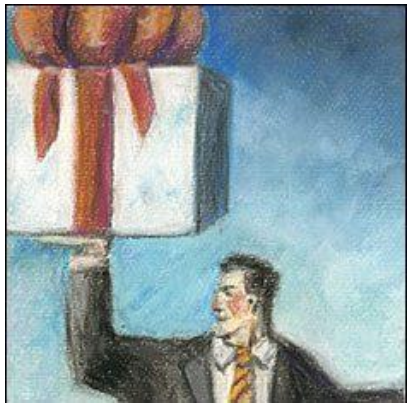


ÇIKAR ÇATIŞMASI
ve
BİLİMSEL ARAŞTIRMALARDA TARAF TUTMA

Prof.Dr. Hamdi Akan
Ankara Tıp Fakültesi Hematoloji Bilim Dalı

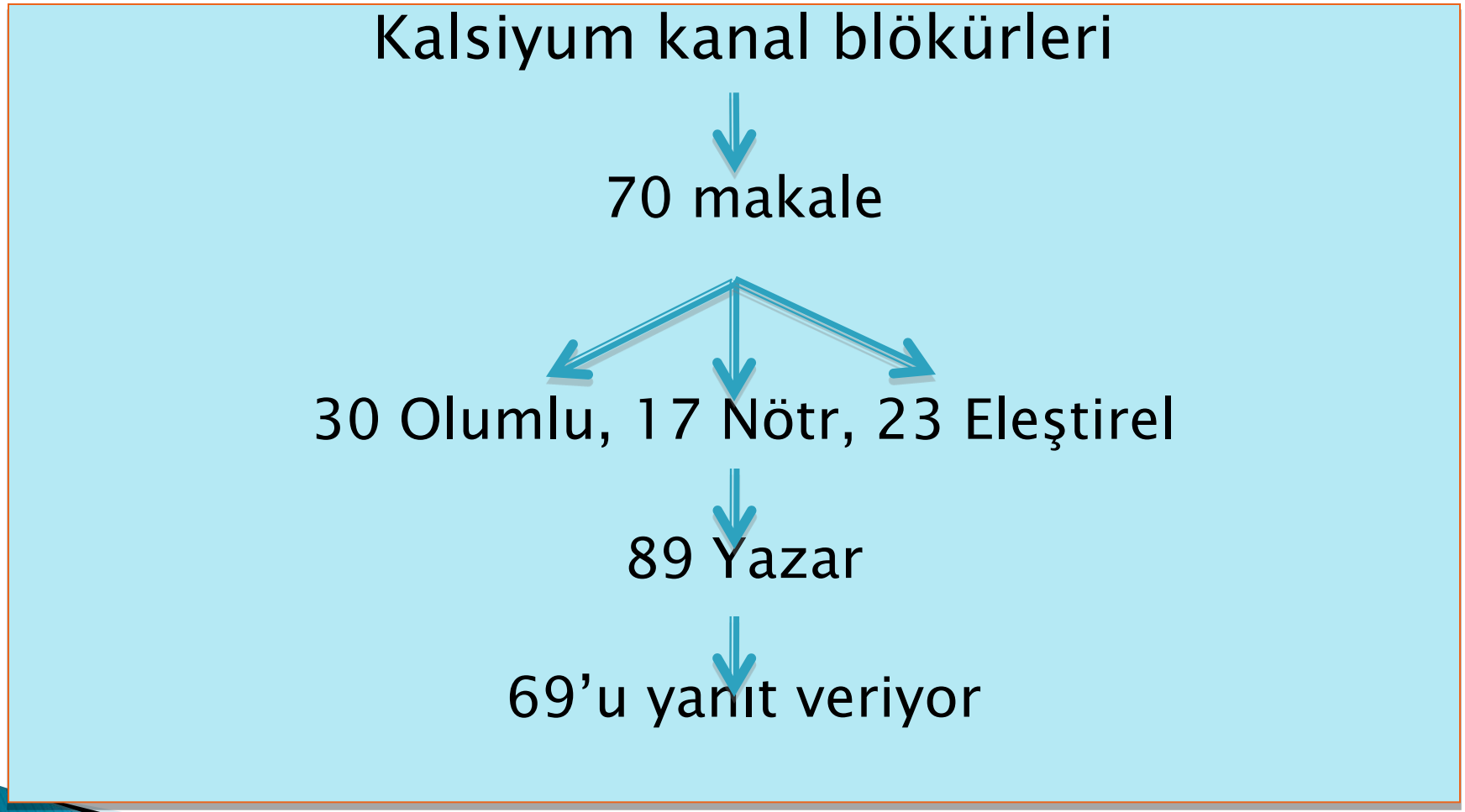
TANIM

Maddi çıkar gibi ikincil çıkarların, kişinin değerlendirme yeteneğini, birincil çıkarları göz ardı etmesine yol açacak şekilde olumsuz etkilemesine ÇIKAR ÇATIŞMASI denir.

Birincil çıkar: Hasta esenliği ve güvenliği

Thompson DF. Understanding financial conflicts of interest. N Engl J Med 1993; 329: 573-576

BÖYLE BİR SORUN VAR MI?



Stelfox HT, Chua G, O'Rourke K, Detsky AS. Conflict of interest in the debate over calcium channel antagonists. N Engl J Med 1998; 338: 101-105

TABLE 3. AUTHORS WITH FINANCIAL RELATIONSHIPS WITH PHARMACEUTICAL MANUFACTURERS.

MANUFACTURER	SUPPORTIVE AUTHORS (N=24)	NEUTRAL AUTHORS (N=15)	CRITICAL AUTHORS (N=30)	CHI-SQUARE FOR LINEAR TREND	P VALUE FOR TREND
	no. of authors (%)				
Manufacturer of calcium-channel antagonist	23 (96)	9 (60)	11 (37)	22.02	<0.001
Manufacturer of competing product	21 (88)	8 (53)	11 (37)	14.84	<0.001
Any manufacturer	24 (100)	10 (67)	13 (43)	22.68	<0.001

- Sigara içiciliği ile ilgili 106 derleme incelenmiş. %37'si pasif içiciliğin zararlı olmadığını belirtmekte.
- Multipl regresyon analizinde, yazarın değerlendirmesindeki en önemli faktör, yazarın tütün endüstrisi ile ilişkisi.
- Çalışmaların ancak %23'ünde çalışma desteği tanımlanmış.

Barnes DE, Bero LA. Why review articles on the health effects of passive smoking reach different conclusions. JAMA 1998; 279: 1566-1570

- Endüstri tarafından destekli 11 çalışma, desteksiz 11 çalışma ile karşılaştırılmış,

- Sponsorlu çalışmalarda endüstri lehine sonuç bulma şansı, sponsorsuz olanlardan 4 kat fazla.

Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research. A systematic review. JAMA 2003; 289: 454-65.

THE NEW YORK TIMES **NATIONAL** WEDNESDAY, NOVEMBER 1, 2000

Company Tried to Bar Report That H.I.V. Vaccine Failed

By PHILIP J. HILTS

A California company tried to block the publication of a scientific paper that showed its H.I.V. vaccine was not effective, and it has asked for damages of more than $7 million from the universities and researchers who published the findings.

The company, the Immune Response Corporation of Carlsbad, Calif., makes Remune, a vaccine intended to increase the body's defenses against H.I.V., the virus that causes AIDS, in people already infected. The drug was tested from 1996 to 1999 on more than 2,500 people with the infection, in one of the largest H.I.V. treatment studies ever

Such disputes between commercial interests and researchers have become more common as drug companies increasingly use independent scientists to test new drugs. Immune Response hopes to get F.D.A. approval for the vaccine within two years.

David Korn, senior vice president of the Association of American Medical Colleges and an expert on financial conflicts between researchers and industry, said such disputes were rarely made public and rarely involved so much money. He would not speculate on the outcome.

"We are now getting into an era when the commercial entanglements

NİYE ?

- ABD'de araştırıcıların dörtte biri farmasötik destek almakta
- Yarısı "araştırma ile ilgili hediye" almakta
- Önemli dergilerde yayınlanan 789 makalede yapılan incelemeye göre, ana araştırmacıların üçte biri çıkar ilişkisine sahip (patent, hisse, danışma kurulu üyeliği, çalışanı)

Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research. A systematic review. JAMA 2003; 289: 454-65.

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Guest authorship and j *se study of industry*

- 96 yayından, 2'si (22/24), derlemelerde ıs.
- Makalelerin akale yazma şirketleri tar an yazarlara yazdırılmış. er verilirken; akademiden doktorlar da makalede yer
- İlacın olumsu nmiş.

DERGİLER NİYE KABUL EDİYOR?

- Alınan reklamlar derginin yaşaması için gerekli
- Sponsorlu ekler ciddi bir gelir kaynağı
- Sponsorlu randomize çalışmaların reprintleri büyük gelir getirmekte
- Olumlu sonuç veren çalışmalar daha çok ilgi çekmekte

ÇIKAR İLİŞKİSİ SUÇ MU?

- Sempozyum, toplantı destekleri
- Konuşma yapma ücretleri
- Eğitim toplantıları için destek
- Firma Araştırma fonları
- Danışma/Konsültasyon desteği
- Çalışma sonuçlarından olumlu ya da olumsuz etkilenecek bir firmada çalışmış olma
- Çalışma sonuçlarından olumlu ya da olumsuz etkilenecek bir firmada hisse ya da pay sahibi olma

Klinik Araştırmaya katılıp, hasta başı ödeme almak “çıkar ilişkisi” mi?

TANIM

Kişinin değerlendirme yeteneğinin maddi çıkar gibi ikincil çıkarlar nedeni ile,

hasta sağlığı ve esenliği ve bilimsel tutarlılık gibi birincil çıkarları göz ardı etmesine yol açacak şekilde olumsuz etkilenmesine ÇIKAR ÇATIŞMASI denir.

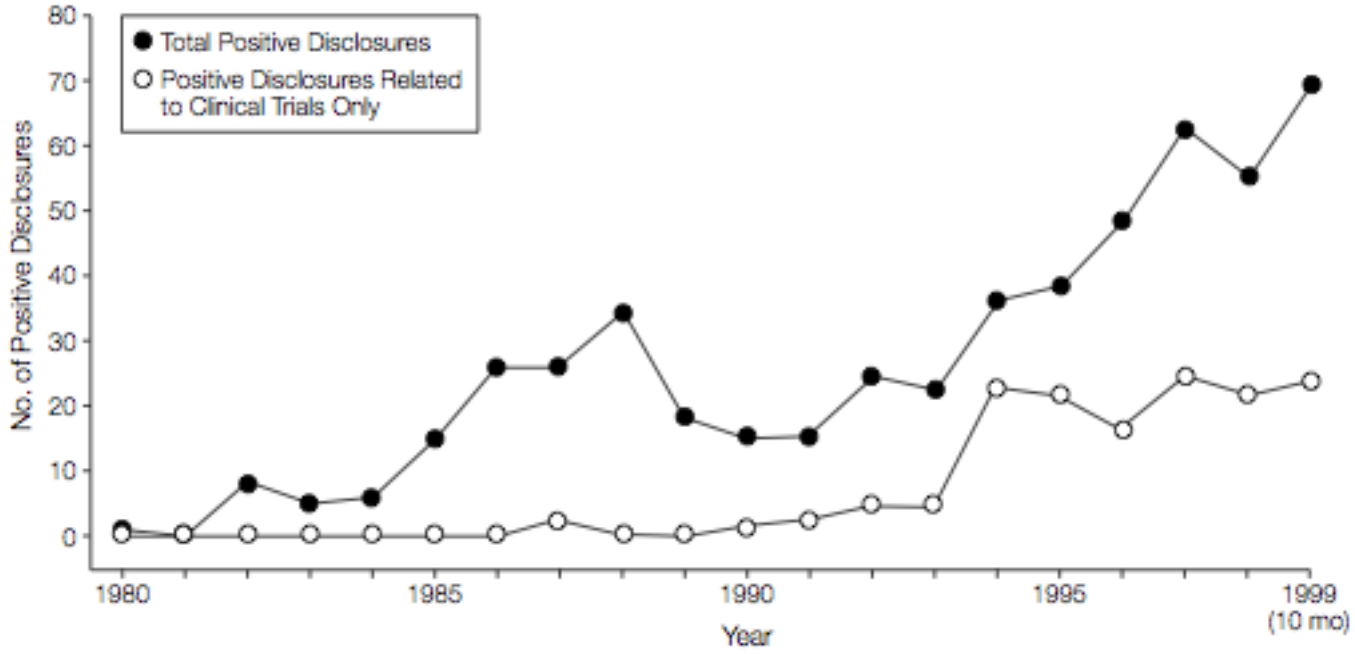
Thompson DF. Understanding financial conflicts of interest. N Engl J Med 1993; 329: 573-576

Sponsorship, Authorship, and Accountability
Frank Davidoff, M.D., Editor Emeritus

- ABD'de yeni ilacı piyasaya çıkarma maliyeti 500 milyon – 1 milyar USD.
- Masrafları kontrol etmek için SAK'lar kullanılmakta ve aslan payını bunlar alıyor.
- 2000 yılında SAK'lar araştırma burslarının %60'ını alırken, akademik araştırmacılar %40'ını aldılar.

Annals of Internal Medicine
Volume 345:825-827, September 13, 2001

Figure. Number of Total Positive Disclosures and Positive Clinical Trial Disclosures by Year, 1980-1999



Assessing Faculty Financial Relationships With Industry: A Case Study

Elizabeth A. Boyd; Lisa A. Bero

JAMA. 2000;284(17):2209-2214 (doi:10.1001/jama.284.17.2209)

NE YAPALIM?

Sponsorship, Authorship, and Accountability

Frank Davidoff, M.D., Editor Emeritus

- Editörler olarak, araştırmacıların verileri bağımsız olarak incelemelerini önleyen veya sponsorun onayını almadan yayınlamalarını engelleyen her türlü anlaşmaya karşıyız.
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Annals of Internal Medicine
Volume 345:825-827, September 13, 2001

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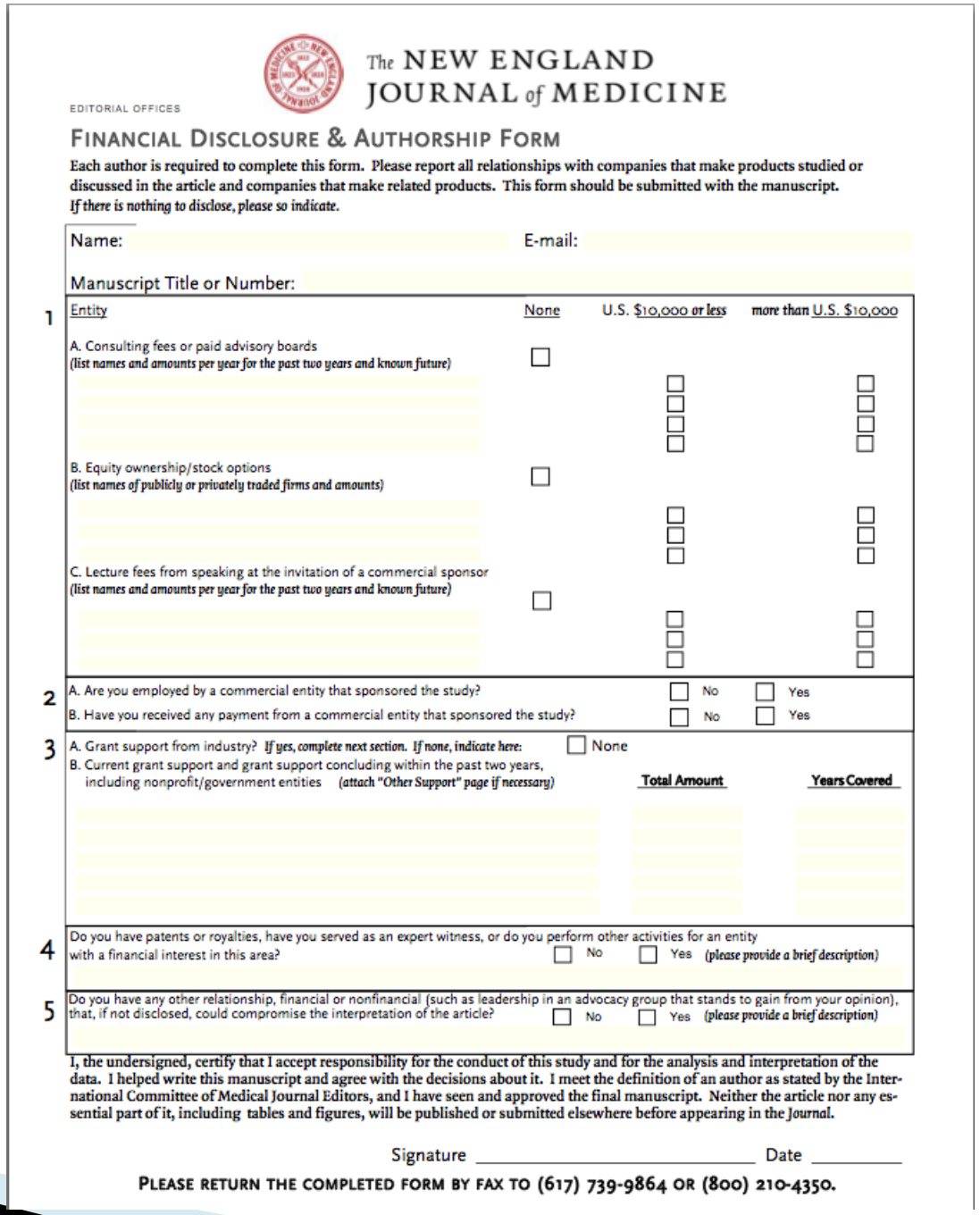

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B. Equity ownership/stock options *(list names of publicly or privately traded firms and amounts)*	☐	☐ ☐ ☐	☐ ☐ ☐
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A. Grant support from industry? *If yes, complete next section. If none, indicate here:* ☐ None

B. Current grant support and grant support concluding within the past two years, including nonprofit/government entities *(attach "Other Support" page if necessary)*

	Total Amount	Years Covered

4

Do you have patents or royalties, have you served as an expert witness, or do you perform other activities for an entity with a financial interest in this area? ☐ No ☐ Yes *(please provide a brief description)*

5

Do you have any other relationship, financial or nonfinancial (such as leadership in an advocacy group that stands to gain from your opinion), that, if not disclosed, could compromise the interpretation of the article? ☐ No ☐ Yes *(please provide a brief description)*

I, the undersigned, certify that I accept responsibility for the conduct of this study and for the analysis and interpretation of the data. I helped write this manuscript and agree with the decisions about it. I meet the definition of an author as stated by the International Committee of Medical Journal Editors, and I have seen and approved the final manuscript. Neither the article nor any essential part of it, including tables and figures, will be published or submitted elsewhere before appearing in the Journal.

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MUTLAKA ŞEFFAFLIK

Conflict-of-interest disclosure: J.-L.H. has received honoraria from OrthoBiotech Janssen Cilag. G.M. has been a consultant to Novartis and Bristol-Myers Squibb and has received research funding from Novartis. Y.C.P. and A.B. are employed by Johnson & Johnson Pharmaceutical Research & Development. P.D.P. and A.J.H. are employed by Ortho-Biotech Oncology Research & Development. Y.C.P., A.B., P.D.P., and A.J.H. own stock in Johnson & Johnson. The remaining authors declare no competing financial interests.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Acknowledgement

This is an observational study and does not require an Ethical committee approval. My conflict of interests are summarized below:

Clinical Research: MS&D, Pfizer

Speaker: MS&D, Pfizer, Gilead

Advisory Board: MS&D

Conflicts of Interest Often Under-reported in Clinical Trials

Published: Sep 10, 2013

By Ivan Oransky, Global Editorial Director, MedPage Today

save | A A

CHICAGO -- At least half of clinical trial study authors fail to report relevant conflicts of interest, according to an analysis of papers presented here Monday at the Peer Review Congress.

Kristine Rasmussen, of the Nordic Cochrane Centre in Copenhagen, and colleagues took advantage of the fact that Danish physicians are required to apply for permission for paid collaboration with industry, and then publicly disclose all of their conflicts, to look at 100 consecutive drug trials with at least one Danish author.

About half -- 48% -- of researchers with conflicts related to the trial sponsor or manufacturer failed to disclose some or all of them. That number rose to 88% when the authors looked at conflicts related to competing manufacturers, and 89% for any drugmaker at all.

Of the 100 reports, 49 were funded by industry, 30 had mixed sponsorship, 19 were not funded by industry, and two did not specify.

Self-publishing editor set to retire

The editor of a theoretical-physics journal, who was facing growing criticism that he used its pages to publish numerous papers written by himself, is set to retire early next year.

Five of the 36 papers in the December issue of *Chaos, Solitons and Fractals* alone were written by its editor-in-chief, Mohamed El Naschie. And the year to date has seen nearly 60 papers written by him appear in the journal.

A civil engineer by training, El Naschie attempts to combine aspects of particle physics and chaos theory. Many of his papers revolve around the idea that fractal properties of space-time can influence elemental particles and physical constants.

Most scientists contacted by *Nature* comment that El Naschie's papers tend to be of poor quality. Peter Woit, a mathematical physicist at Columbia University in New York, says he thinks that "it's plain obvious that there was either zero, or at best very poor, peer review, of his own papers". There is, however, little evidence that they have harmed the field as a whole.

El Naschie, who was born in Cairo and now

H. WINKLER/ZEFA/CORBIS

Apparent misuse of editorial privileges has sparked calls for a clearer peer-review process across journals.

Bilimsel Yanıltma

I. KORSANLIK (PIRACY)

II. PLAJERİZM (PLAGIARISM)

III. SAPTIRMA, YALAN BEYAN
(FRAUD, FABRICATION – FALSIFICATION)

Sciencexpress Report 2004

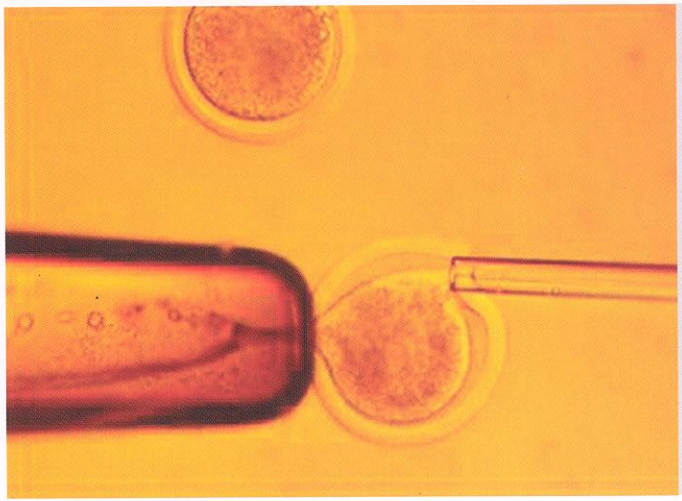
Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst

Woo Suk Hwang,[1,2]* Young June Ryu,[1] Jong Hyuk Park,[3] Eul Soon Park,[1] Eu Gene Lee,[1] Ja Min Koo,[4] Hyun Yong Chun,[1] Byeong Chun Lee,[1] Sung Keun Kang,[1] Sun Jong Kim,[3] Curie Ahn,[5] Jung Hye Hwang,[6] Ky Young Park,[7] Jose B. Cibelli,[8] Shin Yong Moon[5]*

[1]College of Veterinary Medicine, Seoul National University, Seoul 151-742, Korea. [2]School of Agricultural Biotechnology, Seoul National University, Seoul 151-742, Korea. [3]Medical Research Center, Mizmedi Hospital, Seoul, 135-280, Korea. [4]Gachon Medical School, Incheon, 417-840, Korea. [5]College of Medicine, Seoul National University, Seoul, 110-744, Korea. [6]School of Medicine, Hanyang University, Seoul, 471-701, Korea. [7]College of Natural Science, Sunchon National University, Sunchon, 540-742, Korea. [8]Department of Animal Science-Physiology, Michigan State University, East Lansing, MI 48824, USA.

*To whom correspondence should be addressed. E-mail: hwangws@snu.ac.kr (W.S.H.); shmoon@plaza.snu.ac.kr (S.Y.M.)

In May 2005, Prof. Woo Suk Hwang's team announced that they had established embryonic stem cell lines using the somatic cells obtained from a diverse group of patients with diseases hard to cure. [Hwang et al., 2005]



In February 2004, Professor Woo Suk Hwang of Seoul National University and his team announced that they had succeeded in human therapeutic cloning through somatic cell nuclear transplantation(SCNT) [Hwang et al., 2004].

Cloning Scientist Falsified Data, Colleague Says

By Antonio Regalado
And Gordon Fairclough

BREAKTHROUGHS ONCE seemed to come easily to South Korea's Hwang Woo Suk's cloning lab. This year, the lab reported it had devised a formula for easily clone human embryos to make stem cells. Then it said it had created the world's first cloned dog, Snuppy. The pooch even made it to the cover of Time magazine.

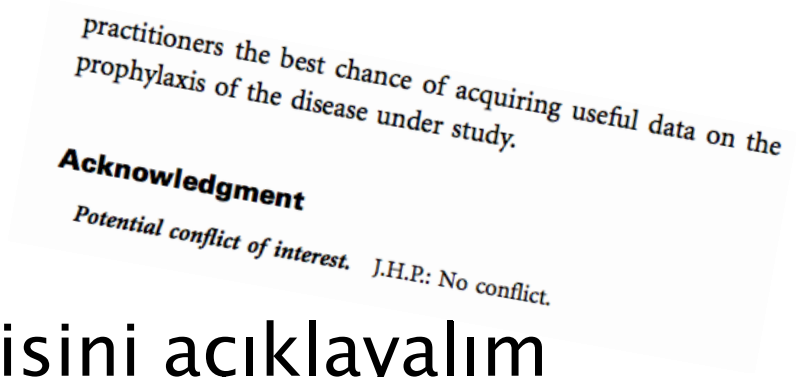
Today, the scientific reputation that propelled Dr. Hwang to the forefront of stem-cell research has been shattered, and along with it the hopes of millions of patients who dreamed his stem-cell technology could help them.

Following weeks of escalating concerns about Dr. Hwang's blockbuster findings, one of his Korean colleagues yesterday charged that Dr. Hwang had largely fabricated evidence for the reported human-embryo cloning breakthrough earlier this year.

Hwang Woo Suk

Roh Sung Il, a Korean researcher who co-wrote the paper, said in television and newspaper interviews in Korea that Dr. Hwang had told him that he hadn't succeeded in producing stem cells from 11 cloned human embryos as was claimed and instead faked at least some

NE YAPALIM?


practitioners the best chance of acquiring useful data on the prophylaxis of the disease under study.

Acknowledgment

Potential conflict of interest. J.H.P.: No conflict.

- Şeffaf olalım = Çıkar ilişkisini açıklayalım
  - *Yazarlar*
  - *Editörler*
  - *Hakemler*
  - *Ruhsat Komisyonları*
  - *Etik Kurullar*
- Çalışma başlamadan çalışmaları açık bir veri tabanına kaydedelim (clinicaltrials.gov)
- Tüm yazarlar, yazarlık kriterlerine sahip olsun

Üye Bilgileri Güncelle

KLİNİK ARAŞTIRMALAR DERNEĞİ

Ana Sayfa English İleti

- Hakkımızda
- Başkanın Mesajı
- Yönetim
- Tüzük
- Misyon/Vizyon
- İletişim
- Toplum İçin

clinicaltrials.gov Türkiye Analizi

Sözlük

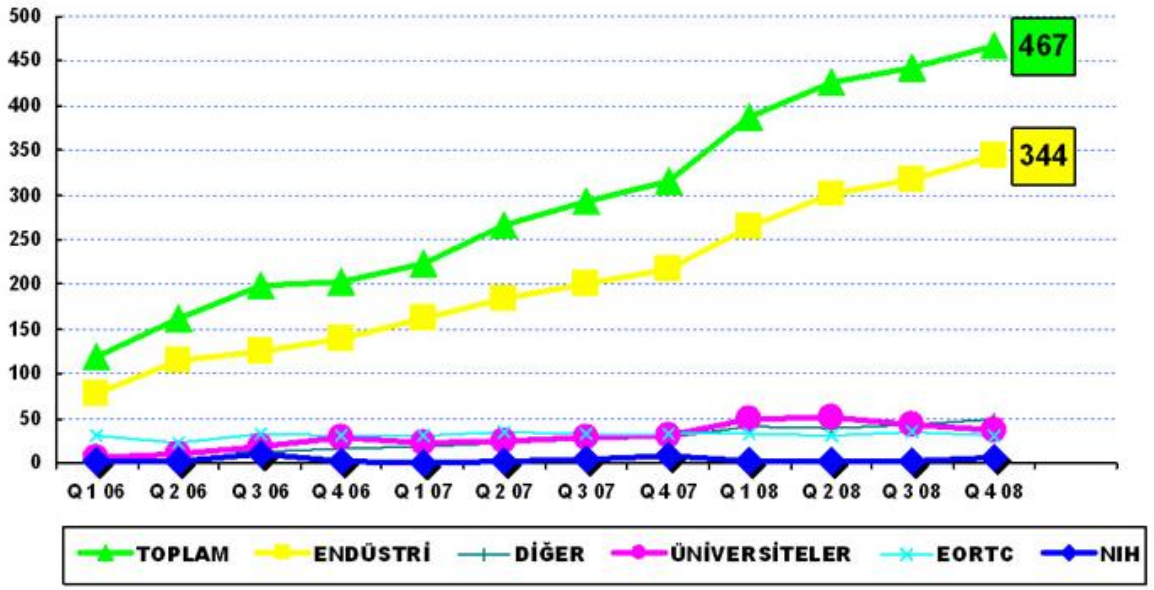
Dokümantasyon [Arşiv]

- Kök Hücre Çalışmaları
- Biyoyararlanım/Biyoeşdeğerlilik
- Genel veriler
- Yasalar

Clinicaltrials.gov Türkiye Analizi

Clinicaltrials.gov dünyada klinik araştırmaların kaydedildiği en büyük veri tabanıdır. Bu veri tabanında Türkiye'de yapılan çalışmalar ayrıca analiz edilecek ve 3 ayda bir yenilenerek sunulacaktır.

Türkiye'deki Klinik Çalışma Sayısı



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- Sektör-doktor ilişkisi etik kodları belirlensin

Code on Interactions with Healthcare Professionals

N. HALL/REUTERS

GlaxoSmithKline chief executive Andrew Witty, who announced the firm's commitment to openness.

BIOMEDICINE

Drug firm to share raw trial data

Full disclosure could improve health care and restore trust.

it has carried out since 2007 for both approved and abandoned drugs (the company says that only post-2007 data is in formats suitable for sharing). It will also set up an expert panel at arm's length from the company to review requests to access data for scientific merit, a restriction that some researchers dislike.

James Shannon, chief medical officer of GSK, justifies the restriction as a way to stop people from trawling through the data without a solid scientific question or hypothesis. Such fishing trips could lead to flawed analyses that could alarm the public unnecessarily and damage public health, he says.

WAIT AND SEE

Peter Gøtzsche, director of the Nordic Cochrane Centre in Copenhagen, says that he has "huge problems" with the restrictions, however. He argues that they could lead to arbitrary decisions about data release, which might favour the company rather than the public interest. Any risk of scares is outweighed by having more eyeballs on the data, he says, arguing that the lack of sharing of trial data by industry has been "far more harmful".

Kay Dickersin, director of the Center for Clinical Trials at the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland, agrees with GSK that some access restrictions can be helpful. She cautions that the value of GSK's new openness will ultimately depend on how much detail it supplies in the patient-level data and, crucially, on the extent of documentation about how the trials were designed and data were collected, processed and analysed. "Let's wait and see," she says.

POLICY

Drug-company data vaults to be opened

European agency will publish firms' clinical-trial results.

BY DANIEL CRESSEY

International calls for the pharmaceutical industry to share the results of clinical trials have grown ever more intense amid revelations that high-profile companies have hidden crucial data on safety and efficacy. Now Europe is moving towards measures that would significantly increase disclosure of such data.

The European Medicines Agency (EMA) in London, which licenses drugs for use in the European Union, is developing a policy to publish some clinical-trial data submitted by companies. And next month, major players in the UK medical community will meet to discuss the practical problems of data openness.

The meeting is likely to take place on 19 April and could feature representatives from biomedical charity the Wellcome Trust, as well as the Academy of Medical Sciences, the Association of the British Pharmaceutical Industry and the Association of Medical Research Charities. It marks a move from discussion to action, says Nicola Perrin, head of policy at the Wellcome Trust in London. "We should all stop discussing whether [the issue is] important or not and start having practical discussions about how we move forward," she says.

The United States already requires that clinical trials used to secure drug approvals are listed in a public online registry. Other countries have rules that encourage registration. But some researchers and campaigners fear that key details are not getting into the public domain, making it difficult to assess a drug's safety and depriving researchers of data.

Critics note, for example, that in recent years the London-based drug company AstraZeneca has been mired in legal problems including accusations that it concealed data on the side effects of its antipsychotic drug Seroquel (quetiapine). And GlaxoSmithKline (GSK), also based in London, has paid out billions of dollars after pleading guilty to charges including misrepresenting the safety of its diabetes drug Avandia (rosiglitazone) and the effectiveness of its antidepressant Paxil (paroxetine) in children. The Cochrane Collaboration, an international group of medical experts, has called for Roche in Basel, Switzerland, to open up its data on the influenza drug Tamiflu (oseltamivir) so that the group can assess the drug's efficacy.

Drug companies are making concessions. GSK and Roche have agreed to share data with scientists whose requests are deemed legitimate. But critics say that Roche has not established a fully independent group to assess requests.

Last year, following pressure from campaigners, the EMA said that it would proactively publish certain data submitted by drug companies. The agency is consulting industry and academic researchers and funders on how this would work; it is likely to have a policy ▶

Pharmaceuticals

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month.

March 10, 2013 5:36 pm

Pharma group sues European regulator over data

By Andrew Jack

A leading US pharmaceutical group has sued Europe's medicines regulator, in a sharp intensification of the battle between advocates for greater transparency on drugs and companies who fear their competitive position will be undermined by more openness.

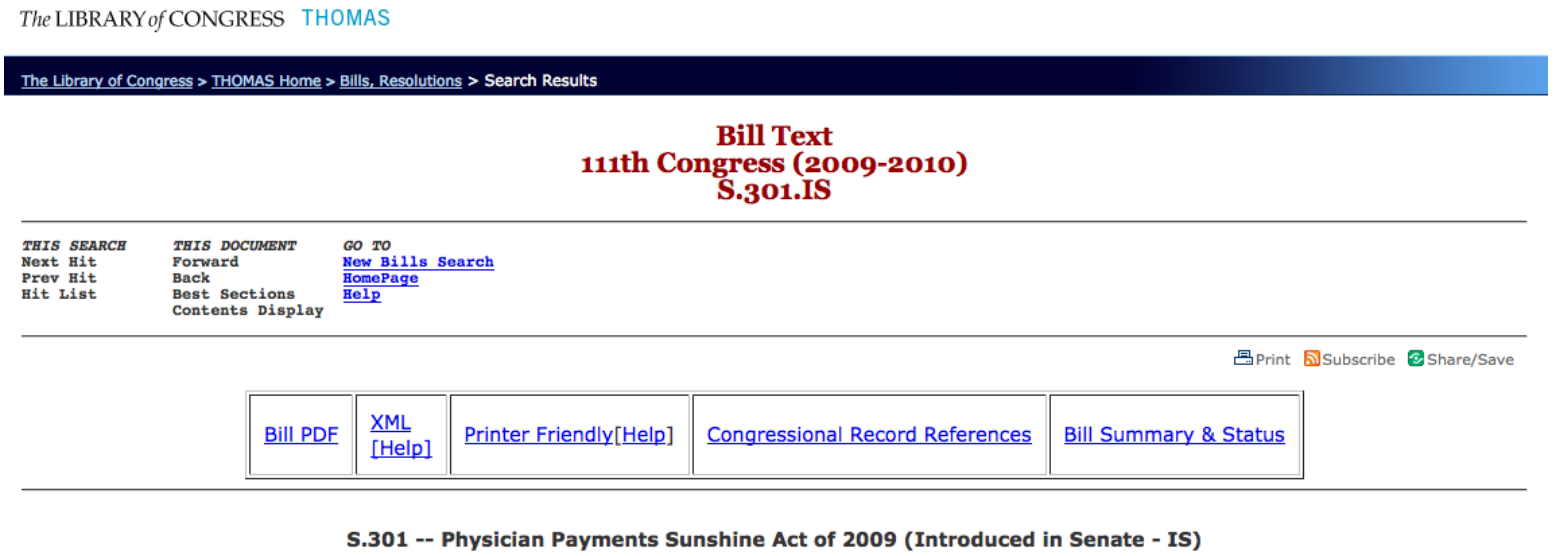
No more sales targets for GSK reps

Pharma company will also stop direct payments to doctors

GlaxoSmithKline (GSK) is overhauling the compensation scheme for its sales reps - doing away with individual sales targets - as it tries to restore its reputation following allegations of bribery in China.

- Duke Üniversitesi tüm araştırmacılarına soruyor:
  - “Çıkar çatışması doğurabilecek herhangi bir firma ilişkiniz var mı?”
- Ne kadar para elde ediyorsunuz?
- Eğer bu rakam 25,000 USD üzerinde ise ayrıntıları nelerdir?

- Senatör Charles Grassley, Kongreye Harvard'da çalışan 3 psikiyatristin 7 yılda 4 milyon dolar alıp, bunu bildirmediğini açıkladı.



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S.301 -- Physician Payments Sunshine Act of 2009 (Introduced in Senate - IS)

Açıklama (disclosure)

Specifications of the Physician Payments Sunshine Act (S. 2029).*

Annual electronic reporting, beginning March 31, 2011, by drug, device, and medical-supply companies of payments or other transfers of value to any physician or medical practice. Physician ownership or investment interests in manufacturers, group purchasing organizations, or distributors also reported.

The term "physician" includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors.

Disclosure of name of recipient, city and state, value, and date of payment or other transfer of value and the form (e.g., cash, stock, or stock option) and reason (such as consulting fee, education, research, royalty or license, honorarium, gift, entertainment, food, travel, or charitable contribution).

Şeffaflık

Public availability no later than September 30, 2011, and on June 30 of each subsequent year, of information for the previous calendar year on a searchable, "clear and understandable" government Web site. Background information and overall context can be provided. Appeal and correction process established.

Sınır

Reporting required if aggregate amount paid or transferred exceeds $500 in a calendar year. Exclusions include anything below $25 in value, product samples intended for patients, certain educational materials and direct training, and items used for providing charity care.

State reporting requirements preempted. Delayed reporting of payments made pursuant to product-development agreements or clinical investigations for 2 years or until approval of a product by the Food and Drug Administration, whichever is first.

Yaptırım

Penalties of $1,000 to $5,000 for each failure to report, with an annual cap of $50,000, and $5,000 to $50,000 for every instance of knowledge of failure to report, with an annual cap of $250,000.

Payments to physicians who are full-time employees of manufacturers excluded.

* Information is from the Senate Finance Committee as of July 2008. A bill similar to the Senate bill has been introduced in the House (H.R. 5605).

Guidance for Clinical Investigators, Industry, and FDA Staff

Financial Disclosure by Clinical Investigators

2013

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

Helsinki Bildirgesi yeni versiyonunun Türkçesi...

Fortaleza kentinde yapılan toplantıdaki değişiklikleri içeren metin AİFD'nin çevirisi ile Klinik Araştırmalar Derneği web sitesinde..

Devamı >>

Helsinki Bildirgesi yenilendi..

Brezilya'nın Fortaleza şehrinde yapılan WMA 64. toplantıda Helsinki Bildirgesi yenilendi. Yeni versiyon 1 Ocak 2014'ten itibaren geçerli.

Devamı >>

Araştırmanın Kaydının Yapılması ve Bulguların Yayınlanması ve Dağıtımı

- İnsan gönüllülerin yer aldığı tüm araştırma çalışmaları, ilk gönüllü araştırmaya dahil edilmeden önce açıkça erişilebilir bir veritabanına kaydedilmelidir.

Helsinki

- Araştırmacı, yazar, destekleyici, editör ve yayıncıların tümünün araştırma sonuçlarının yayımlanmasına ve dağıtılmasına ilişkin etik yükümlülükleri bulunmaktadır. Araştırmacıların, insan gönüllüler üzerinde yürüttükleri çalışmanın sonuçlarını umuma açıklama görevi bulunmaktadır ve bildirilerinin doğru ve eksiksiz olmasından sorumludurlar. Tüm taraflar, etik raporlama konusunda kabul edilmiş kılavuzlara uymak zorundadır. **Araştırmadan elde edilmiş olumsuz ve yetersiz sonuçlar da olumlu sonuçlar gibi yayımlanmalı** veya başka yollarla topluma duyurulmalıdır. **Finansman kaynakları, kurumsal bağlar ve çıkar çatışmaları yayında beyan edilmelidir.** Bu bildirgede yer alan ilkelere uymayan araştırma bildirileri yayına kabul edilmemelidir.

Helsinki

ACCME STANDARDS FOR COMMERCIAL SUPPORT℠

Standards to Ensure the Independence of CME Activities

Finansal İlişki bireyin maaş, ve başka adla para alarak bireysel yarar gördüğü ilişkiler

ACCME finansal ilişkinin çıkar çatışmasına dönmesi için 2 koşul birden aramakta:

1. Ticari bir niteliği olan finansal ilişki **ve**
2. Bu ticari ilişki ile ilgili ürün ve hizmetleri igilendiren toplantıyı etkileme potansiyeli.

Son 12 ayda her hangi bir miktarda…

Kişiye, eşine ya da partnerine ait

- Maaş
- Entellektüel katkı payı
- Telif hakkı
- Danışma Ücreti
- Honoraryum
- Mülkiyet (hisse ve diğer)
- Diğer maddi kazançlar

Kişisel çıkar ilişkisinin çözülmesi

- Herkes açıklar
- Açıklayanlar çalışır
- Tanımlayacak ve çözecek mekanizmalar kurulur

Açıklama

- Aktiviteden önce dinleyenlere açıklama (olmadığını da..)
- Ticari desteğin açıklanması
- Açıklama sırasında ticari marka veya ürün grubu kullanılmaz

Türk Hematoloji Derneği Çıkar İlişkisi bildirimi	
Bu konuşmamda yer alan ilaçlarla ilgili firmalardan konuşma ödemesi/ honorarium/çalışma desteği aldım/almadım	
Bu konuşmamda yer alan firmalarla ticari bir bağlantım vardır/yoktur	
Bu konuşmamda yer alan firmalara danışmanlık yaptım/yapmadım	

Financial Relationships between Institutional Review Board Members and Industry

Eric G. Campbell, Ph.D., Joel S. Weissman, Ph.D., Christine Vogeli, Ph.D., Brian R. Clarridge, Ph.D., Melissa Abraham, Ph.D., Jessica E. Marder, and Greg Koski, Ph.D., M.D.

N Engl J Med 2006;355:2321-9.

- 100 Akademik kurumda bulunan 893 Etik Kurul üyesi
- %67.2 yanıt vermiş

Etik Kurul Üyeleri ve Endüstri ilişkileri

Endüstri ile ilişkisiniz var mı?	%36 Evet		
Bu ilişki kararları etkiler mi?	%85.5 Hayır	%11.9 Nadir	%2.4 Bazen
Son 1 yılda ilişkiniz olan firmaya ait dosya incelediniz mi?	%15.1 en az 1 tane		
Eğer varsa Çİ açıklaması yaptınız mı? (78 üye)	%57.5 Evet	%19.2 bazen	%23.1 Hayır
O dosya ile ilgili kararlara katıldınız mı?	%64.5 Hayır	%16.1 Seyrek	%19.4 Evet
Endüstri ile ilişkisi olanların etik kurul üyesi olması yararlı mı?	>%70 Evet		

- Bu tip ilişki kaçınılmaz
- Mutlaka açıklanmalı
- Bu tip ilişki varsa, kararlara katılmaları yasalara aykırı
- Etik Kurullar bu süreçlere sahip değil
- Etik Kurul üyeleri bu süreçler hakkında bilgi sahibi değil

- Finansal ilişkisi olan büyük çoğunluk o firma dosyalarına bakmıyor
- Bu ilişkinin yararlı olduğu durumlar var
- Bu ilişkiye sahip üyelerin dışlanması sakıncalı

Yeni Yönetmelik (2013)

KLİNİK ARAŞTIRMALAR HAKKINDA YÖNETMELİK

ALTINCI BÖLÜM. Etik Kurullar

Madde 26.

(6) Etik kurul üyelerinden en az üçü etik kurul sekretaryasının bulunduğu Kurumun dışından belirlenir.

(7) Bir etik kurul üyesi birden fazla etik kurulda üye olamaz.

(8) Etik kurullarda klinik araştırma yapılan yerin üst yöneticileri görev alamaz.

MADDE 27(1)

a) Etik kurullar, klinik araştırma başvurularını bilimsel ve etik yönden değerlendirme ve karar verme hususlarında bağımsızdır.

b) Etik kurul üyeleri, kendilerine ulaşan her türlü bilgi için gizlilik ilkesine uymak zorundadır.

c) Etik kurul üyeleri, Kurum tarafından hazırlanan gizlilik belgesi ve taahhütnamesini imzalayarak görevlerine başlar.

ç) İncelenen araştırmayla ilişkisi bulunan veya araştırmada görevi olan etik kurul üyesi, bu araştırmanın etik kuruldaki tartışmalarına ve oylamasına katılamaz, etik kurul kararını imzalayamaz.

Bir örnek: Etik Kurulda Çıkar Çatışması

- Doğrudan veya Dolaylı
  - Araştırmacı ile aynı kurumda çalışıyor olmak
  - Destekleyici ile çalışıyor olmak
  - Araştırıcıların iş arkadaşı/dostu olmak
  - Sponsor ya da araştırıcının akrabası olmak
  - Araştırıcı ya da sponsorun rakip kurumunda çalışıyor olmak
  - Öğrencisinin projesini değerlendirmek

- Çoğu durumda çıkar ilişkisini ortadan kaldırmak mümkün değildir..
- Olduğu zaman ortaya çıkmalı
- Açıklanması için gerekli girişimler yapılmalı
- Etkilerinin önlenmesine çalışılmalı

SOP ile düzenle

- Bilgi vermek/açıklamak:
  - Etik kurul başkanı
  - Etik kurula açıklama

- Çalışma odasını terketmek:
  - Toplantının başında?
  - Tartışmadan önce?
  - Karardan önce?
  - Tüm aşamalarda yer almak?

Teşekkür ederim