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**Sample Consent Form and Checklist**

This checklist is designed for researchers who have an existing consent form template provided by an industry sponsor or an external lead site. The elements below are required to be added (if not already present) to the consent form template being used.

Note: If you have not been provided with a consent form template please use the one located on the MGH website and modify it as needed. Please ensure your modified version includes all of the elements below.

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| **The consent form clearly identifies:** | |
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|  | The researcher(s) and their contact information on the front page and in the “Contact” section.  NOTE: If the researcher is a resident/student, their supervisor must be clearly identified first (including their contact information). Residents/students may include a contact number (work); personal /institutional e-mail is not permitted. You may contact Information Technology Services to set up a research project email address if required. The resident/student must be identified as such in the consent form. |
|  | The sponsor(s) of the research. Indicate the benefits to the sponsor. |
|  | Please include the following contact statement for the MGH REB Chair:  *“This study has been reviewed by the Michael Garron Hospital (MGH) Research Ethics Board (REB). The REB is independent of the researchers. If you have any concerns or questions about your rights or your experiences as a research participant, you may contact Dr. Sherry Rezaie, Chair of the MGH REB at 416-469-6580 ext. 3853, during business hours.”*  **Note:** It should not be stated to the participant that any Research Ethics Board has approved the study, since this may appear to offer a guarantee of safety or effectiveness. |
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| **The consent form clearly explains:** | |
|  | That the proposed intervention is for research. (Test, drug, survey, interview, device, procedure, etc., used for research purposes.) |
|  | The general purpose of the study and clear description of what the participant is expected to do.  (Why the research is being done.) Describe the total number of anticipated participants. |
|  | The nature of the proposed research. (What the research involves; this should include specific details of what will happen to the participant, the nature of any randomization, the need to discontinue standard practice or therapy, and any possible use of a placebo.) |
|  | The likely duration of participation. Include a flow chart or summary of visits, if this will assist the participant. (How long the research and each intervention will take for a participant.) |
|  | The potential harms and inconveniences associated with the research. (The nature of the harms and inconveniences and the likelihood of their occurrence.) |
|  | The potential benefits associated with the research. Avoid overestimating the potential benefit to individual participants. (The nature of the benefits to the participant or to others, and the likelihood of their occurrence.) |
|  | The alternative(s) to research participation, if applicable. (E.g., available standard medical therapy, other treatments, other activities.) |
|  | How confidentiality will be protected and the measures taken to ensure the security of data collected. (Who will have access to the data? How will it be stored and for how long? Will individual participants be identified in publications?) |
|  | A statement indicating that by consenting, participants do not waive any legal rights.  *"When you give your consent, you keep all your legal rights relating to the research team members and the hospitals. The research team members and hospitals involved in this study have legal and professional duties to you and others taking part."* |
|  | Possible conflicts of interest. Possible interests of researchers or participants in commercialization opportunities. |
|  | Your plan for sharing the findings with the participants and the affected community. |
|  | That participation in research is voluntary. Avoid using the term of ‘penalty’ which refers to contractual obligations or criminal activities. (E.g., The right to refuse and the right to withdraw without affecting the care they receive.)  Clarify if the participant withdraws from the study, what will happen to any data/biological samples already collected until the time of withdrawal.  Clarify if participants withdraw from the study if they will still be entitled to receive any study findings. |
|  | A reminder of their right to refuse to do anything they find disturbing or uncomfortable. Describe if they may decline to respond to a question or an intervention and still continue in the study. |
|  | Contact information for the research assistant, if applicable. |
|  | A statement indicating that the participant will receive a signed and dated copy of the consent form. |
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| **The consent form does not include:** | |
|  | Any statement releasing the researcher(s), sponsor(s), institution(s), or agent(s) from liability for negligence. |
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| **The consent form is written:** | |
|  | In the prospective participant’s (or her or his substitute decision-maker’s) preferred language. |
|  | **In lay terms (plain language).** |
|  | At an appropriate reading level taking into consideration the nature of the participant (e.g., child or adult). Using simple language and employing a health literacy approach. |
|  | With simple explanations of all terms. |
|  | All acronyms are spelled out. |
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| **The consent form contains a summary page:** | |
|  | Include a participant summary page/section of all main points contained in the consent form. Avoid introducing new topic in the summary page. This should be at the end of the document, but prior to the signature page. Provide sections for both participant and person obtaining consent. |