In certain circumstances [Insert name of paediatric cancer centre] provides health care services to young adults with cancer, as part of a clinical trial.

A young adult with a paediatric-type cancer will normally be under the care of an adult cancer centre due to their age. Based on the paediatric nature of their disease, it is unlikely that a clinical trial will be available to them in the adult oncology setting.

This procedure aims to provide paediatric cancer centre staff with a transparent, equitable and clear process to apply to Hospital Executive for permission to transfer young adults with a paediatric-type cancer to the paediatric cancer centre to access a paediatric cancer clinical trial.

The procedure acknowledges the differing requirements for clinical trials requiring outpatient or inpatient admission.

# 2. Scope

In a situation in which a young adult with a paediatric cancer seeks to access a cancer clinical trial open at the paediatric centre, the following should be taken into consideration:

* Is the patient considered to meet all ethically approved eligibility criteria (pending final screening), or can these criteria be amended to accommodate the patient?
* Will the likelihood of survival be increased, or quality of life and survivorship improved, through participation on the trial?
* Does the clinical trial present a remaining treatment option for a patient that has not responded to prior treatment and has poor prognosis?
* Will participation in the trial contribute important trial data that represents the full age range across which the disease occurs?

# 3. Responsibilities

The Principal Investigator (PI) is responsible for the overall conduct of the study; this includes overseeing the assessment of eligibility of the young adult patient and preparing the application for paediatric oncology centre access.

# 4. Definitions

A young adult is a person aged between 18 and 25 years.

A cancer clinical trial open at the paediatric cancer centre is a clinical trial actively recruiting at that centre.

Ethically approved clinical trial eligibility criteria are those criteria required to be met by the potential participant in order to be recruited to the trial, as stated in the Human Research Ethics Committee (HREC) approved trial protocol. Such criteria might include age, cancer type/subtype, cancer stage, treatment history. Deviations from the protocol criteria in order to accommodate a particular patient must be approved by a HREC.

# 5. Equipment and supplies

Application for Young Adult Access to Paediatric Cancer Clinical Trial Form

# 6. Procedure

Where a young adult with cancer is considered eligible for recruitment to a clinical trial open at the paediatric cancer centre, and their participation is considered to have potential benefit to the patient and/or to the research, the following procedure should be followed in order to gain approval for over-age access to the paediatric centre:

1. The adult oncologist providing care to the young adult should liaise with the paediatric centre in the first instance, who will work collaboratively to confirm eligibility for the trial, and refer the case to the relevant paediatric oncologist acting as the trial’s Responsible Investigator.
2. The Responsible Investigator will consider clinical eligibility and need, and if participation is recommended, prepare an application to Hospital Executive using a standard form for over-age access to the paediatric centre in order to enrol in the trial.
3. The completed form is sent to Chief Medical Officer and Chief Operating Officer (where necessary) for review.
4. Following review, any special requirements as specified by Hospital Executive must be met and confirmed in writing.
5. If amendments or deviations to the trial protocol are required in order to enrol the patient, these must be approved by the trial’s lead HREC prior to patient enrolment.
6. The patient is then enrolled in the clinical trial, and is permitted access to the paediatric cancer centre for the purposes specified in the access application in order to participate in the clinical trial.

# 7. Endpoint

Consistent and equitable approach for the assessment of young adults for enrolment onto clinical trials.

# 8. Attachments

Application for Young Adult Access to Paediatric Cancer Clinical Trial Form

# 9. References

Paediatric Hospital Access Policy