HSC Research & Development Division

Public Health Agency

Office for Research Ethics Committees Northern Ireland (ORECNI)

Briefing Note Regarding Research on Adults Lacking Capacity Studies- Northern Ireland (Non- Clinical Trials of Investigational Medicinal Products (CTIMPS) only)

Audience: Researchers and research sponsors involved in research in Northern Ireland, Northern Ireland based Health and Social Care (HSC) research ethics and R and D staff.

Current Position

The Mental Capacity Act (Northern Ireland) became law on 9th May 2016 however it has not yet been implemented in Northern Ireland. The provisions of this Act therefore cannot be relied upon. The most recent timetable suggested the earliest date for implementation would be in or about 2019/2020 however, this is subject to change.

The position therefore remains that there is no specific legislation within Northern Ireland applicable to non-CTIMP research involving adults who lack capacity. All research must be approved by a Health and Social Care Research Ethics committee and must comply with common law principles.

This guidance note applies to non_CTIMP research involving adults lacking capacity aged 16 or over.

Principle

In deciding whether to carry out non-CTIMP research with persons who lack capacity (ALC), the common law principle of Best Interests will apply.

- *Participation in research enables the patient to receive the benefits of standard care as well as the potential benefits of the intervention being delivered through the research study. In addition, participation in research is generally associated with enhanced monitoring which may contribute to better outcomes.
- ** The MDT would include the group of health professionals normally involved in making the clinical decisions/undertaking the care of the patient. Its composition will vary from patient to patient and according to the clinical setting but, for example, may include, consultant, nurse, pharmacist, allied health professional or social worker depending on their individual needs.

This guidance has been subject to input from Northern Ireland Based researchers who perform research with adults lacking capacity. It has also been equality screened and has been subject to both patient public involvement and legal advice.

Best interests in this sense should consider the subjective best interests of one person rather than the community at large. One must therefore weigh the potential positive impact* on a patient against the risk to that patient, not to society as a whole.

Mental Incapacity

Mental incapacity exists in a broad sense e.g. persons who temporarily lack capacity (e.g. patient in intensive care unit in hospital, and therefore with likelihood of regaining capacity) and adults who may fluctuate in their capcity to consent (e.g. late stage dementia). Therefore lack of capacity is not restricted to those with mental health problems but may include persons with learning disabilities and persons who have difficulty making a decision due to injuries inflicted by a stroke. It may be either a temporary or a permanent loss of capacity. It is also important to note that capacity is decision specific and therefore although a person may lack capacity to make a decision regarding a certain matter, it does not automatically follow that they lack capacity in any other or all respects.

Procedural and Practical Advice to HSC RECs on review of the protocol information sheets and consent forms for NI adults lacking capacity where they are involved in the UK wide context until the NI law goes live or for NI based studies only.

In a non-CTIMP study involving adults lacking capacity at various sites throughout the UK, the procedure is that a REC based in England, Wales or Scotland will perform the main ethical review but will forward the protocol, information sheets and consent/consultation forms appropriate to the adults lacking capacity in the study to an HSC sub-committee for advice. (Where an amendment is being processed to add a NI site on to a study already having had a favourable opinion from a REC, then the same process is followed). The HSC REC can comment on the appropriateness of the wording of the documents for use with NI based participants lacking capacity, and feed this back to the main REC who will advise the applicant in its overall response.

The HSC REC will also expect to be assured on any data processing required as part of a non-CTIMP study involving adults lacking capacity based in Northern Ireland. The Chief Investigator must consider requirements under data protection legislation in relation to any

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required processing of personal data whilst the adult research participant lacks capacity. Advice should be sought from the HSC organisation's (or equivalent organisation with data processing responsibility under GDPR) information governance team in design of the research protocol and other study documentation to meet data protection legislation requirements.

What happens now: Currently when the HSC RECs make decisions on Northern Ireland based studies involving sites in GB, they should generally advise the following:

- *Participation in research enables the patient to receive the benefits of standard care as well as the potential benefits of the intervention being delivered through the research study. In addition, participation in research is generally associated with enhanced monitoring which may contribute to better outcomes.
- ** The MDT would include the group of health professionals normally involved in making the clinical decisions/undertaking the care of the patient. Its composition will vary from patient to patient and according to the clinical setting but, for example, may include, consultant, nurse, pharmacist, allied health professional or social worker depending on their individual needs.

This guidance has been subject to input from Northern Ireland Based researchers who perform research with adults lacking capacity. It has also been equality screened and has been subject to both patient public involvement and legal advice.

Case 1: Urgent intensive care/ emergency room study (Non–CTIMP) in an emergency situation the patient is involved into a study whilst unconscious.

The HSC Research Ethics Committee will have reviewed the research protocol with a view to assessing the benefits and risks of including that particular section of the population. The REC, where necessary, will modify the inclusion/exclusion criteria based upon that assessment.

Once a patient within this section of the population presents within one of the settings referred to above, an assessment should be undertaken to establish whether inclusion in the research study is in their particular best interests. This will require consideration as to whether the potential positive impact* outweighs the risk to this particular patient.

The patient's best interests should be considered by a multi-disciplinary team (MDT)** which consists of all professionals involved in the holistic care of the patient. Any decision to include the patient must be taken solely in the best interests of the patient and must be unanimous. Clear records around decision making should be made and retained. Best practice is always use of the MDT in decision making however this may not always be possible before the initial intervention is made in a urgent care situation. In those circumstances, at least one Registered Medical Practitioner (RMP), unrelated to the research study, should make assessment of the patient in his/ her best interest.

Close relatives/close friends, if available, will play a vital role in this process. They should be informed and consulted about the research project and they can inform the MDT/RMP about the patient's likely views. The close relative or friend cannot however consent on behalf of the patient and therefore, their views are not determinative. Ultimately, the decision regarding the participation of a patient in the non CTIMP shall be made by a RMP under emergency circumstances or wherever possible a MDT in the patient's best interests. If there were differences between the views of relatives and the RMP or MDT, it would be unusual for the patient to be included in the research study.

Therefore the approach elsewhere in the UK of using e.g. a personal consultee (England and Wales) to consent on behalf of their close relative/ close friend cannot be used yet in

- *Participation in research enables the patient to receive the benefits of standard care as well as the potential benefits of the intervention being delivered through the research study. In addition, participation in research is generally associated with enhanced monitoring which may contribute to better outcomes.
- ** The MDT would include the group of health professionals normally involved in making the clinical decisions/undertaking the care of the patient. Its composition will vary from patient to patient and according to the clinical setting but, for example, may include, consultant, nurse, pharmacist, allied health professional or social worker depending on their individual needs.

This guidance has been subject to input from Northern Ireland Based researchers who perform research with adults lacking capacity. It has also been equality screened and has been subject to both patient public involvement and legal advice.

Northern Ireland. Under current Northern Irish law, the close relative/close friend should be informed and consulted however they cannot consent nor assent on behalf of their close relative/close friend. It is sensible to maintain a paper trail around the input of the close relative/close friend, however one must be careful to ensure this does not stray into the signing of a consent form in view of the legal position outlined above.

If the unconscious patient regains consciousness and has capacity, then he/she is given a patient information sheet and a CONSENT form. Consent is sought from the patient as to whether to continue in the study and whether tissue /data obtained up to that point may be retained.

Please refer to accompanying flowcharts A and B

- *Participation in research enables the patient to receive the benefits of standard care as well as the potential benefits of the intervention being delivered through the research study. In addition, participation in research is generally associated with enhanced monitoring which may contribute to better outcomes.
- ** The MDT would include the group of health professionals normally involved in making the clinical decisions/undertaking the care of the patient. Its composition will vary from patient to patient and according to the clinical setting but, for example, may include, consultant, nurse, pharmacist, allied health professional or social worker depending on their individual needs.

This guidance has been subject to input from Northern Ireland Based researchers who perform research with adults lacking capacity. It has also been equality screened and has been subject to both patient public involvement and legal advice.

CASE 2: Non-CTIMP study involving patients with stroke/ dementia or other who lack capacity to consent.

The HSC Research Ethics Committee will have reviewed the research protocol with a view to assessing the benefits and risks of including that particular section of the population. The REC, where necessary, will modify the inclusion/exclusion criteria based upon that assessment.

Once a patient within this section of the population presents within one of the settings referred to above, an assessment should be undertaken to establish whether inclusion in the research study is in their particular best interests. This will require consideration as to whether the potential positive impact* outweighs the risk to this particular patient.

The patient's best interests should be considered by a multi-disciplinary team (MDT) which consists of all professionals involved in the holistic care of the patient.

Close relatives/close friends, if available, will play a vital role in this process. They should be informed and consulted about the research project and they can inform the MDT about the patient's likely views. The close relative or friend cannot however consent on behalf of the patient and therefore, their views are not determinative. Ultimately, the decision regarding the participation of a patient in the non-CTIMP shall be made by a MDT in the patient's best interests and must be unanimous. If there were differences between the views of relatives and the MDT, it would be unusual for the patient to be included in the research study.

Therefore the approach elsewhere in the UK of using a personal consultee (England and Wales) to consent on behalf of their close relative/close friend or Welfare Attorney/ Close relative consent in Scotland cannot be used yet in Northern Ireland. Under current Northern Irish law, the close relative/close friend should be informed and consulted however they cannot consent nor assent on behalf of their close relative/close friend. It is sensible to maintain a paper trail around the input of the close relative/close friend, however one must

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- ** The MDT would include the group of health professionals normally involved in making the clinical decisions/undertaking the care of the patient. Its composition will vary from patient to patient and according to the clinical setting but, for example, may include, consultant, nurse, pharmacist, allied health professional or social worker depending on their individual needs.

This guidance has been subject to input from Northern Ireland Based researchers who perform research with adults lacking capacity. It has also been equality screened and has been subject to both patient public involvement and legal advice.

be careful to ensure this does not stray into the signing of a consent form in view of the legal position outlined above.

If the mentally incapacitated patient regains capacity, then he/she is given a patient information sheet and a CONSENT form. Consent is sought from the patient as to whether to continue in the study and whether tissue /data obtained up to that point may be retained.

In summary for non-CTIMP studies with adults lacking capacity:

Any protocol should reflect the legal position in Northern Ireland and the HSC REC should expect to see:

- That a MDT (or at least one RMP unrelated to the study in an urgent intensive care or emergency situation) has considered the best interests of the patient with regard to whether they should be included in the study.
- A Close relative/ Close Friend information sheet which explains why their loved one may be involved in the research study.
- A consent sheet to cover consent of the patient should they regain capacity.

Reference Example Flow Charts in the Appendix of this Guidance.

- *Participation in research enables the patient to receive the benefits of standard care as well as the potential benefits of the intervention being delivered through the research study. In addition, participation in research is generally associated with enhanced monitoring which may contribute to better outcomes.
- ** The MDT would include the group of health professionals normally involved in making the clinical decisions/undertaking the care of the patient. Its composition will vary from patient to patient and according to the clinical setting but, for example, may include, consultant, nurse, pharmacist, allied health professional or social worker depending on their individual needs.

This guidance has been subject to input from Northern Ireland Based researchers who perform research with adults lacking capacity. It has also been equality screened and has been subject to both patient public involvement and legal advice.

FLOW CHART A - RESEARCH STUDY: Non CTIMP with adult participant lacking capacity

Setting: Emergency room, urgent care, intensive care.

Working Assumptions: Patient is unconscious (and by virtue lacks capacity) or has a condition were they lack capacity and must receive either a single intervention or ongoing interventions whilst lacking capacity, for the purpose of the research study, the first of which must be given in a short timeframe or
Patient is unconscious (and by virtue lacks capacity) or has a condition were they lack capacity and is being involved in a non-interventional research study e.g. observational

Before entering the patient into research study

Preliminary Step A qualified member of staff assesses suitability of patient according to the research study protocol's inclusion or exclusion criteria.

Option A: not suitable continue to treat participant with standard care [Ensure appropriate record keeping]

Option B: Patient deemed suitable for research protocol [Ensure appropriate record keeping]

Step 1: Suitable patient is assessed by Multidisciplinary Team or if this cannot be convened due to emergency situation, by a Registered Medical Practitioner (RMP) unrelated to the research study. The MDT/RMP either agrees or disagrees that it is in the patient's best interest to be entered into the research study. [Ensure appropriate record keeping]

Option A: Not in patient's best interest to enter the research study- continue into standard care only. [Ensure appropriate record keeping]

Option B: In patient's best interest to enter the research study- enter into the research study. Note reasoning and decision on medical record.

After entering the patient into the research study

Step 2: (this step is applicable only where ongoing interventions or observations are occurring in the research protocol). The patient is then assessed by the Multidisciplinary team (MDT) which includes all professionals involved in the holistic care of the patient as soon as possible after the emergency situation has passed, who agrees or disagrees that it is patient's best interest to continue in the research study and this decision is filed on the medical record.

Option A: Not in patient's best interest to continue in the trial- remove from research study continue with standard care only and note reasoning and decision on medical record

Option B: Agree it is in patients best interest to enter research study- continue in research study intervention (s). Note reasoning and decision on medical record.

Step 3A: Patient entered into research study regains consciousness. He/ she is informed about the research study

Option A: consents to continue and for data and/or tissue collected to date to be used in the research study

Option B: Discontinues in research study. Data and/or tissue collected to date is destroyed or retained with patient consent.

Step 3B: Patient does not regain consciousness. Patient is continued in research study in his/her best interests

Throughout this process where a close relative or close friend is available they should be consulted however it is important to note, under current Northern Irish law; they do not have the ability to consent or assent. Therefore, a Close relative/ Close Friend information sheet which will explain why their loved one may be involved in the research study should be provided.

FLOW CHART B - RESEARCH STUDY: Non CTIMP with adult participant lacking capacity

Setting: clinical or social care setting (Non-Emergency room, urgent care, intensive care).

Typical patient: stroke, dementia or other condition where the person lacks capacity

Working Assumptions: Patient lacks capacity (determined by formal capacity assessment), and must receive either a single intervention or ongoing interventions in the research study. Or patient lacks capacity (determined by formal capacity assessment), and is being involved in a non-interventional study e.g. observational.

Before entering the patient into research study

Preliminary Step A qualified member of staff assesses suitability of patient according to the research study protocol's inclusion or exclusion criteria.

Option A: not suitable, continue to treat patient/service user with standard care [Ensure appropriate record

Option B: Patient/service user deemed suitable for entry into research study [Ensure appropriate record keeping]

STEP 1: Suitable patient is assessed by Multidisciplinary team (MDT) which includes all professionals involved in the holistic care of the patient who agrees or disagrees that it is patient's best interest to participate in the research study and this decision is filed in the medical record.

Option A: Not in patient's best interest to enter the research study- continue with standard care only. Note reasoning and decision on medical record.

Option B: In patient's best interest to enter study- enter him/her into the study. Note reasoning and decision on medical record.

After entering the patient into the research study

Step 2A: Patient entered into research study regains capacity. He/ she are informed about the research study.

Option A: Patient consents to continue and for data or tissue collected to date to be used in research study

Option B: Discontinues in research study. Data and/or tissue collected to date is destroyed or retained with patient consent.

Step 2B: Patient does not regain capacity. Patient is continued in the research study in his/her best interests

Throughout this process where a close relative or close friend is available they should be consulted however it is important to note, under current Northern Irish law; they do not have the ability to consent or assent. Therefore, a Close relative/ Close Friend information sheet which will explain why their loved one may be involved in the research study should be provided.

Close Relative or Close Friend Information Form Northern Ireland

Non-Clinical Trial of an Investigational Medicinal Product (CTIMP) involving an adult participant who is unable to consent for themselves (non-emergency situation)

Study Title

What is the xxx study?

Provide a summary in lay language.

Use text from standard participant sheet template HRA version 2 available at http://www.hra-decisiontools.org.uk/consent/examples.html editing where necessary to your specific study.

Who decides if it is in the patient's best interest to be a participant in the study?

The multidisciplinary team (MDT) includes all professionals involved in the holistic care of your close relative/close friend, who after assessment, have considered that your close relative/close friend is not able to consent for themselves. Together, the MDT will decide whether or not it is in the best interest of your close relative/ close friend to be involved in this research study. You should discuss this with a member of the MDT and ask any questions you may have, including your knowledge of your close relative/close friend's likely views on being involved in this research study. It is important to understand that legally you cannot consent on behalf of the patient. Involvement of your close relative or close friend in this research study will not change any standard care being given to him/her. If you require any further information please contact xxxxxx-.

Assessment of Adult's capacity

An adult will lack capacity to consent if he/she is:

- Unable to understand the information relevant to the decision.
- Unable to retain that information.
- Unable to use and weigh that information as part of the process of making the decision.
- Unable to communicate his/her decision.

Include where appropriate

If after entering the study, your close relative/close friend regained his/her capacity to consent for themselves, the study will be explained to them and he/she will be allowed to consent to continue or can choose to withdraw from the study.

Who has reviewed this study?

A Health and Social Care Research Ethics Committee (REC) (XXXX), whose role is to protect people involved in research, has reviewed this research study with a view to assessing the benefits and risks of including this patient group. The inclusion/exclusion criteria have been reviewed, and where necessary, modified based on the assessment made by the committee.

Patient details	Place Small Patient Label Here

To be completed by a close relative/close friend of patient:

I (name) have been involved in a discussion with a member of the multidisciplinary team (MDT) about involvement of my close relative/close friend in this research project**. I understand that the MDT considers unanimously that it is in the best interest of my close relative/close friend to be involved in this study**

Multidisciplinary Team (MDT) Form Northern Ireland

Non-Clinical Trial Investigational of an Investigational Medicinal Product (CTIMP) involving an adult participant who is unable to consent for themselves (non-emergency situation)

Study Title

What is the xxx study?
Provide a summary in lay language.

Use text from standard participant sheet template HRA version 2 available at http://www.hra-decisiontools.org.uk/consent/examples.html editing where necessary to your specific study.

Who has reviewed this study?

Health and Social Care Research Ethics Committee (REC) (XXXX), whose role is to protect people involved in research, has reviewed this research study with a view to assessing the benefits and risks of including this patient group. The inclusion/exclusion criteria have been reviewed, and where necessary, modified based on the assessment made by the committee.

Who decides if it is in the patient's best interest to be a participant in the study?

Note: Please refer to accompanying Briefing Note Regarding Research on Adults Lacking Capacity Studies- Northern Ireland (Non- Clinical Trials of Investigational Medicinal Products (CTIMPS) only)

The multidisciplinary team (MDT), which includes all professionals involved in the holistic care of the patient, needs to decide unanimously if it is in this patient's best interest to be involved in this research study. This patient is unable to consent for themselves. A member of the MDT will inform and consult with this patient's close relative/close friend about this study and assess from him/her the patient's likely views on being involved in this research study. The close relative/ close friend cannot consent on behalf of the patient for them to participate in this study. The MDT will then consider if the potential positive impact of being involved in this study, outweighs the risk to the patient. Only in these circumstances will the MDT decide to include this patient in this study; determining that it is in their best interest. A record of this decision should be maintained. Irrespective of being involved in this study or not, this patient shall continue to receive standard care.

Assessment of Adult's capacity

An adult will lack capacity to consent if he/she is:

- Unable to understand the information relevant to the decision.
- Unable to retain that information.
- Unable to use and weigh that information as part of the process of making the decision.
- Unable to communicate his/her decision.

Include where appropriate

If after entering the study, the patient regained his/her capacity to consent for themselves, the study will be explained to them and he/she will be allowed to consent to continue or can choose to withdraw from the study.

Patient details	Place Small Patient Label Here

To be completed on behalf of the Multidisciplinary (MDT):

I (name, job title) on behalf of this patient's multidisciplinary team (MDT) verify that the MDT has:

- consulted and informed this patient's close relative/close friend
- The MDT has agreed unanimously to continue to include this patient in this research study in his/her best interest.

Close Relative or Close Friend Information Form Northern Ireland

Non-Clinical Trial of an Investigational Medicinal Product (CTIMP) involving an adult participant who is unable to consent for themselves (Emergency situation)

Study Title

What is the xxx study?

Provide a summary in lay language.

Use text from standard participant sheet template HRA version 2 available at http://www.hra-decisiontools.org.uk/consent/examples.html editing where necessary to your specific study.

Who decides if it is in the patient's best interest to be a participant in the study?

A Registered Medical Practitioner (RMP), who is independent of the research team, has assessed your close relative/ close friend whilst s/he was unable to consent for themselves. The RMP considered that the potential positive impact of being involved in this study outweighed the risk to your close relative/ close friend. S/he included your loved one in this research study in their best interest. As this was an emergency situation there was no time to inform and consult with you before the decision to include your loved one in the study was taken by the RMP.

Now that the emergency had passed, a member of the Multidisciplinary Team (MDT) (which includes all professionals involved in the holistic care of your loved one) will inform and consult with you about this research study and about your loved one's likely views on being involved. The MDT will need to agree unanimously that it is still in your loved one's best interest to continue on this research study. It is important to understand that you cannot legally consent on behalf of your close relative/close friend. Irrespective of being involved in this research study your close relative/ close friend shall continue to receive standard care.

Assessment of Adult's capacity

An adult will lack capacity to consent if he/she is:

- Unable to understand the information relevant to the decision.
- Unable to retain that information.
- Unable to use and weigh that information as part of the process of making the decision.
- Unable to communicate his/her decision.

Include where appropriate

If after entering the study, your close relative/close friend regained his/her capacity to consent for themselves, the study will be explained to them and he/she will be allowed to consent to continue or can choose to withdraw from the study.

Who has reviewed this study?

A Health and Social Care Research Ethics Committee (REC) (XXXX), whose role is to protect people involved in research, has reviewed this research study with a view to assessing the benefits and risks of including this patient group. The inclusion/exclusion criteria have been reviewed, and where necessary, modified based on the assessment made by the committee.

Patient details	Place Small Patient Label Here

To be completed by a close relative/close friend of patient:

I (name) have been involved in a discussion with a member of the multidisciplinary team (MDT) about involvement of my close relative/close friend in this research project**. I understand that the MDT has agreed unanimously that it is in the best interest of my close relative/close friend to be involved in this study.**

Multidisciplinary Team Form Northern Ireland

Non-Clinical Trial of an Investigational Medicinal Product (CTIMP) involving an adult participant who is unable to consent for themselves (emergency situation)

Study Title

What is the xxx study?

Provide a summary in lay language.

Use text from standard participant sheet template HRA version 2 available at http://www.hra-decisiontools.org.uk/consent/examples.html editing where necessary to your specific study.

Who has reviewed this study?

Health and Social Care Research Ethics Committee (REC) (XXXX), whose role is to protect people involved in research, has reviewed this research study with a view to assessing the benefits and risks of including this patient group. The inclusion/exclusion criteria have been reviewed, and where necessary, modified based on the assessment made by the committee.

Who decides if it is in the patient's best interest to be a participant in the study?

Note: Please refer to accompanying Briefing Note Regarding Research on Adults Lacking Capacity Studies- Northern Ireland (Non- Clinical Trials of Investigational Medicinal Products (CTIMPS) only).

A Registered Medical Practitioner (RMP), who is independent of the research team, has assessed the patient whilst s/he was unable to consent for themselves. The RMP considered that the potential positive impact of being involved in this study outweighed the risk to the patient. S/he included the patient in this research study in their best interest. As this was an emergency situation there was no time to inform and consult with a close relative/ close friend or with the patient's multi-disciplinary team MDT (which includes all professionals involved in the holistic care of the patient) before the decision to include the patient in the research study was taken by the RMP.

Now that the emergency had passed, a member of the MDT needs to inform and consult with a close relative/close friend about this research study, and about the patient's likely views on being involved. The MDT will then need to agree unanimously that it is still in the patient's best interest to continue in this research study. It is important to note that the close relative/close friend cannot legally consent on behalf of the patient. Irrespective of being involved in this research study the patient shall continue to receive standard care. A record of the MDT's decision should be maintained.

Assessment of Adult's capacity

An adult will lack capacity to consent if he/she is:

- Unable to understand the information relevant to the decision.
- Unable to retain that information.
- Unable to use and weigh that information as part of the process of making the decision.
- Unable to communicate his/her decision.

Include where appropriate

If after entering the study, the patient regained his/her capacity to consent for themselves, the study will be explained to them and he/she will be allowed to consent to continue or can choose to withdraw from the study.

Patient details	Place Small Patient Label Here

To be completed on behalf of the Multidisciplinary (MDT):

I (name, job title) on behalf of this patient's multidisciplinary team (MDT) verify that the MDT has:

- consulted and informed this patient's close relative/close friend
- The MDT has agreed unanimously to continue to include this patient in this research study in his/her best interest.

Registered Medical Practitioner (RMP) Form Northern Ireland

Non-Clinical Trial of an Investigational Medicinal Product (CTIMP) involving an adult participant who is unable to consent for themselves (emergency situation)

Study Title

What is the xxx study?

Provide a summary in lay language.

Use text from standard participant sheet template HRA version 2 available at http://www.hra-decisiontools.org.uk/consent/examples.html editing where necessary to your specific study.

Who has reviewed this study?

Health and Social Care Research Ethics Committee (REC) (XXXX), whose role is to protect people involved in research, has reviewed this research study with a view to assessing the benefits and risks of including this patient group. The inclusion/exclusion criteria have been reviewed, and where necessary, modified based on the assessment made by the committee.

Who decides if it is in the patient's best interest to be a participant in the study?

Note: Please refer to accompanying Briefing Note Regarding Research on Adults Lacking Capacity Studies- Northern Ireland (Non- Clinical Trials of Investigational Medicinal Products (CTIMPS) only)

A qualified member of the research team has assessed this patient (who is unable to consent for themselves) for suitability for inclusion in this research study against the approved inclusion and exclusion criteria. As a Registered Medical Practitioner (RMP), who is independent of the research team, you need to assess if the potential positive impact of this patient being involved in this study, outweighs the risk to this patient. S/he may then be included in this research study, in their best interest. As this is an emergency situation there is no time to inform and consult with a close relative/ close friend or with the patient's multi-disciplinary team (which includes all professionals involved in the holistic care of the patient) before the decision to include the patient in the research study is taken by you. A record of your decision should be maintained.

However, after the emergency passes, a member of the Multidisciplinary Team (MDT) (which includes all professionals involved in the holistic care of the patient) needs to inform and consult with a close relative/close friend about this research study, and about the patient's likely views on being involved. The MDT will then need to agree unanimously that it is still in the patient's best interest to continue in this research study. It is important to note

that the close relative/close friend cannot legally consent on behalf of the patient. Irrespective of being involved in this research study the patient shall continue to receive standard care.

Assessment of Adult's capacity

An adult will lack capacity to consent if he/she is:

- Unable to understand the information relevant to the decision.
- Unable to retain that information.
- Unable to use and weigh that information as part of the process of making the decision.
- Unable to communicate his/her decision.

Include where appropriate

If after entering the study, the patient regained his/her capacity to consent for themselves, the study will be explained to them and he/she will be allowed to consent to continue or can choose to withdraw from the study.

Patient details	Place Small Patient Label Here
To be completed by the RMP: I (Name, Job Title) have assessed XXXXX and consider it to be in this patient's best interest to be entered into this research study.	