KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

INA RESPOND
INDONESIA RESEARCH PARTNERSHIP ON INFECTIOUS DISEASE

NIH National Institutes of Health

CLINICAL RESEARCH ETHICS: CURRENT CHALLENGES IN INDONESIA

MOHAMMAD SUDOMO

NIHRD-HEALTH RESEARCH ETHICS COMMITTEE

RESEARCH ETHICS TRAINING WORKSHOP

J.W. Marriott Hotel, Jakarta, 17-19 July 2018

INTRODUCTION

- **BELMONT REPORT, 1978**
- **COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) GENEVA**
  - **CIOMS 2011 → 7 STANDARDS**
  - **CIOMS 2016 → 25 STANDARDS**

ETHICAL PRINCIPLES

BELMONT REPORT

1. RESPECT FOR PERSON
2. BENEFICENT
3. JUSTICE

CIOMS 2011 (7 STANDARDS)

1. SCIENTIFIC DESIGN AND CONDUCT OF THE STUDY
2. RISK AND POTENTIAL BENEFIT
3. SELECTION OF STUDY POPULATION AND RESCRUITMENT OF RESEARCH PARTICIPANTS
4. INDUCEMENTS, FINANCIAL BENEFIT AND FINANCIAL COST
5. PROTECTION OF RESEARCH PARTICIPANTS' PRIVACY AND CONFIDENTIALITY
6. INFORMED CONSENT PROCESS
7. COMMUNITY CONSIDERATION

RESEARCH ETHICS COMMITTEE

- **RESEARCH ETHICS COMMITTEE IS THE MOST INDEPENDENT BODY REGULATING ETHICS**
- **TO DATE THE EFFECTIVENESS OF LOCAL ETHICS COMMITTEE TO FULLFILL ITS JOB HAS BEEN CHALLENGED BY THE NEED OF RESEARCHERS**
- **THE CHALLENGE IS AMONG OTHERS, MULTICENTERS RESEARCH**

KEY CHALLENGES

- **VOLUME AND NATURE OF RESEARCH**
- **MULTICENTRE RESEARCH STUDIES, RESEARCH SYNTHESIS**
- **DETECTION OF SCIENTIFIC MALPRACTICE AND FRAUD**
- **COMMITTEE MEMBERSHIP**
- **RESOURCES**
- **TRAINING**
- **MONITORING**
- **INVESTIGATORS WHO ARE INVOLVED IN SEVERAL TRIALS**
- **FAILURE TO PUBLISH RESULTS**

VOLUME AND NATURE OF RESEARCH

- **VARIATION AND VOLUME OF PROTOCOLS REVIEWED → LOCAL EC MEMBERS NEED MORE DEMANDING TASKS**
- **THE WORKLOAD OF LOCAL EC ALSO VARIES, DEPEND ON THE INSTITUTON**

MULTICENTRE RESEARCH STUDIES

- **MULICENTRE STUDIES MORE COMPLEX → NEED COMPETENCE AND UNIFORMITY OF REVIEWERS**
- **SOMETIMES LOCAL EC HAVE BEEN CRITISIZED FOR DELAYING THE REVIEW OF GOOD PROTOCOLS ESPECIALLY MULTICENTRES RESEARCH PROTOCOLS**
- **THE MAIN ISSUES ARE: THE EFFICIENCY OF THE EC'S REVIEW, THE DIVERSITY OF THE EC MEMBERS, WASTE OF FUNDS AND TIME**
- **LESS CAPABILITY TO REVIEW RESEARCH PROTOCOLS**
- **NEED A GOOD SYSTEMS HOW TO OVERCOME THIS ISSUES**

CHALLENGES FROM MULTI CENTRE SYNTHESIS

- **FAILURE TO DO RESEARCH SYNTHESIS – TO AGGREGATE AND INTEGRATE THE RESEACH RESULTS**
- **RESEARCHERS FAILED TO INITIATE/UNDERTAKE SATISFACTORY ANALYSES**
- **FAIL TO MEET THE TIME FRAME TO REPORT THE RESULTS OF THEIR RESEARCH**

  → LEAD TO LOW STANDARDS OF RESEARCH

DETECTION OF SCIENTIFIC MALPRACTICE AND FRAUD

- **THIS RELATED TO DETECTION OF FRAUD IN CLINICAL RESEARCH**
- **CARELESSNESS, OVERCOMMITMENT, AND OVERAMBITION CAN ALL CONTRIBUTE TO SECOND RATE, EVEN UNETHICAL, PRACTICES.**
- **EACH INVESTIGATOR HAS A DUTY TO FULLY UNDERSTAND THE NATURE OF THE RESEARCH BEFORE ACCEPTING RESPONSIBILITY TO IMPLEMENT**

POSSIBLE SOLUTION TO THOSE CHALLENGES

COMMITTEE MEMBERSHIP

- **RESEARCH ETHICS COMMITTEES MUST HAVE AN APPROPRIATE MEMBERSHIP WITH A DIVERSE RANGE OF EXPERTISE AND EXPERIENCE.**
- **COMMITTEES SHOULD INCLUDE AT LEAST ONE MEMBER WITH A THOROUGH KNOWLEDGE OF THE SCIENTIFIC ASPECTS OF CLINICAL RESEARCH AND OF METHODS OF RESEARCH SYNTHESIS (CLINICIAN AND SCIENTIST WITH GCP CERTIFICATION).**
- **VALUABLE CONTRIBUTIONS CAN BE MADE BY BIOSTATISTICIANS, BIOETHICISTS, LAWYERS, AND LAY PEOPLE FROM COMMUNITY GROUPS.**
- **COMMITTEES HAVE POWER TO CO-OPT MEMBERS. THIS IS ESPECIALLY IMPORTANT WHEN DEALING WITH NEW TECHNOLOGIES SUCH AS GENETIC RESEARCH.**

POSSIBLE SOLUTION TO THOSE CHALLENGES

RESOURCES

- **AUTHORITIES SHOULD ENSURE THAT LOCAL RESEARCH ETHICS COMMITTEES HAVE ADEQUATE SUPPORT AND ADMINISTRATIVE HELP.**
- **WE SUGGEST THIS SHOULD BE FROM TRAINED STAFF WORKING SOLELY FOR THE LOCAL COMMITTEE.**
- **CORE MATERIAL FOR MEMBERS AND CONTINUING TRAINING FOR NEW AND EXISTING MEMBERS SHOULD BE BUDGETED.**
- **THIS SUPPORT HAS BEEN RECOGNISED FOR MULTICENTRE RESEARCH ETHICS COMMITTEES.**

POSSIBLE SOLUTION TO THOSE CHALLENGES

TRAINING

- **SOP SHOULD BE DEVELOPED TO ENSURE THAT THERE IS CONSISTENCY IN DECISION MAKING, IN ACCORDANCE TO THE SOP.**
- **MEMBERS NEED TIME TO STUDY THE SOP AND FOLLOW IT IN EVERY DECISION MAKING.**
- **IN THE SOP SHOULD ALSO BE MENTIONED ABOUT TRAINING COURSES: INTERNATIONAL, NATIONAL AND IN-HOUSE TRAINING.**
- **THE TRAINING ALSO APPLY TO THE LAY PERSON(S).**

POSSIBLE SOLUTION TO THOSE CHALLENGES

MONITORING

- **TO AVOID MALPRACTICE AND FRAUD, IDEALLY MONITORING SHOULD BE DONE FROM THE SUBMISSIONS OF PROTOCOLS, PROGRESS OF THE STUDY, AND PUBLICATION.**
- **ETHICS COMMITTEE, AFTER GRANTING THE ETHICAL APPROVAL FOR A RESEARCH PROTOCOL, HAS THE RESPONSIBILITIES TO:**
  - **REVIEW PROGRESS/ANNUAL REPORT,**
  - **REVIEW AND APPROVING AMENDMENTS, AND**
  - **REVIEW REPORTS OF ADVERSE EVENTS, NON-COMPLIANCE**

POSSIBLE SOLUTION TO THOSE CHALLENGES

INVESTIGATORS WHO ARE INVOLVED IN RESEARCH TRIALS

- **RESEARCH ETHICS COMMITTEES SHOULD KNOW IF AN INVESTIGATOR IS PARTICIPATING IN CONCURRENT TRIALS**

- **RESEARCH ETHICS COMMITTEES SHOULD BE SATISFIED THAT INVESTIGATORS WHO TAKE ON SEVERAL RESEARCH COMMITMENTS CAN CONDUCT THESE STUDIES ADEQUATELY.**

POSSIBLE SOLUTION TO THOSE CHALLENGES

FAILURE TO PUBLISH RESULTS

- **RESEARCH APPROVED BY ETHICS COMMITTEES MUST BE MONITORED TO ENSURE SCIENTIFIC INTEGRITY.**
- **ETHICS COMMITTEES HAS THE RIGHT TO ENCOURAGE RESEARCH RESULTS TO BE PUBLISHED AND AVAILABLE FOR PUBLIC.**
- **IN COMMERCIALLY SPONSORED STUDIES, PRESSURE EXISTS TO KEEP THE FINDINGS SECRET, TO PREVENT PUBLICATION**

RESPONSIBLE CONDUCT OF RESEARCH

- *CONDUCTING RESEARCH IN A RESPONSIBLE MANNER,*
- *ADHERING TO ETHICAL RESEARCH PRACTICE*
- *TO MAINTAIN RESEARCH INTEGRITY*
- *LEADING TO BETTER & CREDIBLE SCIENTIFIC RESULTS FOR APPLICATION*

→THERE WILL BE LESS RESEARCH MISCONDUCT

HOW TO ACHIEVE RESPONSIBLE CONDUCT OF RESEARCH?

- PRACTICING HIGHEST STANDARDS OF ETHICS & ACCOUNTABILITY IN EACH STEP OF RESEARCH PROCESS, FROM PLANNING TO PUBLICATION & UTILIZATION OF RESEARCH
- PRACTICING RESEARCH INTEGRITY
- TO ACHIEVE RESEARCH INTEGRITY, I.E., *"ADHERENCE TO RULES, REGULATIONS, GUIDELINES, SOP, & COMMONLY ACCEPTED PROFESSIONAL CODES OR NORMS"*
- SIMPLY A PRACTICE OF GOOD CITIZENSHIP APPLIED TO PROFESSIONAL LIFE

FOUR BASIC PRINCIPLES OF RCR

- **HONESTY**: CONVEYING INFORMATION TRUTHFULLY & HONORING COMMITMENTS
- **ACCURACY**: REPORTING FINDINGS PRECISELY & TAKING CARE TO AVOID ERRORS
- **EFFICIENCY**: USING RESOURCE WISELY & AVOIDING WASTE
- **OBJECTIVITY**: LETTING FACTS SPEAK FOR THEMSELVES & AVOIDING BIAS
- RESPONSIBLE RESEARCH IS "**RESEARCH BUILT ON ABOVE & OTHER IMPORTANT VALUES**"

In relation to RCR, some issues :

INFORMED CONSENT PROCESS ELECTRONICALLY

- SUBJECT UNDERSTANDING OF THE ELECTRONOC CONSENT PROCESS
- SECURITY OF THE CONSENT
- TO DEVELOP METHOD TO PROVIDE INFORMED CONSENT
- IS THE COMMUNITY READY TO ACCEPT THE METHODS?
- STILL NEED SOMETIME TO COME TO USE MODERN TECHNOLOGY TO OBTAIN INFORMED CONSENT FROM SUBJECTS

CLINICAL RESEARCH IN INDONESIA

- **CLINICAL RESEARCH IMPLEMENTED IN ASIAN COUNTRIES, INCLUDED INDONESIA BASED ON ISSUES :**
- **CHEAP TRIAL COST**
- **REGULATIONS: NOT AS STRICT AS IN DEVELOPED COUNTRIES**
- **WIDE VARIETY OF DISEASES**
- **AVAILABILITY OF RESEARCH SUBJECT**

CLINICAL RESEARCH IN INDONESIA

- **BETWEEN 2016-2018, ABOUT 72 CLINICAL TRIALS (ON DRUGS) AND 6 ON VACCINE HAVE BEEN CONDUCTED IN INDONESIA.**
- **COMPLAINT FROM INVESTORS DUE TO COMPLICATED TO OBTAIN MTA (MATERIAL TRANSFER AGREEMENT) APPROVAL.**

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CLINICAL RESEARCH IN INDONESIA

WEAKNESSES

- NOT STANDARDIZE ETHICS COMMITTEE
- LESS NETWORK IN DRUG DEVELPOMENT RESEARCH
- LOW QUALITY OF SOME CLINICAL RESEARCH
- SOME “LESS FRIENDLY” REGULATIONS
- LACK OF INSURANCE COMPANY
- SMALL NUMBER OF RESEARCH-ORIENTED LOCAL PHARMACEUTICAL INDUSTRY

(Prof Rianto Setyabudhi)

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CLINICAL RESEARCH IN INDONESIA

STRENGTH

1. **HOSPITALS AND PUBLIC HEALTH CENTRES**
2. **CAPABLE AND QUALIFIED MANPOWER IN SOME INSTITUTIONS AND UNIVERSITIES**
3. **ACCREDITED CLINICAL LABORATORY**
4. **VARIETY OF DISEASES**

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THANK YOU

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