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Assessing the quality of human research protection programs to improve protection of human subjects participating in clinical trials

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Introduction: Institutions conducting research involving human subjects establish human research protection programs to ensure the rights and welfare of research participants as well as to meet ethical and regulatory requirements. It is important to determine whether human research protection programs have achieved these objectives.

Methods: The Department of Veterans Affairs has developed quality indicators and annually collected human research protection program quality indicator data from its 108 research facilities since 2010.

Results: Analysis of Department of Veterans Affairs human research protection program quality indicator data revealed that facilities using affiliated university institutional review boards performed as well as those using their own Department of Veterans Affairs institutional review boards and that facilities with small research programs, that is, less than 50 human research protocols, performed at least as well as those with larger research programs. These quality indicator data also provided Department of Veterans Affairs facilities with valuable information for quality improvement. Many of these quality indicators have improved in subsequent years, and none has deteriorated. Lapse rates in institutional review board continuing reviews remained high and relatively constant at above 6.0% over a 4-year period from 2010 through 2013.

Discussion: Future efforts should be directed at developing a set of human research protection program quality indicators truly reflecting the quality of human research protection programs that are applicable to both Department of Veterans Affairs and non-Department of Veterans Affairs institutions and determining whether high-quality human research protection programs as measured using these quality indicators translate into better human subject protections.

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Development of functional foods with β glucans from medicinal mushrooms

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Beta-glucans, especially beta 1, 3-linked and beta 1, 6-linked -glucans, from eukaryotic organisms particularly medicinal edible mushrooms can be incorporated into various foods creating novel "functional foods" with many health promoting benefits beyond their nutritional value. Medicinal mushrooms have long been valued for their properties as immune system boosters and modulators, as antioxidants, as blood glucose regulators, reducing cholesterol and blood lipids as well as having many more therapeutic and recuperative properties reducing the risk of chronic diseases and promoting general health. The health benefits of mushrooms are attributed to many bioactive compounds among which the most valued and well studied ones are the β-glucans. These can be isolated and incorporated to various foods and food products enhancing their nutritive value and creating novel "functional foods".

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