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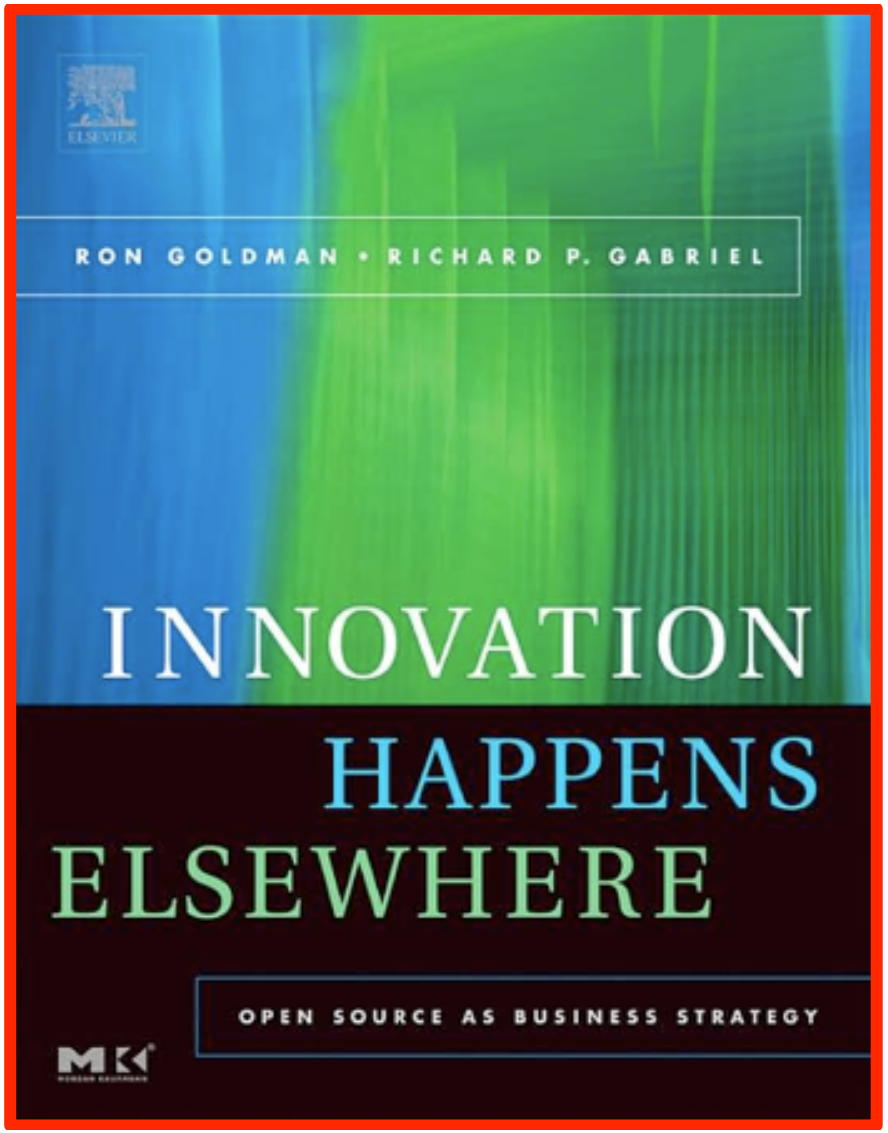
RON GOLDMAN • RICHARD P. GABRIEL
INNOVATION
HAPPENS
ELSEWHERE
OPEN SOURCE AS BUSINESS STRATEGY

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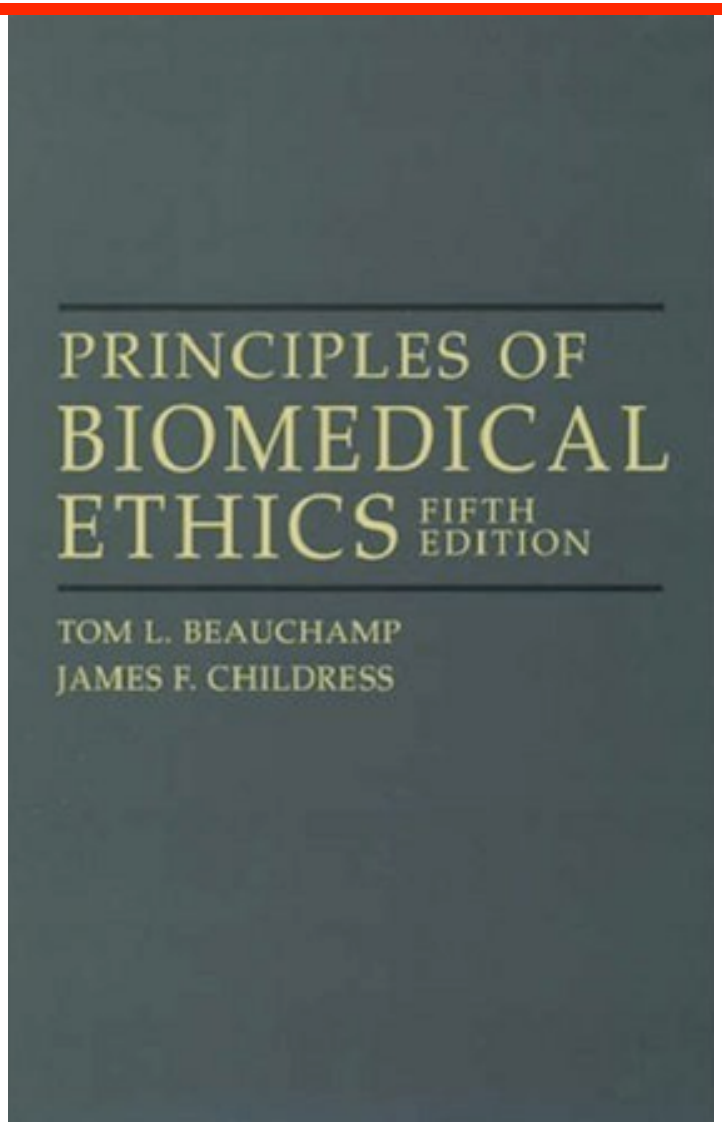
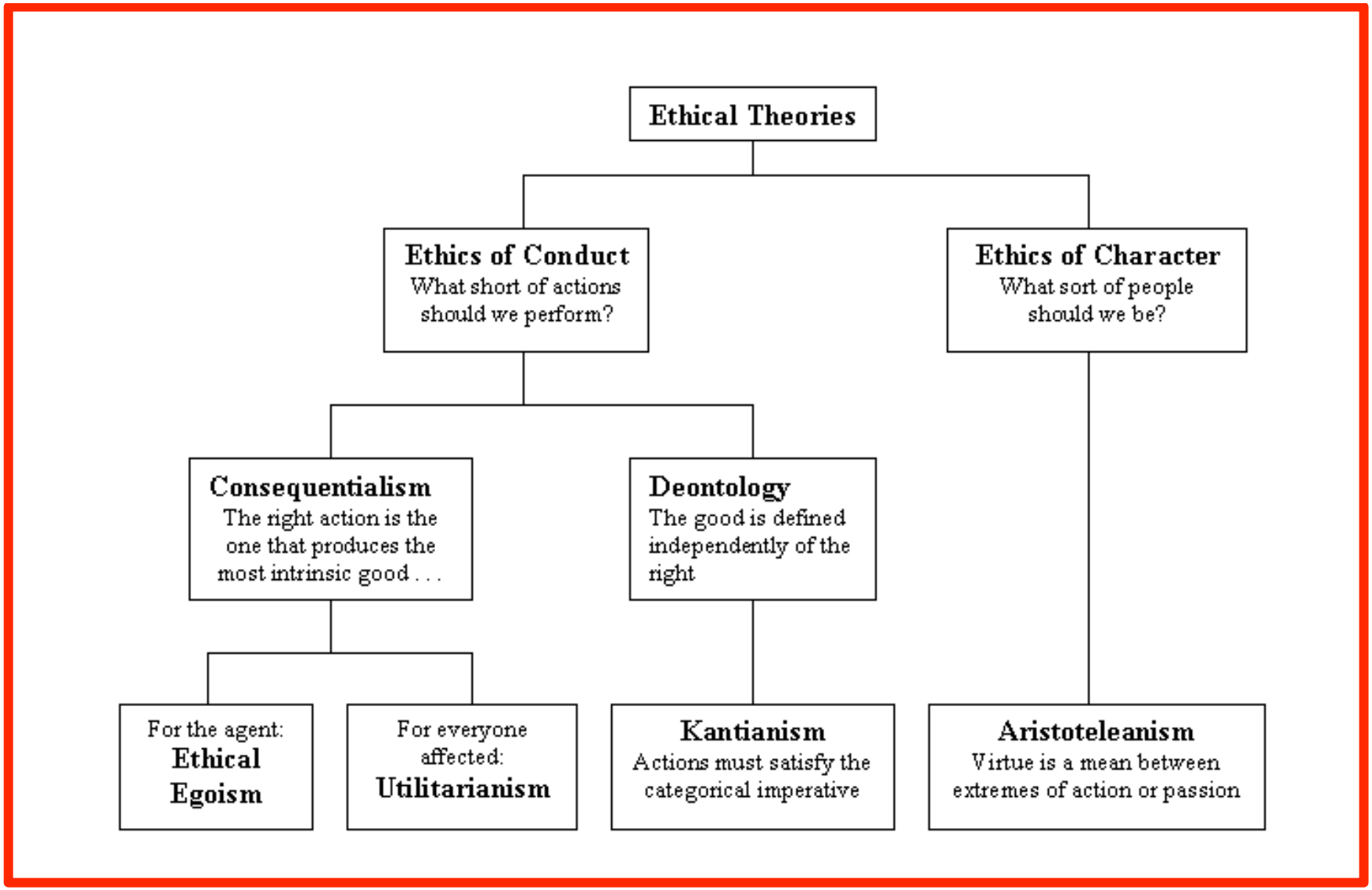
autonomy
justice
beneficence
non-
maleficence


autonomy
justice
beneficence
non-
maleficence


PRINCIPLES OF
BIOMEDICAL
ETHICS FIFTH EDITION
TOM L. BEAUCHAMP
JAMES F. CHILDRESS


Ethical Theories
Ethics of Conduct
What short of actions should we perform?
Ethics of Character
What sort of people should we be?
Consequentialism
The right action is the one that produces the most intrinsic good . . .
Deontology
The good is defined independently of the right
For the agent:
Ethical Egoism
For everyone affected:
Utilitarianism
Kantianism
Actions must satisfy the categorical imperative
Aristoteleanism
Virtue is a mean between extremes of action or passion


LIBERALISM


community
building the future together

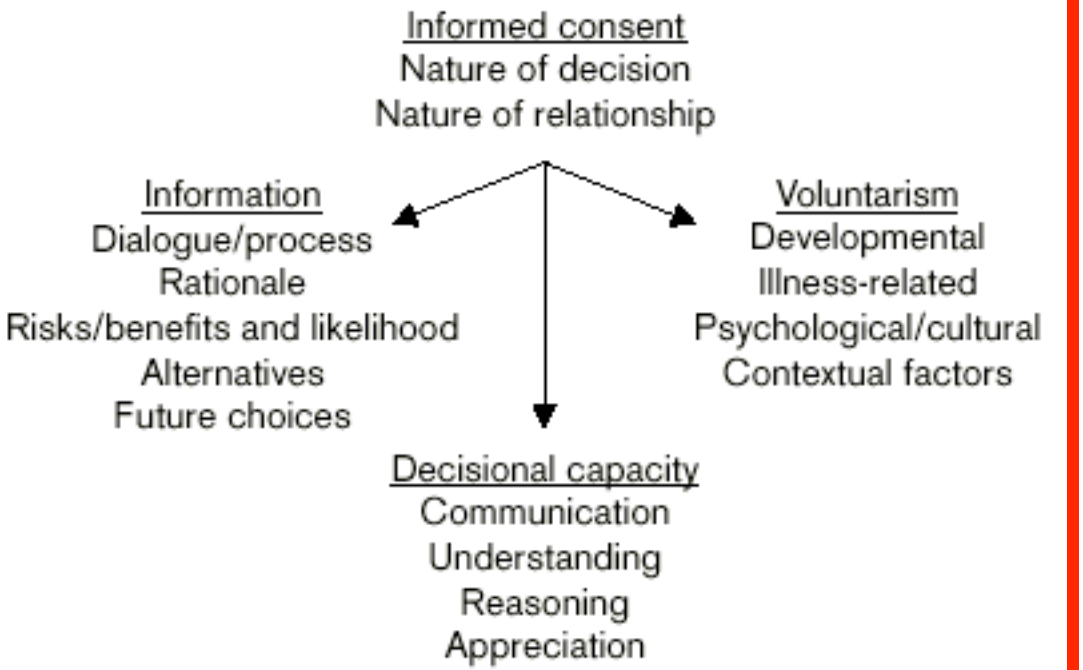
Your Holy Grail

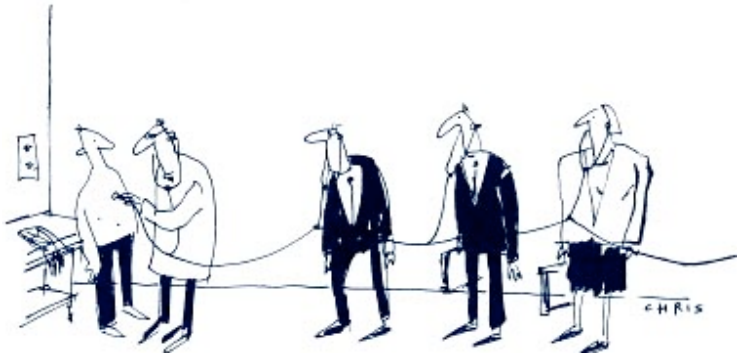
Justification	Optimization	Limitation
no practice shall be carried out unless its introduction produces a positive net benefit	all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account	the dose equivalent to individuals shall not exceed the limits recommended by ICRP

Other ethical issues

Malpractice	Communication of risk	Conflict of interests
concerning 1) you do not know what you should know 2) you do (not do) what you should (not) do	concerning 1) known stochastic or determinist effects 2) unknown stochastic effects	between practitioners' duties and practitioners' advantages

Another Holy Grail: Informed consent





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TRUSTED CONSENT AND RESEARCH BIOBANKS: TOWARDS A 'NEW ALLIANCE' BETWEEN RESEARCHERS AND DONORS

GIOVANNI BONIOLO, PIER PAOLO DI FIORE AND SALVATORE PECE

Keywords
biobank,
consent,
trust,
new alliance

ABSTRACT
We argue that, in the case of research biobanks, there is a need to replace the currently used informed consent with trusted consent. Accordingly, we introduce a proposal for the structure of the latter. Further, we discuss some of the issues that can be addressed effectively through our proposal. In particular, we illustrate: i) which research should be authorized by donors; ii) how to regulate access to information; iii) the fundamental role played by a Third Party Authority in assuring compliance with the reciprocal expectations and obligations of donors and scientists. Finally, we briefly analyse two issues that might represent important elements of a 'new alliance' between researchers and donors to which the trusted consent could pave the way: i) the correlations between needs and rights of the two parties, and ii) possible economic transactions.

from

informed consent

to

participation pact

based on **trust** and furnishing the **contextualized relevant information**

Ethical counselling

Ethical counselling is a dialogic service by means of which an ethical counsellor helps a patient (or one of his/her relatives) to undergo a particular solution of what could be said an ethical and decisional paralysis concerning a particular diagnostic or therapeutic procedure.

Carla, 32, is married with 2 children. She is at the third month of pregnancy and decides to go to the dentist for the usual yearly control. The dentist finds something strange and asks for tests and for an oncological control. The diagnosis is frightening: jaw sarcoma.

She is told she has two options: the best diagnostic and therapeutic one (a first staging step with CAT total body and PET; a second therapeutic step with pre-surgery chemotherapy, surgery and post-surgery chemotherapy) and one "adapted" (no diagnostic staging, just surgery).

If she chooses the first, the pregnancy has to be interrupted but she has great possibilities of having a normal and long life. If she chooses the second, she has the possibility to keep pregnancy on, but there is no certainty about her life.

Carla does not know what to do: saving her life and letting the new child die, or saving the latter and probably die?

Participation pact & Ethical counselling

for a real

patient empowerment

Patient empowerment is about designing and delivering health and social care services in a way that are inclusive and enable citizens to take control of their health care needs. Patient empowerment puts the patient at the heart of services.

CDC Home

Centers for Disease Control and Prevention

CDC 24/7: Saving Lives. Protecting People.™

Genomic Testing

ACCE Model Process for Evaluating Genetic Tests

From 2000 – 2004, CDC's Office of Public Health Genomics (OPHG) established and supported the ACCE Model Project, which developed the first publicly-available analytical process for evaluating scientific data on emerging genetic tests. The ACCE framework has guided or been adopted by various entities in the United States and worldwide for evaluating genetic tests; the CDC-supported EGAPP™ initiative builds on the ACCE model structure and experience.

ACCE … is a model process that includes collecting, evaluating, interpreting, and reporting data about DNA (and related) testing for disorders with a genetic component in a format that allows policy makers to have access to up-to-date and reliable information for decision making.

….

An important by-product of the ACCE model process is the identification of gaps in knowledge that will help to define future research agendas.

A	**Analytic validity** How accurately and reliably the test measures the genotype of interest.
C	**Clinical validity** How consistently and accurately the test detects or predicts the intermediate or final outcomes of interest.
C	**Clinical utility** How likely the test is to significantly improve patient outcomes.
E	**ELSI** Ethical, legal, and social implications that may arise in the context of using the test.

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ACCE for radioprotection

A	**Analytical validity**. It concerns both the experimental accuracy of the diagnostic or therapeutic intervention and the scientific quality of the equipment and of the personnel.
C	**Clinical validity**. It concerns the accuracy and precision that the diagnostic or therapeutic intervention predicts or treats the pathological situation.
C	**Clinical utility**. It concerns the clinical significance for the patient's benifit of the diagnostic or therapeutic intervention.
E	**Empowerment of the patient**. It concerns to enable patients/citizens to take control of their diagnostic or therapeutic needs for a shared decision making.

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ACCE for radioprotection

A	**Analytical validity**. It concerns both the experimental accuracy of the diagnostic or therapeutic intervention and the scientific quality of the equipment and of the personnel.	• **Limitation** • **Malpractice**
C	**Clinical validity**. It concerns the accuracy and precision that the diagnostic or therapeutic intervention predicts or treats the pathological situation.	• **Optimisation**
C	**Clinical utility**. It concerns the clinical significance for the patient's benifit of the diagnostic or therapeutic intervention.	• **Justification** • **Optimisation** • **Malpractice**
E	**Empowerment of the patient**. It concerns to enable patients/citizens to take control of their diagnostic or therapeutic needs for a shared decision making.	• **Justification** • **Optimisation** • **Malpractice** • **Communication of risk and of the relevant information** • **Participation pact** • **Ethical counselling**

The ACCE model process is composed of a standard set of 44 targeted questions that address disorder, testing, and clinical scenarios, as well as analytic and clinical validity, clinical utility, and associated ethical, legal, and social issues.

Element	Component	Specific Question
Disorder/Setting		1. What is the specific clinical disorder to be studied? 2. What are the clinical findings defining this disorder? 3. What is the clinical setting in which the test is to be performed? 4. What DNA test(s) are associated with this disorder? 5. Are preliminary screening questions employed? 6. Is it a stand-alone test or is it one of a series of tests? 7. If it is part of a series of screening tests, are all tests performed in all instances (parallel) or are only some tests performed on the basis of other results (series)?
Analytic Validity		8. Is the test qualitative or quantitative?
	Sensitivity	9. How often is the test positive when a mutation is present?
	Specificity	10. How often is the test negative when a mutation is not present?
		11. Is an internal QC program defined and externally monitored? 12. Have repeated measurements been made on specimens? 13. What is the within- and between-laboratory precision? 14. If appropriate, how is confirmatory testing performed to resolve false positive results in a timely manner? 15. What range of patient specimens have been tested? 16. How often does the test fail to give a useable result? 17. How similar are results obtained in multiple laboratories using the same, or different technology?
Clinical Validity	Sensitivity	18. How often is the test positive when the disorder is present?
	Specificity	19. How often is the test negative when a disorder is not present?
		20. Are there methods to resolve clinical false positive results in a timely manner?
	Prevalence	21. What is the prevalence of the disorder in this setting?
		22. Has the test been adequately validated on all populations to which it may be offered? 23. What are the positive and negative predictive values? 24. What are the genotype/phenotype relationships? 25. What are the genetic, environmental or other modifiers?

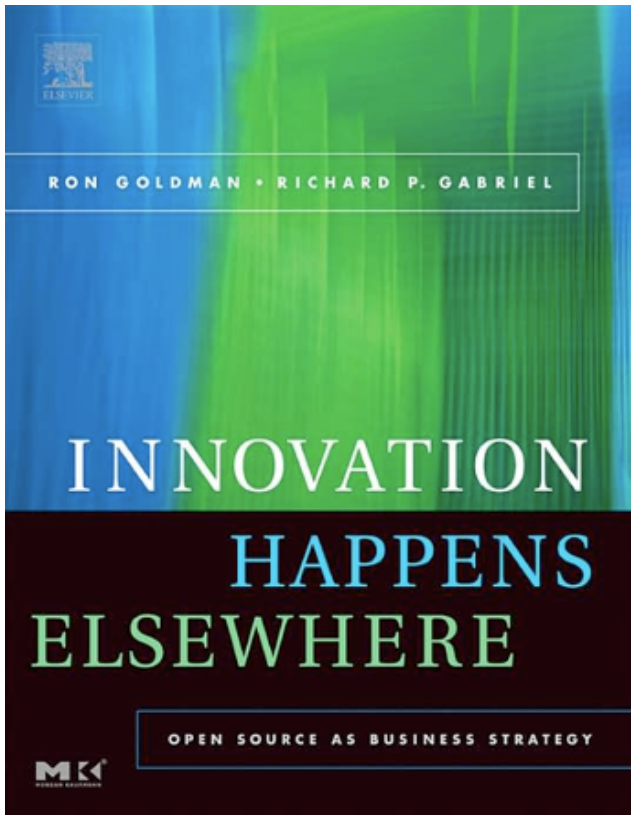
Clinical Utility	Intervention	26. What is the natural history of the disorder?
	Intervention	27. What is the impact of a positive (or negative) test on patient care?
	Intervention	28. If applicable, are diagnostic tests available?
	Intervention	29. Is there an effective remedy, acceptable action, or other measurable benefit?
	Intervention	30. Is there general access to that remedy or action?
		31. Is the test being offered to a socially vulnerable population?
	Quality Assurance	32. What quality assurance measures are in place?
	Pilot Trials	33. What are the results of pilot trials?
	Health Risks	34. What health risks can be identified for follow-up testing and/or intervention?
		35. What are the financial costs associated with testing?
	Economic	36. What are the economic benefits associated with actions resulting from testing?
	Facilities	37. What facilities/personnel are available or easily put in place?
	Education	38. What educational materials have been developed and validated and which of these are available?
		39. Are there informed consent requirements?
	Monitoring	40. What methods exist for long term monitoring?
		41. What guidelines have been developed for evaluating program performance?

ELSI	Impediments	42. What is known about stigmatization, discrimination, privacy/confidentiality and personal/family social issues?
		43. Are there legal issues regarding consent, ownership of data and/or samples, patents, licensing, proprietary testing, obligation to disclose, or reporting requirements?
	Safeguards	44. What safeguards have been described and are these safeguards in place and effective?

ACCE: XX targeted questions concerning radioprotection

ELEMENT	COMPONENT	SPECIFIC QUESTION
Disorder/Setting		
Analytic Validity	• **Limitation** • **Malpractice**	• Which is the "right" patient-centred dose for the procedure? • Is the personell rightly trained? • Is the lab rightly equipped and constructed?
Clinical Validity	• **Optimisation**	• Is the only possible alternative?
Clinical Utility	• **Justification** • **Optimisation** • **Malpractice**	• Is really useful for the patient the procedure?
Empowerment	• **Justification** • **Optimisation** • **Malpractice** • **Communication of risk and of the relevant information** • **Participation pact** • **Ethical counselling**	• Is the patient properly informed about the procedure and about the stochastic and deterministic possible harmful effects? • Has been patient-centred the information? • Is there any conflict of interest? • Has the patient agreed with the participation pact? • Is there the necessity of an ethical counselling and has this been rigtly instantied?

REALLY?



JUST A PROPOSAL

ACCE

for radioprotection