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## EDITORIAL NOTE

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# Informed Consent in the Protection of Human Rights

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Both prospective authors and readers should be advised that the *Instructions to Authors* for *Pain Practice* has been modified to include an “Author’s Responsibilities” section. While the guiding principles and policies of *Pain Practice* have not changed, the added section explicitly defines the standards required for manuscript submission. Chief among these standards is adherence to Good Clinical Practice and appropriate use of informed consent, as defined by the International Conference on Harmonisation (ICH; <http://www.ich.org>). The informed consent, when applicable, must be reviewed and approved by an Institutional Investigational Review Board (IRB).

While informed consent, defining risks, potential benefits, and alternative treatments, is a requirement prior to invasive procedures, experimental protocols involving human subjects need additional consent specific to the study. This additional informed consent must be used whenever study subjects undergo any evaluation, testing, treatment, or procedure that is not part of standard medical care. Further, if the subject’s involvement in the protocol can in any way modify or impact the course of their care (as when subjects are randomly assigned into different treatment groups), then they

must be provided study-specific informed consent. This is required even if no “standard treatment” exists.

Institutional Human Investigation Committees (IRBs) will not approve the informed consents unless they satisfy some 20 specific criteria as defined by the ICH. Perhaps the most important of these is the statement that participation in the study is completely voluntary. This means that subjects may elect to leave the study at any time, for any reason, and that if they do withdraw consent they do not need to provide an explanation. They must be assured that their decision to withdraw consent will not jeopardize their subsequent care in any way. Compliance with these internationally accepted standards is an absolute requirement for publication in *Pain Practice*.

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