

# Research Biopsies

## An integrative review of the experiences of patients with cancer

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**BACKGROUND:** Research biopsies (RBs) are essential to understanding tumor biology and mechanisms of resistance and to advancing precision medicine. However, RBs have associated risks and may not benefit the patient.

**OBJECTIVES:** The purpose of this integrative review is to summarize and synthesize the current literature on the experience, attitudes, and understanding of patients with cancer related to RBs.

**METHODS:** Articles from January 2010 to February 2017 were retrieved via a search of MEDLINE®. Articles included reported on the willingness, perceptions, understanding, attitudes, and/or experience of patients with cancer related to RBs.

**FINDINGS:** Nine of 216 identified studies were selected. Studies exploring patient willingness to undergo RBs (n = 6) identified RBs as a potential barrier to clinical trial participation. Studies exploring patient understanding and informed consent (n = 3) revealed variable patient knowledge of the risks and benefits of RBs.

### KEYWORDS

research; biopsy; cancer; patient; experience

### DIGITAL OBJECT IDENTIFIER

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**THE UNDERSTANDING OF TUMOR BIOLOGY IS ENHANCED** through obtaining tissue from research biopsies (RBs) and/or liquid biopsies via circulating tumor cells in oncology clinical trials (Judge, Chianese-Bullock, Schroen, & Slingluff, 2013; Patel & Tsui, 2015). RBs allow researchers to examine tumor tissue at various time points during treatment and to explore mechanisms of response and resistance to therapeutic agents. Oncology literature data demonstrate that metastatic tissue can harbor unique genomic alterations compared to the primary tumor, and heterogeneity can also be seen among different metastatic sites in the same patient (Juric et al., 2015). The information acquired from clinical tumor biopsies can help guide treatment decisions for patients with cancer. To date, RBs are performed only to collect tissue for scientific endeavors and do not guide treatment decisions or directly benefit the patient. Ethical concerns surrounding RBs for patients with cancer exist, particularly in the absence of standard informed consent, such as when a patient misunderstands the purpose of the RB or the level of risk involved (Moorcraft et al., 2016; Olson, Lin, Krop, & Winer, 2011; Peppercorn et al., 2010). Understanding patients' experiences and perceptions surrounding RBs is critical to identifying areas for process improvement, in terms of the biopsy experience and the intent and quality of the informed consent, and to decreasing patient barriers to enrollment in clinical trials.

An RB can be a stand-alone procedure for research purposes or involve additional collection of tissue during a clinically indicated biopsy. RBs can be integral to determining clinical trial eligibility (such as tumor receptors) or used purely for correlative purposes, not affecting patient treatment. Therefore, clinical trial participation rates can depend on whether an RB is mandatory, the number of biopsies involved, the site of the RB (and, therefore, the invasiveness of the procedure), and whether a synchronous clinical biopsy is needed (Peppercorn et al., 2010; Seah et al., 2015).

### Research Biopsy Safety

Data on the safety of RBs are limited; such data often are not reported in clinical trials because of the lack of consensus on adverse event reporting strategies (Olson et al., 2011). However, serious patient complications from RBs appear to be low. El-Osta et al. (2011) reported that RBs from a variety of anatomical sites performed for phase 1 oncology trials demonstrated a serious complication rate of 1.4%, with events such as pneumothorax requiring chest tube placement, infection requiring admission, and arrhythmia with hypotension. Risks vary based on the site of biopsy; for example, higher rates of complications are reported for intrathoracic RBs compared to liver biopsies (Overman