



HACETTEPE UNIVERSITY

FACULTY OF MEDICINE

DEPARTMENT OF HISTORY OF MEDICINE AND MEDICAL ETHICS

Ethical Issues of Medical Research and Publication Elective Training

Education Program

(Term V)

Ankara

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Presentation

Medicine always has the effort to constantly produce stable and dependable knowledge in its specific areas. Most of the information about medicine is obtained through “scientific research”. Professionals of science should follow scientific standards together with ethical principles. Therefore, a wider meaning of “science ethics” can be discussed. Science ethics is described as the field in which solutions to value conflicts are discussed that arose during academic-practical activities. It is always possible to talk about the existence of different cultural elements for different societies where scientific knowledge is produced; however, no matter how different their cultural structures, social and economic development levels are, there are “universal ethical principles” that can bind scientists living in very different parts of the world.

In the Term 5 “Ethical Issues of Medical Research and Publication” Elective Training conducted by Hacettepe University Medical Faculty, Department of History of Medicine and Medical Ethics, the basic ethical rules that will guide the scientific research to be planned, conducted and published by the student who will graduate from the medical faculty and the future prospective specialist student, it is aimed to teach ethical and legal requirements and to

raise awareness. Within the medical education program, there is a compulsory 1-hour course in research and publication ethics in the "Public Health, Medical Ethics, Forensic Medicine and Biostatistics Board" in Term 3. After this committee, there is no compulsory course in which the History of Medicine and Medical Ethics Department is in contact with undergraduate students. This elective training in Term 5 is considered to be an important stage that prepares students for academic and specialist life within the scope of research and publication ethics.

Inevitably, one of the important determinants of the fact that HÜTF is training physicians suitable for the academic field is the development of knowledge/skills/attitudes on these issues.

Learning Objectives

At the end of the Ethical Issues of Medical Research and Publications Elective Training, students will be able to comprehend the basic ethical and legal regulations that will guide the scientific research that they will plan, carry out and publish. At the end of the Ethical Issues of Medical Research and Publications Elective Training, students will achieve the following learning objectives:

- Comprehend the place and importance of scientific knowledge in science, scientific knowledge, historical process,
- Will be able to discuss the scope, types, and conditions of biomedicine researches that can evaluate biomedical research in terms of methodology and purpose,
- Evaluate the cornerstones of research ethics in the historical process, the emergence of basic principles and rules based on unethical research examples,
- Identify the informed consent process in the research, observe the necessary items and prepare the conditions compatible with them,
- Identify and secure the rights of volunteers and vulnerable groups participating in the research,
- Be aware of current national and international ethical and legal regulations related to research/publication ethics, explain and explain them accordingly,
- Explain the structuring and evaluation criteria of Bioethics Committees and Research Ethics Committees, be aware of their duties and responsibilities,
- Count the 3/4 R rule applied in animal research,
- Identify the main types of research and publication ethics violations and discuss at what stages these violations may occur,

- Understand the concept of “conflict of interest” in the scope of researches, determination in research practices, management of detected cases,
- Will be able to design an ethical committee application file by designing an ethical human and animal research project.

At the end of the training, students will be asked to:

- Evaluate and discuss the national and international examples on violation of publication ethics,
- In the context of the subject, write a one-page essay about the films watched in the relevant weeks and upload this assignment to the Turnitin system,
- Independently prepare a sample ethics committee application file

Importance of Training in Medical Curriculum

Pre-Learnings

In Term II, within the courses of our department in the “Biological Basis of Diseases” course board, basic concepts, ethical theories and principles, ethical responsibilities of healthcare professionals are explained. For the Clinical Ethical Case Analysis elective training to be completed successfully, students are expected to repeat their previous knowledge.

The learning objective of the courses given on the board is to enable the student to define and evaluate the determinants of the physician-patient relationship within the framework of the basic principles and concepts of medical ethics.

The topics within the scope of the course are listed below:

- Ethics, Bioethics, Medical Ethics, and Related Concepts
- Basic Bioethics Theories and Principles
- Physician Identity and Good Medicine in Terms of Physician's Virtues
- Non-maleficence and Beneficence Principles
- Respect for Autonomy and Justice principles
- Paternalism and Informed Consent
- Privacy and Medical Anonymity
- Ethical Dilemma, Ethical Analysis, Clinical Ethical Decision Making Processes

- Physician-Patient Relationship and Communication

In addition, there are theoretical courses on clinical ethics and case analysis in the Term III Public Health, Medical Ethics, Forensic Medicine and Biostatistics committees.

The learning objective of our courses given in this board is to help students to identify ethical issues and problems frequently encountered in medical practices and research in all stages of life, to recognize ethical values to be protected and appropriate solution methods.

Within the context, topics are listed below:

- Clinical Ethics
- Euthanasia
- Reproduction Technology and Ethics
- Ethics in Medical Research and Publications
- Legal Issues in Medicine
- Ethics in Organ Transplantation
- Genetic and Ethics
- Patient Rights

Additional Learning Facilities

Before the Ethical Issues of Medical Research and Publication Elective Training, students are given the opportunity to take elective courses including research and publishing ethics films, ethical problem discussions and invited expert academician presentations in Term 1, Term 2 and Term 3.

Term I

The learning objectives of the "Bioethics and Cinema" elective course include the ability of students to identify bioethical problems encountered in daily life through films and documentaries. The films shown in each academic year are updated. Some of the prominent themes of bioethics discussed within the scope of this elective course are as follows:

- End of life decisions
- Euthanasia

- Aging and ethical problems
- Ethical aspects of stem cell research
- Cloning, genetics, and ethics
- Environment ethics, animal rights, and biosecurity
- Feminist bioethics, ethical aspects of assistant reproduction technologies

Term II

The learning objective of our “Physician Representations in Cinema” elective course is to help students gain awareness about physician identity by discussing physician representations in local and foreign cinema samples. Within the context of this course, prominent themes of our field, listed below, especially occupation and professionalism in terms of medical ethics, are open to discussion:

- Physician identity
- Limits of medicine
- Concepts of researcher physician identity and informed consent
- Consultant physician role
- Virtues over physician identity
- Physician-patient relationship

Term III

It is aimed to be aware of social and cultural determinants of health (poverty, literacy, gender discrimination, marginalization, liberty restrictions (prisoners), natural resources eradication (desertification), wars (refugees), hierarchical relationships (students included in research projects run by their trainers, those working in environments where there is no job security, members of the army or police), whatever the other (migrants, nomads, ethnic minorities, AIDS patients and those struggling with rare diseases), exploitation of resources in developing countries (consequences of deforestation that could put responsibilities towards future generations at risk), humanitarian negative activities such as climate change or different types of environmental pollution within the scope of the elective course “Vulnerable /Defenseless Groups and Bioethics”.

In this course, the phenomenon of health inequality that vulnerable/defenseless groups are exposed is explained in economic and cultural dimensions. In this context, the bioethical importance of the “The Principle of Respect for Human Vulnerability and Personal Integrity - Report of the International Bioethics Committee" and "Bioethics and Universal Declaration of Human Rights" of UNESCO "is emphasized.

After Training Learning Facilities

Our department does not have a post-Term V course. However, activities such as ASET (Assistant Ethics Training) professional training programs, TETKON (Medical History and Ethics Department Conferences) series, Meetings with Specialists (Uzmanıyla Söyleşi) and literature hours of our department are open to students, students can benefit from these training opportunities after their training.

It is aimed that the student who will graduate from medical school and future prospective specialty students will learn and apply the basic standards in research/publication ethics that will guide the scientific researches that they will plan, carry out and publish.

Fig 1. Importance of Ethical Issues of Medical Research and Publication Elective Training in Medical Curriculum

6	Pediatrics + Pediatrics Elective (1 month + 1 month)	Internal Medicine+Internal Medicine (1 month+1 month)	Gynaecology and Obstetrics (1 months)	Emergency Medicine (2 months)	Pshychiatry (1 month)	General Surgery (1 month)	Rural Medicine+Rural Medicine Elective (1 month+1 month)	Elective (1 month)						
5	Neurology	Physical Medicine and Rehabilitation	Orthopedics and Traumatology	Otorhinolaryngology	Ophthalmology	Social Psychiatry	Dermatology	Urology	Neurosurgery	Child and Adolescent Mental Health	Physical Medicine and Rehabilitation	Radiology+Nuclear Medicine	Plastic Surgery	Pediatric Surgery
	Elective (Ethical Issues of Medical Research and Publication Elective Training)													
4	Internal Medicine	General Surgery/Anesthesiology	Pediatrics	Obstetrics and Gynaecology/Urology										
	Elective (Internal Medicine)	Elective (General Surgery)	Elective (Pediatrics)	Elective (Obstetrics and Gynaecology/Urology)										
3	Neoplasia and Hematopoietic System Diseases Committee	Infectious Diseases Committee	Endocrinology and Metabolism Disease Committee	Gastrointestinal System Committee	Cardiovascular, Blood and Respiratory System Diseases Committee	Urogenital System Diseases Committee	Neuroscience, Psychiatry and Musculo-Skeletal System Diseases Committee	Public Health, Medical History & Ethics, Forensic Medicine And Biostatistics Committee						
	Elective Courses I. Term (Vulnerable/Defenseless Groups and				Elective Courses II. Term									
2	Tissue-skeletal and Peripheral Nervous System Committee	Cardiovascular, Blood and Respiratory System Diseases Committee	Gastrointestinal System and Metabolism Committee	Nervous System Committee	Endocrine and Urogenital System Committee	Biological Fundamentals of Diseases Committee								
	Elective Courses I. Term (Representations of				Elective Courses II. Term									
1	Cell Sciences I Committee	Cell Sciences II Committee	Cell Sciences III Committee	Cell Sciences IV Committee										
	Elective Courses I. Term		Elective Courses II. Term											

Scope

For students to reach the aims in Ethical Issues of Medical Research and Publications Elective Training, theoretical and practical courses below are given (Table 1 and Table 2)

Theoretical Courses:

- Basic Concepts in Research/Publication Ethics
- Informed consent in Clinical Research
- Ethical and Legal Legislations in Clinical Research
- Bioethics Committees
- Ethical Problems of Animal Research
- Problems of Publication Ethics

Practical Courses:

- Selection of research topic with literature search
- Determination of project topics
- Determination of reason, objectives, and methods of the projects
- Determination of suitable ethics committee, preparation of ethics committee application file, analysis of these applications in an ethical committee environment established by students.
- Visitations to the animal experimentation laboratories

Methodology and expectations of the courses are stated at the end of the guide in the “Course Plans” section.

Table 1. Relations of the Course with the Objectives of Ethical Issues of Medical Research and Publications Elective Trainin

Courses	Theoretical Courses						Practical Courses				
Objectives	Basic Concepts in Research/Publication Ethics	Responsibilities of the Researcher in Clinical Research	Ethical and Legal Legislations in Clinical Research	Bioethics Committees	Ethical Problems of Animal Research	Problems of Publication Ethics	Selection of research topic with literature search	Determination of project topics	Determination of reason and objectives of the project	Determination of the methods of the project	Visitation to the animal experimentation laboratories
Comprehend the place and importance of scientific knowledge in science,	X										
Will be able to discuss the scope, types, and conditions of biomedicine researches that	X	X		X						X	
Evaluate the cornerstones of research ethics in the historical process, the emergence of		X		X						X	
Identify the informed consent process in the research, observe the necessary items	X		X	X	X						
Identify and secure the rights of volunteers and vulnerable groups participating in the		X	X	X	X						
Be aware of current national and international ethical and legal regulations related to	X					X					
Explain the structuring and evaluation criteria of Bioethics Committees and Research							X	X		X	
Count the 3/4 R rule applied in animal research					X						
Identify the main types of research and publication ethics violations and discuss at what			X								
Understand the concept of "conflict of interest" in the scope of researches,				X							
Will be able to design an ethical committee application file by designing an ethical					X					X	

Table 2. Program of Ethical Issues of Medical Research and Publications Elective Training

Week										
Friday 13.40- 17.30	1. week	2. week	3. week	4. week	5. week	6. week	7. week	8. week	9. week	10. week
	Introduction, Basic Concepts		Informed Consent in clinical research		Movie Display and Discussion	Preparation and Directives about the Final Homework: Literature Review	Ethical and Legal Legislation		Bioethics Commitees	
Friday 13.40- 17.30	11. week	12. week	13. week	14. week	15. week	16. week				
	Ethical Problems of Animal Research, Visitation to an Animal Laboratory		Publication Ethics		General Preparation	General Exam, Presentation of Ethical Commitee Applications				

Learning and Teaching Strategies

In the theoretical lessons of Research and Publication Ethics Elective Internship, case-based education, film discussions, group work, and project-based education are provided in applied courses.

In theoretical lessons, learning resources related to research and publication ethics are shared and discussions are held on the case at scheduled hours. The cases are given to the students one week before the lessons and they are asked to come prepared for the lessons

The videos, movie pieces, documentaries, films selected in accordance with the subject of the course are used as course material. The discussions to be carried out on these materials related to research and publication ethics are important in ethical education, which is also an attitude education.

A research protocol is prepared for the application of the ethics committee at the end of the semester with individual or group work depending on the class size.

During the education, the following teaching methods are used:

- Case-based learning
- Movie Screenings
- Discussion
- Expression
- Application (Project-based teaching)
- Visits

Case-Based Learning: Case-based learning is a learning method that develops problem-solving and decision-making skills, and works on real or lifelike situations where analytical skills are practiced. Analysis and discussion of real cases, which will be shared by the responsible lecturer, will be carried out on the conceptual ground that they have been transferred to students and gained from their previous education.

Film Screenings: Cinema and documentary screenings involving course topics aim to identify ethical issues. Therefore, ethical dilemmas will be opened to discussion when the films related to research and publication ethics coincide with the topics described in the course.

Discussion: Discussion and exchange of views will be supported both during cases and during theoretical lectures. Students will be reinforced by using the concepts they have acquired in reasoning and discussion.

Lecture: The main concepts of the subject are explained by the instructor. In order to reach a consensus on the meaning of a concept, the concepts related to the subject will be explained in accordance with the literature.

Application (Project-based teaching): During the Ethical Issues of Medical Research and Publications Elective Training, students will prepare a sample ethics committee application file. Students will be directed towards the preparation of this file, and related resources will be provided. With this practice, which will be done under the consultancy of the responsible lecturer during the practical hours of the program, it is aimed to develop skills related to how a scientific research should be ethically planned, carried out and reported.

Visits: Within the scope of this internship, an animal experiment laboratory will be visited and information will be obtained on the work done in the unit.

Evaluation

An important part of the evaluation of the Ethical Issues of Medical Research and Publications Elective Training is the ethics committee application file prepared by the students. In this context, required documents should be prepared in the application files of research ethics committees (clinical research ethics committee, non-interventional clinical research ethics committee, animal experiments local ethics committee and ethical commission).

For detailed information, see:

www.etikkurul.hacettepe.edu.tr

Preparation and presentation of ethical committee application files	50 points* *Evaluation criteria are listed on the chart below.
Homeworks and responsibilities for each lesson given before (Preparation to the lesson)	18 points
Continuation to the lessons	20 points
Participation performance in lessons	12 points
General	100 points

**Ethical Issues of Medical Research and Publications Elective Training Ethical Committee
Application File Evaluation Form**

Does the name of the research fully reflect the content of the research?	3 points
Is the type of research specified? (Retrospective Research Project, Survey Study, Laboratory Study, Case-Control Study, Methodological Study, etc.	3 points
Is the rationale for the research sufficient?	5 points
Is the research design chosen appropriately for this study?	3 points
Have the study's end and start times been specified? Is there a research calendar?	3 points

Are evaluation methods (statistical analysis etc.) compatible with the design?	2 points
<p>Informed consent form</p> <ol style="list-style-type: none"> 1. Are all the steps of the research related to the participant explained and the descriptions of the disease and other statements written in non-technical terms, as the volunteer can understand? 2. Is there a child consent form, consent form for control individuals, etc. (if necessary)? 3. Are the risks specified? 4. Have the phone numbers to be reached be added if there is a risk? 5. Is the name of the project responsible or the researcher who will take clinical responsibility included in the form? 6. Is it stated how long the research will take participant's time? 	15 points
Has the budget and its justification and where it will be covered been added? Are the research budget items and payments available?	5 points
If biological material changes will be made in national or international studies, has BMTA (Biological Material Transfer Agreement) been added?	3 points
If a transaction will be made by the service purchase, has a security agreement been added?	3 points
Are all relevant documents fully and carefully filled?	5 points

Learning Environment

Deanery of the Faculty of Medicine H Gate Classroom No. 6104

During the internship, theoretical courses are carried out in this classroom.

Department of History of Medicine and Medical Ethics Meeting Hall

There is one meeting room in the History of Medicine and Medical Ethics Department, where doctoral courses are also held. Students can participate in our department's activities such as literature presentations, movie screenings, which are carried out continuously and regularly, and our trainee students can work in our meeting room when they need it, and t can get the support of academic personnel.

History of Medicine and Medical Ethics Department Assistant Room

At the entrance of the M door of the Faculty of Medicine, there are Assistant rooms at the Department of History of Medicine and Medical Ethics. Here, our department has a common study area where research assistants study philosophy. This room provides an environment for our training students to work freely.

History of Medicine and Medical Ethics Department Library

In the History of Medicine and Medical Ethics Department, there is a library that can meet the basic resource needs of our training students. Training students can benefit from this library.

Hacettepe University Library

Training students can use the library in Hacettepe University Sıhhiye Campus to carry out their studies and access current resources.

Example Course Programs

Introduction - Basic Concepts in Research/Publication Ethics

Duration: 8 hours

Responsible Academic: Prof. Nüket Örnek Büken

Learning Objectives:

- At the end of this course, students will be able to;
- Comprehend the importance of science and scientific knowledge within the historical process.
- Will be able to evaluate biomedical research in terms of methodology and objectives, discuss the scope, types, and conditions of biomedicine research,
- Will be able to evaluate the cornerstones of research ethics in the historical process and the emergence of basic principles and rules based on unethical research examples.

Scope of the Course:

- Objectives of the course, learning objectives, and evaluation method,
- The path followed by biomedicine research in the historical process and normative texts on this subject,
- Research ethics concept, related sub, and top concepts,
- The most discussed research ethics issues today,
- Clinical trials, non-interventional clinical trials, animal experiments,
- The most common research ethics violations and methods for prevention.

Preliminary Preparation:

References below can be used in order to get acquainted for the discussions of the course:

- Büken NÖ. "İnsanlar Üzerinde Yapılan Araştırmaların Tarihçesi", Sendrom, 14(9): 130-139. 2002.
Access:http://www.deontoloji.hacettepe.edu.tr/programlar/SBE601_2017/Insanlar%20Uzerinde%20Yapilan%20Arastirmalarin%20Tarihcesi.pdf p.7.

- European Textbook on Ethics in Research- https://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf Yükseköğrenim Kurumları Bilimsel Araştırma ve Yayın Etiği Yönergesi. Access:http://www.yok.gov.tr/web/guest/icerik/journal_content/56_INSTANCE_rEHF8BIsfYRx/10279/18187

Course Plan:

- **First week - 4 Hours**

- After learning the expectations of the students about the course, the content of the training, evaluation methods, the course rules are shared with the students.
- The phenomenons, topics, assignments and resources to be discussed in the course are given in the first course. The students are asked to come by reading the lecture notes.
- Lectures about the relevant conceptual framework are carried out by the responsible lecturer.
- Students are asked to have small group discussions by giving examples of unethical research.
- Groups will select one spokesperson and present their arguments to the big group.

- **Second week - 4 hours**

- Examples of unethical research and regulations related to research ethics that mature in this process are discussed comparatively.
- Examples of unethical research reflected today will be reinforced with discussions.

Evaluation:

Preliminary preparation and class participation (during two weeks) will be evaluated over 5 points.

Name Surname	Preparation	Participation	Total
-----	3	2	5

Informed Consent in Clinical Research

Duration: 8 hours

Responsible Academic: Asst. Prof. Önder İlgili

Learning Objectives:

At the end of this course, students will be able to;

- Identify the informed consent process in the research,
- Observe the necessary items for obtaining informed consent for the research and preparing the conditions compatible with them,
- Define and secure the rights of volunteers and vulnerable groups participating in the research.

Scope of the Course:

- Brief historical development of informed consent in the research,
- Rights of research participants and vulnerable/defenseless groups,
- Researcher/volunteer and physician/patient relationship,
- Ethical and legal responsibilities of the researcher and dual responsibilities of the researcher physician with case examples.

Preliminary Preparation:

References below can be used in order to get acquainted for the discussions of the course:

- Büken NÖ. “İnsanlar Üzerinde Yapılan Araştırmaların Tarihçesi”. Erişim tarihi: 04/07/2017 Access: http://www.deontoloji.hacettepe.edu.tr/programlar/SBE601_2017/Insanlar%20Uzerinde%20Yapilan%20Arastirmalarin%20Tarihcesi.pdf. p.7.
- Ersoy N. “Aydınlatılmış Onam”. Demirhan Erdemir A., Öncel Ö., Aksoy Ş. Editör. Çağdaş Tıp Etiği. İstanbul: Nobel Tıp Kitabevi; p. 204–35. 2003.
- İlbars H. “Gönüllülerin Bilgilendirilmesi ve Bilgilendirilmiş Gönüllü Olur Formu”. Akan H. editor. Klinik Araştırmalar Kitabı. Ankara: Bilimsel Tıp Yayınevi; p. 231-237. 2006.
- İyi Klinik Uygulamaları Kılavuzu. Access: <http://www.titck.gov.tr/PortalAdmin/Uploads/UnitPages/İyi%20Klinik%20Uygulamaları%20Kılavuzu.pdf>
- Unesco İnsanın Savunmasızlığı ve Kişisel Bütünlüğüne Saygı İlkesi Erişim adresi: http://unesco.org.tr/dokumanlar/kitaplar/insanin_savunmasizligi.pdf
- Clinician and Researcher vakası. Access: <http://virtualmentor.ama-assn.org/2003/07/ccas2-0307.html>)
- İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik. 2013. Erişim tarihi: 24/03/2016. Access: <http://mevzuat.basbakanlik.gov.tr/Metin.Aspx?MevzuatKod=7.5.17285&MevzuatIliski=0&sourceXmlSearch=ila%C3%A7%20ve%20biyolojik%20%C3%BCr%C3%BCnlerin%20klinik%20ara%C5%9F%C4%B1rmalar>
- Tıbbi Cihaz Klinik Araştırmaları Yönetmeliği. 2014. Access: <http://mevzuat.basbakanlik.gov.tr/Metin.Aspx?MevzuatKod=7.5.20028&MevzuatIliski=0&sourceXmlSearch=t%C4%B1bbi%20cihaz#>

Lesson Plan:

- **First week - 4 hours**

- Theoretical information is conveyed by making a presentation by the lecturer in charge.
- Topics such as informed consent in research, rights of the volunteer, vulnerable groups are discussed with the whole class through video screenings, movie screenings (such as House MD series).
- The group is divided into small groups of 3-4 people to discuss in the next week. They are asked to find a research paper for the last five years and prepare an informed consent form, which should be included in the ethics committee file as if they were planning the work in this research paper themselves.

- **Second week - 4 hours**

- Informed consent forms prepared by small groups are presented to the large group by evaluating them according to Good Clinical Practices guide Article 10 and the theoretical framework discussed in the course. It is provided to reinforce the theoretical knowledge given in the first lesson through homework.

Evaluation: For the evaluation of the course, the students are asked to answer the forms with the following five questions. After each student answers the questions, replaces it with a friend. The answers are shared in the large group and students are asked to evaluate the questions and give feedback to their friends in line with these answers.

1. What are the elements of informed consent?
2. Briefly give information about one of the elements of the informed consent.
3. Write five of the minimum information that should be included in the informed consent form in the study.
4. Define and exemplify vulnerable groups.
5. Indicate the points to be considered when carrying out clinical research in children.

Name Surname	Preparation	Participation	Total
-----	3	2	5

Movie Screening and Discussion

Duration: 4 hours

Responsible: Department

Learning Objectives:

At the end of this course, students will be able to;

- In the context of the Wit film, reinforce the theoretical knowledge received in the previous lesson on the relationship between the researcher /physician-volunteer/patient.

Scope of the Course:

- Watching Wit movie
- Movie discussion
- Preparation of homework on film

Preliminary Preparation:

Attendance to the previous theoretical lesson

Lesson Plan:

- Wit movie is watched, discussions are held with the students on their thoughts and scenes that attract their attention and related to the medical ethics they noticed in the film.
- Students are asked to write a one-page essay. Assignments are uploaded to the Turnitin system.

Evaluation Course

Duration: 4 hours

Responsible: Department

Learning Objectives:

At the end of this course, students will be;

- Prepared for the final assignment at the end of the elective training. The steps required for the preparation of the ethics committee file will be explained.

Scope of the Course:

- Literature search
- Ethics committee application file steps

Preliminary Preparation:

Participating in the internship program

Lesson Plan:

- General information is given to the students about the literature search, determining the subject of the project, creating a research question, determining the method, preparing the documents requested in the relevant ethics committee application file.
- The course continues in a question and answer manner.

Ethical and Legal Regulations in Clinical Research

Duration: 8 hours

Responsible Academic: Asst. Prof. Müge Demir

Learning Objectives:

At the end of this course, students will;

- Be aware of current national and international ethical and legal regulations regarding research ethics,
- Explain ethical and legal regulations regarding research ethics,
- Be able to make plans in accordance with ethical and legal regulations regarding research ethics in scientific studies.

Scope of the Course:

- Ethical Regulations: Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects, Turkish Medical Association Ethical Declarations, TMA Medical Professional Rules, Council of Europe Bioethics Executive Board Research Ethics Committee Guidelines, International Ethical Guidelines for Health-related Research Involving Humans (CIOMS)
- Legal Regulations: The Convention on the Protection of Human Rights and Human Dignity in Terms of the Application of Biology and Medicine, TCK Article 90, Regulation on Clinical Research of Pharmaceuticals and Biological Products, Patient Rights Regulation, Medical Deontology Regulation, Medical Device Clinical Research Regulation, Effectiveness of Cosmetic Products or Raw Materials Regulation on Safety Studies and Clinical Research

Preliminary Preparation:

References below can be used to get acquainted for the discussions of the course:

- İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları hakkında yönetmelik-

- <http://mevzuat.basbakanlik.gov.tr/Metin.Aspx?MevzuatKod=7.5.17285&MevzuatIliski=0&sourceXmlSearch=ila%C3%A7%20ve%20biyolojik%20%C3%BCr%C3%BCnlerin%20klinik%20ara%C5%9F%C4%B1rmalar>
- Helsinki bildirgesi- İngilizce <http://www.wma.net/en/30publications/10policies/b3/>
<http://www.ttb.org.tr/images/stories/file/2013/helsinki.pdf> 28
- Biyoloji ve Tıbbın Uygulanması Bakımından İnsan Hakları Ve İnsan Haysiyetinin Korunması Sözleşmesi - Türkçe
<http://mevzuat.basbakanlik.gov.tr/Metin1.Aspx?MevzuatKod=1.5.5013&MevzuatIliski=0&sourceXmlSearch=insan hakları ve biyotıp sözleşmesi&Tur=1&Tertip=5&No=5013>

English

- <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98>
- Hasta Hakları Yönetmeliği-
<http://mevzuat.basbakanlik.gov.tr/Metin.Aspx?MevzuatKod=7.5.4847&MevzuatIliski=0&sourceXmlSearch=hasta hakları>
- TTB Etik bildirgeleri- http://www.ttb.org.tr/kutuphane/etik_bldgeler2010.pdf
- TTB Hekimlik Meslek Etiği Kuralları -http://www.ttb.org.tr/kutuphane/h_etikkural.pdf
- Tıbbi Deontoloji Tüzüğü- <http://www.mevzuat.gov.tr/MevzuatMetin/2.3.412578.pdf>
- TCK Madde 90 (internette araştırın 2005 sonrası)
<http://www.mevzuat.gov.tr/MevzuatMetin/1.5.5237.pdf>
- CIOMS Biyomedikal araştırmalara dahil olan insan denekler için uluslararası etik rehber http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm

Lesson Plan:

- **First Week - 4 hours**

- The facts, topics, homework, and resources to be discussed in the course are reminded in the first lesson.
- Ethical and legal regulations regarding informed consent are evaluated in the research within the scope of the Wit assignment.
 - Ethical problem areas and ethical and legal regulations related to clinical research are shared with short videos from Ted Talks by the lecturer. (Such as The-hidden-side-of-clinical-trials - Sile-Lane TEDxMadrid, Paula Johnson women in clinical researches and BoghumaKabisenTitanji_HIV researches)
- In the first week, students are divided into groups of at least three and at most five. The following discussion topics are distributed to the groups.
 - Are there conditions for conducting medical research on women? What source did you find in?
 - Are there conditions for conducting medical research on children? What source did you find in?
 - Are participants paid in medical research? What source did you find in?
 - Are there conditions for conducting medical research on prisoners? What source did you find in?
 - What are the rules of placebo use in clinical trials? What source did you find in?
- Within the framework of the questions distributed to the groups, they are told to compile ethical and legal regulations on the subject and make a preparation to share with the large group in the next week's lesson.

Course evaluation: Wit assignment 3 points, attendance 2 points

- **Second Week - 4 hours**

- Within the framework of the homework given in the first week, small groups present their preparations to the large group and the topics are discussed.
- At the end of the two-week course, important points related to ethical and legal regulations are shared and discussed in a summary.

Evaluation: For the evaluation of the course, students are asked to answer and submit forms containing five questions related to ethical and legal regulations. After each student answers the questions, they replace the form amongst each other. The answers are shared with the large group and students are asked to evaluate the questions and give feedback to their friends in line with these answers.

- What are the conditions for conducting clinical research on vulnerable groups according to the legal regulations of our country?
- What are the conditions for placebo use in clinical trials?
- What are the payment terms for participants in clinical trials according to the legal regulations of our country?
- Provide information on the content of the Helsinki Declaration. By which institution was this declaration prepared? Which year was the last one updated?
- Give two examples of the ethical declarations and legal regulations applicable in our country regarding clinical research.

Course evaluation: Group presentations 3 points, quick exam 2 points

Bioethical Committees

Duration: 8 hours

Responsible Academic: Academics of the Department

Learning Objectives:

- At the end of this course, students will be able to;
- Explain the structures of Bioethics and Research Ethics Committees,
- Aware of the duties and responsibilities of Bioethics Committees and Research Ethics Committees,
- Explain the evaluation criteria of Bioethical Committees and Research Ethics Committees,
- Aware of the work carried out in Hacettepe University Ethics Committees.

Scope of the Course:

- Information about what ethical boards are, why ethical boards are needed,

- Bioethics committee definition and types,
- Research ethics committee definition,
- Bioethics and research ethics committees' responsibilities,
- Research ethics committee members, functioning style, job description,
- Ethical committees at Hacettepe University.

Preliminary Preparation:

References below can be used to get acquainted for the discussions of the course:

UNESCO Bioethics Guides

- **Guide 1: Establishment of Bioethical Committees**

http://www.unesco.org.tr/dokumanlar/biyotetik_komitesi/biyotetik_kurullari.pdf. (Türkçe)

<http://unesdoc.unesco.org/images/0013/001393/139309e.pdf> (İngilizce)

- **Guide 2: Bioethics Committees on Duty: Type of Duties and Policies**

<http://unesdoc.unesco.org/images/0014/001473/147392TUR.pdf> (Türkçe)

<http://unesdoc.unesco.org/images/0014/001473/147392e.pdf> (İngilizce)

- **Guide 3: Education of Bioethical Committees**

http://www.unesco.org.tr/dokumanlar/biyotetik_komitesi/BiyotetikKurullarininEgitilmesi.pdf (Türkçe)

<http://unesdoc.unesco.org/images/0015/001509/150970e.pdf> (İngilizce)

- **Council of Europe - Guide to Research Ethics Committee Members**

http://www.coe.int/t/dg3/healthbioethic/Activities/02_Biomedical_research_en/Guide/Guide_TR.pdf (Türkçe) <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680307e6c> (İngilizce)

- **For the Hacettepe University Ethical Committees, please see:**

www.etikkurul.hacettepe.edu.tr

Lesson Plan

- **First week - 4 Hours**

- Students are informed about the topics and resources in the first lesson.
- Students are divided into seven groups in the first lesson. Each group is given the responsibility of one of the ethical committees within Hacettepe University.

The list of ethical committees to be given to the groups is given below:

- Group 1: Clinical Research Ethics Committee
 - Group 2: Ethics Committee
 - Group 3: Non-Interventional Clinical Research Ethics Committee
 - Group 4: Ethics Commission
 - Group 5: Animal Experiments Ethics Committee
 - Group 6: Journal Evaluation and Publishing Commission
 - Group 7: Publication Ethics Commission
- Each group is asked to be prepared for the content of the legislation of the ethics committee and how to apply to the ethics committee. Responsible students are asked to research the information about the ethical committee they are responsible for and to come to the next lesson in a way that will be presented to the class.

- **Second week - 4 Hours**

- Groups who take responsibility within the framework of the responsibilities given in the first week present their preparations to the class.
- After the presentation, each student in the presentation group is expected to answer the questions posed to them by the class.
- At the end of the two-week course, important points about bioethical committees and research ethics committees are discussed and the issue is reinforced.

Evaluation:

Presentations will be taken into account in the evaluation of the lesson. Each member of a group is evaluated according to the answers given by a particular student. Preparation and participation to the lesson are evaluated over 5 points (for 2 weeks).

Name Surname	Preparation	Participation	Total
-----	3	2	5

Ethical Problems Encountered in Animal Research Duration: 8 hours

Responsible Academic: Assoc. Prof. Müge Demir, Dr. Çağrı Zeybek Ünsal

Learning Objectives:

At the end of this course, students will be able to;

- Count the 3/4 R rule applied in animal research

Scope of the Course:

- History of animal rights,
- Ethical problems frequently encountered in animal research and 3/4 R rule,
- Animal experiments local ethics committees,
- Ethical guides on animal research,
- Legal legislation for our country in animal research,
- Visit to the Hacettepe Animal Experiment Laboratory.

Preliminary Preparation:

References below can be used in order to get acquainted for the discussions of the course:

- Nüket Örnek Büken, Hayvan Deneylerinde Araştırmacı Sorumluluğu ve Deney Hayvanının Hakları -
http://www.tip.hacettepe.edu.tr/actamedica/2006/sayi_1/baslik1.pdf

- WMA Statement on Animal Use in Biomedical Research-
<https://www.wma.net/policies-post/wma-statement-on-animal-use-in-biomedical-research/>
- CIOMS and ICLAS- INTERNATIONAL GUIDING PRINCIPLES FOR BIOMEDICAL RESEARCH INVOLVING ANIMALS.
https://grants.nih.gov/grants/olaw/guiding_principles_2012.pdf
- Tuncay Altuğ, Hayvan Deneyleri Etiği -
<http://uvt.ulakbim.gov.tr/tip/sempozyum7/altug.pdf>
- HÜ. Hayvan Deneyleri Yerel Etik Kurulu Yönergesi
<http://www.etikkurul.hacettepe.edu.tr/hdek/yonerge280316.pdf>
- Hayvan Deneyleri Etik Kurullarının Çalışma Usul ve Esaslarına Dair Yönetmelik (15 Şubat 2014-28914) Orman ve Su İşleri Bakanlığı
<http://www.etikkurul.hacettepe.edu.tr/hdek/yonetmelik150214.pdf>
- Deneyisel ve Diğer Bilimsel Amaçlar İçin Kullanılan Hayvanların Refah ve Korunmasına Dair Yönetmelik (13.12.2011-28141) Gıda, Tarım ve Hayvancılık Bakanlığı - http://www.etikkurul.hacettepe.edu.tr/hdek/yonetmelik_3.php

Lesson Plan:

First week - 4 Hours

- Theoretical information is conveyed by making a presentation by the lecturer in charge.
- Animal rights and animal use in biomedical research through video screenings, movie screenings (such as The Earthlings - The Cove document) are discussed with the whole class.
- The group is divided into small groups of 3-4 people to discuss in the next week. They are asked to find an animal research article for the last five years and prepare an animal experiments ethics committee file as if they were planning the experiment in this research article themselves.

Second week - 4 Hours

- Ethics committee files prepared by small groups are presented to the large group. It is provided to reinforce the theoretical knowledge given in the first lesson over the files.
- HU Animal Experiment Laboratory is visited.

Evaluation: For the evaluation of the course, students are asked to answer and submit forms containing five questions related to animal research. After each student answers the questions, he replaces his paper with his friend. The answers are shared in the large group and students are asked to evaluate the questions and give feedback to their friends in line with these answers. In the evaluation, class preparation and class participation (during two weeks) will be evaluated over 5 points.

Name Surname	Preparation	Participation	Total
-----	3	2	5

Publication Ethics Issues

Duration: 8 hours

Responsible Academic: Asst. Prof. Önder İlgili

Learning Objectives:

- At the end of this course, students will be able to;
- Identify the main types of research and publication ethics violations,
- Explain at which stages the research and publication process may occur,
- List the requirements of publication ethics in the process of translating the research into a publication,
- Understand the concept of "conflict of interest" in the scope of researches, determination in research practices, management of the detected cases,
- Recognizes national and international normative texts related to research and publication ethics.

Scope of the Course:

- Descriptions of the main types of publication ethics violations and categorization of publication ethics violations.
- Responsibilities of institutional and individual subjects who are parties to the ethical problem in the publication ethics.
- Detection of violations in publication ethics and sanctions that can be applied,
- Conflict of interest in the context of research ethics,
- National normative texts on publication ethics.

Preliminary Preparation:

References below can be used in order to get acquainted for the discussions of the course

- Yükseköğretim Kurulu Bilimsel Araştırma ve Yayın Etiği Yönergesi [Internet]. Available from: http://www.ege.edu.tr/gd/eu_bilimselrastirmayonergesi.pdf
- Hacettepe Üniversitesi Yayın Yönergesi Erişim adresi: <https://www.hacettepe.edu.tr/duyuru/yonergeler/50,yayinyonergesi151210.pdf>
- Wagner E. How should editors respond to plagiarism? COPE Discussion Document [Internet]. [cited 2013 Nov 21]. Available from: <http://publicationethics.org/files/Discussion%20document>.
- Hexham, Irving. 2013. “The Plague of Plagiarism: Academic Plagiarism Defined.” Hexham 2013. Documents. <http://people.ucalgary.ca/~hexham/content/articles/plague-of-plagiarism.html>
- Albert T, Wagner E. How to Handle Authorship Disputes: A Guide for New Researchers. COPE Rep, p. 32–4. 2003.
- Irzık, G, Kansu E, Ruacan Ş, Tekcan A, Tolun A, Yılmaz Y and Erzan A. “Bilim Etiği El Kitabı”. Edited by Ayşe Erzan. Ankara: Türkiye Bilimler Akademisi Yayınları. 2008.
- İnci, Osman. nd. “Bilimsel Yayın Etiği İlkeleri, Yanıltmalar Yanıltmaları Önlemeye Yönelik Öneriler.” In Sağlık Bilimlerinde Süreli Yayıncılık. Türk Tıp Dizini. 2009. Accessed October 7, 2013. <http://uvt.ulakbim.gov.tr/tip/sempozyum7/inci.pdf>.

Lesson Plan:

First week - 4 Hours

- Two video recordings prepared for educational purposes are watched by the instructor in charge. Students are asked to identify ethical issues related to the incident in the videos and discussions are conducted.
- Accompanied with a detailed theoretical presentation on violations of publication ethics, information is given about the definitions, categorization of the types of publication ethics, and the responsibilities of individuals and institutions that are parties to the problem.
- Students will be divided into groups of 3-4 people, and they will do group work. The groups will prepare a presentation of a publication ethics violation case of their choice by making literature research on violations of publication ethics.

Second week - 4 Hours

- Two videos prepared for educational purposes related to the concept of “conflict of interest” are watched. Students are asked to identify ethical issues related to the incident in the videos and discussions are conducted.
- Accompanied by the presentation, information about the concept of conflict of interest is given.
- The studies prepared at the end of the group work on publication ethics are presented to the group.

Evaluation:

Preparation and class participation (during two weeks) will be evaluated over 5 points.

Name Surname	Preparation	Participation	Total
-----	3	2	5

Responsible Lecturers

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