AUTRALIAN INSTITUTE OF HEALTH INNOVATION
Faculty of Medicine
and Health Sciences
75 Talavera Rd, Macquarie University, NSW 2109, Australia

Appendix 1

Focus Group and Semi-Structured Interview Questions

Phase One

1. What processes exist at this hospital around surgical innovation?

2. How are they used and perceived?

3. What extra support might you want?

4. Please have a look at the MSIIT and familiarise yourself with it
    a. First Impressions?

5. Can you please think back to your last surgery and complete the form for it?
    a. Any difficulties?
    b. Observations?

6. If you were to use the MSIIT for future surgeries, how would you go about it?

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Appendix 2

Survey 1

Profession: Consultant/Registrar/Anaesthetist/Anaesthetic nurse/scrub nurse/scout nurse (circle)
Other:_____ Time since qualifying: _____ years

Time in this organisation: _____ years Time in this unit: _____years

Gender: M/F (circle) Age: 20-30/30-40/40-50/50-60/60+ (circle)

	Strongly Disagree				Strongly Agree
Usability of MSIIT					
1. I think that I would like to use the MSIIT frequently	1	2	3	4	5
2. I found the MSIIT unnecessarily complex	1	2	3	4	5
3. I thought the MSIIT was easy to use	1	2	3	4	5
4. I think that I would need the support of a more senior person to be able to use the MSIIT	1	2	3	4	5
5. The questions on the MSIIT flow logically	1	2	3	4	5
6. The yes/no format made some questions on the MSIIT hard to answer	1	2	3	4	5
7. I would imagine that most people would learn to use the MSIIT very quickly	1	2	3	4	5
8. I found the MSIIT very time consuming to use	1	2	3	4	5
9. I felt very confident using the MSIIT	1	2	3	4	5
10. I needed to seek clarification before I could answer the MSIIT	1	2	3	4	5
Personal Experience					
The result of the MSIIT fits with my original perception of the level of innovation in our example case	1	2	3	4	5
The MSIIT appropriately identifies cases of innovative surgery	1	2	3	4	5

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Context

When would the MSIIT best be completed? E.g. when the patient signs for consent.

_____

Which members of staff should complete the MSIIT?

_____

In your experience, are the types of surgeries you are involved in typically innovative?

_____

Over the last _____ how many surgeries have you performed?

_____

Over the last _____ how many surgeries do you think involved a surgical innovation?

_____

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Appendix 3

Survey 2

Profession: Consultant/Registrar/Anaesthetist/Anaesthetic nurse/scrub nurse/scout nurse (circle)
Other:_____ Time since qualifying: _____ years

Time in this organisation: _____ years Time in this unit: _____years

Gender: M/F (circle) Age: 20-30/30-40/40-50/50-60/60+ (circle)

	Strongly Disagree				Strongly Agree
Usability of MSIIT					
1. I think that I would like to use the MSIIT frequently	1	2	3	4	5
2. I found the MSIIT unnecessarily complex	1	2	3	4	5
3. I thought the MSIIT was easy to use	1	2	3	4	5
4. I think that I would need the support of a more senior person to be able to use the MSIIT	1	2	3	4	5
5. The questions on the MSIIT flow logically	1	2	3	4	5
6. The yes/no format made some questions on the MSIIT hard to answer	1	2	3	4	5
7. I would imagine that most people would learn to use the MSIIT very quickly	1	2	3	4	5
8. I found the MSIIT very time consuming to use	1	2	3	4	5
9. I felt very confident using the MSIIT	1	2	3	4	5
10. I needed to seek clarification before I could answer the MSIIT	1	2	3	4	5
Personal Experience					
The result of the MSIIT fit with my original perception of the level of innovation during the pilot	1	2	3	4	5
Overall, the MSIIT appropriately identifies cases of innovative surgery	1	2	3	4	5

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	Not Often Enough				Too Often
Did the MSIIT, in your opinion, appropriately identify surgeries as innovative?	1	2	3	4	5

Context

When did you complete the MSIIT? E.g. when the patient signs for consent.

_____

Was this the right timing? Y/N If No please comment: _____

_____

Which members of staff, in your opinion, should complete the MSIIT?

_____

In your experience, are the types of surgeries you are involved in typically innovative?

_____

Over the pilot period how many surgeries have you performed?

_____

Over the pilot period how many surgeries do you think involved a surgical innovation?

_____

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Consent forms for the private hospital

PHASE ONE

Participant Information and Consent Form

Name of Project: The Macquarie Surgical Innovation Identification Tool: usability and pilot test.

You are invited to participate in Phase One of this research project, The Macquarie Surgical Innovation Identification Tool: usability and pilot test. The purpose of the study is to test the usability of the Macquarie Surgical Innovation Identification Tool (MSIIT). The MSIIT is a simple set of questions designed as a practical tool for surgical teams or hospitals to identify any planned surgical innovations. It was developed by researchers at Macquarie University through Australian Research Council (ARC) Linkage Grant LP110200217, with Partner Organisations including the Western Sydney Local Health District.

Phase one of the project focuses on usability, including determining whether clinicians like the MSIIT and whether they anticipate that it will be useful in their work. This phase aims to determine the best implementation strategy for the MSIIT and to obtain a broad indication of the prevalence of innovation in surgery.

If you decide to participate, you will be asked to be interviewed face-to-face or to join a focus group asking about your reactions to the MSIIT. As part of this activity you will have an opportunity to interact with the tool. Interviews and focus groups will be audio-recorded and transcribed, and will last no longer than one hour. You will also be asked to complete a 10-minute questionnaire about your experience of using the MSIIT during the interactions and the current levels and types of surgical innovations that you typically encounter in your work.

There are no physical risks to taking part, or costs associated with participating; nor will you be paid. If you do not wish to answer an interview, focus group or survey question, you may skip it, or you may stop immediately, or ask us to stop the recording at any time.

Any information or personal details gathered in the course of the study will remain confidential, except as required by law. Only the research team at the Australian Institute of Health Innovation, Macquarie University will have access to the data. A summary of the findings of the study can be made available to you on request.

Participation in this study is entirely voluntary: you are not obliged to participate and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence.

I,_____ *(participant's name)* have read *(or, where appropriate, have had read to me)* and understand the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this research, knowing that I can withdraw from further participation in the research at any time without consequence. I have been given a copy of this form to keep.

Participant's Name:_____

(Block letters)

Participant's Signature: _____ Date:_____

AUTRALIAN INSTITUTE OF HEALTH INNOVATION
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75 Talavera Rd, Macquarie University, NSW 2109, Australia

Investigator's Name:_____

(Block letters)

Investigator's Signature: _____ ___ Date:_____

The ethical aspects of this study have been approved by the xxx Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone (xx) xxxx xxxx; email xxx@xxx.xx.xx). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

PHASE TWO

Participant Information and Consent Form

Name of Project: The Macquarie Surgical Innovation Identification Tool: usability and pilot test.

You are invited to participate in Phase Two of this research project, The Macquarie Surgical Innovation Identification Tool: usability and pilot test. The purpose of the study is to test the usability of the Macquarie Surgical Innovation Identification Tool (MSIIT) and pilot it in the surgical setting. The MSIIT is a simple set of questions designed as a practical tool for surgical teams or hospitals to identify any planned surgical innovations. It was developed by researchers at Macquarie University through Australian Research Council (ARC) Linkage Grant LP110200217, with Partner Organisations including the Western Sydney Local Health District.

Phase Two of the project is a pilot study trialling the MSIIT in the surgical setting. Phase Two will investigate operational aspects of using the MSIIT. These aspects include the appropriate timing to complete it, which members of the surgical team should complete it, and any changes that may be required to improve the usability of the tool. Various personnel will complete the MSIIT, and the results will be compared to the hospitals' existing methods for identifying surgical innovation.

If you decide to participate, you will be asked to complete the MSIIT for each surgery performed during a trial period of six weeks or 100 surgeries, whichever occurs first. Following the trial, you will be asked to be interviewed face-to-face or to join a focus group asking about your experience of using the MSIIT during the trial period. Interviews and focus groups will be audio-recorded and transcribed, and will last no longer than one hour. You will also be asked to complete a 10-minute questionnaire about your experiences of using the MSIIT.

There are no physical risks to taking part, or costs associated with participating; nor will you be paid. If you do not wish to answer an interview, focus group or survey question, you may skip it, or you may stop immediately, or ask us to stop the recording at any time.

Any information or personal details gathered in the course of the study will remain confidential, except as required by law. Only the research team at the Australian Institute of Health Innovation, Macquarie University will have access to the data. A summary of the findings of the study can be made available to you on request.

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I,_____ *(participant's name)* have read *(or, where appropriate, have had read to me)* and understand the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this research, knowing that I can withdraw from further participation in the research at any time without consequence. I have been given a copy of this form to keep.

Participant's Name:_____

(Block letters)

Participant's Signature: _____ Date:_____

Investigator's Name:_____

(Block letters)

Investigator's Signature: _____ ___ Date:_____

The ethical aspects of this study have been approved by the xxx Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone (xx) xxxx xxxx; email xxx@xxx.xx.xx). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

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Consent forms for the public hospital

PHASE ONE

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in phase one of this research project, The Macquarie Surgical Innovation Identification Tool: Usability and Pilot Test. The research project aims to test the usability of the Macquarie Surgical Innovation Identification Tool (MSIIT) and pilot it in the surgical setting. Phase one will involve an interview or focus group as well as a brief questionnaire.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Continual improvement in medicine relies on innovation. However, innovation is potentially risky, and not all innovations are successful. It is, therefore, important to prospectively identify innovations and provide appropriate support, to make the process as safe and effective as possible. One challenge is that surgical innovations may be difficult to identify, especially where they do not require the purchase of new equipment or tools. The Macquarie Surgical Innovation Identification Tool (MSIIT) is a simple set of questions designed as a practical tool for surgical teams or hospitals to identify any planned surgical innovations. It was developed through Australian Research Council (ARC) Linkage Grant LP110200217, with Partner Organisations including the Western Sydney Local Health District.

This project will test the usability of the MSIIT tool and pilot it in the surgical setting as the preliminary stage of a larger national and international trial.

Phase one of the project focuses on usability, determining whether clinicians' like the MSIIT and whether they anticipate that it will be useful in their work. This will include obtaining information on its potential utility and the likely system requirements for its use. This phase aims to determine the best implementation strategy for the MSIIT and to obtain a broad indication of the prevalence of innovation in surgery in public and private hospitals. Those with roles in management will also, in particular, be asked for details about any existing mechanisms for the identification and support of innovative surgery in their hospital.

Phase Two will be a pilot study trialling the MSIIT in the surgical setting. Based on the feedback from Phase One, Phase Two will investigate operational aspects of using the MSIIT including

appropriate timing for its completion, which members of the surgical team should complete it, and

any required modifications that may be required to improve the usability of the tool. Various personnel will complete the MSIIT, and the results will be compared to the hospitals' existing methods for identifying surgical innovation.

3 What does participation in this research involve?

Your participation in phase one of the research project will involve either a face-to-face interview, or participation in a focus group. These will be audio-recorded and transcribed. During the activity, which will last no longer than one hour, you will be asked about your reactions to the MSIIT and be provided with an opportunity to interact with the tool. You will also be asked to complete a brief questionnaire to collect your experience of using the MSIIT during these interactions as well as your estimates of current levels and types of surgical innovations that you typically encounter in your work. The questionnaire should take no more than 10 minutes to complete. All information provided will be kept confidential and anonymous, and cannot be linked back to you.

This research project has been designed to minimise bias, and to make sure that researchers interpret the results in a way that represents the hospital truthfully and accurately.

There are no costs associated with participating in this research project, nor will you be paid.

4 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with your employer or professional staff at Westmead Hospital or your relationship with Macquarie University.

5 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, we may learn ways to improve the identification of innovative surgery that may benefit future hospital patients.

6 What are the possible risks and disadvantages of taking part?

There are no physical risks to taking part. You may feel that some of the questions we ask in interviews, focus groups or surveys are stressful. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately, or ask for the recording to be stopped at any time. If you become upset or distressed as a result of your participation in the research, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

7 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time

you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Part 2 How is the research project being conducted?

8 What will happen to information about me?

By signing the consent form you consent to the research team at Macquarie University collecting and using information provided by you for the research project. We will only collect non-identifiable data from you. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Any information obtained from you for the purpose of this research project will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. If you choose to participate, your signed consent form, completed MSIIT forms and surveys, and interview recording or focus group observations will be sealed separately and transported securely by the research team to Macquarie University. Once at Macquarie University, paper files will be kept in a locked cabinet, and any electronic files will be password protected. The stored data will be non-identified. Only non-identified data will be analysed by the research team at Macquarie University.

9 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

10 Who is organising and funding the research?

This research is being conducted by the Australian Institute of Health Innovation, at Macquarie University.

11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the xxx Local Health District HREC [LNR/16/xxxx/91].

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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Name of Participant (please _____

Signature _____ Date _____

Declaration by Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Senior Researcher†
(please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

PHASE TWO

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in phase two of this research project, The Macquarie Surgical Innovation Identification Tool: Usability and Pilot Test. The research project aims to test the usability of the Macquarie Surgical Innovation Identification Tool (MSIIT) and pilot it in the surgical setting. Phase two will involve using the MSIIT for each surgery during a trial period followed by an interview or focus group participation and a brief questionnaire.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described

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Continual improvement in medicine relies on innovation. However, innovation is potentially risky, and not all innovations are successful. It is, therefore, important to prospectively identify innovations and provide appropriate support, to make the process as safe and effective as possible. One challenge is that surgical innovations may be difficult to identify, especially where

they do not require the purchase of new equipment or tools. The Macquarie Surgical Innovation Identification Tool (MSIIT) is a simple set of questions designed as a practical tool for surgical teams or hospitals to identify any planned surgical innovations. It was developed through Australian Research Council (ARC) Linkage Grant LP110200217, with Partner Organisations including the Western Sydney Local Health District.

This project will test the usability of the MSIIT tool and pilot it in the surgical setting as the preliminary stage of a larger national and international trial.

Phase one of the project focuses on usability, determining whether clinicians' like the MSIIT and whether they anticipate that it will be useful in their work. This will include obtaining information on its potential utility and the likely system requirements for its use. This phase aims to determine the best implementation strategy for the MSIIT and to obtain a broad indication of the prevalence of innovation in surgery in public and private hospitals. Those with roles in management will also, in particular, be asked for details about any existing mechanisms for the identification and support of innovative surgery in their hospital.

Phase Two will be a pilot study trialling the MSIIT in the surgical setting. Based on the feedback from Phase One, Phase Two will investigate operational aspects of using the MSIIT including appropriate timing for its completion, which members of the surgical team should complete it, and any required modifications that may be required to improve the usability of the tool. Various personnel will complete the MSIIT, and the results will be compared to the hospitals' existing methods for identifying surgical innovation.

3 What does participation in this research involve?

Your participation in phase two of the research project will involve completing the MSIIT for each surgery performed during a trial period of six weeks or 100 surgeries, whichever occurs first. The timing of its use will depend on the findings of phase one. Following the trial, your participation will involve either a face-to-face interview or participation in a focus group. These will be audio-recorded and transcribed. During either activity, which will last no longer than one hour, you will be asked about your experience of using the MSIIT during the trial period. You will also be asked to complete a brief questionnaire to collect your experiences of using the MSIIT. The questionnaire should take no more than 10 minutes to complete. All information provided will be kept confidential and anonymous, and cannot be linked back to you.

This research project has been designed to minimise bias, and to make sure that researchers interpret the results in a way that represents the hospital truthfully and accurately.

There are no costs associated with participating in this research project, nor will you be paid.

4 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with your employer or professional staff at Westmead Hospital or your relationship with Macquarie University.

5 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, we may learn ways to improve the identification of innovative surgery that may benefit future hospital patients.

6 What are the possible risks and disadvantages of taking part?

There are no physical risks to taking part. You may feel that some of the questions we ask in interviews, focus groups or surveys are stressful. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately, or ask for the recording to be stopped at any time. If you become upset or distressed as a result of your participation in the research, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

7 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Part 2 How is the research project being conducted?

8 What will happen to information about me?

By signing the consent form you consent to the research team at Macquarie University collecting and using information provided by you for the research project. We will only collect non-identifiable data from you. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Any information obtained from you for the purpose of this research project will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. If you choose to participate, your signed consent form, completed MSIIT forms and surveys, and interview recording or focus group observations will be sealed separately and transported securely by the research team to Macquarie University. Once at Macquarie University, paper files will be kept in a locked cabinet, and any electronic files will be password protected. The stored data will be non-identified. Only non-identified data will be analysed by the research team at Macquarie University.

9 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

10 Who is organising and funding the research?

This research is being conducted by the Australian Institute of Health Innovation, at Macquarie University.

11 Who has reviewed the research project?

AUTRALIAN INSTITUTE OF HEALTH INNOVATION
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75 Talavera Rd, Macquarie University, NSW 2109, Australia

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the xxx Local Health District HREC [LNR/16/xxxx/91].

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please _____

Signature _____ Date _____

Declaration by Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Senior Researcher†
(please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature