# Evaluation of Functionality of In-country IRBs in Compliance with National and International Standards

## Preliminary Report

by

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# Background

- Formal medical research has been going on in Nigeria since 1920
- But no formal established structure to regulate the conduct of medical research
- FMoH established the National Health Research Ethics Committee (NHREC) in the late 1990s
- Has the mandate to provide oversight to the activities of all Health Research Ethics Committees (HREC) or Institutional Review Boards (IRB) operating within Nigeria.

# Functions of IRBs

- To protect the rights and welfare of human subjects in research
- To promote the general welfare of the society through the conduct of health research
- To scrutinize proposed scientific methods to ensure the highest quality research

# Functionality of IRBs

- Required to have policies and procedures that comply with national and international guidelines.
- Substantial differences exist between functionalities of HRECs
- In Nigeria, NHREC is responsible for regulation of health research, enforcing the guidelines and monitoring the conduct of the IRBs, research institutions and clinical investigators.
- However, each HREC defines how these regulations are implemented in their various institutions.
- It is important to investigate the functionality of HRECs in Nigeria, to determine compliance to national and international guidelines.

# Objectives

- To evaluate the performance of HRECs in Nigeria and their compliance with national and international guidelines

- To disseminate the findings to relevant stakeholders through workshops, symposium and publications

- To train members of ethics committees in the regulations and operations of IRB and the observed gaps from the study

# Methodology….1

**Study design**-mixed method using qualitative and quantitative approaches

**Study Instrument**

- **For qualitative component:** an in-depth interview guide was used to interview chairmen/secretaries of the ethics committees.
- **Quantitative component:** An international self-evaluation checklist for IRBs was used to assess policies and procedures of the HRECs to determine their adequacy.
- **Field Testing:** A field test of the questionnaire was done at NIMR

# Methodology….2

## Study site and sample size determination

- All 79 registered HRECs distributed across the 6 geo-political zones in Nigeria were included in quantitative component of this study. These include:
  - Teaching Hospitals [26],
  - Federal Medical Centers [22]
  - Federal Specialist Hospitals [14]
  - State Ministries of Health [10]
  - Private, Faith Based & Others [7]

- 19 HRECs distributed by zone, level and type were randomly selected for the qualitative phase of the study

# Methodology….3

**Study Procedure:**

- Questionnaires sent by courier to all focal persons of ethics committees through their CMD/MDs.

- The questionnaires were also sent using online survey tool called "survey monkey" by email to 75 persons with available addresses and as an attachment by emails.

- One month timeline was given them to return completed questionnaires

- Data was analysed by descriptive statistics which includes mean, frequencies and percentages.

# Results

- Out of a total of 79 questionnaires sent by courier, 19 (24%) were returned
- Out of a total of 75 persons sent survey monkey and email, 6 (8%) responded
- A total of 25 completely filled questionnaires were received but 2 were duplicated hence excluded making a total of 23 analysed
- Questionnaires were received from 20 institutions
- While 3 institutions had 2 different people fill the questionnaires
- All 19 institutions selected for interview were contacted but 6 (32%) granted us interview

# Table 1:Institutions that participated in the survey

| | Frequency | Percent |
|---|---|---|
| Abubakar Tafawa Balewa University Teaching Hospital | 1 | 4.3 |
| African University of Science and Technology | 1 | 4.3 |
| Ambrose Alli University Health Research Ethics Committee | 1 | 4.3 |
| Bauchi State Health Research Ethics Committee Ministry of Health Bauchi State | 1 | 4.3 |
| Benue State University Teaching Hospital, Makurdi | 2 | 8.7 |
| Bingham University Teaching Hospital, Jos | 1 | 4.3 |
| Bowen University Teaching Hospital | 1 | 4.3 |
| Cross River State Ministry of Health-CRS Health Research Ethics Committee | 1 | 4.3 |
| Federal Medical Centre, Yola | 1 | 4.3 |
| Federal Neuropsychiatric Hospital, Benin | 1 | 4.3 |
| Federal Teaching Hospital, Gombe | 2 | 8.7 |
| Jos University Teaching Hospital | 1 | 4.3 |
| Ministry of Defence Health Research Ethics Committee | 1 | 4.3 |
| National Orthopedic Hospital, Lagos | 1 | 4.3 |
| Neuropsychiatric Hospital, Aro, Abeokuta | 1 | 4.3 |
| Nnamdi Azikiwe University Teaching Hospital, Anambra | 1 | 4.3 |
| Olabisi Onabanjo University Teaching Hospital | 1 | 4.3 |
| University of Ilorin Teaching Hospital | 1 | 4.3 |
| University of Nigeria Teaching Hospital, Ituku-Ozalla, Enugu | 1 | 4.3 |
| Yobe State Minsitry of Health Research Ethics Committee, Damaturu | 2 | 8.7 |
| Total | 23 | 100.0 |

# Table 2: Institutions by State and Zones

| zone | | state | Number(%) |
|---|---|---|---|
| North Central | African University of Science and Technology | Abuja | 1 |
| | Ministry of Defence Health Research Ethics Committee | Abuja | 1 |
| | Benue State University Teaching Hospital, Makurdi | Benue | 2 |
| | Bingham University Teaching Hospital, Jos | Jos | 1 |
| | Jos University Teaching Hospital | Jos | 1 |
| | University of Ilorin Teaching Hospital | Kwara | 1 |
| | | **Total** | **7(30.4)** |
| North East | Abubakar Tafawa Balewa University Teaching Hospital | Bauchi | 1 |
| | Bauchi State Health Research Ethics Committee Ministry of Health Bauchi State | Bauchi | 1 |
| | Federal Medical Centre, Yola | Adamawa | 1 |
| | Federal Teaching Hospital, Gombe | Gombe | 2 |
| | Yobe State Minsitry of Health Research Ethics Committee, Damaturu | Yobe | 2 |
| | | **Total** | **7(30.4)** |
| South East | Nnamdi Azikiwe University Teaching Hospital, Anambra | Anambra | 1 |
| | University of Nigeria Teaching Hospital, Ituku-Ozalla, Enugu | Enugu | 1 |
| | | **Total** | 2(8.7) |
| South South | Ambrose Alli University Health Research Ethics Committee | Edo | 1 |
| | Cross River State Ministry of Health-CRS Health Research Ethics Committee | Cross River | 1 |
| | Federal Neuropsychiatric Hospital, Benin | Edo | 1 |
| | | **Total** | **3(13.0)** |
| South West | Bowen University Teaching Hospital | Oyo | 1 |
| | National Orthopedic Hospital, Lagos | Lagos | 1 |
| | Neuropsychiatric Hospital, Aro, Abeokuta | Ogun | 1 |
| | Olabisi Onabanjo University Teaching Hospital | Ogun | 1 |
| | | **Total** | **4(17.4)** |

# Table 3: Background of Institutions

| Background of Institutions | | Number(%) |
|---|---|---|
| Type Of Institution | Private | 1(4.3) |
| | Faith based | 2(8.7) |
| | Public | 20(87) |
| Level of Institution | Primary | 0(0) |
| | Secondary | 2(8.7) |
| | Tertiary | 21(91.3) |
| Main Source of funding | Federal | 12(52.2) |
| | State | 8(34.8) |
| | Private | 3(13.0) |
| How long IRB had been Established | < 3years | 6(27.3) |
| | 3-5 years | 5(22.7) |
| | 6-10 years | 2(9.1) |
| | >10 years | 9(40.9) |

# Table 4: Existence of institutional procedure on authority, purpose and principles that govern IRB, relationship and membership of IRB

| Existence of Institutional written policies or procedures that describe: | Yes(%) | No(%) |
|---|---|---|
| The Institutional Authority Under which the IRB is Established And Empowered | 18(81.8) | 4(18.2 |
| The Definition Of The Purpose Of The IRB i.e. Protection Of Human Subjects Of Research | 17(77.3) | 5(22.7) |
| The Principles which Govern The IRB in Assuring that the Rights and welfare of subjects are protected. | 17(77.3) | 5(22.7) |
| The authority of the IRB which includes: type of study to be reviewed, disapproved, modified or approved request for progress reports suspend or terminate approvals a Place restrictions on studies | 18(78.2) | 5(21.8) |
| The IRB's relationship to the top administration of the institution, research investigators, other institutions and regulatory bodies | 14(61.8) | 9(38.2) |
| The membership of the IRB in terms of numbers, qualifications, diversity of members (sex, profession, scientific and non-scientific), alternate members | 17(72.4) | 6(27.6) |

# Table 5: Management of IRB

| Existence of Institutional written policies or procedures that describe management o the IRB: | Yes(%) | No(%) |
|---|---|---|
| The Chairperson's selection, appointment, length of term, duties and removal | 15(67.1) | 8(32.9) |
| The IRB Member's selection, appointment, length of term, duties and removal | 15(64.4) | 8(35.6) |
| Training of IRB Chair and members (orientation, continuing education and reference materials) | 13(55.7) | 10(44.3) |
| Compensation of IRB members. | 4(21.1) | 14(78.9) |
| Liability coverage for IRB members. | 1(5.3) | 18(94.7) |
| Use of consultants. | 10(45.5) | 12(54.5) |
| Secretarial/administrative support staff (duties) | 13(61.9) | 8(38.1) |
| Resources (for example, meeting area, filing space, reproduction equipment, computers). | 14(63.6) | 8(36.4) |
| Conflict of interest policy (no selection of IRB members by investigators, prohibition of participation in IRB deliberations and voting by investigators) | 11(46.4) | 12(53.6) |

# Table 6: Functions of IRB

| Existence of Institutional written policies or procedures that describe functions of IRB on: | Yes(%) | No(%) |
|---|---|---|
| Conducting initial and continuing review. | 18(81.8) | 4(18.2) |
| Reporting, in writing, findings and actions of the IRB to the investigator and the institution. | 18(81.8) | 4(18.2) |
| Determining which studies require review more often than annually. | 14(63.6) | 8(36.4) |
| Determining which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review. | 14(66.7) | 7(33.3) |
| Ensuring prompt reporting to the IRB of changes in research activities. | 18(81.8) | 4(18.2) |
| Ensuring that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards. | 17(77.3) | 5(22.7) |
| Ensuring prompt reporting to the IRB, appropriate institutional officials, NHREC and NAFDAC of unanticipated problems involving risks to subjects or others and serious or continuing noncompliance with NHREC codes and guidelines. | 16(69) | 7(31) |
| Determining which device studies pose significant or non-significant risk. | 13(72.2) | 5(27.8) |

# Table 7: Operations of IRB

| Existence of Institutional written policies or procedures that describe operations of the IRB on: | Yes(%) | No(%) |
|---|---|---|
| Schedule of meetings | 14(70) | 6(30) |
| Pre-meeting distribution to members, of, for example, place and time of meeting, agenda, and study material to be reviewed | 15(75) | 5(25) |
| The review process; description, all members receive complete study, one or more primary reviewers receive complete docs. | 14(62.2) | 9(37.8) |
| Criteria for IRB approval contain all requirements in NHREC guidelines | 14(73.7) | 5(26.3) |
| Voting requirements (quorum, diversity, full, no proxy votes and exclusion of conflict of interest) | 13(56.1) | 10(43.9) |
| Further review/approval of IRB actions by others within the institution. (Override of disapprovals is prohibited) | 3(17.6) | 14(82.4) |
| Communication from the IRB. | 16(67.5) | 7(32.5) |
| Appeal of IRB decisions. | 7(30.6) | 16(69.4) |

# Table 8: IRB Record Requirement

| Existence of Institutional written policies or procedures that describe IRB record equipment on: | Yes(%) | No(%) |
|---|---|---|
| IRB membership roster showing qualifications. | 13(65) | 7(5) |
| Written procedures and guidelines. | 14(66.7) | 79(33.3) |
| Minutes of meetings. | 17(73) | 6(27) |
| Retention of protocols reviewed and approved consent documents | 18(81.8) | 4(18.2) |
| Communications to and from the IRB | 18(81.8) | 4(18.2) |
| Adverse reactions reports, and documentation that the IRB reviews such reports. | 13(57.9) | 10(42.1) |
| Records of continuing review. | 13(65) | 7(5) |
| Record retention requirements. | 13(72.2) | 5(27.8) |
| Budget and accounting records. | 9(47.4) | 10(52.6) |
| Emergency use reports. | 6(37.5) | 10(62.5) |
| Statements of significant new findings provided to subjects | 6(35.3) | 11(64.7) |

# Table 9: Information the Investigator provides to the IRB

| Existence of Institutional written policies or procedures that describe management o the IRB: | Yes(%) | No(%) |
|---|---|---|
| Professional qualifications to do the research | 17(81) | 4(19) |
| Study protocol which includes/addresses(Title, purpose and sponsor of the study, etc.) | 17(72.3) | 6(27.7) |
| Investigator's brochure | 12(66.7) | 6(33.3) |
| The case report form | 15(71.4) | 6(28.6) |
| The proposed informed consent document | 1772.7) | 6(27.3) |
| Requests for changes in study after initiation | 16(72.7) | 6(27.3) |
| Reports of unexpected adverse effects | 10(50) | 10(50) |
| Progress reports | 14(63.6) | 8(36.4) |
| Final report | 15(68.2) | 7(31.8) |
| Institutional forms/reports | 13(59.1) | 9(40.9) |

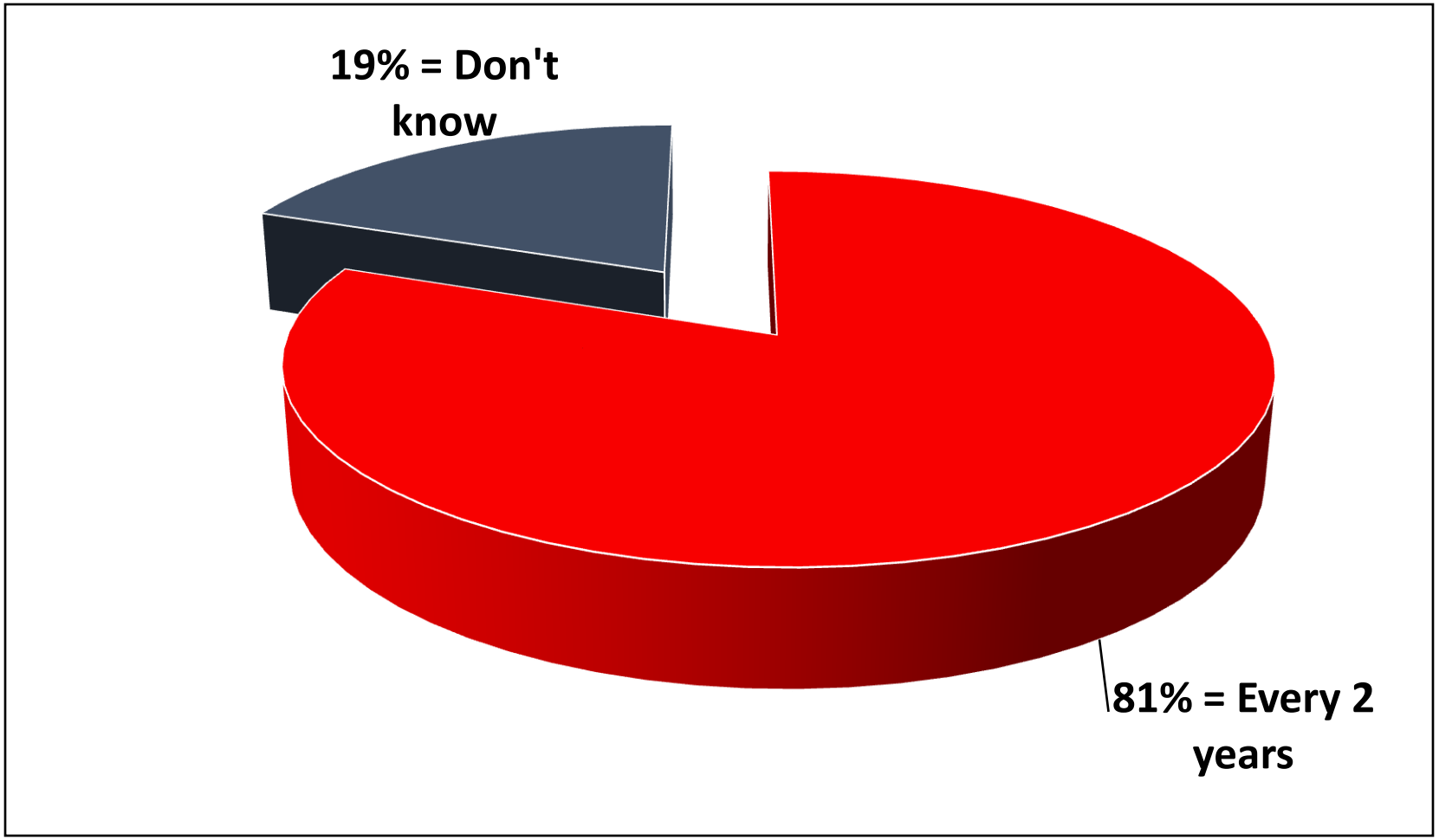
## Table 10: Exception from IRB review

| Existence of Institutional written policies or procedures that describe exception from IRB review on | Yes (%) | No (%) |
|---|---|---|
| Notify IRB approval within 5 working days | 5(31.3) | 11(68.8) |
| Emergency use | 4(25.0) | 12(75.0) |
| Review protocol and consent when subsequent use is anticipated | 7(38.9) | 11(61.1) |

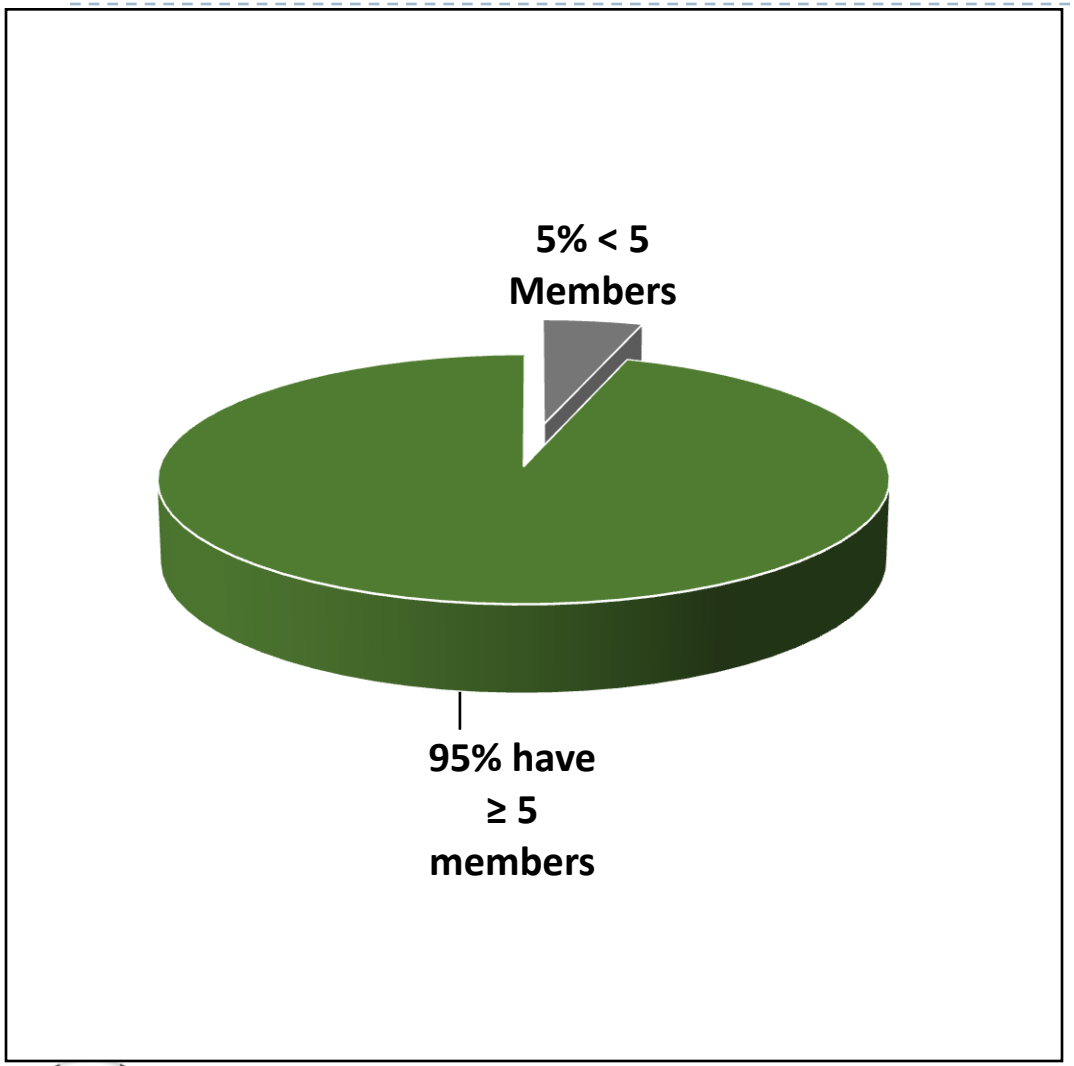
## Table 11: Emergency research consent exception

| Existence of Institutional written policies or procedures that describe emergency research consent exception: | Yes(%) | No(%) |
|---|---|---|
| The IRB may find that the NHREC requirements are met | 9(52.9) | 8(47.1) |
| The IRB shall promptly notify in writing the investigator and the sponsor when it determines it cannot approve this study | 12(60) | 8(40) |
| In order to approve an emergency research consent waiver study | 8(35) | 15(65) |

# Figure 1: Knowledge of 2 yearly requirement for NHREC registration

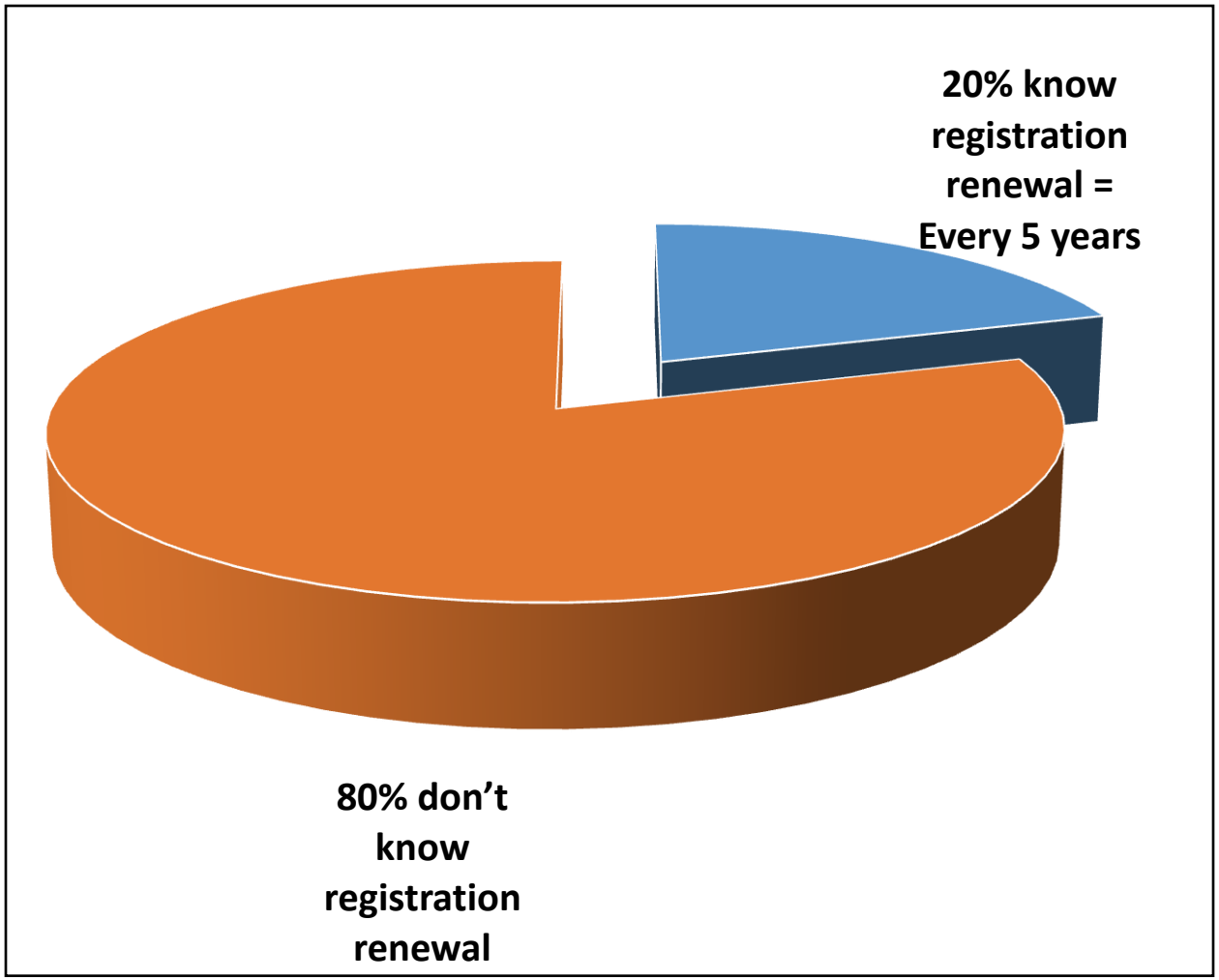


# Figure 2: IRB membership




- 20% of those with ≥ 5 members had even number of members Vs odd number as stated in NHREC guidelines

# Figure 3: Knowledge of Federal Wide Assurance Number registration




- 10(50%) of the institutions have FWA number

# Table 12: Distribution of Respondents from In-depth Interview

| Facility type | No and Categories Targeted | No and Categories Responded (%) |
|---|---|---|
| Teaching hospitals | 7 | 3 (43) |
| FMC | 5 | 0 (0) |
| Specialist hospital | 4 | 1 (25) |
| SMOH | 2 | 1 (50) |
| Faith based | 1 | 1 (100) |

# Additional information from In-depth interview with HRECs

## Strengths

- Have all undergone training
- All meet regularly
- All charge processing fee for sustainability
- Have document archival system in place

## Weaknesses

- No administrative office (50%)
- Inadequate manpower (33%)
- No site monitoring of approved research projects (50%)
- No oversight functioning by NHREC (67%)
- No institutional SOP developed, uses NHREC guideline (33%)

# Conclusion

- Majority of the HRECs are not fully in compliance with national and international guidelines

- Oversight function of NHREC is not fully implemented

# Limitations of the study

- Difficulty in contacting the HRECs due to incorrect email addresses, phone numbers and staff relocations

- Poor responses from institutions for several reasons such as:
  - Not familiar with the online survey tool
  - Busy work schedule
  - Non functioning of some ethics committees
  - Required approval from NHREC

# Next Steps

- Organize another dissemination meeting for stakeholders
- Conduct workshop to address the identified gaps

# Thank you for listening