# iHOLDS Telephone Randomisation Service
User Guide

## Introduction

The purpose of the iHOLDS Trial Randomisation Service is to allocate a treatment to participants in the iHOLDS Trial.

The Randomisation Service system is telephone based. As you use the system you will be required to respond to it in one of two ways - dialling numbers on your telephone keypad, or speaking a response into the telephone handset.

To make it easier for you, the image below will clearly indicate if you will need to interact with the telephone randomisation service.

Use your telephone keypad to enter data when prompted.

Speak into the telephone when prompted

**Randomisation Telephone No.**
0800 2802 307

**Your Trial ID Code**
216XXX

**Any problems?**
Chart support
01224 43 8188
chart.support@abdn.ac.uk

# iHOLDS Trial Randomisation Service
## User Guide

### SECTION A - Randomising a new participant

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| **Tel: 0800 2802 307**<br>**Part 1 – Entering the Centre number** |

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| **Prompt** |
| *Welcome to the Aberdeen Trials Service.  Please enter your six digit trial id code then press the * (star) key.* |
| **Your response** |
| You should respond with the 6-digit centre number supplied by the iHOLDS Study Co-ordinator.<br>For example, **216XXX*** |
| **Prompt** |
| *This is the iHOLDS trial, investigating the effect on caesarean section rates of high versus standard dose oxytocin regimen for induction of labour.  Your trial centre is [centre name].* |

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| **Part 2 – Main Menu** |

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| **Prompt** |
| *To randomise a new participant press 1, to re-allocate treatment for an existing participant press 2, to report a major temperature deviation press 3.* |
| **Your response** |
| You should respond by dialling **1** |

# iHOLDS Trial Randomisation Service
## User Guide

## Part 3 – Introduction message

### Prompt

Randomise a new participant.

I will be asking you questions from the Trial Entry Form which should be completed in advance.

Please do not end the call until you are given both a Participant Number of 4 digits <u>and</u> a Treatment Pack Number of 5 digits, after which you are told to hang up.

### Your response

No response is required

## Part 4 – Confirmation of Eligibility

### Prompt

*Does the woman meet the iHOLDS trial eligibility criteria with no exclusions?*
*Enter 1 for yes or 2 for no.*

### Your response

You should respond by dialling 1 or 2
For example, **1**

## Part 5 – Confirmation of Eligibility

### Prompt

*You said the woman was eligible.  Has eligibility been confirmed by an obstetrician who has completed iHOLDS training?  Enter 1 for yes or 2 for no.*

### Your response

You should respond by dialling 1 or 2
For example, **1**

## Part 6 – Cervical dilation

### Prompt

*Please enter the current cervical dilation in centimetres as two digits using the phone keypad.*

### Your response

You should respond by pressing a number from 00-09
For example, for 6cm dilated enter **06**

### Prompt

You said … Press 1 to continue or 2 to modify.

### Your response

You should respond by dialling 1 or 2
For example, **1**

## Part 7– Cervical ripening method

### Prompt

*Please select the method used for cervical ripening. Enter 1 for Prostaglandin (Prostin or Propess) only, Enter 2 for Mechanical methods only, Enter 3 for Both Prostaglandin and Mechanical methods, Enter 4 for none.*

### Your response

You should respond by dialling 1, 2, 3 or 4
For example, **1**

### Prompt

*You said … Press 1 to continue or 2 to modify.*

### Your response

You should respond by dialling 1 or 2
For example, **1**

## Part 8 – Date of Birth

### Prompt

*Please enter the participants date of birth as 8 digits.*

### Your response

You should respond by dialling the date of birth as 8 digits.
For example, the date 18th February 1990 would be **18021990**

### Prompt

*You said … Press 1 to continue or 2 to modify.*

### Your response

Respond by dialling 1 or 2 on the telephone keypad

## Part 9 – Gestation

### Prompt

*Please select gestation: Enter 1 for Less than or equal to 38 weeks plus 6 days, Enter 2 for greater than or equal to 39 weeks*

### Your response

 You should respond by dialling 1 or 2
For example, **1**

### Prompt

*You said … Press 1 to continue or 2 to modify.*

### Your response

 You should respond by dialling 1 or 2
For example, 1

## Part 10 – Allocated Participant Number

### Prompt

*Please write down the allocated Participant number which is...*
*Please confirm the allocated Participant number by dialling it on the telephone keypad after the tone.*

### Your response

 You should respond by dialling the allocated *Participant number*
For example, **6001**

### Prompt

*You keyed … Press 1 to continue or 2 to modify.*

### Your response

 Respond by dialling 1 or 2 on the telephone keypad
For example, **1**

| **Part 11 – Treatment Number** |
| --- |
| |
| **Prompt** |
| *Please write down the allocated Treatment Pack number which is...* <br> *Please confirm the allocated Treatment Pack number by dialling it on the telephone keypad after the tone.* |
| **Your response** |
| You should respond by dialling the allocated treatment number <br> For example, **20001** |
| **Prompt** |
| *You keyed … Press 1 to continue or 2 to modify.* |
| **Your response** |
| Respond by dialling 1 or 2 on the telephone keypad |

| **Part 12 – Finish** |
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| **Prompt** |
| *Correct. Thank you for calling the iHOLDS telephone randomisation service.* |
| **Your response** |
| Hang up. |

## SECTION B - RE-ALLOCATED TO AN EXISTING PARTICIPANT

**Tel:** 0800 2802 307

### Part 1 – Entering the Centre number

**Prompt**

*Welcome to the Aberdeen Trials Service.  Please enter your six digit centre number then press the * (star) key.*

**Your response**

You should respond with the 6-digit centre number supplied by the iHOLDS Study Co-ordinator.
For example, **216XXX***

**Prompt**

*This is the iHOLDS trial, investigating the effect on caesarean section rates of high versus standard dose oxytocin regimen for induction of labour.  Your trial centre is [centre name].*

### Part 2 – Main Menu

**Prompt**

*To randomise a new participant press 1, to re-allocate treatment for an existing participant press 2, to report a major temperature deviation press 3.*

**Your response**

You should respond by dialling **2**

## Part 3 – Introduction message

### Prompt

Reallocate an existing participant.

I will be asking you for details from the Repeat Treatment Form which should be completed in advance.

### Your response

 No response is required

## Part 4 – Participant Number

### Prompt

*Please enter the participant's 4-digit Participant number.*

### Your response

 You should respond by dialling the Participant number you wish to re-allocated for
For example, **6001**

### Prompt

*You said … Press 1 to continue or 2 to modify.*

### Your response

 Respond by dialling 1 or 2 on the telephone keypad

## Part 5 – Date of Birth

**Prompt**

*Please enter the participants date of birth as 8 digits in the form day-day month-month year-year-year-year.*

**Your response**

You should respond by dialling the date of birth as 8 digits.
For example, the date 18th February 1990 would be **18021990**

**Prompt**

*You said … Press 1 to continue or 2 to modify.*

Your response

Respond by dialling 1 or 2 on the telephone keypad

## Part 6 – Treatment pack number

**Prompt**

*Please write down the allocated treatment pack number which is …. Please confirm the treatment pack number by dialling it on the telephone keypad after the tone*

**Your response**

You should respond by dialling the allocated treatment pack number
For example, **20001**

**Prompt**

*You said … Press 1 to continue or 2 to modify.*

**Your response**

Respond by dialling 1 or 2 on the telephone keypad

| Part 7 – Finish |
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| |
| **Prompt** |
| *Thank you for calling the iHOLDS telephone randomisation service.* |
| **Your response** |
| Hang up. |

## iHOLDS Trial Randomisation Service
## User Guide

### SECTION C – REPORT A TEMPERATURE DEVIATION

**Tel:** 0800 2802 307

**Part 1 – Entering the Centre number**

**Prompt**

*Welcome to the Aberdeen Trials Service.  Please enter your six digit centre number then press the * (star) key.*

**Your response**

You should respond with the 6-digit centre number supplied by the iHOLDS Study Co-ordinator.
For example, **216XXX***

**Prompt**

*This is the iHOLDS trial, investigating the effect on caesarean section rates of high versus standard dose oxytocin regimen for induction of labour.  Your trial centre is [centre name].*

**Part 2 – Main Menu**

**Prompt**

*To randomise a new participant press 1, to re-allocate treatment for an existing participant press 2, to report a major temperature deviation press 3.*

**Your response**

You should respond by dialling **3**

# iHOLDS Trial Randomisation Service
## User Guide

| Part 3 – Report variation |
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| **Prompt** |
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*Report a temperature deviation.*

***This option is only to be used if you wish to report a major temperature deviation of under 2ºC or 30ºC and above.  If you confirm a deviation has taken place it will no longer be possible to randomise or reallocate participants to the iHOLDS trial***

*If you wish to report that a major temperature deviation of under $2^oC$ or $30^oC$ and above has taken place press 1, otherwise press 2 or hang up to end the call.*

| **Your response** |
| --- |

You should respond by dialling 1 to report a major temperature deviation or 2 to end the call without reporting a temperature deviation.
For example, **1**

| **Prompt** |
| --- |

*You said … Press 1 to continue or 2 to modify.*

| **Your response** |
| --- |

Respond by dialling 1 or 2 on the telephone keypad

| Part 4 – Confirmation message (reported) |
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| **Prompt** |
| --- |

Thank you – a major temperature deviation has been successfully reported. Recruitment at your centre will be temporarily suspended with immediate effect pending investigation. Please immediately quarantine the IMP by removing it from the drugs fridge and applying the supplied quarantine labels. If HOLDS drugs are stored with iHOLDS drug and have therefore also been subject to a major temperature deviation, please repeat this call using your HOLDS trial ID to ensure recruitment is suspended to both studies.

| **Your response** |
| --- |

No response is required

## Part 4 – Confirmation message (not-reported)

**Prompt**

A major temperature deviation has **not** been reported.

**Your response**

No response is required

## Part 5 – Finish

**Prompt**

*Thank you for calling the iHOLDS telephone randomisation service.*

**Your response**

Hang up.