**Patient Information and Consent in Tele-Trials**

**Example - Participant Information Sheet for Tele-Trials**

|  |
| --- |
| **Title** |
| **Short Title** |
| **Protocol Number** |
| **Study Sponsor** |
| **Principal Investigator** |
| **Location All sites within cluster to be added to PICF**  **Th** |

**This step needs to be repeated on all pages of the PICF where this information is required.**

**Part 1 What does my participation involve?**

**1 Introduction** – As per standard PIS

**2 What is the purpose of this research?** – As per standard PIS

**3 What does participation in this research involve?**

Optional Additional Explanation for Tele-Trials:

This research project is being undertaken under the tele-trial model, which involves the use of telehealth including video conferencing, telephone and web-based systems. This model uses a network of hospitals under the supervision of a primary hospital and primary study doctor. In this research project the primary hospital is [insert name of primary site] and the primary study doctor is [insert name of PI].

You [will not/may] need to visit the primary hospital and your involvement will be limited to onsite visits at [insert name of Satellite site] your clinic wherever possible. The study team will explain where you will need to attend study visits.

Medical personnel at [insert name of Satellite site] will communicate with the primary hospital using telehealth to conduct study visits and review medical records.

**4 What do I have to do?** – As per standard PIS

**5 Other relevant information about the research project** – As per standard PIS

**6 Do I have to take part in this research project?**

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with [name of site] OR\* [(name of Satellite site) and (name of Primary site)]

**7 What are the alternatives to participation?** – As per standard PIS

**8 What are the possible benefits of taking part?** – As per standard PIS

**9 What are the possible risks and disadvantages of taking part?** – As per standard PIS

**10 What will happen to my test samples?** – As per standard PIS

**11 What if new information arises during this research project?** – As per standard PIS

**12 Can I have other treatments during this research project?** – As per standard PIS

**13 What if I withdraw from this research project?** – As per standard PIS

**14 Could this research project be stopped unexpectedly?** – As per standard PIS

**15 What happens when the research project ends?** – As per standard PIS

**Part 2 How is the research project being conducted?**

**16 What will happen to information about me?** – As per standard PIS

**17 Complaints and compensation** – As per standard PIS

**18 Who is organising and funding the research?** – As per standard PIS

**19 Who has reviewed the research project?** – As per standard PIS

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the principal study doctor on [phone number] or one of the following people depending on your local clinical trials site:

**Principal Investigator and Satellite Site Sub Investigators**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position** | **Telephone** | **Site** |
|  | *Principal Investigator* |  | *Primary Site* |
|  | *Sub Investigator* |  | *Satellite Site* |

For any matters clinical or otherwise relating to the study at the site at which you are participating, the details of the clinical contact person are:

**Clinical contact person**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position** | **Telephone** | **Site** |
|  | Clinical Trials Manager Primary Site |  |  |
|  | Clinical Research Coordinator Primary Site |  |  |
|  | Clinical Research Coordinator  Satellite Site |  |  |

For matters relating to study at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Telephone** | **Email** | **Site** |
| Research Governance Officer  Primary Site |  |  |  |
| Research Governance Officer  Satellite Site |  |  |  |

If you have any questions, concerns or complaints about your rights as a participant in a research study, please contact:

**Reviewing HREC approving this study** **and HREC Executive Officer details**

|  |  |
| --- | --- |
| Reviewing HREC Name |  |
| HREC Executive Officer |  |
| Telephone |  |
| Email |  |

**Local HREC Office contact (Research Governance Officer)**

|  |  |
| --- | --- |
| Name | Research Governance Officer |
| Position | Research Governance Officer |
| Telephone |  |
| Email |  |

**Example Consent Form for Tele-Trials**

|  |  |
| --- | --- |
| **Title** | |
| **Short Title** | |
| **Protocol Number** | |
| **Project Sponsor** | |
| **Principal Investigator** | |
| **Sub- Investigator(s)**  *(if required by institution)* | |
| **Location** | |
| *(Name of cluster and primary and satellite sites)* | |
|  |

**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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[(name of Satellite site) and (name of Primary site)]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

{following wording will need to be altered if consent process does not utilise telehealth platform and approach}

*Consent was obtained using telehealth with [Name of Investigator]*

*whose photographic identification was sighted by the Participant who observed the Investigator’s signature being written*

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*Only complete the witness section below if an impartial witness is required as per ICH GCP E6(R2) Dated: 09Nov2016 where a witness\* to informed consent is required.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Witness\* to informed consent process (print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/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.

{include one of the following}

*Consent was obtained using telehealth with* *[Name of Study Participant]*

*whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written*

*Consent was obtained remotely via telephone/internet call with [Name of Investigator]*

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|  | | | | | | |
|  | Name of Study Doctor/  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.

*Optional paragraph:*

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

*Additional component to be added to the consent section when the research project involves the collection, storage, testing and analysis of blood or tissue.*

*If there is an option for blood or tissue samples to be taken and stored for this or further research, it is suggested that consent to the use and storage of tissue be separate from the general consent to participate in the study. This is because it is often the case that participation in the testing and further storage of tissue is contemplated as a separate option for the participant. By utilising an additional consent component (either integrated into the main project Consent Form or through use of a separate additional Consent Form) for this aspect of the research, participants can, in some cases, still consent to the main study but not the additional use of tissue/genetic testing component.*

*If you choose to integrate this component into this Consent Form, the following phrase should be inserted:*

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project

• Other research that is closely related to this research project

• Any future research.

*If appropriate, include the following statement:*

By signing this consent section, I agree to the use of my tissue samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet. *If genetic testing is optional, make this clear.*

*If the study contemplates the use of tissue samples obtained from previous surgery/procedures, a separate specific consent should be obtained for this additional use of tissues previously taken and stored. In this situation, include the following statement:*

By signing this consent section, I agree to the use of tissue samples obtained previously from my *routine biopsy or surgery* for the purposes of additional testing for *[Test to be performed on tissue(s)]*.

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|  | | | | | | |
|  | Name of Participant (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  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.