These checklists should be read in conjunction with the Participant Information video featuring Cheryl Grant

CHECKLIST 1 When reviewing patient information sheets consider the following:	
Is it understandable?	
❒	The forms must be able to support an informed consent
❒	The patient information consent form should be able to be read by a person under stress from the diagnosis, family, friends, a GP and/or other health professionals
❒	The form needs to be clear with simple language to cater for all reading levels. It should be similar to a tabloid newspaper
❒	Acronyms should be explained
❒	Phrasing should be clear and not confusing
❒	Consider what would help make the document more understandable
Does it reflect the protocol?	
❒	The information in the Patient Information Consent Form (PIC) should adequately represent the trial. All arms of the trial should be represented in the PIC
❒	The treatment arms should be described
❒	The commitments required by the participant are described such as treatment schedules and follow-up appointments
❒	Tests and investigations are these described
Does it describe randomization?	
❒	If randomization is part of the trial, its importance and the process should be described and explained
❒	If placebo interventions are being used then the rationale for this must also be explained.
❒	Why blinding is used should also be clear
Are trial drugs or other treatment interventions described and explained?	
❒	Are all the treatment drugs or interventions described, the standard therapies as well as the trial drug
❒	Are the side effects and likely risk/prevalence of each described
❒	Is management of the side effects explained
Are the following procedural issues covered?	
❒	Relapse while on the trial
❒	Withdrawing from the trial
❒	Confidentiality issues
❒	Monitoring of investigation site by central trial organization, and by regulatory authorities
❒	Costs

CHECKLIST 2

REVIEWING A PROTOCOL

There's no hard and fast formula for reviewing a trial protocol, each one is different.

Questions to ask yourself	
❒	What is the significance of the trial?
❒	Does it fill a treatment gap?
❒	Does it meet community values?
❒	If it's an international trial is it relevant in the Australian setting?
❒	Does it have the potential to enhance or advance current treatment standards?
After reading the scientific background consider	
❒	Is it relevant to the protocol?
❒	Does it inform the trial?
❒	What is the age of the research referred to? If it appears old, look for an explanation of why it's now relevant. Consider what's changed?
❒	Does background material justify trial?
Review the treatments and consider	
❒	What are the side effects? What is risk/prevalence of side effects? Are these reflected in the patient information sheet?
❒	How will the side effects be managed?
❒	Will test results be acted on if abnormal?
❒	Can you foresee any implications for participants?
❒	Is quality of life being monitored and maintained?
❒	Is there a schema?
Review the eligibility and exclusion criteria	
❒	Are the criteria relevant?
❒	Do they relate to the known side effects of the trial drugs, or treatment interventions?
❒	Do baseline tests reflect eligibility criteria?
❒	Is confidentiality of issues such as tissue banking considered?
Timing and opportunities of reviews	
❒	If the trial originates from an international collaborative trials group, are the patient information and consent materials tailored to Australian conditions?
❒	If the trial originates locally from within Australia, are there opportunities for consumer to be involved in developing the protocol from the concept stage and work collaboratively with the clinical investigators?