



ICF Template Development Checklist

Study Title:	
Principal Investigator:	
Type of Study:	<input type="checkbox"/> RCT <input type="checkbox"/> Non-RCT
ICF Developed By:	
Version Reviewed:	
Reviewed By:	
Date Reviewed:	

Please select the boxes of topics covered in the informed consent. If they are not covered in the informed consent, please provide the reason why.

As per ICH: Good Clinical Practices section 4.8.10, the following essential elements are required to be incorporated into the Informed Consent Form.

GCP Ref (4.8.10)	Essential Element	Y	N	N/A	Location (ICF pg #)
a	The trial involves research				
b	The purpose of the trial				
c	The trial treatment and the probability of for random assignment to each treatment				
d	Description of all study procedures (including invasive procedures)				
e	The patient's responsibilities				
f	The aspects of the trial that are experimental				
g	Reasonably foreseeable risks and inconveniences to the patient				
h	Reasonably expected benefits. When there is no intended clinical benefit to the patient, the patient is made aware of this.				
i	Alternative treatments and procedures available to the patient, including any potential benefits or risks.				
j	Compensation and/or treatment available to the patient in the event of a trial related injury				
k	Any anticipated payment or compensation for participation in the trial.				
l	Any anticipated expenses to the patient for participation in the trial				
m	The patient's participation in the study is completely voluntary. The patient may refuse to participate or withdraw from the trial at any time, without any loss of benefits to which the patient is otherwise entitled.				
n	Monitors, auditors, REBs, regulators may be granted direct access to the subject's original medical records for verification of clinical trial procedures/data without violating the confidentiality of the patient, to the extent permitted by the applicable laws. Signing the consent form is authorizing such access.				
o	Records identifying the patient will be kept confidential. Any publications resulting from this trial will not reveal the patient's identity, confidentiality will be maintained.				
p	The patient will be informed in a timely manner of any information that becomes available relevant to the patient's willingness to continue participation.				
q	The person to contact regarding patient rights and in the event of a trial related injury (usually REB chair)				
r	Foreseeable circumstances in which the patient's participation in the trial may be terminated.				
s	The expected duration of the patient's participation in the trial				
t	The approximate number of patients involved in the trial.				

