Comparison of Draft NCQA and PRIM&R Accreditation Standards

Organization preparing standards	Strengths	Weaknesses
NCQA	• Direct link to quality improvement programs • Grounded in baseline regulatory requirements • Measurement criteria and data sources specified • Interpretive guidance provided • Accreditation process specified • IRB decision appeals process specified • Thresholds for compliance specified • Formulation of standards and accreditation of VA facilities by the same organization	• Because of an exclusive focus on VA facilities, will need to be modified for use for organizations for which standards were not originally designed[i] • Insufficient standards relating to participant involvement beyond informed consent • Insufficient attention to role of human research participant protection program (HRPPP) accreditation vis à vis external research sponsors • Insufficient standards for research monitoring • Uncertain application to nonmedical research
PRIM&R	• Grounded in ethical principles of The Belmont Report[ii] • Reflect strong expertise about IRB operations in academic health centers • Differentiate substandards for IRBs, institutions, and investigators	• Lack of specificity in standards for investigator and institutional obligations • Documentation standards for IRB record-keeping inapplicable to many IRBs • Uncertain application to nonmedical research, independent IRBs, contract research organizations, clinical trials cooperative groups, central IRBs, and other research organizations • Lack of cross-tabulation of standards to regulations • Inadequate specification of data sources, except documentation standards • Insufficient attention to role of HRPPP accreditation vis à vis external research sponsors • Insufficient standards relating to participant involvement beyond informed consent • Insufficient standards for research monitoring • Lack of specificity regarding measures and thresholds for compliance • Lack of interpretive guidance • Lack of specificity regarding accreditation judgments • Formulated with an inadequate link between responsibility for developing standards (an ongoing process) and responsibility for implementing accreditation process

[i] Although it is identified as a weakness in this table, the NCQA standards were designed only for VA facilities, so a lack of more general applicability is not a criticism of the NCQA formulation but is an observation about their use of the NCQA standards for purposes that the committee recommends, that is, for non-VA organizations.

[ii] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979).

Source: Preserving Public Trust: Accreditation and Human Research Participant Protection Programs. Committee on Assessing the System for Protecting Human Research Subjects, Board on Health Sciences Policy, Institute of Medicine, Washington, DC, 2001.