-led discussion (approx. 45-75 mins), using a similar questionnaire framework to that used in [**1.2a**] (see appendix G). This activity will be audio recorded and open-ended questions will be transcribed verbatim.

3.4b Evaluation questionnaire-led discussion: PIP

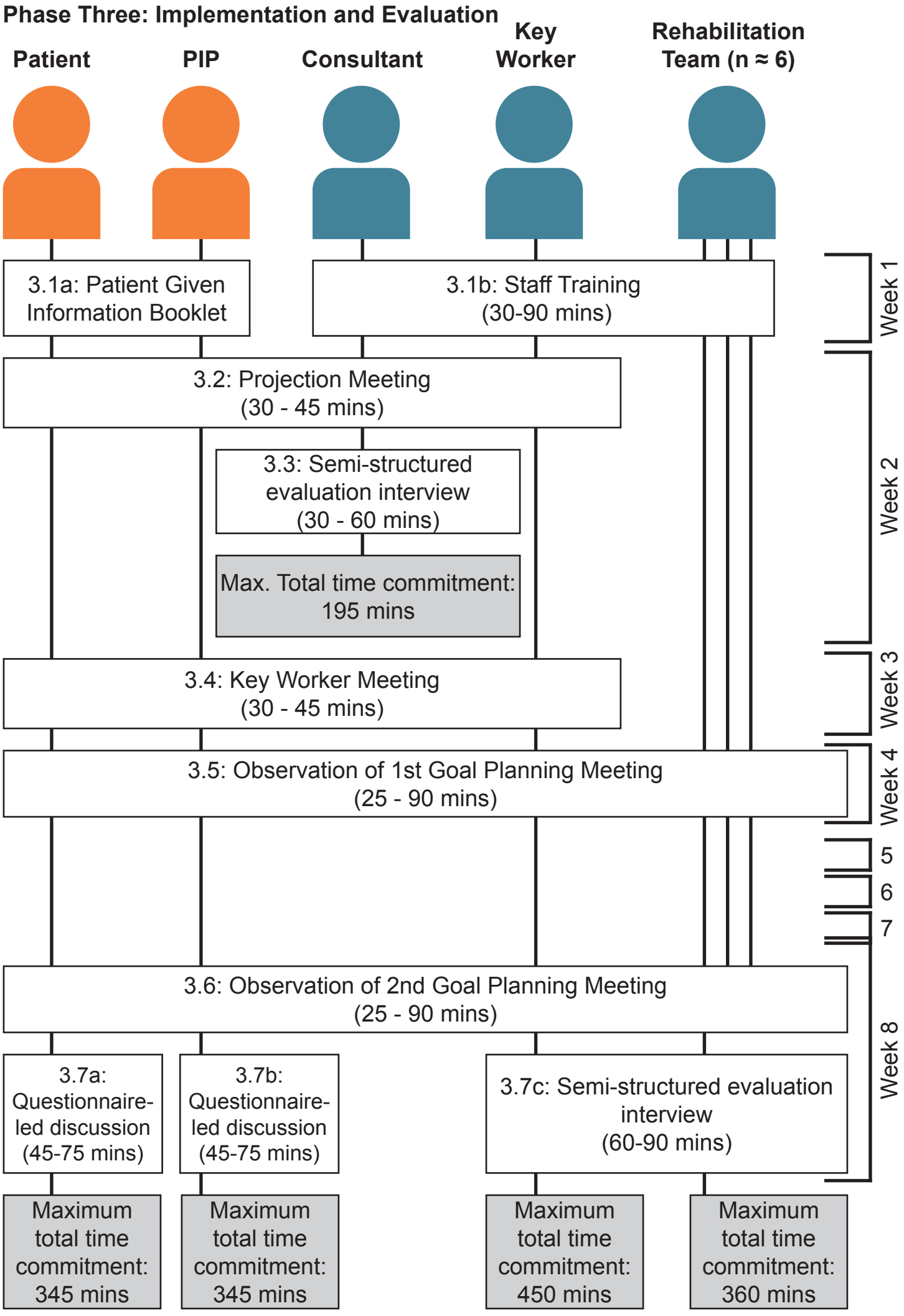
After each patient's second meeting, the PIP (n=3) will be invited to an individual questionnaire-led discussion (approx. 45-75 mins), using a similar questionnaire framework to that used in [**1.2b**] (see appendix H). This activity will be audio recorded and open-ended questions will be transcribed verbatim.

3.4c Evaluation interview: Key Worker and staff member

After each patient's second meeting, the key worker and one other staff member from each meeting (total n=6) will be invited in pairs to a semi-structured interview (total of 3 interviews, approx. 60-90 mins each). This interview will begin with a questionnaire-led discussion guided by a framework similar to that used in activity 1.2c, then move on to more open questions. See appendix I for a questionnaire framework and draft interview topic guide (may be subject to change following work conducted during the study). This activity will be audio recorded and open-ended questions will be transcribed verbatim.

NB: Stages 3.2 and 3.4 – 3.6 are existing rehabilitation events/stages, but conducted in a different way with additional supporting materials. As such, the total time commitment from each patient participant is not significantly greater than their normal rehabilitation routine had they not been a part of this study.

Phase 3 analysis: NVivo coding and statistical analysis of survey and interview data. Comparison of findings from initial and evaluation surveys, plus visual comparison of 'GPM maps' (from [**1.1**], [**3.5**] and [**3.6**]) will be used to establish and compare the observed behaviours and reported experiences of the GPM before and after intervention, and any changes therein, with a particular focus on the perceived patient and/or PIP participation within the GPM.


Phase Three: Implementation and Evaluation
Patient
PIP
Consultant
Key Worker
Rehabilitation Team (n ≈ 6)
3.1a: Patient Given Information Booklet
3.1b: Staff Training (30-90 mins)
3.2: Projection Meeting (30 - 45 mins)
3.3: Semi-structured evaluation interview (30 - 60 mins)
Max. Total time commitment: 195 mins
3.4: Key Worker Meeting (30 - 45 mins)
3.5: Observation of 1st Goal Planning Meeting (25 - 90 mins)
3.6: Observation of 2nd Goal Planning Meeting (25 - 90 mins)
3.7a: Questionnaire-led discussion (45-75 mins)
3.7b: Questionnaire-led discussion (45-75 mins)
3.7c: Semi-structured evaluation interview (60-90 mins)
Maximum total time commitment: 345 mins
Maximum total time commitment: 345 mins
Maximum total time commitment: 450 mins
Maximum total time commitment: 360 mins
Week 1
Week 2
Week 3
Week 4
5
6
7
Week 8

SCHOOL OF DESIGN
THE GLASGOW SCHOOL OF ART

Dear Sir/Madam,

Thank you for taking the time to read this information letter. Before you give your written consent to participate in the project, it is my duty to ensure you understand how your contributions will be used and the wider context of my study. Please feel free to contact me if you have any questions or if there is anything you would like to discuss.

Background information
I am working under the supervision of Professor Alastair Macdonald in the School of Design at The Glasgow School of Art. Professor Macdonald and several of his colleagues have a history of working within the healthcare context, and I am appreciative of the rare opportunity to work so closely with the QENSIU community.

I joined the research department at QENSIU in October 2013, and since then I have spent a lot of time with the staff, patients and their families to develop an understanding of how the many and varied roles within QENSIU work together to support a patient's development and how a spinal injury unit operates. I was able to share my observations with senior staff across the unit, and together we identified the Goal Planning Meeting as an opportunity to enhance the participation of patients and/or the people important to them.

I would like to invite patients, the people important to the patients, QENSIU staff and Spinal Injuries Scotland staff to work together to develop the Goal Planning process. We are calling this 'The Co-Plan Project,' and it will begin with a review of the current Goal Planning process.

Your Role
At this stage of the project, I would like to ask your permission to attend one of your Goal Planning Meetings as a passive observer. You will not need to do anything differently or interact with me in the meeting unless you choose to. After the meeting (perhaps later that day, or a time most convenient for you), I would like to invite you to a private, questionnaire-led discussion to learn about your thoughts and experiences. This should take approximately 45-60 minutes, but you are welcome to stop the discussion at any time.

Participant and data protection
With your permission, I would like to audio record the Goal Planning Meeting and take handwritten notes of my observations. I would also like to audio record our discussion after the meeting and take handwritten notes as we complete the questionnaire together. Any and all data will be kept strictly confidential and anonymised. The data will be securely stored and you will not be identifiable from the notes or reports that result from this data.

Your permission for me to use any observations that you are included in is completely voluntary. You are free to withdraw this permission at any time

without giving any reason and without any negative consequences. You are also free to decline answering any question or questions.

With your permission, I would like to record your status as a patient, plus your age, gender, level/type of injury, date of injury and number of Goal Planning Meetings you have attended. However, you are free to decline permission to record any/all of this information.

I am supervised by qualified staff who are obliged to ensure that I am working within the appropriate data collection protocols. This includes ensuring that all materials collected are subject to ethical policies and processes of safeguarding and anonymising of data.

What will happen afterwards?
I would like to use the audio recordings of the meetings to make visual maps of what people talk about in the meeting, and for how long. I will use these maps, my observational notes and notes from our discussion to support future work in the Co-Plan project with staff, patients and the people important to the patients. You will not be identifiable from any information used to support future work in this project. You would be welcome to see these maps once they are created, if you wish. You would also be welcome to read the final set of notes made in our discussion, and suggest changes to them if you feel they are inaccurate or incomplete in any way.

Contact
Thank you for taking the time to read this letter. If you have any questions please feel free to contact me on:

Email: *@student.gsa.ac.uk
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

Or my primary supervisor, Professor Alastair Macdonald, on:

Email: *@gsa.ac.uk
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

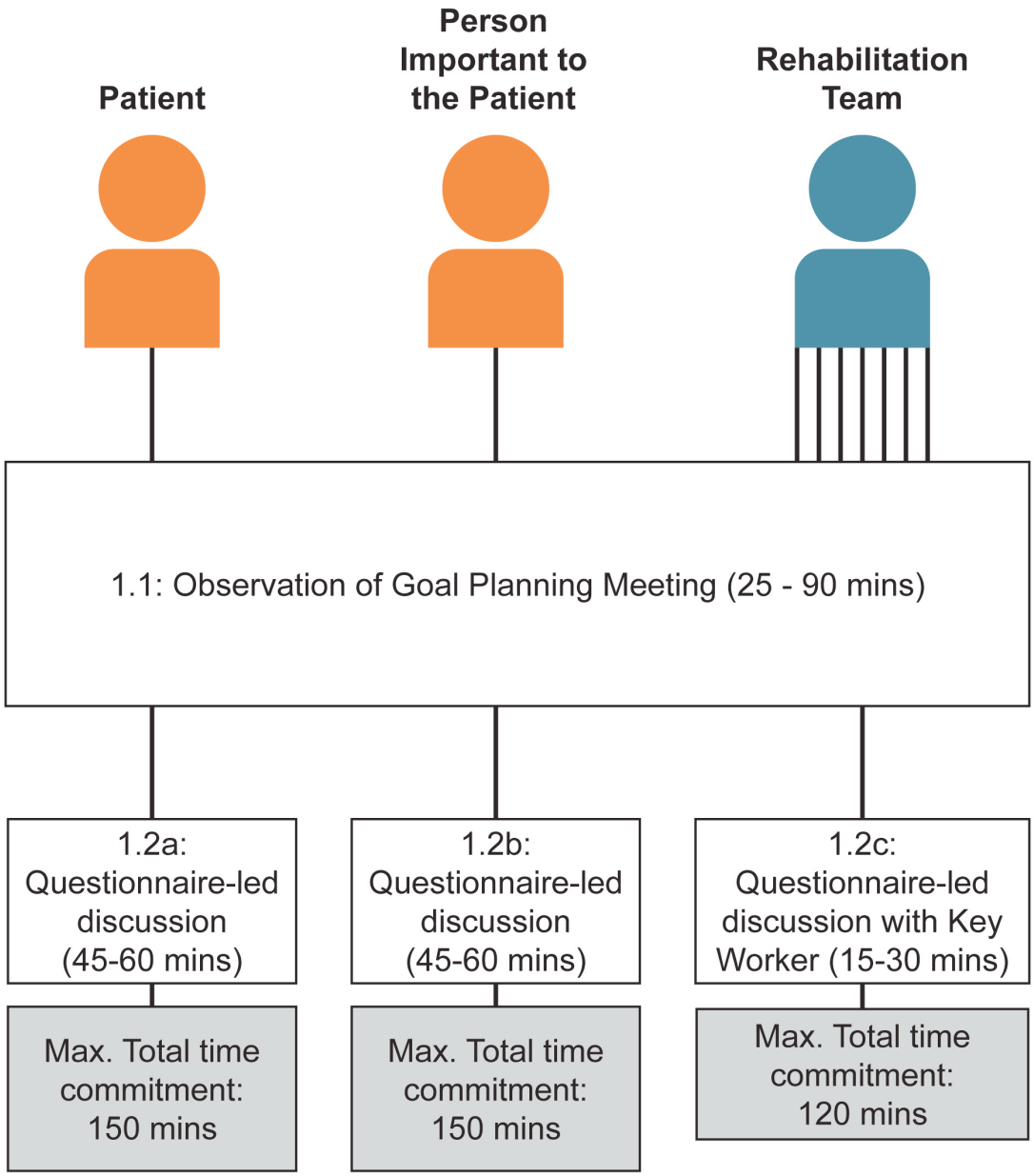
Or my co-supervisor, Dr Mariel Purcell, on:

Email: *@ggc.scot.nhs.uk
Address: The Queen Elizabeth National Spinal Injuries Unit, Scotland South Glasgow University Hospitals Division, Southern General Hospital, 1345 Govan Road, Glasgow, G51 4TF

Thank you again.

Kind regards,
Gemma Wheeler, PhD Candidate, The Glasgow School of Art.

Phase One Activity Flow Chart



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Participation Consent Form

Project Title: "Co-Developing the Goal Planning process of spinal cord injury rehabilitation."

Facilitator: Gemma Wheeler

Please initial box

1. I confirm that I have read the project information letter and I have had the opportunity to ask questions about the project. ☐
2. I understand that my participation in the project is voluntary and that I am free to withdraw at any time without giving any reason and without disadvantage to myself. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐
3. I agree for the researcher to take handwritten notes and audio recordings of the Goal Planning Meeting and questionnaire-led discussion. ☐
4. I understand that my responses and any observations made will be kept strictly confidential. My personal details will be anonymised. I give permission for members of the project team to have access to my anonymised responses and any observations made. I understand that my name will not be linked with the project materials, and I will not be identified or identifiable in the reports, publications or presentations that result from the project. ☐
5. I agree for my contributions and the data collected from me to be used in future reports, publications or presentations. I understand that I have the right to withdraw permission to use the data collected from me at any time, without giving any reason and without disadvantage to myself. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Witness (If appropriate)	Date	Signature
_____	_____	_____
Name of Observer	Date	Signature

Observer contact email: *@student.gsa.ac.uk

Observer contact address: The Glasgow School of Art, 167 Renfrew Street, (Rose Street 2nd floor), Glasgow, G3 6RQ

SCHOOL OF DESIGN
THE GLASGOW SCHOOL OF ART

Dear Sir/Madam,

Thank you for taking the time to read this information letter. Before you give your written consent to participate in the project, it is my duty to ensure you understand how your contributions will be used. Please feel free to contact me if you have any questions or if there is anything you would like to discuss.

Background information
I am working under the supervision of Professor Alastair Macdonald in the School of Design at The Glasgow School of Art. Professor Macdonald and several of his colleagues have a history of working within the healthcare context, and I am appreciative of the rare opportunity to work so closely with the QENSIU community.

I joined the research department at QENSIU in October 2013, and since then I have spent a lot of time with the staff, patients and their families to develop an understanding of how the many and varied roles within QENSIU work together to support a patient's development and how a spinal injury unit operates. I was able to share my observations with senior staff across the unit, and together we identified the Goal Planning Meeting as an opportunity to enhance the participation of patients and/or the people important to them. To do this, as part of my own PhD study, we created 'The Co-Plan Project,' where the QENSIU community will come together to develop the Goal Planning process.

So far, we have completed Phase One, which involved gathering the experiences and opinions of the Goal Planning process from patients, people important to the patient and staff. This will be used to inform Phase Two of the project, in which I would greatly appreciate your contribution.

Your Role
At this stage of the project, I would like to invite you to attend one or all of the upcoming 'Co-Plan' workshops, where patients, people important to the patients, QENSIU staff and Spinal Injuries Scotland staff will come together co-develop the Goal Planning process. We have planned 6 weekly workshops (approximately 60-90 mins each) which will take place in the Step Down Unit. You only need to bring yourself, your thoughts and your experiences, and together we will use a mixture of creative methods to:

- Establish the priorities of patients and the people important to them.
- Explore the current experiences of patients, the people important to patients and staff in the current Goal Planning Format, and decide which aspects could be improved to better meet the QENSIU community's priorities.
- Create a variety of paper-based models of ideas to improve the Goal Planning experience.
- Develop our favourite idea into a material or process to be tested.

Once we have a material or process to test, I would also like to invite a small group of patients to privately 'act out' a Goal Planning Meeting with their rehabilitation team, the person important to them and myself using the co-designed material or process. Together, we will develop the idea 'in use'.

Please see the last page of this letter for a flow chart of how the sessions run and who is involved.

If you choose to attend all of the sessions, including the final development workshop, your maximum total time commitment will be 8.5 hours over 6 weeks (60-90 mins per week). However, you are very welcome to decide how many sessions you would like to attend as we go, without any negative consequences to you or your care if you decide not to attend.

Participant and data protection
With your permission, I would like to take handwritten notes of my observations and photographs during all of the workshops. I would also like to audio record the final developmental session, if you choose to attend. Any and all data and photographs will be kept strictly confidential and anonymised. The data will be securely stored and you will not be identifiable from the notes or reports that result from this data.

Your permission for me to use any observations that you are included in is completely voluntary. You are free to withdraw this permission at any time without giving any reason and without any negative consequences. You are also free to decline answering any question or questions.

With your permission, I would like to record your status as a patient, plus your age, gender, level/type of injury, date of injury and number of Goal Planning Meetings you have attended. However, you are free to decline permission to record any/all of this information.

I am supervised by qualified staff who are obliged to ensure that I am working within the appropriate data collection protocols. This includes ensuring that all materials collected are subject to ethical policies and processes of safeguarding and anonymising of data.

What will happen afterwards?
Contributions to each workshop will be used to inform the next workshop, but you are welcome to attend as many or as few as you like. If you cannot attend a workshop, but still wish to be updated on the project progress, I would be happy to provide a summary of what happened in the session.

The final co-designed material or process will be taken into Phase Three, where it will be implemented into the rehabilitation journey of 3 patients who were not involved in the Co-Plan workshops. They will be observed using the co-designed material or process, and asked to discuss their experience of the Goal Planning process using it. The findings of the Co-Plan project will also be used to inform a PhD project, and may be developed into a regular part of SCI rehabilitation at QENSIU.

Contact
Thank you for taking the time to read this letter. If you have any questions please feel free to contact me on:

Email: *@student.gsa.ac.uk
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

Or my primary supervisor, Professor Alastair Macdonald, on:

Email: *@gsa.ac.uk
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

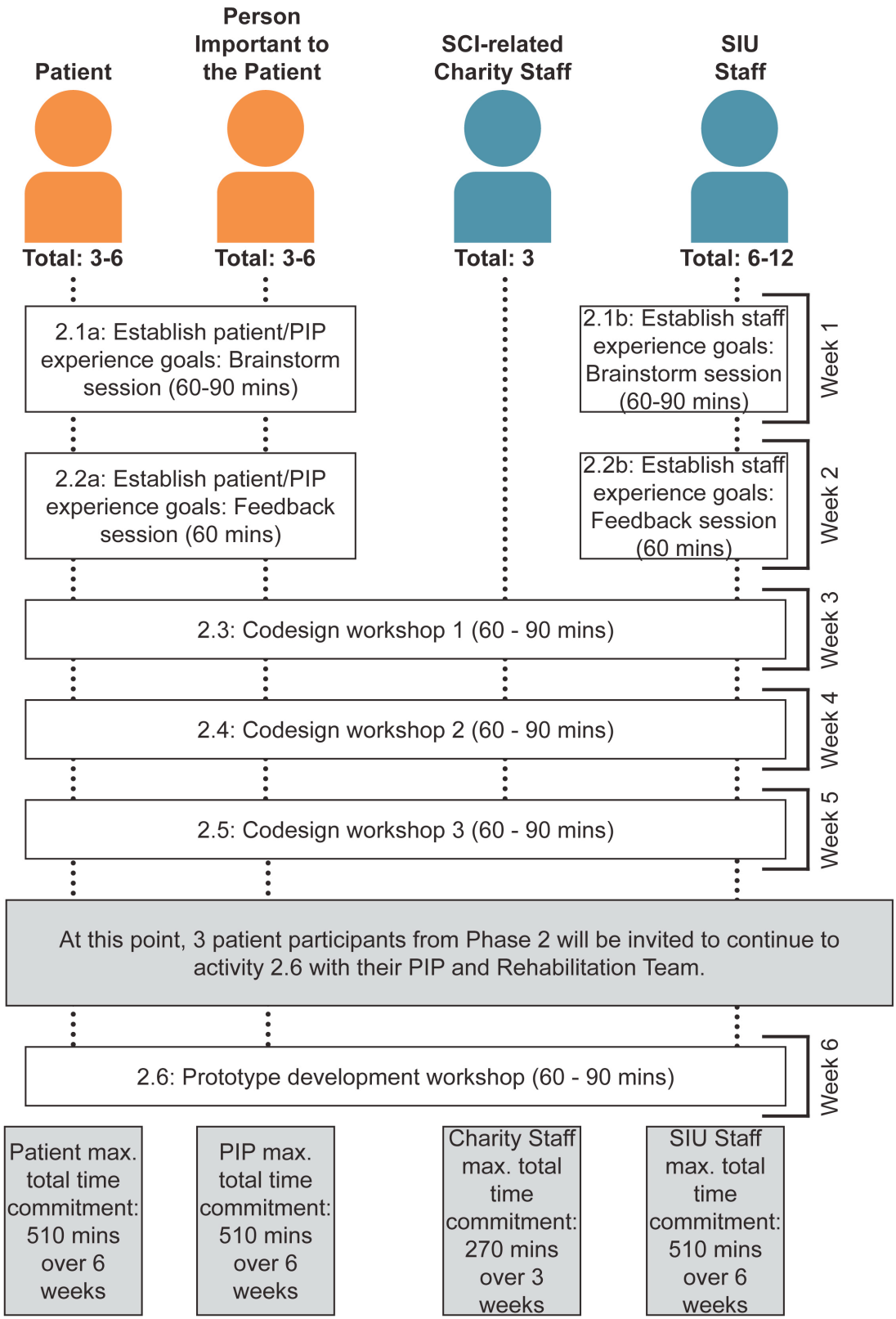
Or my co-supervisor, Dr Mariel Purcell, on:

Email: *@ggc.scot.nhs.uk
Address: The Queen Elizabeth National Spinal Injuries Unit, Scotland South Glasgow University Hospitals Division, Southern General Hospital, 1345 Govan Road, Glasgow, G51 4TF

Thank you again.

Kind regards,
Gemma Wheeler, PhD Candidate, The Glasgow School of Art.

Phase Two Activity Flow Chart



SCHOOL OF DESIGN
THE GLASGOW SCHOOL OF ART

Participation Consent Form

Project Title: "Co-Developing the Goal Planning process of spinal cord injury rehabilitation."

Facilitator: Gemma Wheeler

Please initial box

1. I confirm that I have read the project information letter and I have had the opportunity to ask questions about the project. ☐
2. I understand that my participation in the project is voluntary and that I am free to withdraw at any time without giving any reason and without disadvantage to myself. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐
3. I agree for the researcher to take anonymised handwritten notes, photographs and audio recordings of the workshop sessions. ☐
4. I understand that my responses and any observations made will be kept strictly confidential. My personal details will be anonymised, as will any photographs or audio recordings I am included in. I give permission for members of the project team to have access to my anonymised responses and any observations made. I understand that my name will not be linked with the project materials, and I will not be identified or identifiable in the reports, publications or presentations that result from the project. ☐
5. I agree for my contributions and the data collected from me to be used in future reports, publications or presentations. I understand that I have the right to withdraw permission to use the data collected from me at any time, without giving any reason and without disadvantage to myself. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Witness (If appropriate)	Date	Signature
_____	_____	_____
Name of Observer	Date	Signature

Observer contact email: *@student.gsa.ac.uk
Observer contact address: The Glasgow School of Art, 167 Renfrew Street, (Rose Street 2nd floor), Glasgow, G3 6RQ

SCHOOL OF DESIGN
THE GLASGOW SCHOOL OF ART

Dear Sir/Madam,

Thank you for taking the time to read this information letter. Before you give your written consent to participate in the project, it is my duty to ensure you understand how your contributions will be used and the wider context of my study. Please feel free to contact me if you have any questions or if there is anything you would like to discuss.

Background information
I am working under the supervision of Professor Alastair Macdonald in the School of Design at The Glasgow School of Art. Professor Macdonald and several of his colleagues have a history of working within the healthcare context, and I am appreciative of the rare opportunity to work so closely with the QENSIU community.

I joined the research department at QENSIU in October 2013, and since then I have spent a lot of time with the staff, patients and their families to develop an understanding of how the many and varied roles within QENSIU work together to support a patient's development and how a spinal injury unit operates. I was able to share my observations with senior staff across the unit, and together we identified the Goal Planning Meeting as an opportunity to enhance the participation of patients and/or the people important to them.

Over the last few months, patients, people important to the patient, QENSIU staff and Spinal Injuries Scotland staff have worked together to co-develop the Goal Planning process. We have called this The Co-Plan Process.

The Co-Plan Process includes:

- An information booklet about the rehabilitation journey.
- A 'Projection Meeting' - a one-to-one meeting between the patient and their consultant to discuss the patient's spinal cord injury and its effects. The patient may also invite a family member or friend to this meeting, and another staff member may attend to take notes on the discussion for the patient.
- 'Key Worker Meeting' - A one-to-one meeting between the patient and their Key Worker to set long-term rehabilitation goals. The patient may also invite a family member or friend to this meeting.
- 'Goal Planning Meetings' – the patient meets with their Rehabilitation Team to review their progress and set short-term rehabilitation goals. The patient may also invite a family member or friend to this meeting.

A simple flow chart of these events is available on the last page of this letter. Please be aware that each of these activities already exists in a normal rehabilitation journey, but The Co-Plan Process conducts them in different ways that aim to help the patient be as involved as they wish to be.

Your Role
I would like to invite you to take part in The Co-Plan Process. Staff will be fully trained in the process and taking part in this project will not mean you receive less than your normal care.

I would like to ask your permission to attend your first two Goal Planning Meetings as a passive observer. You will not need to interact with me in the meeting unless you choose to. After the second meeting (perhaps later that day, or a time most convenient for you), I would like to invite you to a private, questionnaire-led discussion to learn about your thoughts and experiences of The Co-Plan Process. This should take approximately 45-75 minutes, but you are welcome to stop the discussion at any time.

If you agree to take part in this project, your maximum total time commitment will be 5 ¾ hours over approximately 8 weeks. However, please remember that most of this time will be spent in meetings that you would already have if you were not a part of this study – they will just be conducted differently.

Participant and data protection
With your permission, I would like to audio record the Goal Planning Meetings and take handwritten notes of my observations. I would also like to audio record our discussion after the second meeting and take handwritten notes as we complete the questionnaire together. Any and all data will be kept strictly confidential and anonymised. The data will be securely stored and you will not be identifiable from the notes or reports that result from this data.

Your permission for me to use any observations that you are included in is completely voluntary. You are free to withdraw this permission at any time without giving any reason and without any negative consequences. You are also free to decline answering any question or questions.

With your permission, I would like to record your status as a patient, plus your age, gender, level/type of injury and date of injury. However, you are free to decline permission to record any/all of this information.

I am supervised by qualified staff who are obliged to ensure that I am working within the appropriate data collection protocols. This includes ensuring that all materials collected are subject to ethical policies and processes of safeguarding and anonymising of data.

What will happen afterwards?
I would like to use the audio recordings of the meetings to make visual maps of what people talk about in the meeting, and for how long. You would be welcome to see these maps once they are created, if you wish. You would also be welcome to read the final set of notes made in our discussion, and suggest changes to them if you feel they are inaccurate or incomplete.

I will compare the visual maps, my observational notes and notes from our discussion with similar data collected in meetings that have not used The Co-Plan Process, to evaluate if it improves the Goal Planning experience for all of those involved. These findings will be used to inform a PhD thesis, and may contribute towards developing The Co-Plan Process further into a regular part of SCI rehabilitation at QENSIU.

Contact
Thank you for taking the time to read this letter. If you have any questions please feel free to contact me on:

Email: *@student.gsa.ac.uk
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

Or my primary supervisor, Professor Alastair Macdonald, on:

Email: *@gsa.ac.uk
Address: School of Design, The Glasgow School of Art, 167 Renfrew Street, (Rose Street), Glasgow, G3 6RQ

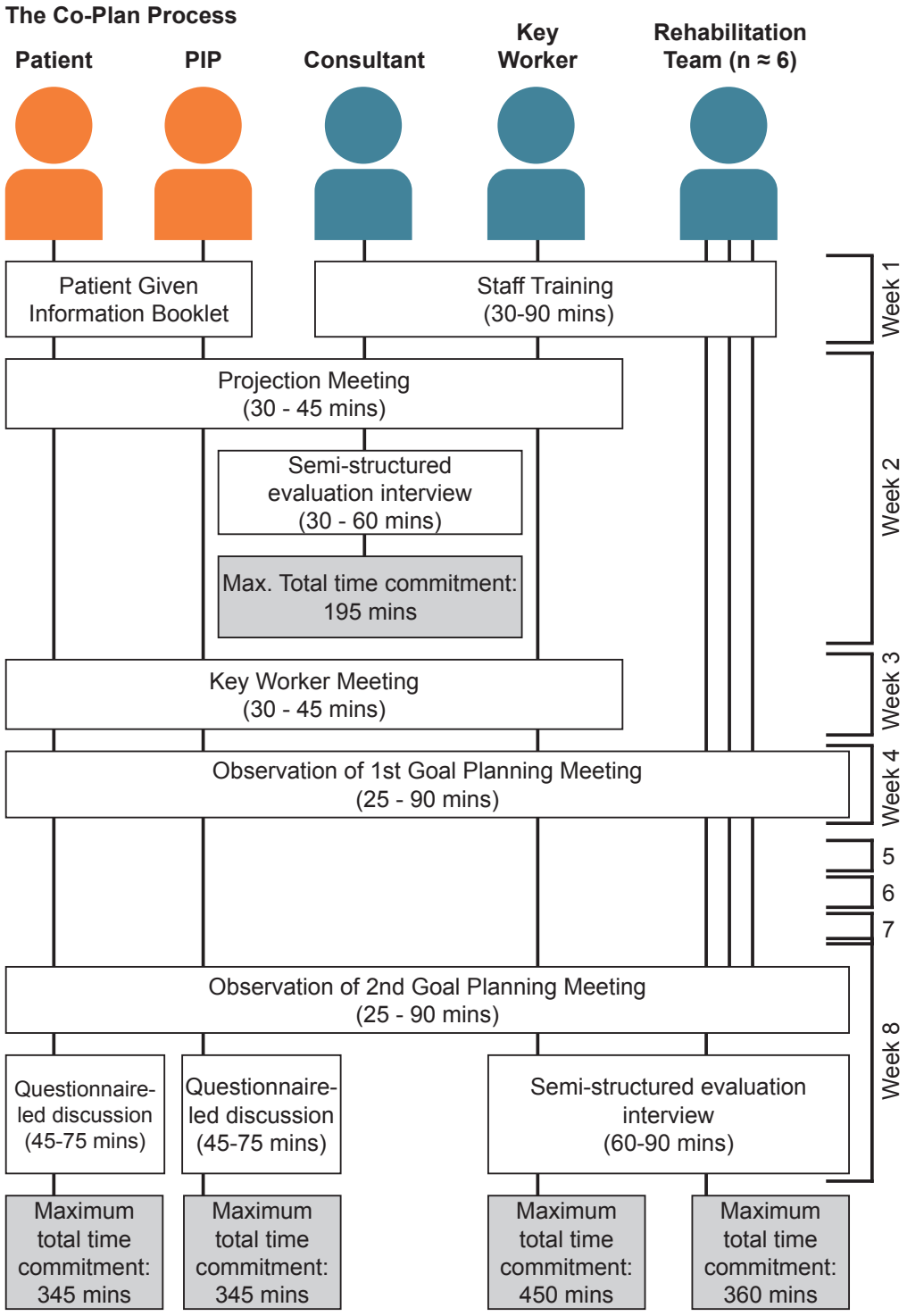
Or my co-supervisor, Dr Mariel Purcell, on:

Email: *@ggc.scot.nhs.uk
Address: The Queen Elizabeth National Spinal Injuries Unit, Scotland South Glasgow University Hospitals Division, Southern General Hospital, 1345 Govan Road, Glasgow, G51 4TF

Thank you again.

Kind regards,
Gemma Wheeler, PhD Candidate, The Glasgow School of Art.

Phase Three Activity Flow Chart



SCHOOL OF DESIGN
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Participation Consent Form

Project Title: "Co-Developing the Goal Planning process of spinal cord injury rehabilitation."

Facilitator: Gemma Wheeler

Please initial box

1. I confirm that I have read the project information letter and I have had the opportunity to ask questions about the project. ☐

2. I understand that my participation in the project is voluntary and that I am free to withdraw at any time without giving any reason and without disadvantage to myself. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐

3. I agree for the researcher to take anonymised handwritten notes and audio recordings of 2 Goal Planning sessions and the questionnaire-led discussion. ☐

4. I understand that my responses and any observations made will be kept strictly confidential. My personal details will be anonymised, as will any photographs or audio recordings I am included in. I give permission for members of the project team to have access to my anonymised responses and any observations made. I understand that my name will not be linked with the project materials, and I will not be identified or identifiable in the reports, publications or presentations that result from the project. ☐

5. I agree for my contributions and the data collected from me to be used in future reports, publications or presentations. I understand that I have the right to withdraw permission to use the data collected from me at any time, without giving any reason and without disadvantage to myself. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Witness (If appropriate)	Date	Signature
_____	_____	_____
Name of Observer	Date	Signature

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