Patient sticker

CHECKLIST for considering BEST INTERESTS under Right 7(4)(a) of the Code of Consumers' Rights - where patient not competent to give informed consent to clinical trial

FOLLOW THE STEPS BELOW

NOTE: This is a guide only and in some cases questions may not have a simple yes/no answer. However, the checklist should assist in considering the patient's best interests.

STEP 1 – ASSUME ALLOCATION TO THE TRIAL TREATMENT OR DRUG GROUP (INCLUDING WHERE THERE IS NO PLACEBO GROUP INVOLVED, THE GROUP HYPOTHESISED TO HAVE THE PREFERABLE TREATMENT OR OUTCOME) Consider whether it will be in the best interests of the patient to be included in the trial if they are allocated to the trial treatment or drug group. Answer all questions, and use them in the process by which you weigh all the factors:	**Yes**	**No**
Is the trial directly related to the illness or symptoms of the patient? (It is much more likely to be in the interests of the patient to be on the trial if it is a directly relevant trial treatment/drug)		
Is the trial treatment/drug already approved/known to be acceptable, with this trial being the identification of best conditions or of which treatment/intervention is more suitable for certain situations? **NOTE:** The more that has already been established about optimum conditions of the trial treatment/drug, the easier it will be to decide whether those conditions suit this patient, and whether it is in their best interests to be on the trial)		
Has the trial treatment/ drug already been the subject of considerable other trial work? Is more known about possible risks and benefits of this trial treatment/drug than would be the case with newer trial treatments/drugs		
Does the sponsor of the trial (if any) have a proven reputation?		
Do you know of other leading or reputable institutions which are enrolling or have enrolled patients in this trial?		
Weigh up the possible (or, rarely, where the trial treatment/drug has already been the subject of a lot of other work, probable) risks and benefits in terms of mortality risks, side effect risks if the trial treatment/drug is or is not administered. **NOTE 1:** This should be based on what you know at the date you are making the decision about whether or not to enroll the patient. **NOTE 2:** Exclude issues of the benefits of trials generally or the good of trials to the wider population. **NOTE 3:** The process of deciding whether or not to include a patient in a trial can be similar to the situation when you are deciding whether or not to administer an existing approved treatment to a particular patient, in that it is never certain how a treatment will affect any given individual. However, extra caution is required when a trial treatment/drug is very new, because less is known about the treatment/drug and its effect than at a later stage in the research process. **Consider issues –best interests indicated?**		

STEP 2 – CONSIDER THE IMPLICATIONS FOR THE PLACEBO OR ANY ALTERNATIVE GROUP - Answer (a) or (b):	**Yes**	**No**
(a) **If there is a placebo group, assume allocation to the placebo group** consider the situation if this patient gets allocated to the placebo group. There are indications that patients in trials tend to experience better outcomes than non-trial patients, even if allocated to the placebo group. Is there anything about the circumstances of this trial or this patient's situation, which would go counter to this indication? **Circumstances of trial** **Circumstances of patient**		
(b) If there is no placebo group involved this may be a trial comparing different time frames for administering the same or similar interventions, or a trial comparing differing interventions or treatments. It may be an observational trial involving measurements and information gathering. In these cases consider whether the treatments or timing of treatments are both approved and established ways of dealing with the patient – will it be in the best interests of the patient to be involved in the trial whichever group he or she is allocated to? **Best interests indicated?** Is there any reason why it would be contrary to the patient's interests to be in the trial, for example if the measurements to be taken for an observational trial will require interventions which could be harmful? **Best interests indicated?**		

STEP 3 - WEIGH THE CONSIDERATIONS	**Yes**	**No**
Consider your answers in **Step 1** concerning the trial treatment/drug. Having weighed all of your answers, and based on what you know at this time about the trial treatment/ drug and at this time about this patient, do you believe that it will be in the best interests **of this patient** to try the trial treatment/ drug? If you hold doubt, do you think your view is likely to be reinforced by colleagues in your field? **Consult further as appropriate**		
Where **Step 2(a)** applied (placebo group), consider your answers under Step 2 concerning the placebo group. If either (or both) of the answers to the Step 2(a) questions was Yes, add this factor into your decision-making. **Any special issues ?**		
Where **Step 2(b)** applied (no placebo group), take into account any factors that have arisen which suggest the trial may not be in the patient's best interests. **Any special issues?**		

STEP 4 – MAKE THE DECISION

I conclude that it is / is not in this patient's best interests to be enrolled in this trial.

Date: **Name of Clinician:** **Signature of Clinician:**

ANY COMMENTS

NOTE: **This Checklist only relates to the first limb of Right 7(4), namely best interests. You must also satisfy yourself as to Right 7(4)(b) and (c) which relate to the views of the patient and family or relevant others.**