Concise Summary Guidance

This document provides guidance for study teams who need to develop a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons one may or may not want to participate.

The guidance below outlines what to include and what to avoid while drafting a summary which meets the new regulatory requirements for informed consent. Template summary language is available for use and reference in the Penn informed consent template documents. Use of this guidance and the Penn template language is not required but is recommended. The concise summary should appear as the first section of the main consent form and be limited to one page. .

Paragraph 1 Elements- Research is voluntary and contact information for questions

Do:	Do not:
• State that the study is research/investigational • Confirm that participation is voluntary • Provide contact information for study questions and questions about subjects' rights • See template summary consent for sample paragraph	

Paragraph 2 Elements- Study Purpose

Do:	Do not:
• Provide a brief, non-complex summary regarding the purpose of the study • Phrase this paragraph in such a way that the subject will understand why they have been chosen • See template summary consent for sample paragraph	• Discuss secondary objectives • Discuss sub-studies

Paragraph 3 Elements- Study Procedures

Do:	Do not:

• Provide a list of research specific procedures
  ○ *List the most significant research procedures that would affect willingness to participate*
  ○ *For most investigational product trials, the procedures listing can be limited to the use of/implantation of the investigational product (i.e. the element of the research that carries the most risk)*
  ○ *When one arm of the study involves placebo, this should be stated specifically*
• See template summary consent for sample paragraph
	• List standard of care procedures
	• List any minimally invasive procedures (i.e. blood draw, vital signs, etc.)

Paragraph 4 Elements- Duration of Participation

Do:	Do not:

• Provide a brief statement about duration of participation
  ○ *Specify expected time of active study participation*
  ○ *Specify active participation time and follow-up time if applicable*
  ○ *Specify whether participants are expected to be in long-term follow-up via their medical record or long-term allowance for use of data or samples*
• See template summary consent for sample paragraph
	• Discuss time commitments for individual study visits or procedures unless participation is limited to a one day / one time interaction

Paragraph 5 Elements- Risks and Benefits of Participation

Do:	Do not:

• Insert a statement regarding potential for subject benefit
  ○ *If subjects are not expected to benefit please state directly*
• Provide a list of risks of the investigational product (if applicable)
• Provide a list of risks associated with the procedures noted in paragraph 3
  ○ *Only include risks that are likely to occur*
  ○ *Only include risks that will most impact daily life for participants*
  ○ *Limit the list of risks to those that are most essential for participants to recall after the initial consent process is complete*
• See template summary consent for sample paragraph
	• Include specific promissory statements regarding subject benefit
	• List risks of standard of care procedures
	• List unlikely or rare risks related to procedures or investigational product

Paragraph 6 Elements- Alternatives to Participation and Other impactful information	
Do:	**Do not:**
• Include a brief description of alternatives to participation if any exist • Assess the contents of the main consent form to determine whether any other impactful information (not categorized above) should be included in the summary document • Include a closing summary paragraph informing subjects that there are additional factors to consider prior to agreeing to participate • State if participants' identifiable information will be sent outside of Penn (i.e. to other collaborators) • See template summary consent for sample paragraph	• Include any HIPAA language • Include information about protection of PHI or sensitive information • Include any legal language Re: costs, injury etc.