Author's response to reviews

Title: An effective multisource informed consent procedure for research and clinical practice: an observational study on patient understanding and awareness as a research stakeholder in a cancer biobank

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Dear Professor Aldcroft

Please find enclosed our manuscript “An effective multisource informed consent procedure for research and clinical practice: an observational study on patient understanding and awareness as a research stakeholder in a cancer biobank”.

There is a growing interest in exploring patient's understanding about the informed consent, mostly in terms of comprehension of the informed consent rather than real awareness and involvement, which still represent quite unknown fields.

We implemented a novel multisource informed consent procedure for patients’ enrolment in a National Cancer Institute Biobank (CRO-Biobank) easily adaptable in both clinic and research clinic and research application. We evaluated the efficiency of this approach by the use of a self-administered questionnaire exploring 550 cancer patients' understanding and needs of information before and after study participation. We also explored how much patients want to be informed and by which other sources, trying to answer the crucial question about the informed consent: when the information can be considered “complete”?

Our multisource information system showed high rates of understanding (>99.0%) and awareness (95.5%) of study participation, the highest results that can be found in the literature. It may be a potential model for others to consider to improve patients’ awareness and understanding of disclosed information pertaining to the informed consent process, both in clinical practice and in research fields.
For these reasons, we believe this manuscript to be of interest to many readers of BMC Medical Ethics and hope it is suitable for publication.

Yours sincerely

Dr. Silvia Cervo