MAHIDOL UNIVERSITY
Wisdom of the Land

Expedited Review
&
Exemption

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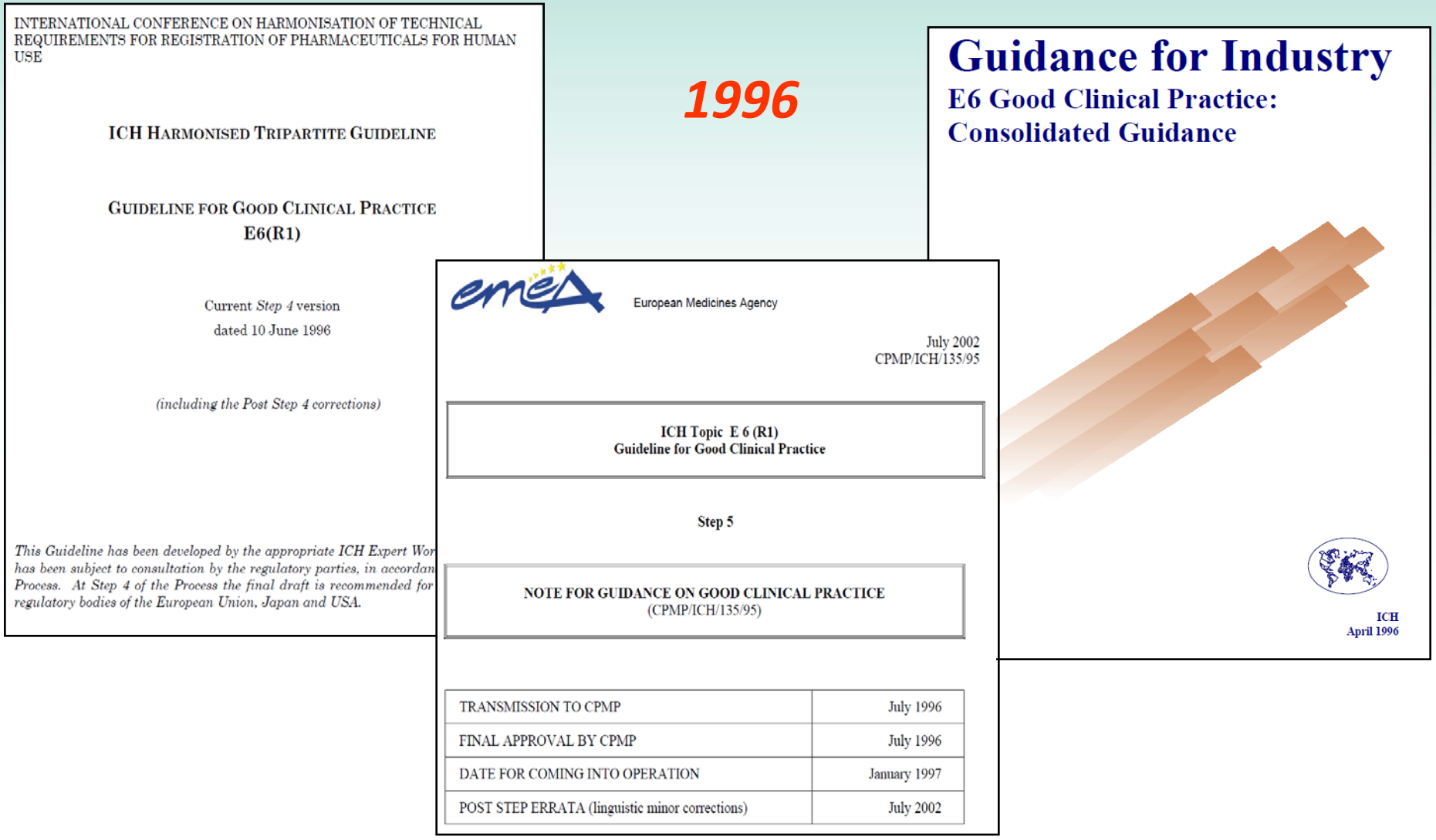
Center of Excellence for Biomedical and Public Health Informatics

Regulatory & Guidelines

ICH & GCP Guidance



INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE
E6(R1)

Current *Step 4* version
dated 10 June 1996

(including the Post Step 4 corrections)

This Guideline has been developed by the appropriate ICH Expert Wor
has been subject to consultation by the regulatory parties, in accordan
Process. At Step 4 of the Process the final draft is recommended for
regulatory bodies of the European Union, Japan and USA.

1996

European Medicines Agency

July 2002
CPMP/ICH/135/95

ICH Topic E 6 (R1)
Guideline for Good Clinical Practice

Step 5

NOTE FOR GUIDANCE ON GOOD CLINICAL PRACTICE
(CPMP/ICH/135/95)

TRANSMISSION TO CPMP	July 1996
FINAL APPROVAL BY CPMP	July 1996
DATE FOR COMING INTO OPERATION	January 1997
POST STEP ERRATA (linguistic minor corrections)	July 2002

Guidance for Industry
E6 Good Clinical Practice:
Consolidated Guidance

ICH
April 1996

ICH & GCP Guidance

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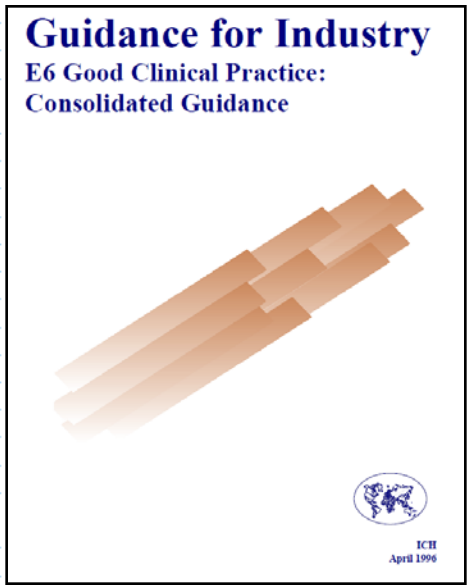
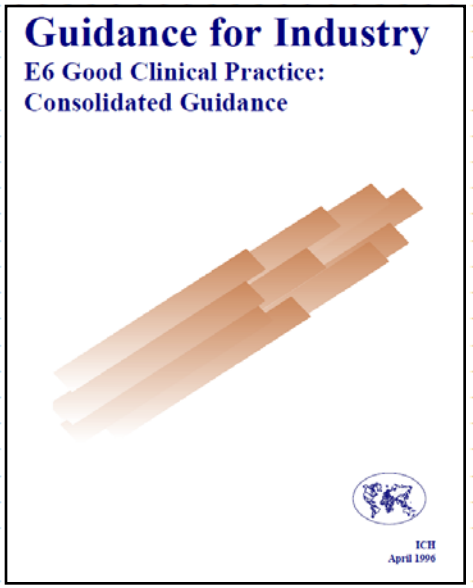


ICH & GCP Guidance



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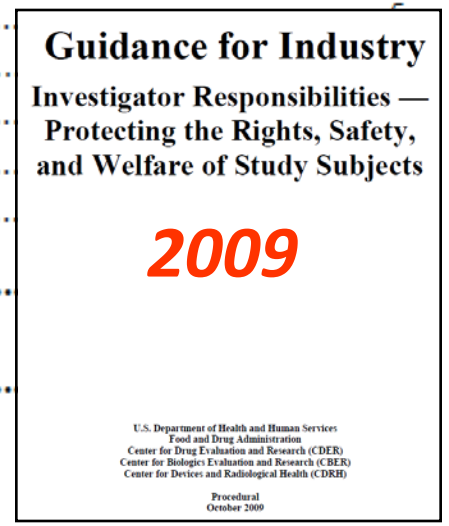

ICH & GCP Guidance

Contains Nonbinding Recommendations

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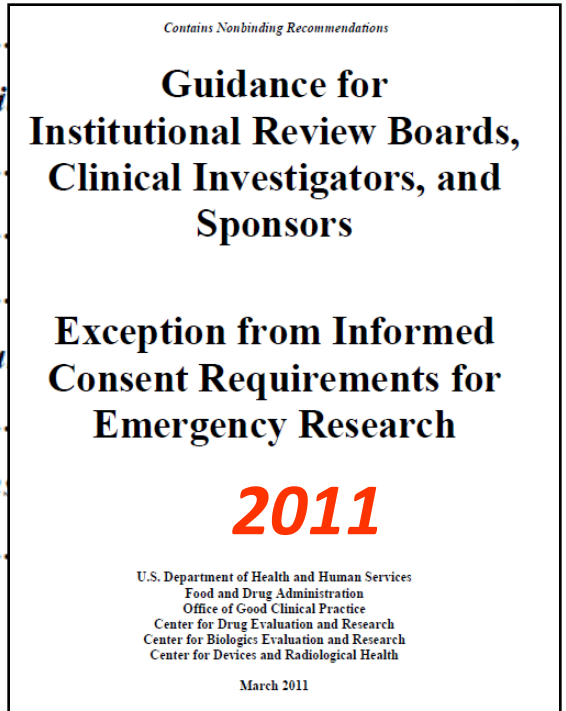

Contains Nonbinding Recommendations

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors

Exception from Informed Consent Requirements for Emergency Research

2011

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

March 2011

ICH & GCP Guidance

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Guidance for Industry
Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Ann Meeker O'Connell at 301-796-3150, (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 301-827-1800, or (CDRH) Chrissy Cochran at 301-796-5490.

2011

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
August 2011
Procedural

ICH & GCP Guidance

Contains Nonbinding Recommendations

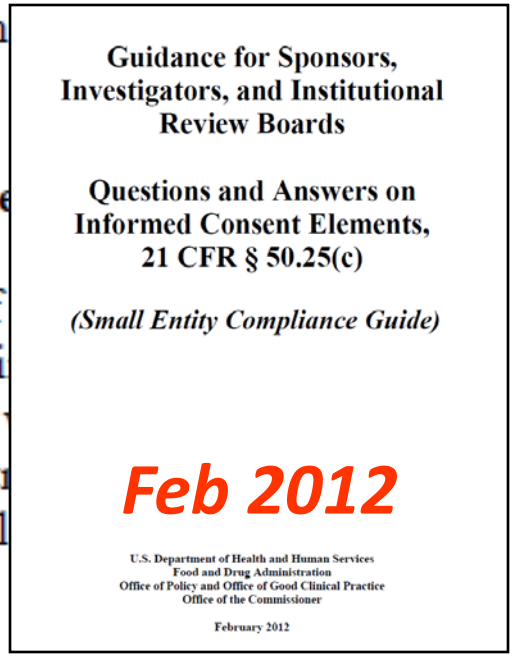
III. Questions and Answers on Informed Consent Elements (21 CFR § 50.25(c))

1. What is the new requirement for informed consent documents?

For applicable clinical trials initiated on or after March 7, 2012, informed consent documents must be in compliance with the new requirement in 21 CFR § 50.25(c) and include a specific statement that refers to the trial's description on www.ClinicalTrials.gov.

2. Why is it necessary to include this new statement in informe

The requirement for this provision was included in section 801 of provided for mandatory registration and results reporting of certai trials on www.ClinicalTrials.gov. The statement is the means by provided for investigators/sponsors to inform applicable clinical t availability of the clinical trial information on the public website l www.ClinicalTrials.gov.



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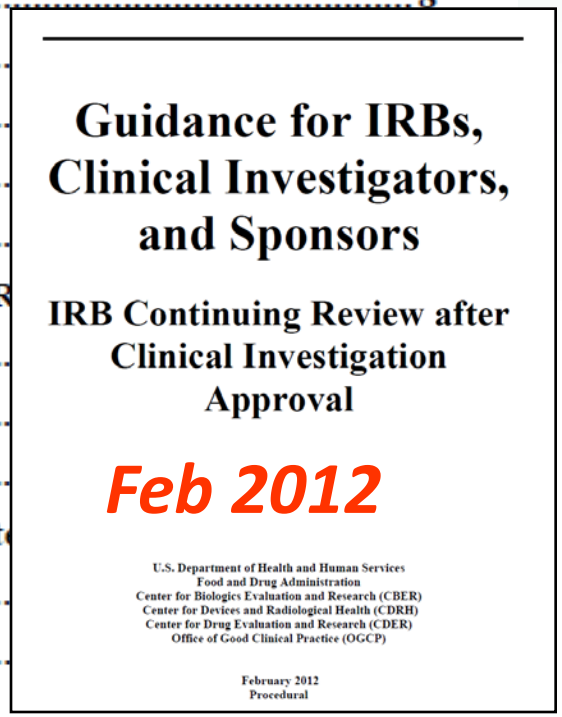
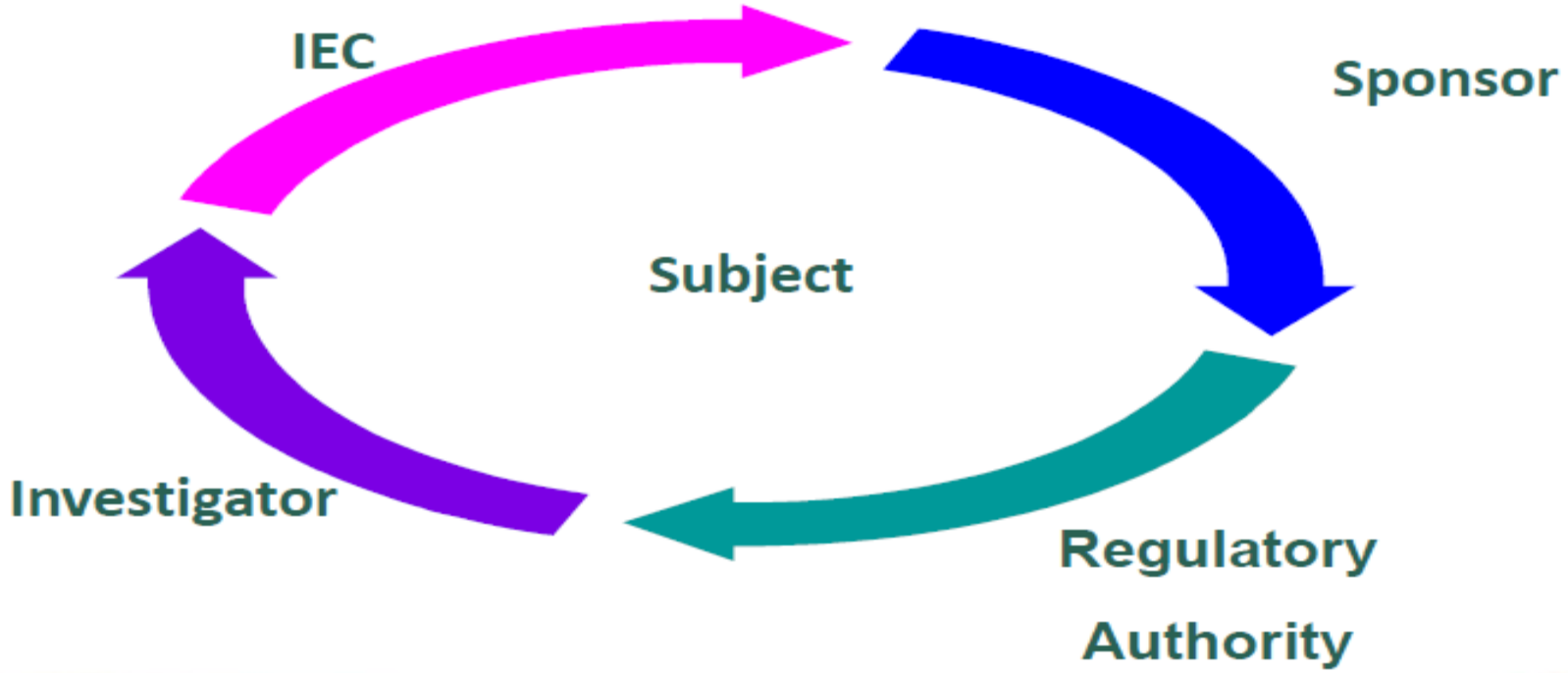


Investigator vs. IEC/IRB

Roles & Responsibility

The Clinical Research "Team"

Protection of human subjects is the responsibility of:

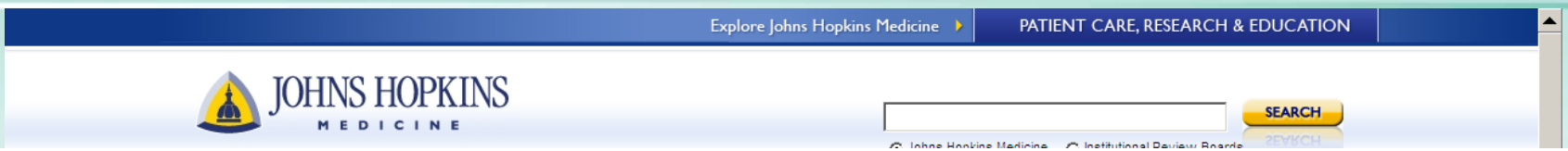


Courtesy: Dr. Niwat Montreewasuwat (modified)

Investigator: Qualifications and Agreements

- qualified by education, training, and experience to assume responsibility for the proper conduct of the trial
- provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation
- familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure
- aware of Good Clinical Practice & the applicable regulatory requirements
- must permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies)
- maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties

Investigator: Qualifications and Agreements



Course Requirements:

The chart below lists the required courses for PIs and study team members listed on JHM IRB human subjects research applications. Courses include: Basic Human Subjects Research (BHSR), Conflict of Interest (COI), HIPAA & Research, Research Ethics Workshops About Responsibilities and Duties of Scientists (REWards - formerly CORE), Clinical Research Billing Orientation (CRBO) and Clinical Research Management Systems (CRMS). **If the required courses have not been completed by all study team members, the application will be returned to the PI.**

Affiliation	BHSR	COI	HIPAA & Research	REWards	CRBO/CRMS
Principal Investigators (PIs)	X	X	X	X(1)	X
JHU SOM and SON faculty, fellows, staff, and students; staff at APL, JHH, JHCP, KKI, HCGH, Suburban Hospital, Sibley Memorial Hospital, Cardiovascular Specialists of Central MD, and Central MD Radiation Oncology Corporation	X	X	X	Fellows Only (1)	X (3)
Engineering, Arts and Sciences faculty, staff and students	X		X		X(3)
School of Public Health faculty, staff and students	X				X (3)
Non-Hopkins study team members	X(2)				X (3)
Clinical Research Network study team members(AAMC, GBMC and INOVA)	X	X			X (3)

Investigator: Communication with the IRB

- have written and dated approval from the IRB for the research application, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects
- provide / update (if any) the IRB with a current copy of the Investigator's Brochure.
- provide the IRB with all documents subject to review according to the IRB's requirements

Cartoon by Amanda Plante and Tim Brown

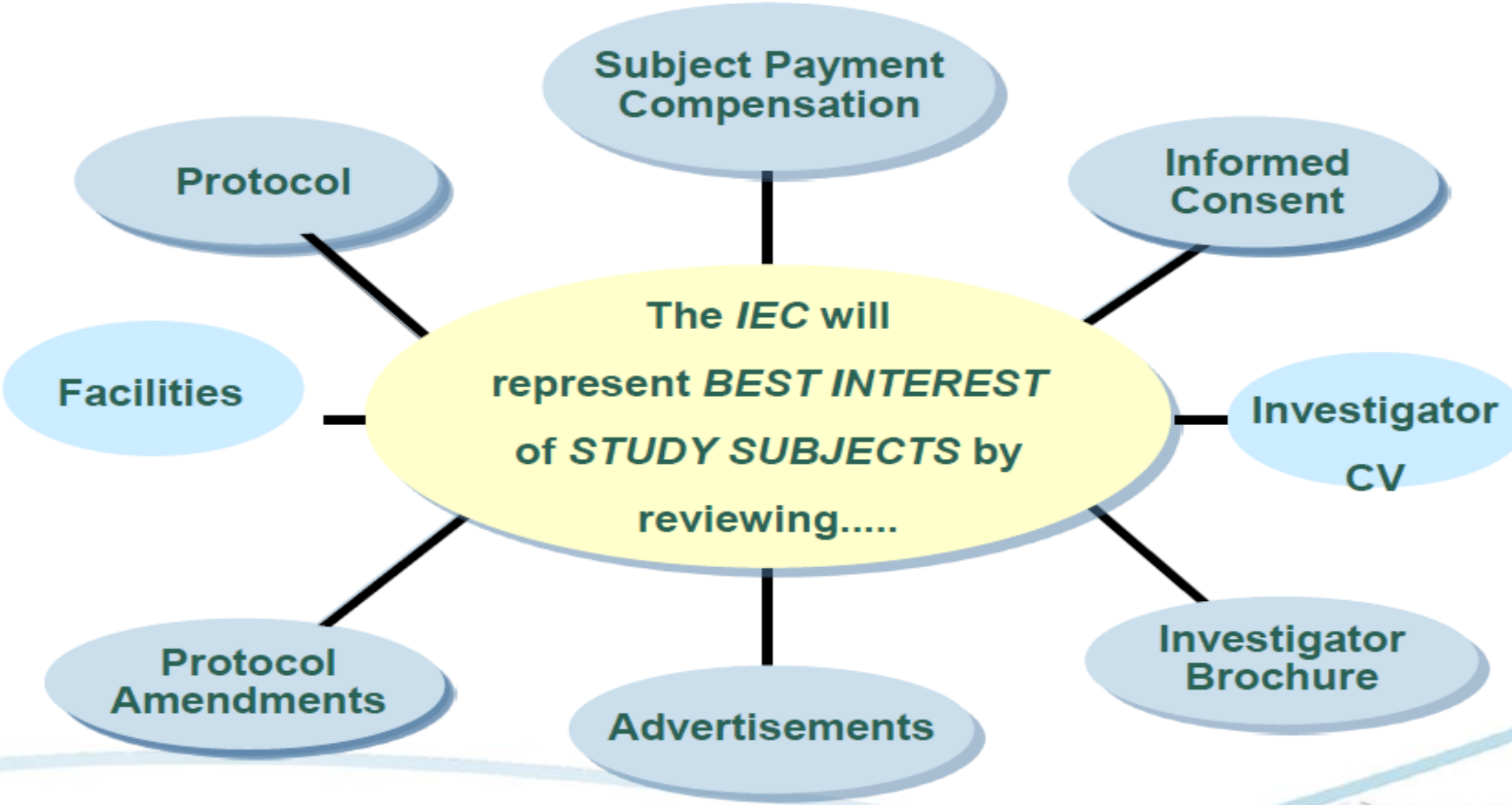
IEC - IRB: Composition

- consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial - recommended compositions:
  - At least five members.
  - At least one member whose primary area of interest is in a nonscientific area.
  - At least one member who is independent of the institution /trial site.

- Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

Documents for EC Review

Roles & Responsibilities of IRB/IEC



Courtesy: Dr. Niwat Montreewasuwat (modified)

Documents for EC Review

Documents Requiring IEC Opinion:

- Protocol and amendments
- Informed consent forms
- Additional information given to subjects
- Recruitment advertisements
- Payments to subjects

Courtesy: Dr. Niwat Montreewasuwat (modified)

Documents for EC Review

Documents requiring IEC review:

- Investigator Brochure (IB) and addenda
- Serious Adverse Events (SAE) reports
- Administrative letters
- Final investigator study report
- Annual study status updates from investigators

Courtesy: Dr. Niwat Montreewasuwat (modified)

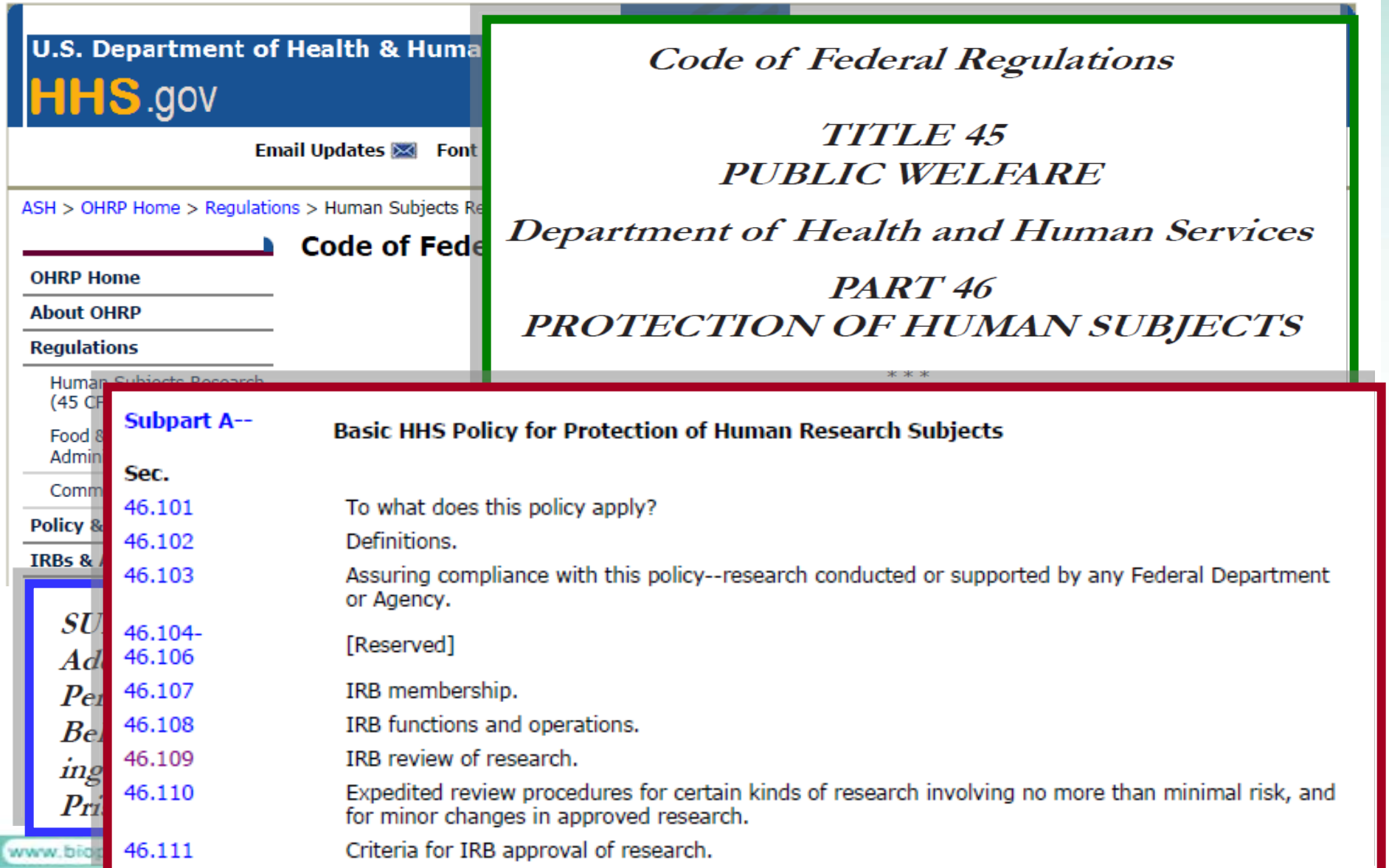
Protocol Review

"Make sure everything is done ethically. Within reason, of course."

Guideline 2: Ethical Review Committees

- All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees.
- The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review.
- The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of its progress.

Regulation& Guidelines: CFR



Types of Review

Convened IRB Review (full committee review): Any study involving greater than minimal risk, including studies with vulnerable populations and/or sensitive questions, as well as studies with the possibility of physical risk.

Expedited IRB Review (individual committee member review): Only research involving no more than minimal risk to subjects, including blood sampling in minimal amounts, review of records collected for non-research purposes (such as chart reviews), and survey research.

Exempt from Continuing IRB Review: Research with very minimal risk to human subjects as determined by regulatory guidelines may be exempted from continuing review at the discretion of the IRB. An exemption is granted by the IRB upon review of the application.

Expedited vs. Exempt

Side by Side Guide to Determine Expedited vs Exempt Review Categories
(note: these are general guidelines, there may be exceptions)

Points to Consider	Expedited	Exempt
Is it Human Subjects Research?		
Involves Human Subjects	X	X
must meet federal definition of human subject		
It is Research	X	X
must meet federal definition of research		
Research Categories		
Project meets one or more of the expedited research categories	X	
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm		
Project meets one or more of the exempt research categories		X
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm		
Number of Interactions / Interventions with Subject		
Interactions once (e.g. one time anonymous survey)		X
no retention of personal / contact information		
Interaction more than once (i.e. design requires repeated interactions)	X	
Retains personal / contact information for additional interaction or follow-up		

http://www.usc.edu/admin/oprs/private/docs/oprs/Expedited_vs_Exempt.pdf

Expedited vs. Exempt

Side by Side Guide to Determine Expedited vs Exempt Review Categories
(note: these are general guidelines, there may be exceptions)

Points to Consider	Expedited	Exempt
Analyzing Data only (no interaction with human subjects)		
Anonymous data / de-identified / no identifiers maintained		X
may qualify as "Not Human Subjects Research" or Coded Specimen Research		
Data linked to personal information	X	
Level of risk		
Minimal	X	
risks not greater than those encountered in daily life, or routine physical / psychological exams / tests		
(e.g. interviews about levels of anxiety or depression, surveying children, blood draws)		
None or less than minimal		X
risk that is less than minimal as defined above (e.g. questionnaire asks for favorite food,		
# of vacations in past year, etc).		
Annual IRB Review (continuing review)		
Continuing Review is Required	X	
Continuing Review is NOT required		X

http://www.usc.edu/admin/oprs/private/docs/oprs/Expedited_vs_Exempt.pdf

Expedited vs. Exempt

Side by Side Guide to Determine Expedited vs Exempt Review Categories
(note: these are general guidelines, there may be exceptions)

Points to Consider	Expedited	Exempt
Are the data (questions) collected (asked) sensitive in nature, or identifiable private information?		
Sensitive	X	
data could put the subject at risk (e.g. job loss, marriage, reputation, etc)		
Not sensitive		X
includes innocuous data/questions only (e.g. food preferences, cell phone usage)		
Identifiable Private Information	X	X
includes information about behavior occurring in a private context, information gathered for specific		
purposes where the individual expects the information to be kept private (e.g. medical records), and		
data/info is identifiable (e.g. name/address). NOTE: identifiable information can qualify as exempt if		
the information is innocuous.		
Intent or use of information gathered		
Generalizeable	X	X
intend to share information to benefit society		
Not intended to contribute to generalizeable knowledge	NA	NA
submit a "Human Subjects Research Determination Request"		

http://www.usc.edu/admin/oprs/private/docs/oprs/Expedited_vs_Exempt.pdf

Expedited vs. Exempt

Side by Side Guide to Determine Expedited vs Exempt Review Categories
(note: these are general guidelines, there may be exceptions)

Points to Consider	Expedited	Exempt
Who are the subjects?		
Children	X	*X
*Exempt category 2 is allowable in studies with children, only when there is passive observation		
and no interaction with the children. Exempt categories 1 and 3 - 6 (45CFR46) can apply to research		
with children or adults.		
Pregnant Women (45CFR46 Subpart B)	X	X
Exempt research is allowable with pregnant women		
Expedited research with pregnant women requires extra considerations (45CFR46.204)		
Prisoners	X	
research with prisoners can not be exempt (45CFR46 Subpart A)		
Normals	X	X
generally healthy adults without physical / mental impairments		
Consent and Waivers of Consent		
Informed Consent	X	
includes all required elements of informed consent, signature required		
Waiver of Consent, if applicable	X	
request to waive entire consent process in some cases (i.e. no consent / no signature required)		
Waiver of Written Consent, if applicable	X	
request to waive signature requirement in some cases (i.e. consent without signature)		
Information Sheet (alternative / shortened consent)	X	X
"alternative" consent (i.e. contains some elements of informed consent, no signature obtained)		
NOTE: Information sheets usually apply to exempt research, but may be used in expedited research with an appropriate waiver of consent.		

http://www.usc.edu/admin/oprs/private/docs/oprs/Expedited_vs_Exempt.pdf

Expedited vs. Exempt

Side by Side Guide to Determine Expedited vs Exempt Review Categories
(note: these are general guidelines, there may be exceptions)

Points to Consider	Expedited	Exempt
Who Can Approve the Study for the IRB?		
IRB Designee	X	X
includes IRB Chair, Vice Chair, Director, or designated members		
IRB Liaison or IRB Staff		X
school / department representatives (liaisons) or the IRB staff		
Research Methods		
Focus groups / Interviews	X	X
anonymity generally allows expedited or exempt		
Voice / Video / Photograph / Recordings	X	X
Involves Deception	X	X
Uses HIPAA identifiers	X	

http://www.usc.edu/admin/oprs/private/docs/oprs/Expedited_vs_Exempt.pdf

Expedited Review

Guidance and Procedure: IRB Review Level – Expedited Review

(last updated April 6, 2012)

Categories of Research That May Be Reviewed By Expedited Review

Protocols may be reviewed via an Expedited review process if they meet the following criteria, as listed in 45 CFR 46.110(b)(1):

- Research poses ***no more than minimal risk to subjects***, as assessed by the reviewer; ***AND***
- Research for which ***each of the procedures falls within one of the DHHS Expedited review categories 1-7*** and the Food and Drug Administration (FDA):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. ***Research on drugs for which an investigational new drug application*** (21 CFR Part 312) ***is not required***.
   NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
   b. ***Research on medical devices*** for which (i) ***an investigational device exemption application*** (21 CFR Part 812) ***is not required***; or (ii) the ***medical device is cleared/approved for marketing*** and the medical device is being ***used in accordance with its cleared/approved labeling***.

Expedited Review

Guidance and Procedure: IRB Review Level – Expedited Review

(last updated April 6, 2012)

Categories of Research That May Be Reviewed By Expedited Review

Protocols may be reviewed via an Expedited review process if they meet the following criteria, as listed in 45 CFR 46.110(b)(1):

- Research poses ***no more than minimal risk to subjects***, as assessed by the reviewer; ***AND***
- Research for which ***each of the procedures falls within one of the DHHS Expedited review categories 1-7*** and the Food and Drug Administration (FDA):

2. ***Collection of blood samples*** by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited Review

Guidance and Procedure: IRB Review Level – Expedited Review

(last updated April 6, 2012)

Categories of Research That May Be Reviewed By Expedited Review

Protocols may be reviewed via an Expedited review process if they meet the following criteria, as listed in 45 CFR 46.110(b)(1):

3. ***Prospective collection of biological specimens for research purposes by noninvasive means***.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Expedited Review

Guidance and Procedure: IRB Review Level – Expedited Review

(last updated April 6, 2012)

Categories of Research That May Be Reviewed By Expedited Review

Protocols may be reviewed via an Expedited review process if they meet the following criteria, as listed in 45 CFR 46.110(b)(1):

4. ***Collection of data through noninvasive procedures*** (not involving general anesthesia or sedation) ***routinely employed in clinical practice***, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited Review

Guidance and Procedure: IRB Review Level – Expedited Review

(last updated April 6, 2012)

Categories of Research That May Be Reviewed By Expedited Review

5. ***Research involving materials*** (data, documents, records, or specimens) ***that have been collected, or will be collected solely for nonresearch purposes*** (such as medical treatment or diagnosis). (**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. ***Collection of data from voice, video, digital, or image recordings made for research purposes***.

7. ***Research on individual or group characteristics or behavior*** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing ***survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies***.

   NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Expedited Review

Guidance and Procedure: IRB Review Level – Expedited Review

(last updated April 6, 2012)

Categories of Research That May Be Reviewed By Expedited Review

8. ***Continuing review of research previously approved*** by the convened IRB as follows:
   a. where (i) the research is ***permanently closed to the enrollment*** of new subjects; (ii) all subjects have ***completed all research-related interventions***; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. ***where no subjects have been enrolled*** and ***no additional risks*** have been identified; or
   c. where the remaining research activities are ***limited to data analysis***.

9. ***Continuing review of research***, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply ***but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified***.

General Restrictions: Expedited review procedures may not be used where

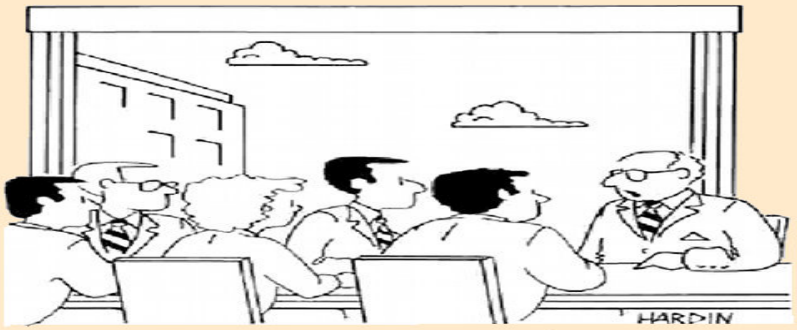
- Identification of the subjects and/or their responses would easily place them at risk of criminal or civil liability or be damaging to the subjects' reputation, financial standing, employability, etc., unless reasonable and sufficient protections will be implemented so that risks related to invasion of privacy and/or breach of confidentiality are no greater than minimal.

Exemption

DHHS Guidelines (45 CFR Part 46.101(b) and (c)) define research as exempt from further IRB review when the research involves no risk to the subject. Research that is considered exempt from Committee review must still be filed with the IRB and screened for exempt status.

Some minimal risk research is exempt from full IRB review. Exemption waives only the need for full IRB review and does not negate the need for the consent of subjects where applicable.

The authority to determine and confirm exempt status rests with the IRB and not with the investigator nor student advisor. Thus, an Exempt Screening Application Form is required for your exemption to be confirmed and granted by the IRB.



http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 1: Investigational Strategies in Educational Setting

Research conducted ineducational settings, involving normal educational practices.

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

1. research on regular and special education instructional strategies, or
2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: This category may be applied to research involving children.

Examples of exempt research:

Evaluating the use of accepted or revised standardized tests
Testing or comparing a curriculum or lesson
A program evaluation of pharmacy continuing education

http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 2: Surveys/Interviews, Standard Educational Tests, Observations of Public Behavior

Research involving the use of educational tests(cognitive, diagnostic, aptitude, achievement),survey procedures, interview procedures or observation of public behavior.

Examples of exempt research:

1. Surveying teachers, nurses, or doctors about a technique or an outcome
2. Interviewing managers about a management style or best practice

Conducting a focus group about an experience or an opinion of a community program

Note: Surveys on sensitive or personal topics which may cause stress to study participants are not exempt from IRB review.

The section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey or interview research involving children.

http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 3: Public Officials, Surveys/Interviews, Educational Tests, Observation of Public Behavior

Research involving the activities in category 2 and the human subjects are elected or appointed public officials or candidates for public office.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

1. the human subjects are elected or appointed public officials or candidates for public office; or
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Examples of exempt research:

Interviewing public officials about a local or global issue

http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 4: Existing Data: Records Review, Pathological Specimens

Research involving the collection or study ofexisting data, documents, records, pathological specimens, or diagnostic specimens.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Examples of exempt research:

Analyzing de-identified tissue samples or data set
Analyzing de-identified national test scores
Analyzing census data about aging or housing

http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 4: Existing Data: Records Review, Pathological Specimens

Research involving the collection or study ofexisting data, documents, records, pathological specimens, or diagnostic specimens.

Examples: Existing Data, Records Review, Pathological Specimens

HIPAA Note: *Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), researchers may obtain access to de-identified health information without the consent of the study subjects. De-identified health information is data that does not identify an individual and reasonably cannot be used to identify an individual. If your research involves de-identified health information, also complete a De-Identification Certification Form along with this application. (See When is data de-identified? on the IRB web site.)*

Pathological or diagnostic specimens which are considered waste and are destined to be destroyed can be used in research and are considered exempt from IRB review if there are no patient identifiers linked to the specimen and if the data is not intended to be used in the diagnosis or treatment of a patient. (If either of these conditions apply, consent of the research subject is required and a higher level of IRB review is required.) Specimens retrieved as "extra" during a clinical procedure require review at a higher level and require written consent from the subject.

Inclusion of fetal tissue in the pathological specimens category of exempt research is prohibited by regulation and requires IRB review.

http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 5: Reserved for Federal Government Research

Not available for local IRB exemptions.

http://www.irb.umn.edu/guidance/exempt.html

Exemption

Category 6: Food Quality and Consumer Acceptance Studies

Taste and food quality evaluation and consumer acceptance studies.

Taste and food quality evaluation and consumer acceptance studies,

1. **if wholesome foods without additives are consumed or**
2. **if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**

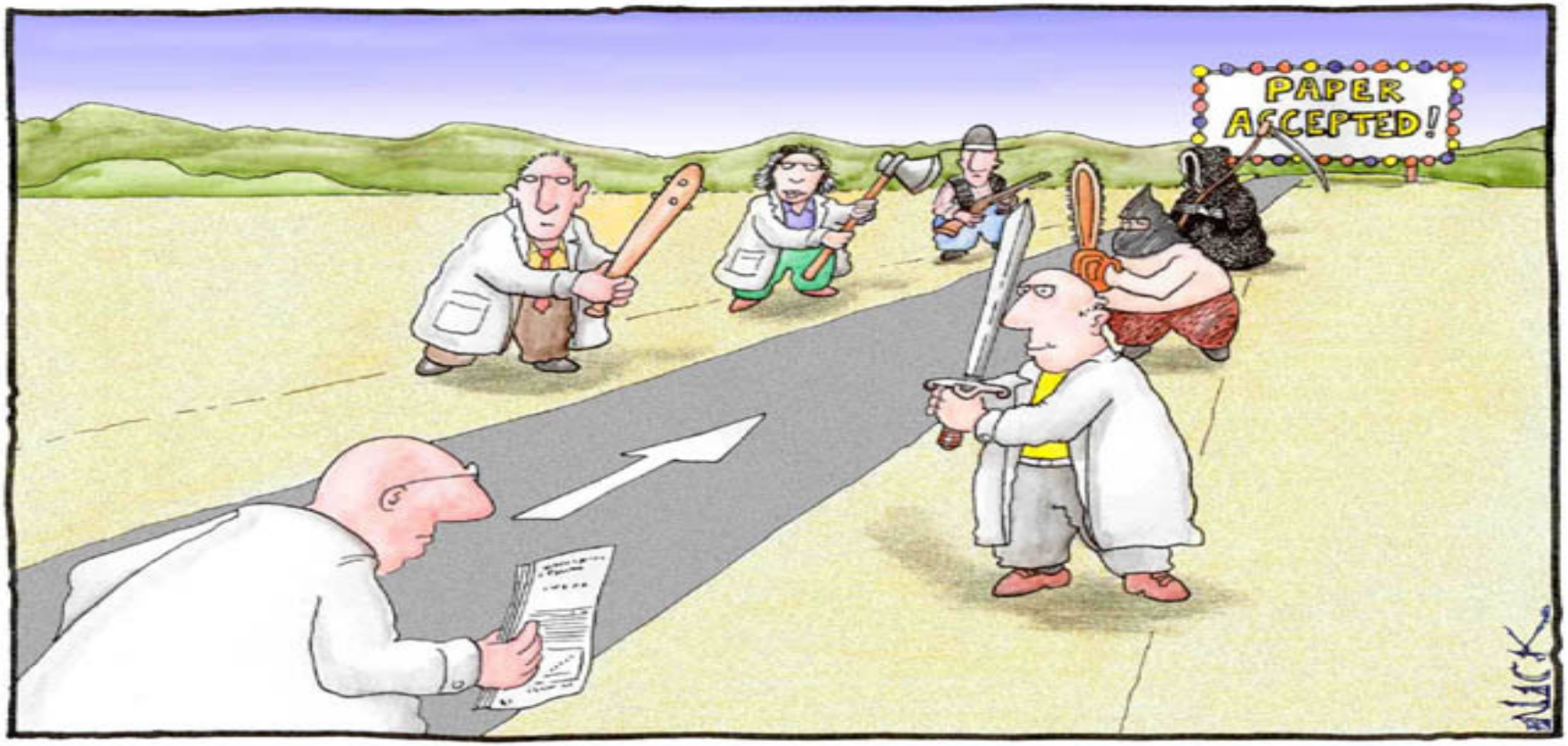
Note: This category may be applied to research involving children; however, University policy requires written parental consent to include children in taste testing studies.

Examples of exempt research:

Taste testing whole grain food products
Comparing taste or smell of molasses, cheese or milk
Sampling texture of ice cream

http://www.irb.umn.edu/guidance/exempt.html

Q & A



Most scientists regarded the new streamlined peer-review process as 'quite an improvement.'