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T4P Trial Consent Guide

Contents

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Introduction

These guidelines are not prescriptive or exhaustive. They are designed to give guidance on approaching the patient and/or Personal Consultee for consent/opinion following enrolment into the T4P trial using the process of 'deferred consent' or 'research without prior consent'. Some examples of script are offered for suggestion only.

This document should be used in association with the T4P trial SOP 006 'Consent Procedures'.

The research nurse/researcher gaining consent/opinion will have undertaken training in 'Good Clinical Practice (GCP)', and potentially supplemented by 'Informed Consent with Adults Lacking Capacity' and relevant consent training local to their site. The research nurse/researcher will need to assess the patient's mental capacity and ability to provide informed consent when deciding whether it is more appropriate to approach a Personal Consultee at that time.

Information giving and the consent procedure will be more thorough, personalised and have a higher chance of success if the research nurse/researcher is a well-integrated member of the critical care clinical team and understands the patient's condition, treatment, relevant interventional procedures and consideration for / use of platelet transfusion. T4P uses a research without prior consent (RWPC) model (also referred to as 'deferred consent'), whereby eligible patients will be randomised to the assigned threshold for platelets as soon as possible (and no later than 72 hours after fulfilling the eligibility criteria).

It is very unlikely that a patient will have full mental capacity and the ability to provide informed consent prior to being randomised. If, however, the patient is deemed to have full mental capacity on meeting eligibility criteria and prior to randomisation, they should be approached for written, verbal or other non-written (e.g., through blinking or hand movement) consent. They are then followed up for written informed consent later if verbal or non-written consent obtained first.

A patient may have been approached about other research trials during their ICU admission and any opinion they offered then should have been documented and should be considered.

It is likely that the initial discussion regarding consent will be with a Personal Consultee. It is likely that this is after randomisation.

However, If the patient lacks capacity and there is a Personal Consultee available, in person, at the time the patient becomes eligible for inclusion into the trial, and if it is deemed appropriate, the trial can be discussed with the Personal Consultee and they will be presented with the T4P information leaflet. Due to the time-sensitive nature of the invasive procedures, if the Personal Consultee does not provide any objection to the patients' participation, the patient will be enrolled, and opinion obtained from the personal consultee later.

At an appropriate, early, opportunity following randomisation, and once the patient's medical situation is no longer deemed to be an emergency, introduce yourself and your role as part of the critical care team. Explain to the Consultee that the patient has been entered into a research study 'relating to platelet infusions' and that when the patient is well enough you will explain this fully to the patient, but at this point you would like to explain it to them (Consultee). This could be clinical staff explaining this briefly and informing them that a member of the research team will talk to them. A T4P information leaflet is available and may have already been provided to them by clinical or research staff.

Assess when it is appropriate to approach the patient for consent or Consultee for opinion. The patient is highly unlikely to have full mental capacity whilst still undergoing interventional procedures in critical

care and may not have for some time afterwards. In the interim, the patient's Personal Consultee should be approached for their opinion as to the patient's likely wishes and feelings with regards to participating in the study. The patient will then be approached directly if/when their condition improves and they have capacity.

This guide is separated into two sections, approaching Consultees and approaching patients, followed by notes on various possible scenarios.

Prior to approaching patients and Consultees

Ensure you are up to date with:

- patient condition, progress and treatment to date,
- treatment plan,
- members of family/Consultees (including names and relationship to patient) and who is likely to be the most appropriate to approach,
- information given to them to date by clinical and research team.
- any other research trial the patient has already been approached for and/or recruited to (and whether co-enrolment is permitted – if not then contact the CTU prior to approaching Consultee).

Discuss and plan with the bedside staff (nursing and medical) prior to your approach, to ensure good communication and consistency in information giving. Ensure that it is appropriate to approach the patient/Consultee and that you are not adding any additional burden. Decide on who will make the approach, how and when.

Approaching Consultees for opinion

Introduce yourself and your role. Confirm the identity of family/friends you are talking to.

Establish that the proposed Consultee knows the patient well and can give a reliable opinion as to the patient's likely wishes.

The Consultee may be anxious and stressed. In this case, consider whether it is appropriate to approach them now or at a later time.

Ensure they understand the patient's condition, progress and treatment to date, and the current treatment plan (if they do not, explain it or liaise with appropriate clinical staff to discuss with them).

Explain that the patient was entered into a study as part of their early 'emergency' treatment.

e.g., *"I would like to discuss with you a research study that [patient name] has been entered into while here in ICU / Critical Care. It is a study about when to give platelet infusions and is called T4P."*

They may have already been given or taken a 'T4P information leaflet' … ask if they have. Have a copy with you (as well as the full information sheet) to show them.

"Have you already seen one of these leaflets (show the leaflet)?"

If 'yes': "Have you had a chance to read it?.....either take the conversation from there or "I would like to explain the study to you in more detail"….

Put it in perspective: Explain that this a 'big, national study that this hospital is participating in'. Sometimes this helps to give context and reassurance. Explain that each patient included in the study is important in providing evidence to improve the care of similar patients in the future.

e.g., *"This is a big national study, involving around 2500 patients in over 60 critical care units across the UK over four years. We are one of the hospitals taking part. It involves assessment of when it is best to give platelet infusions.*

Briefly explain the need for [this patient's] low-bleeding-risk invasive procedure(s) in the context of their illness and then the background / overview of this study:

e.g. *"The full name for the T4P study is 'Threshold for Platelets'. It is looking at when to give platelet infusions when a patient in ICU/critical care needs an invasive procedure that has a low bleeding risk.*

When someone is admitted to ICU/critical care, it is usual for them to require some invasive procedures for monitoring and treatment. Common procedures are insertion of a 'central line / large IV line' into a large vein [or name example procedure]. [Patient name] had a central line / [procedure name].

Explain platelets & platelet 'count' / 'levels'

"Platelets are cells in our blood that help with blood clotting. We measure platelet levels with the routine blood tests, this is called the 'platelet count'. When someone is very unwell it is common for their platelet count to be low.

Sometimes, if a patient's platelet level is low, we give platelet infusions before these low bleeding risk procedures to help prevent bleeding. But, also, giving platelets has some risks. It is not known when it is best to give platelets for these procedures that have a low-bleeding risk – that is, at what level the platelet count has to drop so that the benefit of giving platelets outweighs the risks.

At the moment, doctors in ICU use different levels.

This research study is trying to find out what level of platelet count is the best one to give a platelet infusion prior to invasive procedures".

Make it local to your ICU/hospital

"This ICU / critical care unit is taking part in this study and all our ICU consultants have agreed to this.

So, when a patient is in ICU and their platelet level is low, they are routinely entered into the study. This is what happened to [patient name] on [day/date] – so s/he is already in the study."

Explain reasons for not gaining consent or opinion prior to entering the patient into study, ensuring you give individualized context for this patient e.g., patient not well enough, emergency/urgent treatment required.

"Procedures in ICU / critical care are often in an emergency situation where decisions need to be made very quickly. It is important that these procedures are not delayed, so there is no time to fully discuss the study with the patient [name] or you in advance".

"So, the team will therefore enroll patients into the research study and focus on delivering the treatment".

"[name] needed the [procedure] quickly. We could not delay it ".

"This is one reason why there was no time to fully discuss the study with you in advance".
"Also, it can be quite a stressful time for you with a lot of information to take in".

If appropriate give values to the 'levels / counts' & give context to this patient, e.g., if the consultee appears to have a good grasp of what you are explaining, or they may ask. This can help quantify the information for them and make it more objective.

e.g., "A normal platelet count is around 150-450. If a patient's platelet count is less than 50 they are considered for this study. [patient name]'s platelet count was [X value], so s/he was entered into this study.

Explain what happens in the trial / study

"When a patient is entered into the study they are randomly allocated to one of five groups. This random allocation is done by a computer and we have no say on which group the patient is allocated to.

The five groups are for different thresholds for platelets. The patient is then given a platelet transfusion before a procedure only if their platelet count is below the allocated threshold".

This may sound confusing….allow time & check understanding….before continuing….

"The five groups are :

- *Platelet count less than 50*
- *Platelet count less than 40*
- *Platelet count less than 30*
- *Platelet count less than 20*
- *Platelet count less than 10*

"So, this means that:

"If the platelet count is below the allocated threshold they will receive a platelet infusion".

"If their platelet count is above the allocated threshold they will not receive a platelet infusion".

"All patients involved in the study will be monitored closely"

"[patient name] was entered into the study prior to his/her [xx procedure]. Therefore, we knew whether platelets were allocated to be given before the procedure or not".

Explain that the patient remains in the trial / study & their allocated group for the duration of their ICU stay

"Once the patient is allocated to a group, they stay in that group for the whole time they are in ICU / critical care. We monitor the platelet count/level by taking blood tests every day (& sometimes more frequently). If a patient needs a procedure, first the doctors assess if the procedure has a low bleeding

risk. If so, we review the latest platelet count & use this value to decide whether they have a platelet transfusion before the procedure (according to the study group they are allocated to).”

To avoid bias, it is preferable not to tell them which group the patient was randomised to. However, if they ask you should tell them (the study is not blind), in which case explain which group the patient was entered into i.e., “threshold less than X”, then explain that treatment in relation to the patient and their care.

“[patient name] was entered into the study prior to his/her [xx procedure]. S/he was allocated into the [threshold group, his/her platelet level was [x] so therefore s/he did/did not receive a platelet transfusion prior to that procedure”.

Explain the data / information collected for the study:

“We collect data from all patients, for example some daily blood test results, what procedures they have, etc. This is data we already have in our hospital / ICU records, so there is no need for the patient / family to do anything. No additional tests or procedures are performed purely for the purpose of this study.

Then, in 3 months and one year, [patient name] will receive a letter from the clinical trials unit (ICNARC), who manage the study across the UK, with follow-up questionnaires to complete by post”.

Explain why you need to gain their opinion retrospectively and what that opinion is provided for:

- Patient is unwell (e.g., ventilated / sedated...put in context for the patient) so cannot discuss with them.
- Agreement for future procedures: continuation of study treatment, research staff collecting data from the patient’s medical notes; future postal questionnaire at 3 months & one year (explain the process, emphasising postal method, straight-forward ‘tick-box’ questionnaires, pre-paid envelopes); telephone advice available if required; no requirement for any further ‘tests/appointments/hospital visits’ after discharge from hospital.

Establish who will act as the Consultee and that they agree to act as Personal Consultee and what this means i.e., they know the patient well enough to give the patient’s likely view and feelings regarding participation in the T4P study.

Explain that you will discuss with the patient when possible / appropriate.

If you have discussed research (for any study) with the patient previously then mention this – they may not have told their family.

“When [patient] is better and able to discuss this and before they leave hospital, I will explain it all to them and ask if they are happy to continue in the study and to provide consent themselves. If they then decide that they do not want to participate that’s fine, and their decision will override yours”.

Remember to explain that participation is voluntary, and it will not affect the other elements of their care. You will discuss with the patient later when/if they become well enough, and that if the

patient/they change their minds later they can withdraw at any time by contacting you or ICNARC (detail on PIS).

Explain what happens if they do not feel the patient would agree:

"If you feel that [patient] would not agree to continue in the study, then we can withdraw them. In this case, the patient is removed from the allocated study group and the ICU doctors will decide whether or not to give a platelet transfusion for any low-bleeding-risk invasive procedure. In this case, we would like to retain all data up to now if that's OK. Also, please can I ask you whether you are happy for data to continue to be collected from the medical records for the study?"* (Emphasise that the patient is removed from the study group and this will not require any further contact with the patient/Consultee about the study).

**NB see below "possible scenarios" & protocol section 11.2.2.5.*

Give the Personal Consultee Information Sheet, allow time to read, establish their understanding, give time to ask questions and ensure their questions are answered. The time required for this process will vary considerably. If the patient is due to be discharged from hospital soon and you feel there is not enough time to gain a signed opinion form prior to discharge, then explain the postal and telephone systems. However, it is always better to have face-to-face discussion and gain opinion in the presence of the Consultee.

If the patient has capacity, approach them instead (see: *Approaching patients for deferred consent*).

If the Consultee agrees, ask them to complete and sign the opinion form. Countersign the opinion form in the presence of the Consultee, add the trial number to the opinion form, and give the Consultee a copy.

Document the discussion, process and outcome in the medical records. Then file a copy of the relevant information sheet and consent form.

Approaching patients for deferred consent

Introduce yourself and your role, ask if it is 'OK' to sit with them to discuss their care and a research study.

Ensure they understand their condition, progress and treatment to date, and current treatment plan (if they do not, explain it or liaise with appropriate clinical staff to discuss with them).

Explain to the patient that s/he was entered into a study as part of their early 'emergency' treatment when they were very unwell.

"*We now need to explain this to you so you can decide if you agree to continue participation in the study".*

Sometimes it helps to give context and reassurance:

"This is a big national study, involving around 2500 patients in over 60 Intensive Care Units across the UK over four years. We are one of the hospitals taking part. It involves assessment of when it is best to give platelet infusions.

Explain that each patient included in the study is important in providing evidence to improve the care of similar patients in the future.

If a Consultee has previously been approached and provided opinion for the patient to be involved in the study, explain this to the patient and ensure you know who provided opinion and their relationship to the patient.

e.g., "We have already explained this to your husband, [name], and he thought you would agree/not object to be entered into the study. I explained to him we would discuss it with you when you were well enough, and so I am explaining it to you now. You can decide if you agree to continue to participate or not".

Briefly explain the need for their low bleeding risk invasive procedure(s) in the context of their illness and then the background / overview of this study:

e.g., "*The full name for the T4P study is 'Threshold for Platelets'. It is looking at when to give platelet infusions when a patient in ICU needs an invasive procedure that has a low bleeding risk.*

When someone is admitted to ICU/Critical Care, it is usual for them to require some invasive procedures for monitoring and treatment. Common procedures are insertion of a 'central line / large IV line' into a large vein".

"You needed a [procedure(s) name]".

Explain platelets & platelet 'count' / 'levels'

"Platelets are cells in our blood that help with blood clotting. We measure platelet levels with the routine blood tests, this is called the 'platelet count'. When someone is very unwell it is common for their platelet count to be low.

Your platelet count is/was low because….."[if you know].

"Sometimes, if a patient's platelet level is low, we give platelet infusions before these low bleeding risk procedures to help prevent bleeding. But, also, giving platelets has some risks. It is not known when it is best to give platelets for these procedures that have a low-bleeding risk – that is, at what level the platelet count has to drop so that the benefit of giving platelets outweighs the risks.

At the moment, doctors in ICU use different levels".

"This research study is trying to find out what level of platelet count is the best one to give a platelet infusion prior to invasive procedures".

Make it local to your ICU/hospital

"This ICU / Critical Care Unit is taking part in this study and all of our ICU consultants have agreed to this".

Emphasise they are already in the study

"So, when a patient is in ICU and their platelet level is low, they are routinely entered into the study. This is what happened to you on [day/date] – so you are already in the study."

Explain the 'random' allocation of 'groups' and what happens in the study emphasizing that allocation is 'random', that you/the clinical team have no choice or control over the allocation.

"When a patient is entered into the study, they are randomly allocated to one of five groups. This random allocation is done by a computer and we have no say on which group the patient is allocated to.

The five groups are for different thresholds for platelets. The patient is then given a platelet transfusion before a procedure only if their platelet count is below the allocated threshold".

This may sound confusing…allow time & check understanding…before continuing…

"The five groups are:

- *Platelet count less than 50*
- *Platelet count less than 40*
- *Platelet count less than 30*
- *Platelet count less than 20*
- *Platelet count less than 10*

"So, this means that:

If your platelet count is below the allocated threshold you will receive a platelet infusion.

If your platelet count is above the allocated threshold you will not receive a platelet infusion.

All patients involved in the study will be monitored closely

You were entered into the study prior to your [xx procedure]. Therefore, we knew whether platelets were allocated to be given before the procedure or not".

Explain that the patient remains in the trial / study & their allocated group for the duration of their ICU stay

"Once you are allocated to a group, you stay in that group for the whole time you are in ICU / critical care. We monitor the platelet count/level by taking blood tests every day & sometimes more frequently. If you need another procedure: first the doctors assess if the procedure has a low bleeding risk. If so, we review the latest platelet count & use this value to decide whether you are given a platelet transfusion before the procedure (according to the study group you were allocated to)."

To avoid bias, it is preferable not to tell them which group they were randomised to. However, if they ask you should tell them (the study is not blind), in which case explain which group the patient was entered into i.e., "threshold less than X", – then explain that treatment in relation to them and their care.

"You were entered into the study prior to your [xx procedure]. Then we knew whether platelets were allocated to be given before the procedure or not. You were allocated into the [threshold group], your platelet level was [x] so therefore you did/did not receive a platelet transfusion prior to that procedure".

Explain the data / information collected for the study

"We collect data from all patients, for example some daily blood test results, what procedures you have, etc. This is data we already have in our hospital / ICU records, so there is no need for you or your family to do anything. No additional tests or procedures are performed purely for the purpose of this study. Then, in 3 months and one year, you will receive a letter from the clinical trials unit (ICNARC), who manage the study across the UK, with follow-up questionnaires to complete by post".

Emphasise the fact that either:

(i) they are now still on ICU / critical care but may now be well enough to discuss this;

(ii) improving and out of ICU / critical care, so the study treatment is now finished.

Explain reasons for not gaining consent prior to entering patient into study, ensuring you give individualised context for this patient e.g., they weren't well enough, emergency/urgent treatment was needed, ICU doctors confirmed they were eligible to go into the study, could not discuss with them because they were too unwell, not safe to delay treatment in order to spend time discussing with them or family.

If the research or clinical team did discuss the study with them prior to treatments, make sure you mention this (they may have forgotten).

Explain that, if they agree, you now need to gain consent retrospectively and what that consent is for:

- Consent for continuation of study group allocation (if still in ICU / critical care)
- Consent for research staff collecting data from their medical notes (to date & until hospital discharge, & outcome data via NHS data up to one year); future postal questionnaires at 3 months and one year (explain the process, emphasising postal method, straight-forward 'tick-box' questionnaires, pre-paid envelopes); telephone advice available if required; no requirement for any further 'tests/appointments/hospital visits' after discharge from hospital.
- Any consent they give overrides that given by the Consultee.

Remember to explain that participation is voluntary. If they are now on the ward it will not affect their treatment /care (even if they need a platelet infusion), it will not affect their future care plan for other aspects of their care, and that if they change their mind later they can withdraw at any time by contacting you or ICNARC (detail on PIS).

Explain you will give them an information sheet to read, and you will answer any questions before they decide whether they agree to give their consent to continue. Establish how much time they would like to read the PIS and that they can also have the time to show it to someone else (e.g., family members) to discuss. You can also discuss with that family member if they would like you to.

Explain what happens if they do not agree:

"If you feel you would prefer not to continue in the study, we can withdraw you":

[If still on ICU]: "In this case, you are removed from the allocated study group and the ICU doctors will decide whether or not to give a platelet transfusion for any further low-bleeding-risk invasive procedure.

[If no longer on ICU]: "In this case, since you are no longer in ICU, you are no longer part of the 'treatment' part of this study, so whether or not you receive platelets will be considered as part of your usual care by your doctors here" (individualise this, is it likely?)

[In both scenarios]: "In this case, we would like to retain all data up to now if that's OK. Also, please can I ask you whether you are happy for data to continue to be collected from the medical records for the study?*" (Emphasise that the patient is removed from the study group and this will not require any further contact with them / their Consultee about the study).

*NB see below "possible scenarios"

Give the PIS, allow time to read, establish their understanding, give time to ask questions and ensure their questions are answered. The time required for this process will vary considerably. If the patient is due to be discharged from hospital soon and you feel there is not enough time to gain signed informed consent prior to discharge, then explain the postal and telephone systems. However, it is always better to have face-to-face discussion and gain consent in the presence of the patient if possible.

If they agree, ask them to complete and sign the consent form. Countersign the consent form in the presence of the patient, add the patient's trial number to the consent form and give the patient a copy.

Document the discussion, process and outcome in the medical records. Then file a copy of the relevant information sheet and consent form.

Possible scenarios

Patient/Consultee gives consent/opinion

Outcomes:

- Patient regains capacity and provides full consent.
- Personal Consultee provides opinion (agreement) for patient to be included, patient does not regain capacity.
- Personal Consultee provides opinion (agreement) for patient to be included, patient regains capacity and provides full consent.

Well done! Thank them and ensure contact details are correct and recorded**.**

The Patient / Personal Consultee is concerned about the low thresholds and the patient not receiving a platelet transfusion

The family / Consultee may express concern that the patient will not / has not receive(d) platelets when they need them.

Consider explaining that:

- The trial only includes procedures that are regarded as 'low bleeding risk'.
- The most appropriate threshold level for transfusion of platelets with low-bleeding-risk procedures is not currently known.
- Giving platelets also has risks.
- Undertaking the trial at your hospital has been agreed with the critical care consultant teams.
- The patient's safety is always the clinical teams' primary concern and if, at any point, they felt that care should be changed then it would be.

Personal Consultee declines / considers declining

If the Personal Consultee gives the opinion that the patient would not want to be involved, then the study treatment (i.e., platelet threshold allocation) will be stopped immediately (if ongoing and clinically appropriate). Make sure the Consultee understands this.

Ask the Consultee whether in their opinion the patient would be willing to continue with 1) ongoing data collection, 2) to receive follow-up questionnaires at 3 months & one year. This will be documented by the Consultee on the Opinion Form and then entered on the CRF by the research team.

Make the Consultee aware that all data up to the point of this decision will be retained in the study unless they request otherwise. Where possible, ask the Consultee if they are happy for data to continue to be collected from the medical records for the study, emphasizing that this will not require any further contact with the patient/Consultee about the study.

If Consultee declines:

(i) Study treatment is stopped (i.e., platelet threshold group allocation is removed, they return to 'usual care', platelets are given according to usual local protocols/procedures). Inform clinical staff. Remove any beside paperwork/posters. Explain this to the Consultee.

Collect data as agreed with Consultee i.e., data collected up to date/time of refusal retained, ongoing and further data either collected or not. Ensure these decisions are documented clearly in the patient's medical notes and then entered on the CRF.

(ii) <u>If patient has been discharged from Critical Care.</u>

(NB study 'treatment' has finished, but usually patient remains in trial if readmitted to critical care). Explain that treatment has now finished because patient has been discharged from critical care, if decline & if patient readmitted to critical care they would no longer be in the allocated group and care (regarding platelet transfusion) would be decided as usual local protocol / procedures. Ask the Consultee whether in their opinion the patient would be willing to continue with 1) ongoing data collection 2) to receive follow-up questionnaires at 3 months & one year.

Proceed as agreed with Consultee i.e., ongoing and further data either collected or not. Ensure these decisions are documented clearly in the patient's medical notes and then entered on the CRF.

Patient recovers capacity and declines consent

Follow the procedures outlined in the section *'approaching patients for deferred consent'*.

- To avoid bias, it is preferable not to tell the patient which group they were randomised to. However, if they ask you should tell them which group they were entered into and what it meant for them.
- Consider explaining the threshold group they were allocated to and whether or not they received platelets if you feel this would help their understanding. Keep this in the context of their illness / care / procedures.
- If they are soon to be discharged from critical care explain that the allocated group does not continue after discharge / while on the ward, so if they are unlikely to have any further procedures then their care is unlikely to be further affected.

If a Personal or Nominated Consultee was previously approached and gave their opinion, explain that – i.e., the Consultee (name) previously gave opinion (e.g., agreement). If the patient chooses to decline consent, clarify which options they would like to decline (e.g., questionnaire follow-up, continue to collect data and check their medical records). Ensure these decisions are documented clearly in the patient's medical notes and then entered on the CRF.

If a Consultee was not previously approached, proceed as agreed with the Patient (i.e., ongoing and further data either collected from medical records or not; follow-up questionnaires agreed to or not). Ensure these decisions are documented clearly in the patient's medical notes and then entered on the CRF

Patient dies before the Personal Consultee is approached

In situations where the patient has died prior to consent / opinion being in place, a Nominated Consultee should be approached. You may discuss the study with the patient's family in this circumstance, however this will be at the discretion of the clinical team and following the guidelines below. The family should not be asked to sign an opinion form and a Nominated Consultee should still be approached and provided with details of the discussion with the family.

Try to introduce yourself and the study to the family/Consultee as early in the patient's treatment pathway as possible. If you know death is likely soon, or has occurred, assess whether it is appropriate for you to approach the family – this will depend on your existing relationship with them and time. Discuss with the bedside staff. Decide on the most appropriate person to approach in the family – it may be that the bedside staff have a closer relationship and can introduce the concept of the study to them and ask if they are happy to talk to the research nurse.

If appropriate, briefly explain to the family that during the 'urgent/emergency' phase of treatment, the patient / [patient name] was entered into a study about 'when to give platelet infusions'. At that time it was not appropriate to take time to explain the study to the family (it would delay treatment and probably be 'too much to take in'). Explain that you would like to inform them about the patient's involvement in the study. Take care not to cause the family any additional anxiety or burden, and if they would prefer not to discuss the study assure them that this is 'fine' and you will not discuss again.

If they agree to discuss with you: explain the study as above (adapted to patient outcome and context). It may be preferable not to tell them which group the patient was randomised to. However, if they ask you should tell them. Ensure that all discussions with the family give consistent information (see below).

The family / Consultee may be concerned that involvement in the study, and the consequent administration of platelets or not, caused the death.

Firstly, establish with the critical care consultant whether this is possible in this case. Involve the PI where possible. Report as appropriate (& see notes below).

Ensure that all discussions with the family give consistent information. Discuss any conversations with family that have already occurred, and the information given. Discuss with your colleagues / doctors who have discussed the outcome with the family. Check (preferably in advance of discussion) that the clinical team are aware that the patient is in the trial, whether or not they received platelets, and whether or not this has been discussed with any detail given.

It is useful for the research team member (PI or research nurse) to be present during the conversations to enhance consistency of information given and confirmation of understanding.

Consider explaining that:

- The most appropriate threshold level for transfusion of platelets with low-bleeding-risk procedures is not currently known.
- The patient's safety is always the clinical teams' primary concern and if, at any point, they felt that care should be changed then it would be.
- If the patient received platelets, (whichever group they were allocated to), and this would have been likely to occur regardless of participation in the trial (i.e., if this fits into your unit's usual policies / procedures) then you could explain this.
- If the patient did not receive platelets, explain that the most appropriate threshold level for transfusion of platelets with low-bleeding-risk procedures is not currently known; giving platelets also has risks; undertaking the trial at your hospital has been agreed with the critical care consultant teams.

It is not appropriate or possible to discuss with family / Consultee

In certain circumstances, there may be no family / Personal Consultee available, or it may not be appropriate to approach a Personal Consultee e.g., the Consultee lacks capacity, they are extremely distressed, or they do not wish to be consulted.

In these situations, a Nominated Consultee should be approached for their opinion (i.e., the relatives should not be asked to sign an opinion form).

If the patient regains full mental capacity, they should then be approached for consent.

Communicating the study with Personal Consultees over the phone

Personal Consultees should be approached for their opinion in person where possible. However, if a Personal Consultee is unable to visit the hospital (e.g., due to COVID-19 restrictions), they should be approached for their opinion via telephone.

The approach to a Personal Consultee over the phone should be similar to the process outlined in the section above. Ensure that you are up to date with the patient's situation (see: *Prior to approaching patients and Consultees*). It may be appropriate to provide an update on the patient's progress before letting the family member know that the patient has been entered into the study.

When approaching a Personal Consultee for their opinion over the phone, you should offer to send the Information Sheet to them and should give them time to consider the information and ask any questions they have. This can be sent by post or email (NB ensure you are aware of any local policies regarding communication by email).