

Recommendations about Attachments to the ICD

All required information that is considered mandatory for the participants' understanding of the proposed research should be contained within the ICD itself, not in an attachment.

1. Attachments should contain information for the study participant that is considered optional, and is not required for their understanding of the proposed research. Attachments may provide clarification, additional education, or information about other facets of overall cancer care.
2. It is recommended you include a patient/participant study calendar.
 - a) Patient advocates have recommended attaching a calendar that is easy for study participants to understand and use; conveying what must be done, when, and for how long. It can help the study participant plan his/her life during the study, and assist patients in adhering to the study plan.
 - b) It should not be formidable-looking or too complicated in format, especially as dates and timing often change during treatment due to unforeseen events.
3. Patient advocates have recommended the use of supportive educational materials that could help study participants better understand research-related information, such as biospecimen banking and treatment-related information for radiation therapy, surgery, chemotherapy, and imaging.
 - a) NCI has educational materials that cover many aspects of cancer treatment and research, i.e., the booklet Taking Part in Cancer Treatment Research Studies. This booklet, and other materials, may be viewed on the NCI Web site at <https://pubs.cancer.gov/ncipl/home.aspx> or call 1-800-4-CANCER (1-800-422-6237).
 - b) The FAQs about the NIH Certificate of Confidentiality may be found at <https://humansubjects.nih.gov/coc/faqs>. These FAQs can be printed and used as an attachment.
 - c) NCI offers a video about donating tissue for research: <http://www.cancer.gov/about-nci/overview/contributing/tissue-donation-video>. Brochures on tissue donation are available in English and Spanish: <https://biospecimens.cancer.gov/resources/publications/educational.asp>.
 - d) OHRP offers resources for prospective research participants, see <http://www.hhs.gov/ohrp/education-and-outreach/learning-about-research-participation/index.html>.
4. Since many people do not have access to the Internet, including only web links in an attachment is not considered to be useful.

Reminder: Patient materials attached to the ICD and any other materials given to patients, such as questionnaires, must be reviewed and approved by the IRB.