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Research Ethics Committees in Nigeria: A Survey of Operations, Functions, and Needs

Table 1.
Criteria for Assessing Conformity of Participating Ethics Committees to Guidelines¹

| S/N | Criterion |
|-----|---|
| 1 | Criteria for membership |
| 2 | Membership criteria requiring gender representation |
| 3 | Multiprofessional membership |
| 4 | Commitment to training |
| 5 | Training at least once every two years |
| 6 | Availability of standard operating procedures |
| 7 | Quorum requirement: not less than 50% of members present |
| 8 | Included in review elements: scientific validity, study design, risk-benefit assessment, and informed consent process |
| 9 | Specified application forms |
| 10 | External consultation when necessary |
| 11 | Continuing oversight |
| 12 | Records kept for at least three years |
| 13 | Review turn-around time of not more than three months |
| 14 | Availability of resources (at least 5 of 11 items listed) |
| 15 | Compliance with other international guidelines |
| 16 | Registration with both the NHREC and OHRP |

¹ Adapted from World Health Organization, Operational Guidelines for Ethical Committees That Review Biomedical Research, Geneva: World Health Organization, 2000, and Federal Ministry of Health, National Code for Health Research Ethics, Abuja, Nigeria: Federal Ministry of Health, 2007.

Table 2.
General Characteristics and Training Practices

| <i>Question concerning</i> | <i>N</i> | <i>Category</i> ¹ | <i>n (%)</i> |
|---|----------|----------------------------------|--------------|
| Respondents | 25 | chairperson | 19 (76%) |
| | | other members | 6 (24%) |
| Age of RECs* | 21 | under 10 years | 14 (67%) |
| | | 10 years | 1 (5%) |
| | | more than 10 years | 6 (29%) |
| Location of RECs | 25 | urban area | 22 (88%) |
| | | rural area | 3 (12%) |
| Region of RECs | 25 | Southwest | 7 (28%) |
| | | South South | 2 (8%) |
| | | Northwest | 2 (8%) |
| | | North Central | 7 (28%) |
| | | Northeast | 4 (16%) |
| | | Southeast | 3 (12%) |
| Type of institution hosting REC | 25 | teaching hospital | 15 (60%) |
| | | research institute | 1 (4%) |
| | | federal medical center | 7 (28%) |
| | | nongovernmental organization | 1 (4%) |
| | | other | 1 (4%) |
| REC membership (multiple responses) | 25 | physician | 25 (100%) |
| | | lawyers | 16 (64%) |
| | | bioethicist | 7 (28%) |
| | | both Christian and Muslim clergy | 3 (12%) |
| | | community member or layperson | 14 (56%) |
| Ownership | 25 | public | 24 (96%) |
| | | private | 1 (4%) |
| REC provides training for members | 25 | yes | 16 (64%) |
| | | no | 8 (32%) |
| Types of training provided* | 16 | workshop or seminar only | 10 (63%) |
| | | online course only | 1 (6%) |
| | | both of the above | 5 (31%) |
| Required frequency of training for REC members* | 14 | once every 2 years | 6 (43%) |
| | | once a year | 5 (36%) |
| | | more than once a year | 3 (21%) |
| Members trained in the past 2 years* prior to data collection | 16 | mean | 6.69 |
| | | mode | 2 |
| | | standard deviation | 5.49 |

* Data is missing.

¹ "No" and "don't know" responses are reported only if they constitute more than one-quarter (25%) of all responses.

Table 3.
REC Operations and Review Processes

| <i>Question (paraphrased)</i> | <i>N</i> | <i>Response</i> ¹ | <i>n (%)</i> |
|--|----------|---|--|
| Does the REC have SOPs? | 25 | yes | 20 (80%) |
| What is the frequency of REC meetings? | 25 | only as needed at least quarterly every 2 weeks | 7 (28%) 17 (68%) 1 (4%) |
| What is the quorum requirement?* | 23 | at least 50% of the members present at least 25% of the members present | 21 (91%) 2 (9%) |
| Is primary review required before a committee meeting?* | 24 | yes | 21 (88%) |
| Are there different review procedures according to risk?* | 24 | yes no | 13 (54%) 11 (46%) |
| Does the committee usually seek the input of outside consultants when conducting a review?* | 23 | yes | 18 (78%) |
| How often is the presence of investigators required during the review process? | 25 | decided on case-by-case basis always never most of the time | 17 (68%) 4 (16%) 3 (12%) 1 (4%) |
| Which, if any, international ethics guidelines does the REC use? (Multiple responses could be chosen.) | 25 | World Medical Association's Declaration of Helsinki <i>Belmont Report</i> principles CIOMS ethical guidelines International Council for Harmonisation's Harmonised Tripartite Guidelines Common Rule (CFR 45 Part 46) of the U.S. Federal Regulations UNESCO's Universal Declaration on Bioethics and Human Rights | 20 (80%) 14 (56%) 13 (52%) 11 (44%) 6 (24%) 5 (20%) |
| Does the REC use the Nigerian National Code of Health Research Ethics?* | 22 | yes no | 15 (60%) 7 (32%) |

* Data is missing.

¹ "No" and "don't know" responses are reported only if they constitute more than one-quarter (25%) of all responses.

Table 4.
REC Continuing Oversight, Record Keeping, and Workload

| <i>Question</i> | <i>N</i> | <i>Response</i> ¹ | <i>n (%)</i> |
|--|----------|--|--------------------------------|
| What is the validity period of approvals for studies?* | 24 | one year more than one year the entire length of the study | 9 (38%) 1 (4%) 14 (58%) |
| Does the REC conduct continuing oversight?* | 22 | yes no | 15 (68%) 7 (32%) |
| How is continuing oversight conducted? | 15 | investigators required to submit progress report visit to study site by the ethics committee both of the above | 5 (33%) 3 (20%) 7 (47%) |
| Does the REC keep written or electronic records of meetings and reviews? | 25 | yes | 24 (96%) |
| How long are records kept after completion of a study?* | 21 | 5 years or less 6-10 years more than 10 years | 7 (33%) 7 (33%) 2 (10%) |
| How long is the application processing time? | 25 | less than one month 1-3 months | 8 (32%) 17 (68%) |
| How many protocols did the REC review in 2008?* | 24 | fewer than 30 30-70 more than 70 | 13 (54%) 8 (33%) 3 (13%) |
| What proportion of reviewed studies have international collaboration or funding?* | 24 | under 25% 25-50% 51-75% | 20 (83%) 3 (13%) 1 (4%) |
| What proportion of reviewed studies have no international collaboration or funding?* | 24 | under 25% 50-75% 75-100% | 1 (4%) 9 (38%) 14 (58%) |

* Data is missing.

¹“No” and “don’t know” responses are reported only if they constitute more than one-quarter (25%) of all responses.

Table 5.
Resources Available to RECs

| <i>Questions concerning</i> | <i>N</i> | <i>Responses¹</i> | <i>n (%)</i> |
|--|----------|---|--|
| REC material resources (multiple responses) | 25 | dedicated office space dedicated space for committee meetings lockers, cabinets, and room for keeping records computer, printer, and Internet access | 11 (44%) 20 (80%) 12 (48%) 11 (44%) |
| Types of staff members serving the REC* | 24 | secretary administrative officer clerical assistants | 24 (100%) 13 (54%) 7 (29%) |
| Whether the REC has a dedicated budget line covered by the host institution* | 22 | yes no | 3 (14%) 17 (77%) |
| Whether the REC charges fees for review* | 24 | yes no | 14 (58%) 10 (42%) |
| Whether the REC charges different fees for international and local research | 14 | yes | 13 (93%) |
| Other sources of funding for the REC | 14 | review fees paid by applicants Ministry of Health medical or health research council European Union (EDCTP) | 8 (57%) 2 (14%) 2 (14%) 2 (14%) |
| Remuneration for REC members* | 21 | yes no | 5 (24%) 16 (76%) |

* Data is missing.

¹“No” and “don’t know” responses are reported only if they constitute more than one-quarter (25%) of all responses.

Table 6.
Association between REC Characteristics and the Degree of Conformity with Guidelines

| | | NHREC Compliance Levels | | | | Result of Fisher's exact test |
|---|------------------------|-------------------------|-----------|------------|-----------|-------------------------------|
| | | < 40% | 41-59% | ≤ 60% | Total | |
| Year of establishment | less than 10 years ago | 2 (14.3%) | 4 (28.6%) | 8 (57.1%) | 14 (100%) | P = 0.487 |
| | more than 10 years ago | 1 (14.3%) | 4 (57.1%) | 2 (28.6%) | 7 (100%) | |
| REC's location | urban area | 5 (22.7%) | 7 (31.8%) | 10 (45.5%) | 22 (100%) | P = 0.57 |
| | rural area | 0 (0.0%) | 2 (66.7%) | 1 (33.3%) | 3 (100%) | |
| Chairperson with prior bioethics training | yes | 0 (0.0%) | 7 (50.0%) | 7 (50.0%) | 14 (100%) | P = 0.067 |
| | no | 3 (33.3%) | 2 (22.2%) | 4 (44.4%) | 9 (100%) | |
| Registration with both the NHREC and OHRP | yes | 0 (0.0%) | 7 (63.6%) | 4 (36.4%) | 11 (100%) | P = 0.013 |
| | no | 5 (35.7%) | 2 (14.3%) | 7 (50%) | 14 (100%) | |
| Registration with OHRP only | yes | 2 (66.7%) | 0 (0.0%) | 1 (33.3%) | 3 (100%) | P = 0.128 |
| | no | 3 (13.6%) | 9 (40.9%) | 10 (45.5%) | 22 (100%) | |
| Registration with NHREC only | no | 5 (20.0%) | 9 (36.0%) | 11 (44%) | 25 (100%) | constant |

Figure 1.
Schema for Recruitment of RECs

