





Deputy of Research & Technology
Secretariat of National Committee for
Ethics in Biomedical Research (NREC)

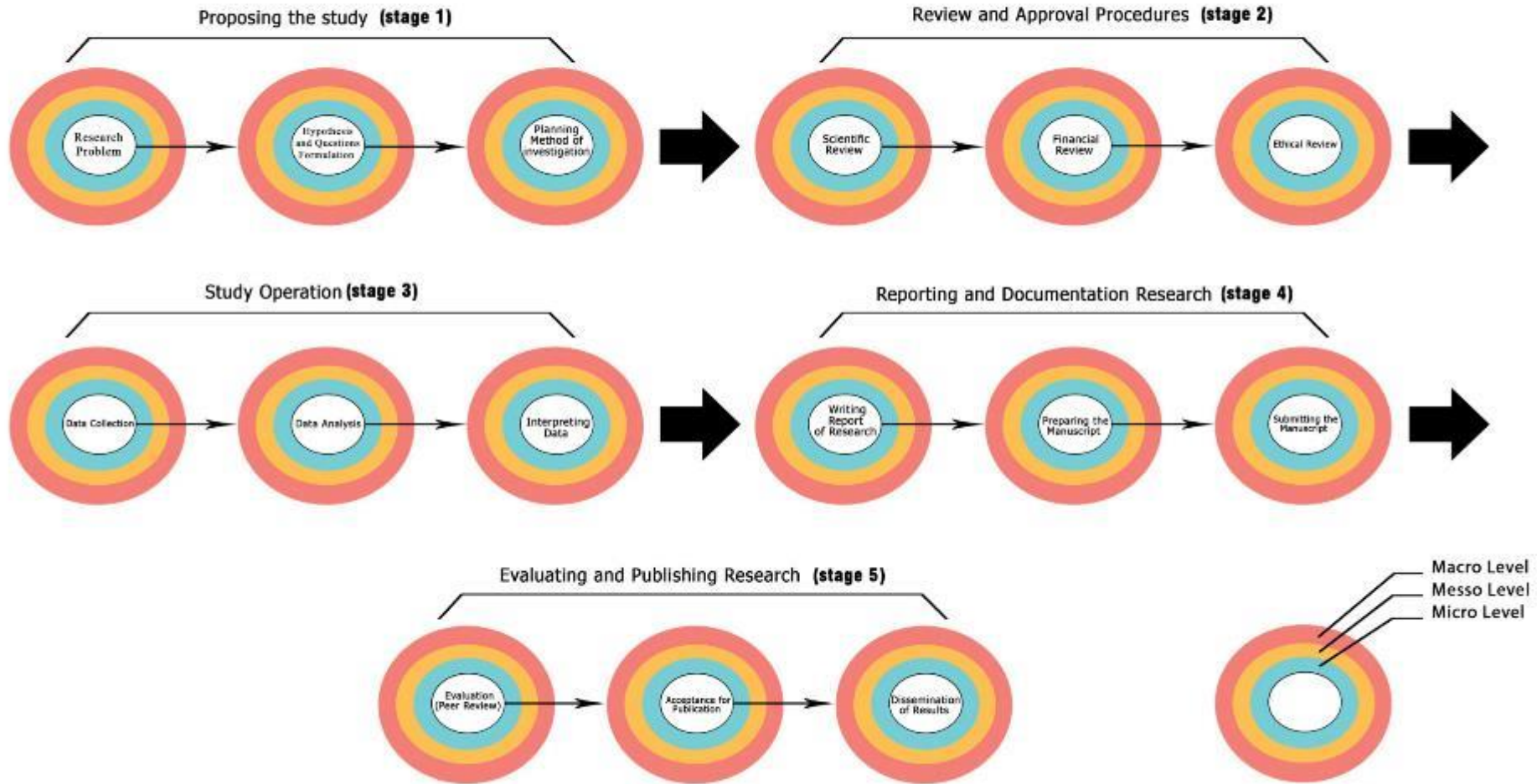
Secretary of NREC, MOHME
Ehsan Shamsi Gooshki MD/Ph.D.
Assistant Professor of Medical Ethics, TUMS



The Main Stakeholders for Ensuring Research Integrity



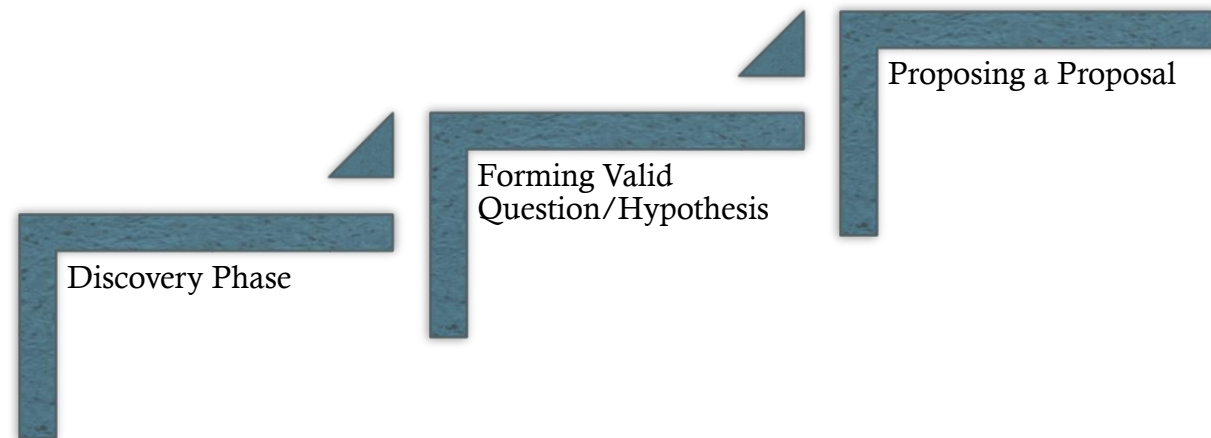
Research Process



How Researchers Start?!

Motivation behind Research:

- Solving Problems
- Graduation
- Academic Promotion
- Institutional Commitments



Approval Process:



Principle Investigator (PI):

- The main Responsible
- Research Team Leader

Institution Review Board (IRB):

- Scientific Evaluation
- Methodology Assessment

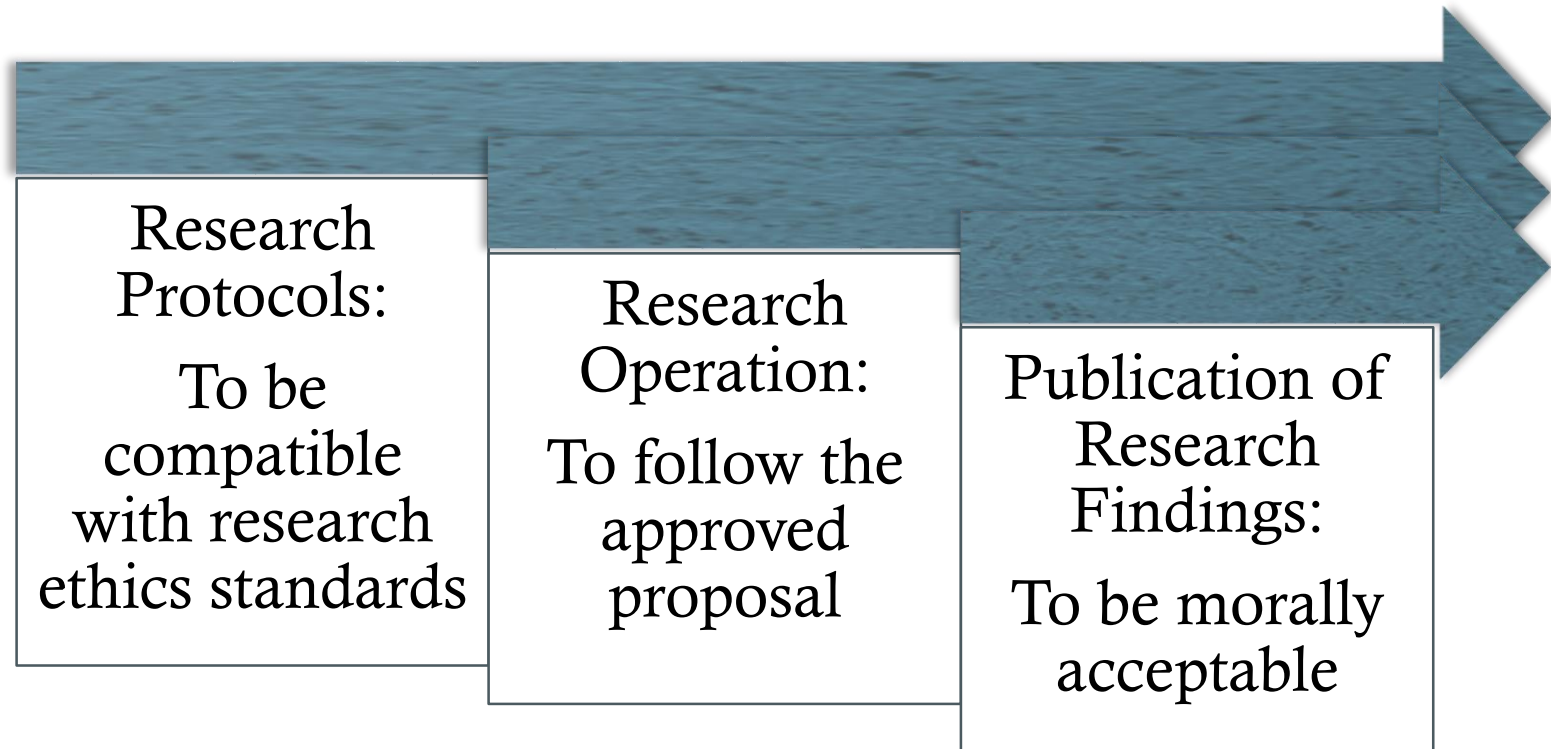
Organizational Review Board (ORB):

- Resource Allocation
- Financial Justification

Research Ethics Committee (REC):

- Consent
- Privacy
- Risk
- Benefit
- Vulnerability
- Religious Evaluation
- Legal Check
- Social Values

Research Integrity:



Research Integrity and Excellence

- Research Infrastructure ((Research Labs' Construction, Research Labs' Equipment, Research Labs' Protocols, Methods and Procedures, Animal Houses, Animal Farms, Animal Models, Research Biobanks, Clean Rooms, Human Resources,...))
- Research Design and Process ((Research Design, Research Scientific Evaluation, Research Ethical Evaluation, Research Management Bureaucracy, Research Management Software, Research Registration (IRCT, ...))
- Policy-Making Integrity (FDO, MoH Education Department,...)
- Medical Journals (Paper Quality, Visibility and Citation, Editorial Management , Publishing Regularity, Indexing)

Iran Research Ethics System Reform

Introduction of Research Ethics Standards

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graph TD; A[Introduction of Research Ethics Standards] --- B[ ]; B --- C[Setting up a Surveillance System]; B --- D[Setting up a Disciplinary System];
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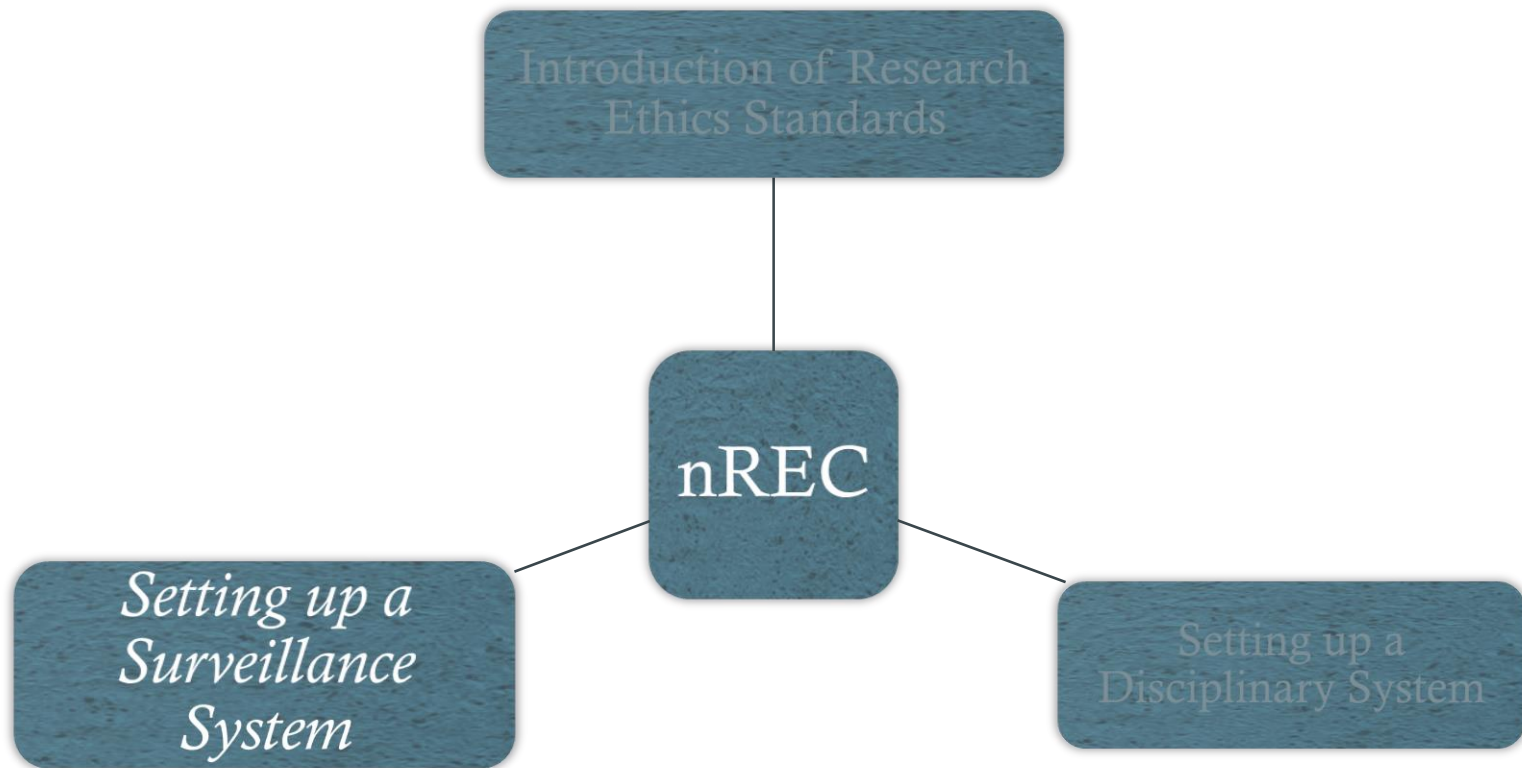
Setting up a
Surveillance System

Setting up a
Disciplinary System

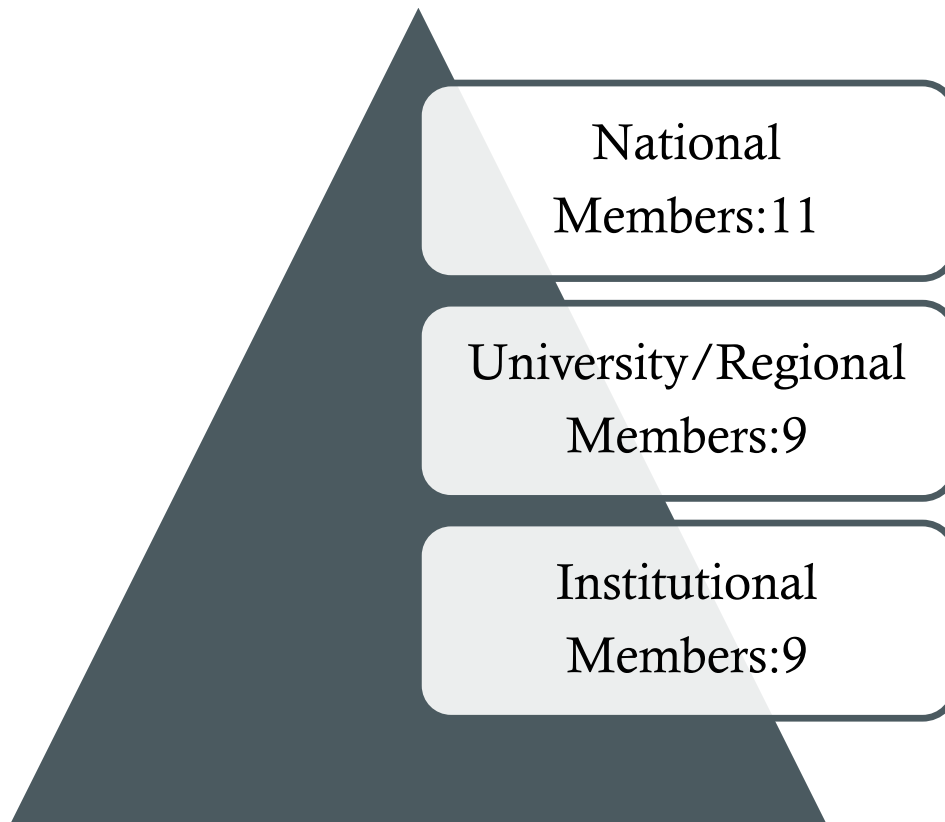
Introduction of Research Ethics Standards

- General National Guideline for Research on Human Participants
- Specific National Guidelines: (e.g. Animal Research, Stem Cell Research, Genetic Research, Research on Vulnerable Populations, Clinical Trials, Research on Embryo & Fetus, Research on Tissue and Organs, AIDS Research,)
- Procedural Guidelines: (e.g. BMT, Publication Ethics, Establishment of RECs Guideline, REC Application Form, Research Misconduct Procedure Guideline..)

Iran Research Ethics System Reform



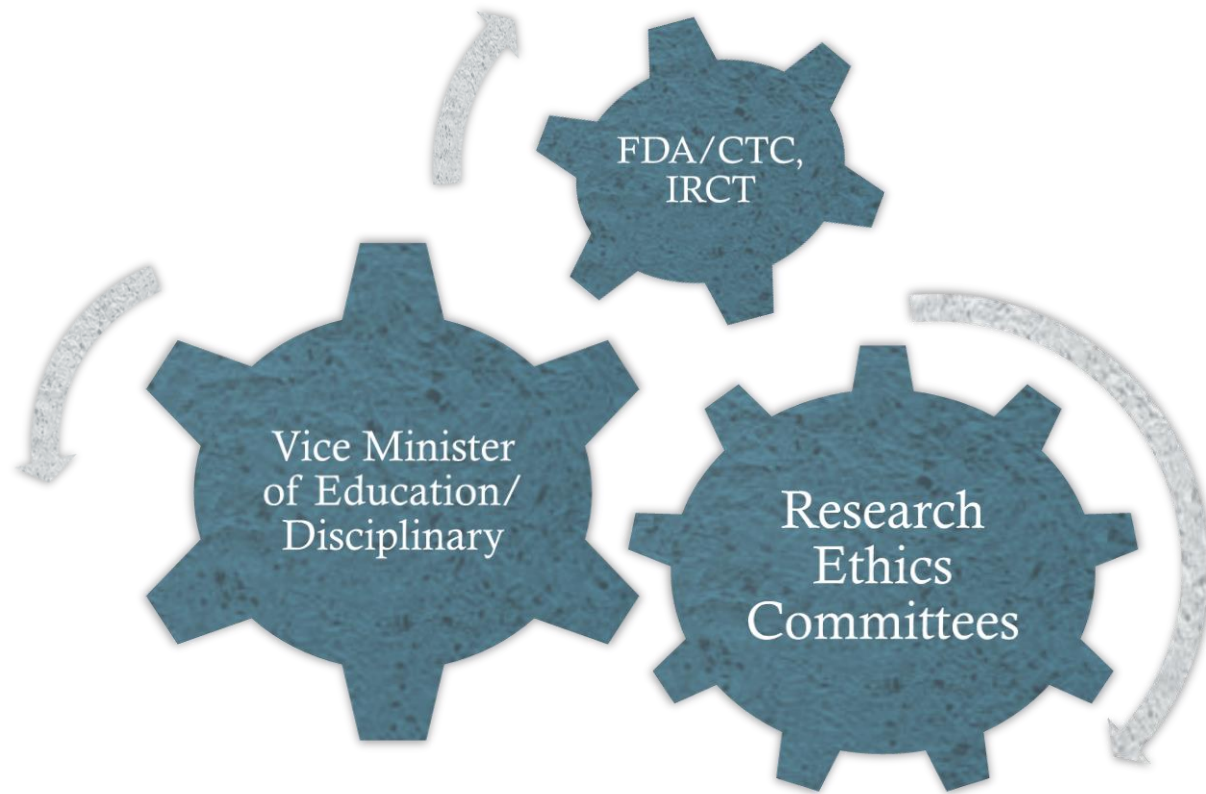
National Guideline for Establishment, Grading & Practice of RECs in 3 Levels



Reestablishment of NREC: by Minister's Official Nomination: New Round: Since Sep 2014



Ethics-Related Parties of MOHME



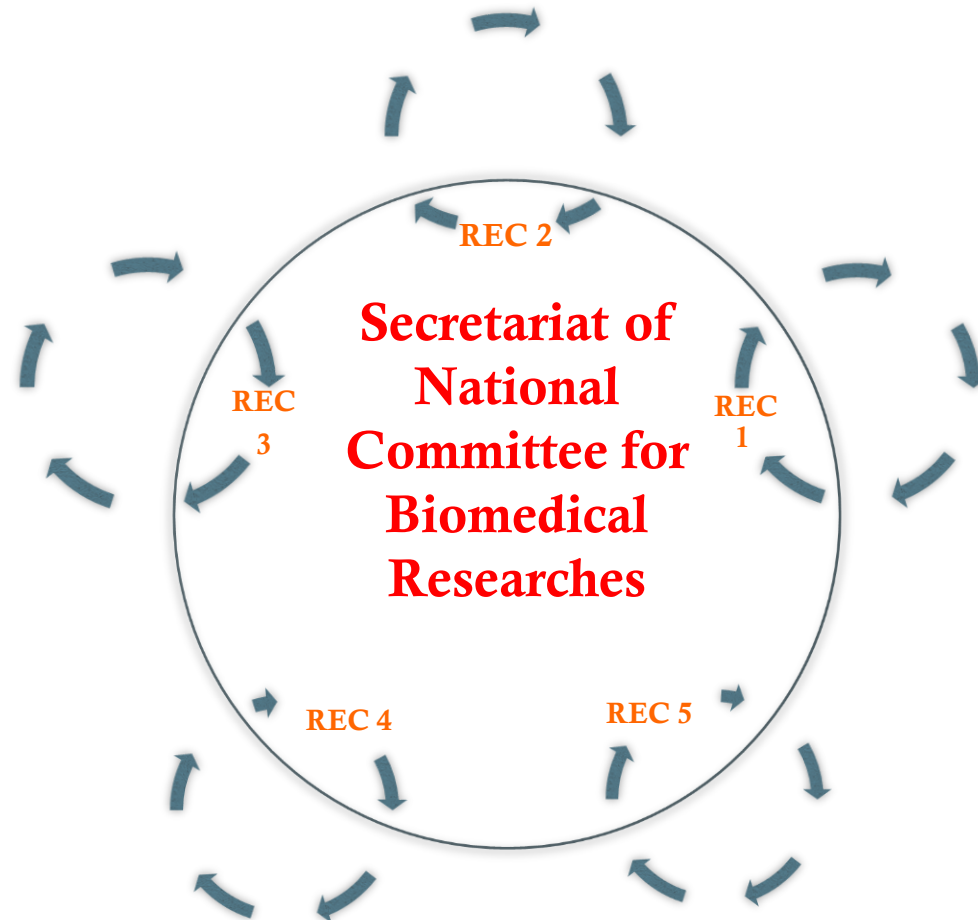
Accredited RECs as Executive Bodies



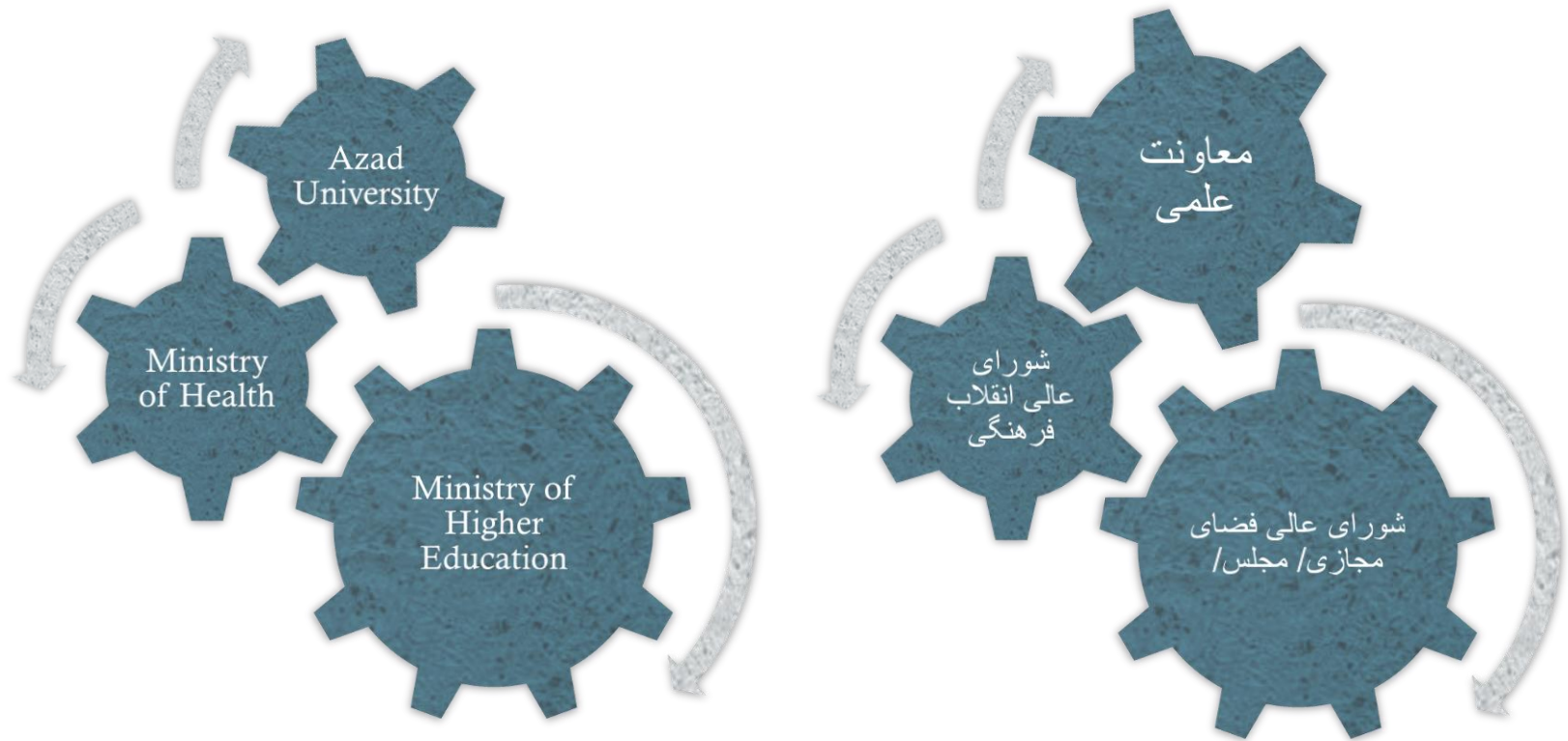
RECs Main Missions :



National Portal for Research Ethics Repository Program



Need for an Integrated System



سامانه علم سنجی اعضای هیات علمی

<http://isid.research.ac.ir>

The screenshot shows the ISID website interface. At the top, there is a navigation bar with the site name and a search bar. Below the navigation bar, there is a map of Iran on the left and a search form in the center. The search form includes dropdown menus for university, faculty, and department, and a search button. On the right side, there is a logo and text in Persian. Below the search form, there is a table with 6 columns: Rank, Name and Family Name, University, Faculty/Department, Academic Rank, and H-index. The table lists 6 faculty members.

سامانه علم سنجی اعضای هیات علمی

زود به سامانه ورود

انتخاب دانشگاه/موسسه: دانشگاه تهران

انتخاب دانشکده/موسسه مربوطه انتخاب گردد: دانشکده علوم پایه

انتخاب رتبه علمی: استادیار

انتخاب مقطع تحصیلی: مقطع تحصیلی انتخاب گردد

رتبه علمی: استادیار

مقطع تحصیلی: مقطع تحصیلی انتخاب گردد

رشته تحصیلی: بیولوژی

نام: جستجو

تعداد نتایج: ۱۸۳۶۸

ردیف	نام و نام خانوادگی	دانشگاه علوم پزشکی / سازمان	مقطع / رشته	رتبه علمی	مقالات	ارجاعات	H-Index	ارجاع برای هر مقاله
۱	محمد عبداللهی	تهران	دکترای تخصصی (PhD) داروسازی / سم شناسی داروشناسی	استاد	۶۷۵	۱۳۹۳۳	۵۸	۲۰/۶۳
۲	رضا ملک زاده	تهران	دکترای فوق تخصصی بالینی / گوارش و کبد باغین	استاد معتز	۳۷۰	۱۹۵۶۳	۵۵	۴۱/۶۳
۳	فریدون عزیزی	شهید بهشتی	دکترای فوق تخصصی بالینی / غدد درون ریز و متابولیسم باغین	استاد	۸۹۳	۱۳۴۶۳	۵۵	۱۵/۰۸
۴	محمود رفیعیان کویایی	شهرکرد	دکترای تخصصی (PhD) داروسازی / داروشناسی	استاد	۳۷۴	۶۱۷۳	۵۰	۱۹/۰۵
۵	باقر لاریجانی	تهران	دکترای فوق تخصصی بالینی / غدد درون ریز و متابولیسم باغین	استاد	۷۴۸	۸۹۲۶	۴۴	۱۱/۹۳
۶	مرتضی محمودی	تهران	دکترای تخصصی (PhD) نانو فناوری، پزشکی	استادیار	۱۵۸	۷۲۳۴	۴۲	۴۵/۷۸

Iran Research Ethics System Reform



Setting up a Disciplinary System

دریافت گزارش/
شکایت

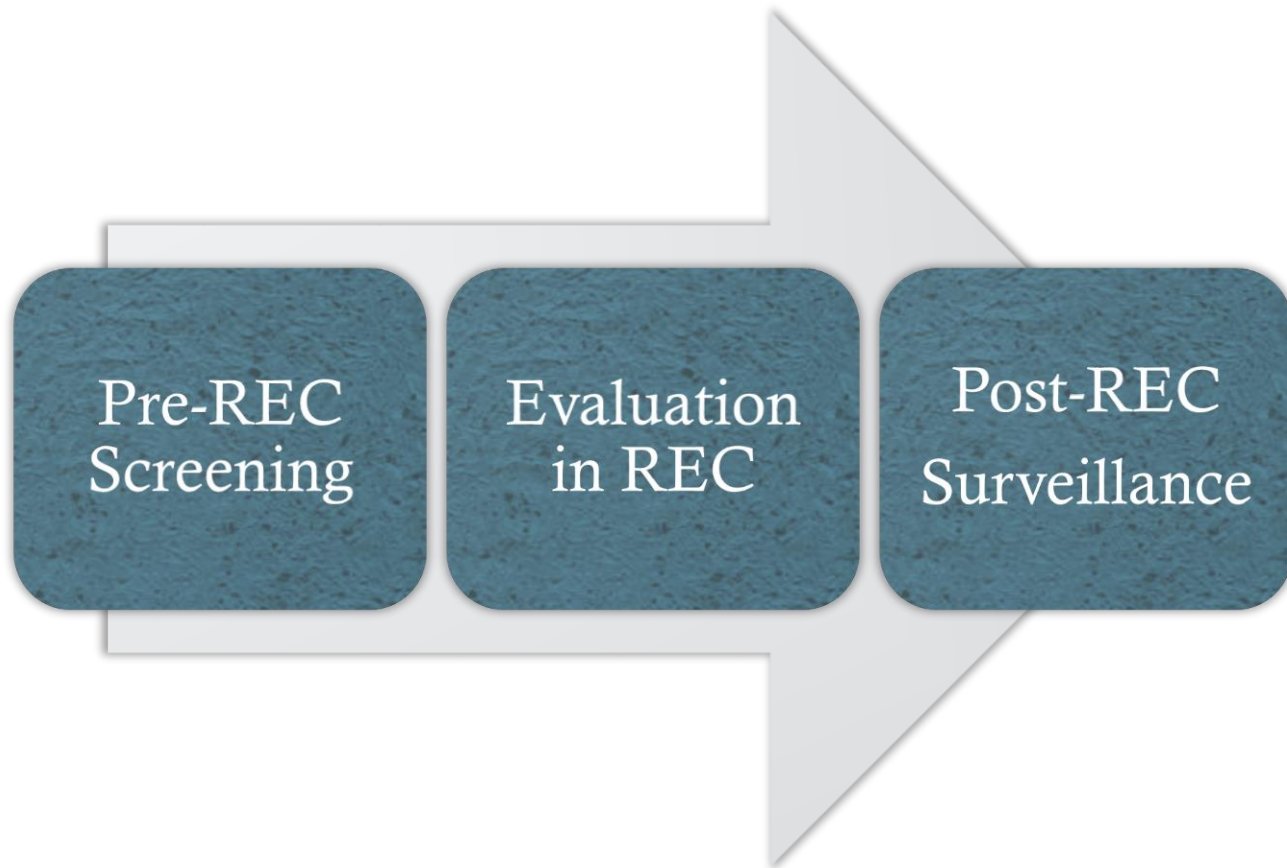
بررسی در کمیته
اخلاق به عنوان نهاد
کارشناسی: احراز یا
عدم احراز تخلف

ارجاع به نهادهای
انتظامی ذی صلاح:
هیات بدوی/ کمیته
انضباطی

Implementation a disciplinary system and national data base for those who commit scientific misconduct in biomedical research

The Proposed Fellow chart for investigation and disciplinary process of Scientific Misconduct cases in MOHME and affiliated universities/institutions



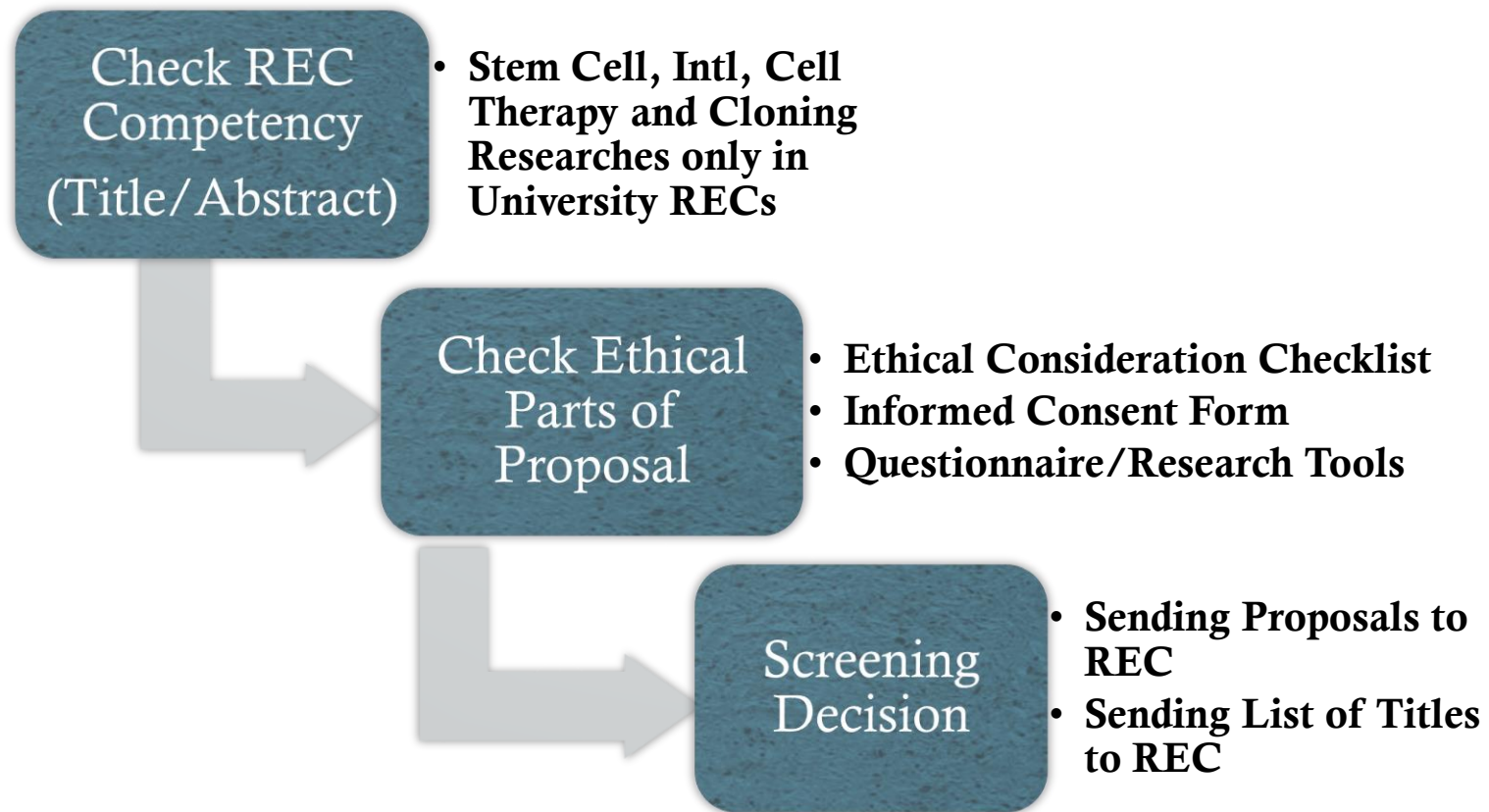


Pre-REC
Screening

Evaluation
in REC

Post-REC
Surveillance

Pre-REC Screening by a 3-Member Subcommittee



Is Research Team Competent?

- Is the PI competent?
- How is the general competency of Research Team?
- The quality of Scientific Peer review?

Is Methodology Clear?

- Does it follows standard trend?
- Is there any safer/cheaper method available?
- The place of research
- The time of research
- Is inclusion & Exclusion criteria clear?

Who is Potentially at Risk?



Individual Participants	<ul style="list-style-type: none">• Participants, Researchers, Population• Vulnerable• Biomaterials• Data
Human Population	<ul style="list-style-type: none">• Social Groups• Vulnerable Groups• Biomaterials• Data
Laboratory Animals	<ul style="list-style-type: none">• Sentience• Cognition• Number• Suffering
Environment	

- Participants, Researchers, Population
- Vulnerable
- Biomaterials
- Data

- Social Groups
- Vulnerable Groups
- Biomaterials
- Data

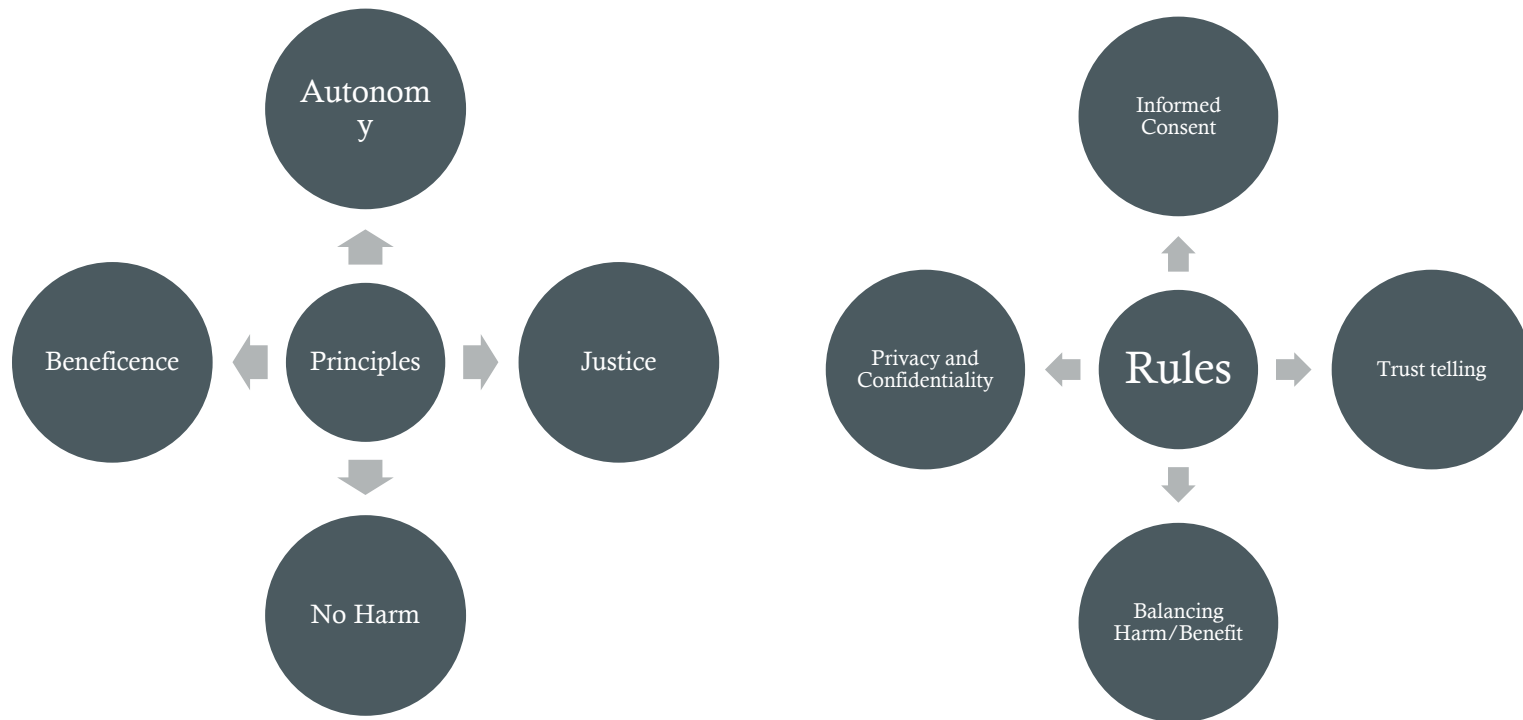
- Sentience
- Cognition
- Number
- Suffering

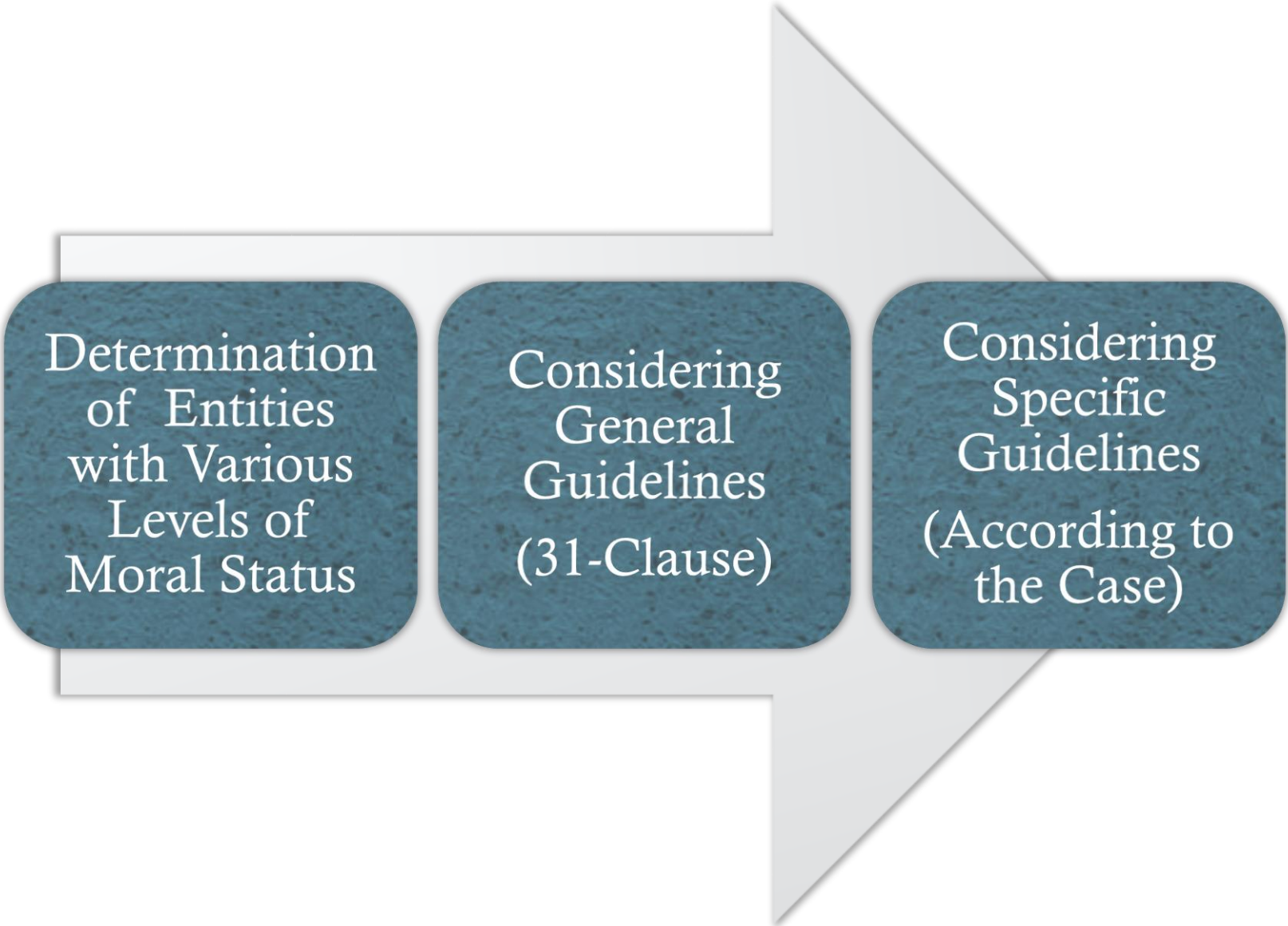


Vulnerability:



What is Potentially at Stake?!





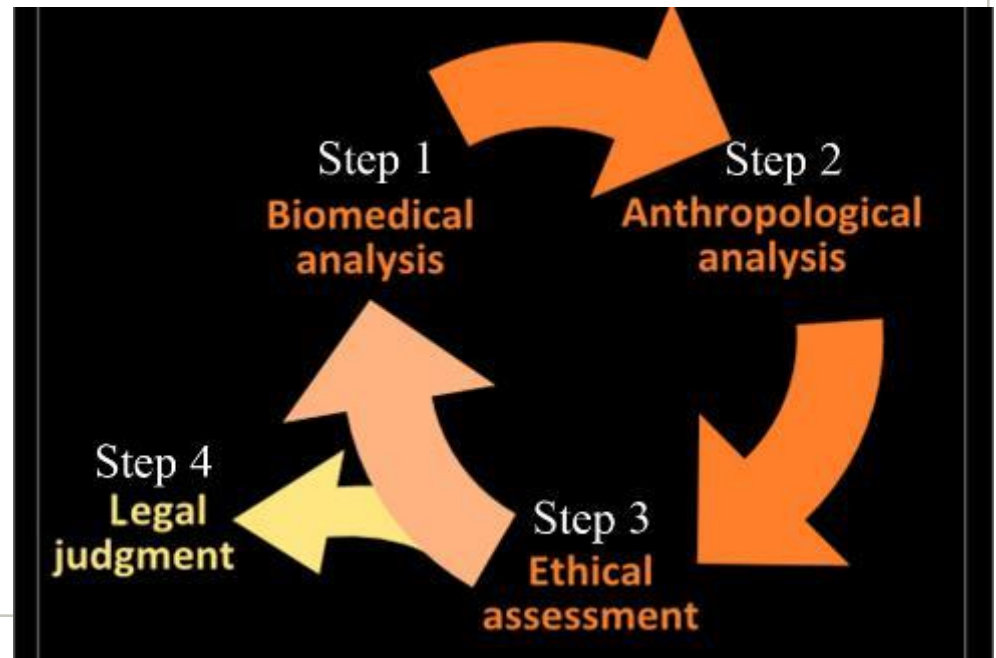
Determination
of Entities
with Various
Levels of
Moral Status

Considering
General
Guidelines
(31-Clause)

Considering
Specific
Guidelines
(According to
the Case)

Does the Research Considers:

- 1- Religious Standards
- 2- Legal Standards
- 3- Local Sensitivities



Publication Ethics Case1:

Nature News Report:
November 2016



Publisher pulls 58 articles by Iranian scientists over authorship manipulation

Cull of papers follows similar discoveries in 2015.

Ewen Callaway

01 November 2016 | Clarified: 03 November 2016

 [Rights & Permissions](#)

A tranche of [58 articles](#) authored by 282 Iran-based researchers were retracted today by a leading

Nature Report Content 1: General Information

- A tranche of 58 articles authored by Iran-based researchers were retracted today by a leading scientific publisher, which said it had found signs that the peer review and publication processes had been compromised.
- آمار دقیق ۱۹۹ کل افراد/ ۹۹ با وابستگی دانشگاه علوم پزشکی/ ۵۴ هیات علمی/ ۲۰ کارمند/ ۷ نفر بدون وابستگی/ بقیه دانشجو
- BioMed Central (BMC) will retract 28 articles and investigate another 40, whereas Springer will pull 30 papers and investigate another 9. Both organizations are run by *Nature's* publisher, Springer Nature.

Nature Report Content :

Type of Misconduct

- The actions follow an investigation, prompted by a whistleblower, that found “evidence of plagiarism, peer review and authorship manipulation, suggestive of attempts to subvert the peer review and publication system to inappropriately obtain or allocate authorship,”.
- All the papers that Springer is retracting showed evidence of authorship manipulation and peer-review manipulation, and 70% showed evidence of plagiarism.
- For the BMC papers, all showed evidence of authorship manipulation, 57% showed evidence of peer-review manipulation and 93% showed evidence of plagiarism.

Journals & Number of Papers:

3 Springer journals (30 papers)

Four papers in the Journal of Parasitic Diseases (IF = 0.28)

One paper in Comparative Clinical Pathology (IF = 0.358)

25 papers in Tumor Biology (IF = 2.926)

4 BMC journals (28 papers)

23 papers in Diagnostic Pathology, (IF = 1.895)

Two papers in Cancer Cell International, (IF = 2.884)

Two papers in Journal of Ovarian Research, (IF = 2.502)

One paper in the World Journal of Surgical Oncology. (IF = 1.286)

The Story:

- Inviting friends/surgeons/ Gynecologists/Orthopedists/ Students who want to apply for international positions/... with excuses such as: Tissue/Editing the manuscript
- Peer Review Manipulation/Author Manipulation/Plagiarism
- Publisher were informed by a whistle-blower
- The Publisher detected the misconduct after checking Mac Address/IP
- Springer asked the authors to explain but received no response.

Lessons Learned:

- Chain Brokers with Fake/Suspicious affiliation
- Invitation to “Paper Party” without having authorship criteria!
- Requesting money for various excuses e.g. publication fee
- No Approved Research Project (1 exception)
- Data Fabrication
- Working with non-familiar researchers/outputs
- Friends as Whistle Blowers!
- Using academic email
- One Medical Student Quoted: “... before this case I was always a ghost author....”



Richard
Stone

A shady market in scientific papers mars Iran's rise in science





آینه چون نقش تو بنمود راست!
خود شکن، آینه شکستن خطا است!