SickKids Informed Consent Form Checklist

This checklist is adapted from the Clinical Trials Ontario Informed Consent Form Checklist.

Instructions:

- This checklist should be used in conjunction with the SickKids Informed Consent Form Templates; for specific wording, please refer to the appropriate template
- This checklist was designed for informed consent forms for interventional studies; however, many of the items are also applicable to non-interventional studies. Thus, some items in the checklist may not apply to your study. Use your judgment to determine if an element is applicable to your study type.
- This checklist is informed by the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Tri-Council Policy Statement (TCPS2); US Code of Federal Regulations (US CFR) 21 CFR 50 and 45 CFR 46; and Canadian General Standards Board (CGSB) "Research ethics oversight of biomedical clinical trials". The requirements of the Food and Drugs Act and applicable Regulations have been considered and incorporated into the "GCP" column. Items from each of these standards have been grouped together when appropriate.
- SickKids specific requirements are found under the "SK" column

Element Number	Description of Element	Present	Application of Element				
		Y/N/NA	TCPS2	GCP	US CFR	CGSB	SK
	General						
1.	The study title						X
2.	The identity of the Researcher and study team members (SickKids co-investigators and research contact).		X			X	X
3.	The identity of the Sponsor and Funder		X			X	
	Is there a conflict of interest?						
4.	Information concerning the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors		X				
5.	A statement concerning any personal benefits that may accrue to the researcher, if applicable and deemed necessary by the REB					X	
	Introduction						
6.	A statement that the participant is being invited to participate in research		X	X	X	X	

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7.	An assurance that prospective participants are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements		X	X	X	X	
	Why is this study being done?						
8.	A statement of the research purpose in plain language		X	X	X	X	
	What other choices are there?						
9.	A description of available alternative procedures or courses of treatment that are available outside of the research project			X	X	X	
10.	The important potential benefits and risks of alternative procedures or courses of treatment that are available			X			
	How many people will take part in this study?						
11.	The approximate number of research participants			X	X	X	
	How long will the study take?						
12.	A description of the total length of the study and the anticipated time until results are known. The amount of time the participant is expected to be involved in the study and the number and length of visits should be described.		X	X	X	X	X
	What will happen during this study?						
13.	The probability of randomization to each intervention			X		X	
14.	A brief, simple description of the study type (blinded, open-label, phase I/II/III, extension, etc.).						X
	What is the study intervention?; What else do I need to know about the study intervention?; What are the study procedures?						
15.	A description of the research intervention and procedures to be used, including clear indication of those aspects that are experimental		X	X	X	X	
16.	The nature of participation (i.e., a description of what participants are expected to do)		X			X	X

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17.	Participants are informed of any therapy that will be withdrawn or withheld for the purposes of the research, and the anticipated consequences of withholding or withdrawing therapy		X				
	Mandatory sample collection						
18.	The type and amount of biological materials to be taken		X				
19.	The manner in which the biological materials will be taken, and the safety and invasiveness of the procedures for acquisition		X				
20.	The intended uses of the biological materials, including any commercial use		X				
21.	The measures employed to protect the privacy and minimize risks to participants		X				
22.	The length of time the biological materials will be kept, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal if applicable		X				
23.	Any anticipated linkage of biological materials with information about the participant		X				
24.	The researchers' plan for handling results and findings, including clinically relevant information and incidental findings		X				
25.	Information on the participant's right to request the withdrawal of biological materials, including any limitations on the feasibility of that withdrawal		X				
	Are there optional components?						
26.	All optional components must be clearly outlined. Participants should opt in using initials.						X
	What are the risks and harms of participating in this study?						
27.	A plain language description of all reasonably foreseeable risks or inconveniences, to participants,			X	X	X	

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	and in general, that may arise from research participation						
28.	A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable				X	X	
	What are the reproductive risks?						
29.	SickKids specific reproductive risk language **must** be used. Refer to interventional template.						X
30.	A statement that the particular treatment or procedure may involve risks to an embryo or fetus (if the participant is or could become pregnant) that are currently unknown				X	X	
31.	A plain language description of all reasonably foreseeable risks to an embryo or fetus or nursing infants, if the participant is or could become pregnant			X		X	
	Are there benefits of participating in this study?						
32.	A plain language description of potential benefits, both to participants and in general, that may arise from participation		X	X	X	X	
33.	If there is no known clinical benefit to the participant, the participant shall be informed			X		X	
	What are the responsibilities of study participants?						
34.	An explanation of the responsibilities of the participant		X	X		X	
	Can participants choose to leave the study?						
35.	The process involved for participation withdrawal				X	X	
36.	The effects of a participant choosing to withdraw.				X		
37.	Information on the participant's right to request the withdrawal of data, including any limitations on the feasibility of that withdrawal		X				
	Can participation in this study end early?						
38.	Information on stopping rules and when researchers may remove		X	X	X	X	

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	participants from the clinical trial without the participant's consent						
39.	A statement identifying those with the authority to modify the research subjects participation (such as the Researcher or Sponsor)					X	
	How will participant information be kept confidential? ***Provisions required by the Personal Health Information Protection Act (PHIPA) must also be considered and included when applicable.**						
40.	SickKids specific privacy language **must** be used.						X
41.	An indication of what information will be collected about participants and for what purpose		X				
42.	An indication of who will have access to information collected about the identify of participants, including specification that the monitor(s), auditor(s), the REB and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data		X	X		X	
43.	A description of how confidentiality will be protected and, to the extent permitted by the applicable laws and regulations, records identifying the participant will not be made publicly available.		X	X	X	X	
44.	A description of the anticipated uses of data		X				
45.	Information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made		X				
46.	Any limits to the confidentiality of the research records					X	
47.	The measures undertaken for dissemination of research results		X				
48.	If the results of the trial are published, the participant's identity will remain confidential		X	X			
	Will the study require information from health care providers?						
49.	If the study protocol requires that the researchers must obtain						X

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	information from other health care providers then this section should be included.						
	Will information about this study be available online?						
50.	The following statement shall be provided to each clinical trial participant: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." *Mandatory for inclusion, verbatim, in US FDA regulated clinical trials				X*		
	What is the cost to participants?						
51.	Any anticipated expenses associated with participation in the study			X	X	X	
	Are participants paid to be in this study?						
52.	Information about any payments, including incentives for participants and reimbursement for participation related expenses		X	X		X	
53.	Information on the possibility of commercialization of research findings		X				
	What if there are injuries resulting from participation in the study?						
54.	A statement of what the participant should do if they suffer any injuries or illness related to participation.						X
55.	A description of the compensation, if any, that will be provided to the participant in the event that he/she is injured during the research		X	X	X	X	
56.	A description of the type of response that will be undertaken if injury occurs to a participant during the research (e.g., that treatment will be made available and covered by[X]), or that no such response is planned			X	X	X	

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57.	A statement that the participant has not waived any legal rights/rights to legal recourse in the event of research-related harm or that releases the investigator, institution, sponsor or their agents from liability for negligence.		X	X	X	X	
	What if a researcher discovers something new about participants?						
58.	If incidental findings are anticipated as a result of the study, describe what information will be provided to participants and provide applicable opt-in options.						X
	Will participants receive study results?						
59.	Describe how results of the study will be communicated to participants.						X
	What are the rights of participants in a research study?						
60.	An assurance that participants will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation		X	X	X	X	
	Whom do participants contact for questions?						
61.	The identity and contact information for a qualified individual who can explain the scientific or scholarly aspects of the clinical trial (e.g., for further information about the clinical trial)		X	X	X	X	
62.	The identity and contact information for an appropriate individual outside the research team whom participants may contact regarding possible ethical issues in the research (e.g., for questions about participant rights)		X	X	X	X	
63.	The person to contact in the event of research-related injuries			X	X	X	
	Signatures						
64.	Signature and date of signature of the participant (or their substitute		X	X	X	X	

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	decision-maker/legally authorized representative, if applicable)						
65.	Signature and date of the person conducting the consent discussion			X			
66.	Signature and date of person assisting in the consent discussion (if participant or their substitute decision-maker/legally authorized representative, as applicable, is unable to read or if translator is used)			X			