**DIRECTORATE OF RESEARCH AND INNOVATION**

**Managing Blinding and Unblinding**

This form should be drafted during study set up and must be finalised before the first participant is recruited to make sure that all the necessary steps to manage blinding and unblinding are in place in good time. If there are any changes to managing the blinding or unblinding during the study, a new version of the form must be completed. The previous version(s) must be retained and marked as ‘superseded’. All finalised versions of the completed form must be stored in the Investigator Site File.

*Please note that red text is used as support/prompts and can be deleted from the final document.*

*If Sponsors provide a blinding plan, this can be referenced in this document rather than copying it out or duplicating work. It would be helpful if these documents are stored together in the site file.*

|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **R&D Number:**  |  |
| **Principal Investigator (PI):** |  |
| **Sponsor** |  |
| **Sponsor contact regarding (un)blinding** |  |
| **Version:** | *e.g. Draft XX or Final XX* |

**Managing the Blind**

|  |
| --- |
| 1. Will any members of staff be unblinded for the study (e.g. pharmacy staff if a randomisation list is used, lab staff performing PK analysis, a nurse who has a prepare and/or administer an infusion from labelled medication)?

[ ]  Yes, only Pharmacy – go to question 2[ ]  Yes, Pharmacy and/or other roles – go to question 2[ ]  No – go to question 5, Managing Unblinding  |
| 1. Will Pharmacy be managing the blinding?

[ ]  Yes, and their controls are detailed in the Pharmacy Site File – go to question 5[ ]  No – go to question 3  |
| 1. Which staff will be unblinded for the study?

*The minimum number of people possible should be unblinded and you should include a reason why this is necessary. You may find it easier to include people by role rather than name.* *The following sections might be helpful:**Unblinded team:*

|  |  |  |
| --- | --- | --- |
| *Role*  | *Anticipated Number of People* | *Reason* |
|  |  |  |
|  |  |  |

*Blinded team:*

|  |  |  |
| --- | --- | --- |
| *Role*  | *Anticipated Number of People* | *Reason* |
|  |  |  |
|  |  |  |

 |
| 1. Staff who are unblinded must take particular care that they do not inadvertently unblind others, what measures are/will be put in place to protect the blind?

*Think through each stage of the study (e.g. the journey of IMP from delivery to site and then through dispensing, administration and returns, and the participant journey, including reporting of results).* *Try to keep these measures as simple as possible. The more people that are involved and/or the more complex the steps, the greater the risk of mistakes in either the intervention being given and/or maintaining the blind.**If any testing was done on these measures before they were finalised (e.g. ‘dry runs’) then include the details here, including any changes that were made as a result.**The following sections might be helpful:****Practical steps****(e.g. setting up physical barriers such notices on doors to keep blinded staff out of a room where drug is being checked)****Documentation in the site file and/or on Epic****Think about how records will be stored to protect the blind while maintaining appropriate documentation and access to information for those who need it (e.g. use of sealed envelopes for essential documents in the site file).****Communication pathways*** *What are the communication pathways within the study team, between the study team and supporting departments (such as imaging, pharmacy and labs), and between the study team and Sponsor to make sure there is effective transfer of information whilst also protecting the blind? May want to consider an unblinded clinician as a contact point for unblinded team if they have queries.*  |

**Managing Unblinding**

|  |
| --- |
| 1. What is the unblinding mechanism?

[ ]  Physical code break (e.g. envelopes or a scratch panel on IMP supply)[ ]  Interactive Response Technology (IRT) system[ ]  Other - Please specify: |
| 1. How is access to the unblinding system controlled?

*Unblinding must be secure, always readily available during the study, and not allow breaks of the blind to go undetected.* *The following questions and examples might be helpful:** *Where is the unblinding information stored and what access and access protection is in place?*

*e.g. The code break envelopes are stored in the record store which is swipe access only/kept locked and can only be accessed by [roles].**e.g. The code break envelope is stored in Pharmacy which is staffed 24/7 and only accessible to the Pharmacy team and those with appropriate security clearance.* *e.g. The IRT system has unique logins which are provided to [roles].** *How would breaks of the blind be detected?*

*e.g. broken seal on envelopes, audit trail on IRT system* |
| 1. What is the step-by-step process for unblinding in the event of an emergency?

*Think through each stage of the process and consider who will do what, and how, where and when it will be done (e.g. any time limits).**Try to keep the process as simple as possible. The more people that are involved and/or the more complex the steps, the greater the risk of mistakes.**If any testing was done on these measures before they were finalised (e.g. ‘dry runs’) then include the details here, including any changes that were made as a result.**The following sections might be helpful:**Consider:** *What would happen if unblinding was required out-of-hours, particularly if out-of-hours cover is provided by non-study staff*
* *Where is the information about how to unblind held and who can/needs to access it? (Consider adding contact information/how to unblind to the participant details section of the research tab in Epic)*
* *Who is best to do the unblinding to minimise the chance of the participant/staff having to be taken off the study?*
* *What the back-up is if the system is not working (particularly for IRT systems) or if staff aren’t available,*
* *How and when the team shall notify the PI, R&D and Sponsor that unblinding took place.*
* *What is the IRT helpdesk contact information or where this is held (as this may be needed if the system isn’t working).*
 |

|  |
| --- |
| **Form completed by:** |
| **Name:** |  | **Role:** |  |
| **Signature:** |  | **Date:** |  |
| **Principal Investigator** |
| **Signature:** |  | **Date:** |  |
| **CRA/Sponsor Representative** |
| **Signature:** |  | **Date:** |  |