OHRP QA Self-Assessment Tool

16. What items are requested and distributed to each designated IRB member(s) for review? *Check all that apply.*

Items Collected for IRB Review		Distributed for Full Committee Review			
Item	Requested by IRB	IRB Chair	Primary Reviewer	Other IRB Members	Alternate Members
a) IRB submission form					
b) Full protocol					
c) Full grant or contract application (if federally funded)					
d) Protocol summary					
e) Informed consent form					
f) Scientific review					
g) Recruitment material (e.g., advertisements, recruitment letters, scripts for telephone conversation or focus groups, etc.)					
h) Investigator's qualifications [e.g., CV, medical license(s), etc.]					
i) Conflict of interests disclosure					
j) List of all investigators					
k) Questionnaires					
l) Other *(Describe)*					
Additional elements that may apply for biomedical research. *Check all that apply.*					
m) Investigator Brochure					
n) Package insert providing drug information					
o) Device manual					
p) IND/IDE number					
q) Copy of FDA 1572 form or Investigator Agreement (for device studies)					
r) Copy of case report forms					

Source: Office for Human Research Protections, Rockville, MD.