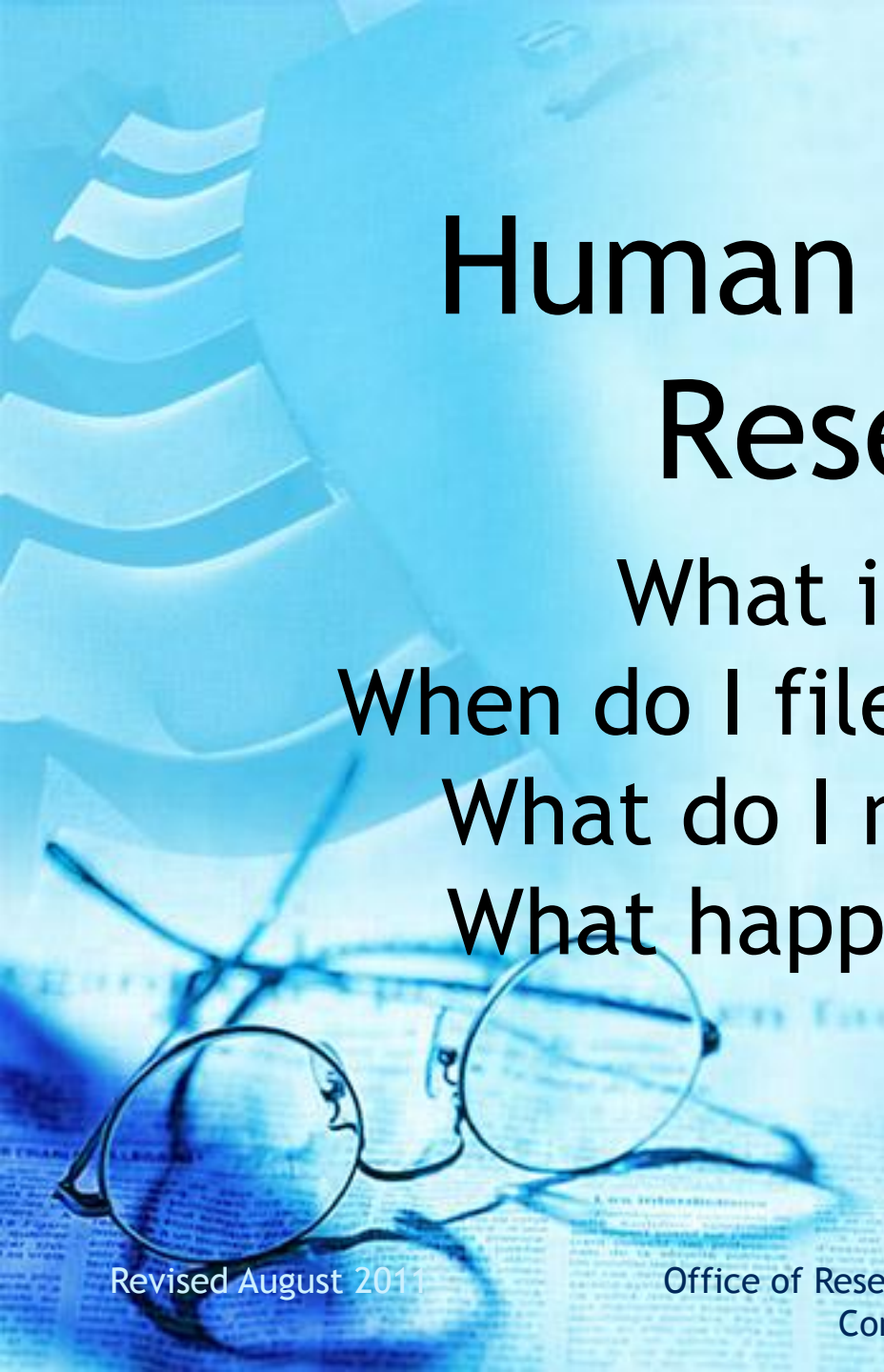
Human Subjects Research

What is the IRB?
When do I file an application?
What do I need to know?
What happens if I don't?



What is the IRB?

- The members of the UT Martin Institutional Review Board (IRB) are listed on the ORGC website www.utm.edu/departments/rgc/irb.php
- The purpose of the IRB is to review human subject research to ensure that human subjects are adequately protected.

Requirements

- At least five members, both genders
- Varied professions, scientific and non-scientific
- Must have one member not otherwise affiliated with UT Martin
- Experience, expertise, diversity
- Sensitivity to community attitudes
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Requirements, continued

- Knowledge of Institutional commitments and regulations, applicable laws, Standards of Professional Conduct
- Knowledgeable and experienced with vulnerable subjects
- Special competencies of Ad Hoc consultants

What does the IRB do?

- Approve, disapprove, or suggest modifications to human subjects research.
- Conduct continuing review.
- Observe, monitor, or audit human subject research.
- Suspend or terminate approval.

IRB Autonomy and Support

The UT Martin IRB has the ultimate approval authority on this campus. Approval by other officials cannot supersede the authority of the university IRB.

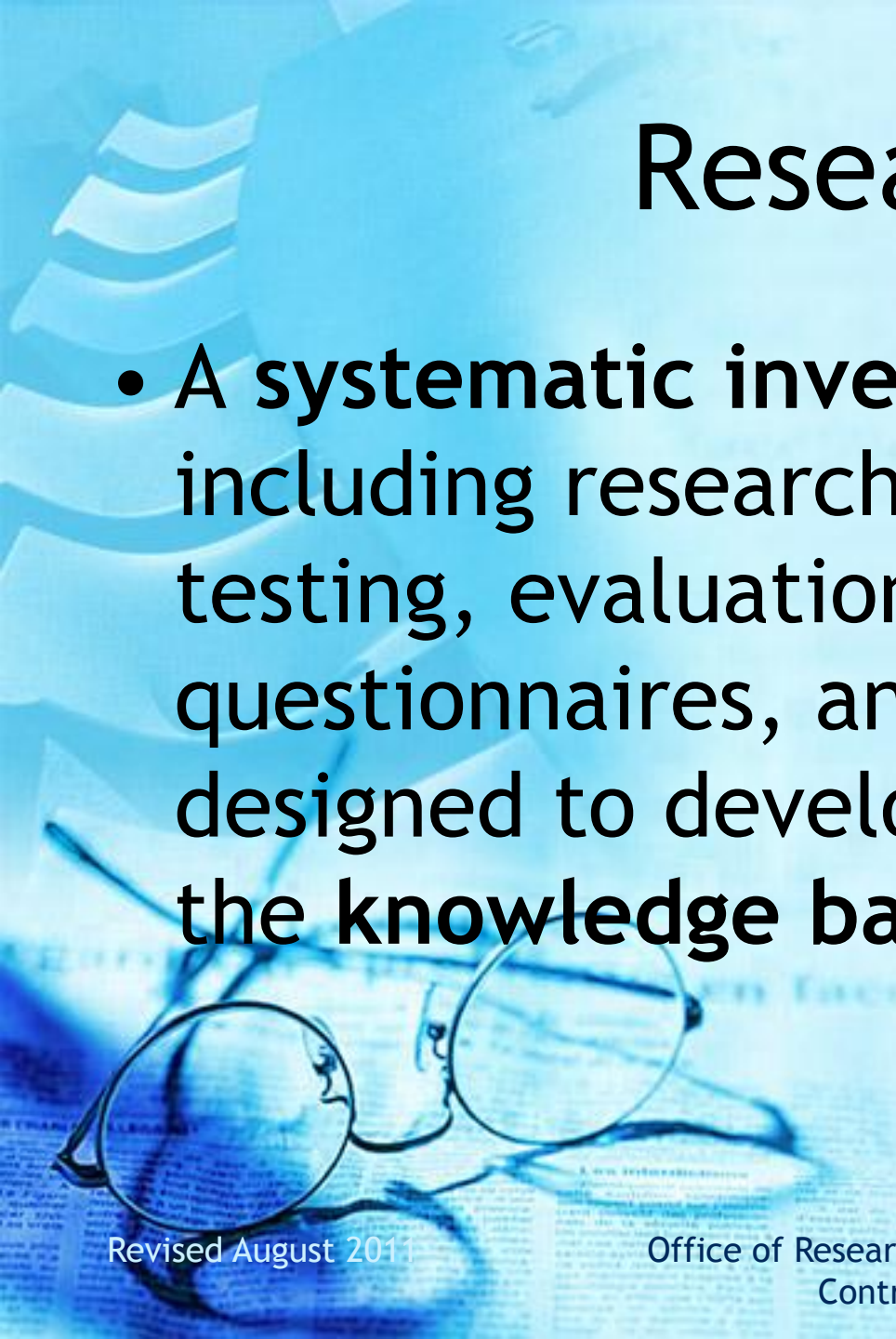
45 CFR 46.112 and 21 CFR 56.11

When must I file an IRB application?

- If you are planning any **research** involving **human subjects**, you **must** file an IRB application and receive IRB approval **before** you begin to collect any data.
- This takes time.

Research?

- A **systematic investigation**, including research development, testing, evaluation, surveys, questionnaires, and/or interviews, designed to develop or contribute to the **knowledge base**.

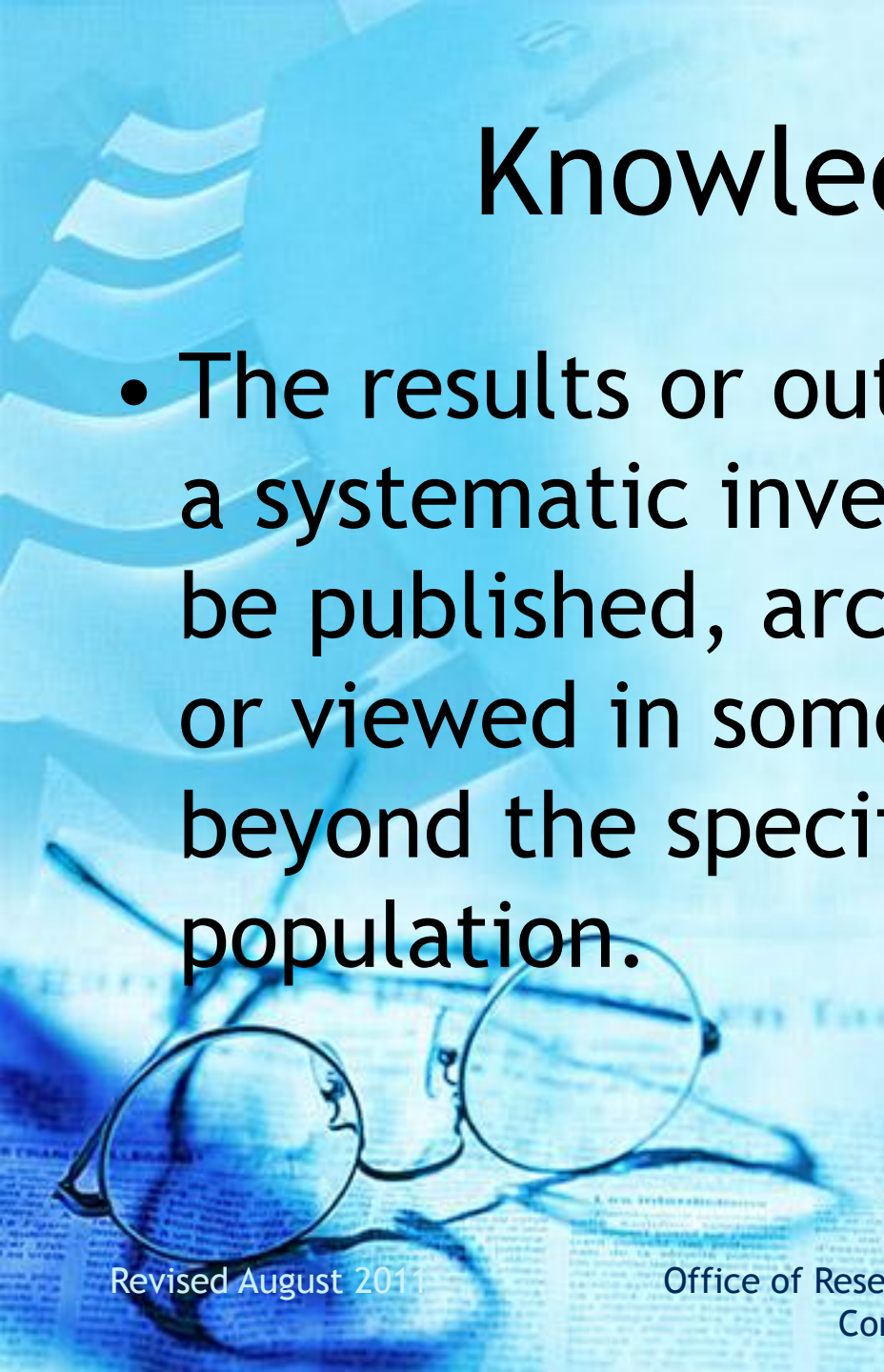


Systematic investigation?

- A cohesive approach involving data collection (quantitative and/or qualitative) from one or more individuals for analysis to address a question or test a hypothesis.

Knowledge base?

- The results or outcomes gained from a systematic investigation that may be published, archived, presented, or viewed in some way as relevant beyond the specific participant population.



Questions to consider

- Is there a chance this activity will lead to a publication?
- Will the results be presented in a professional forum?
- Will the results be archived?
  - If human subjects are involved and you answer yes to any of these questions, this research is subject to IRB review and approval.

Human Subjects?

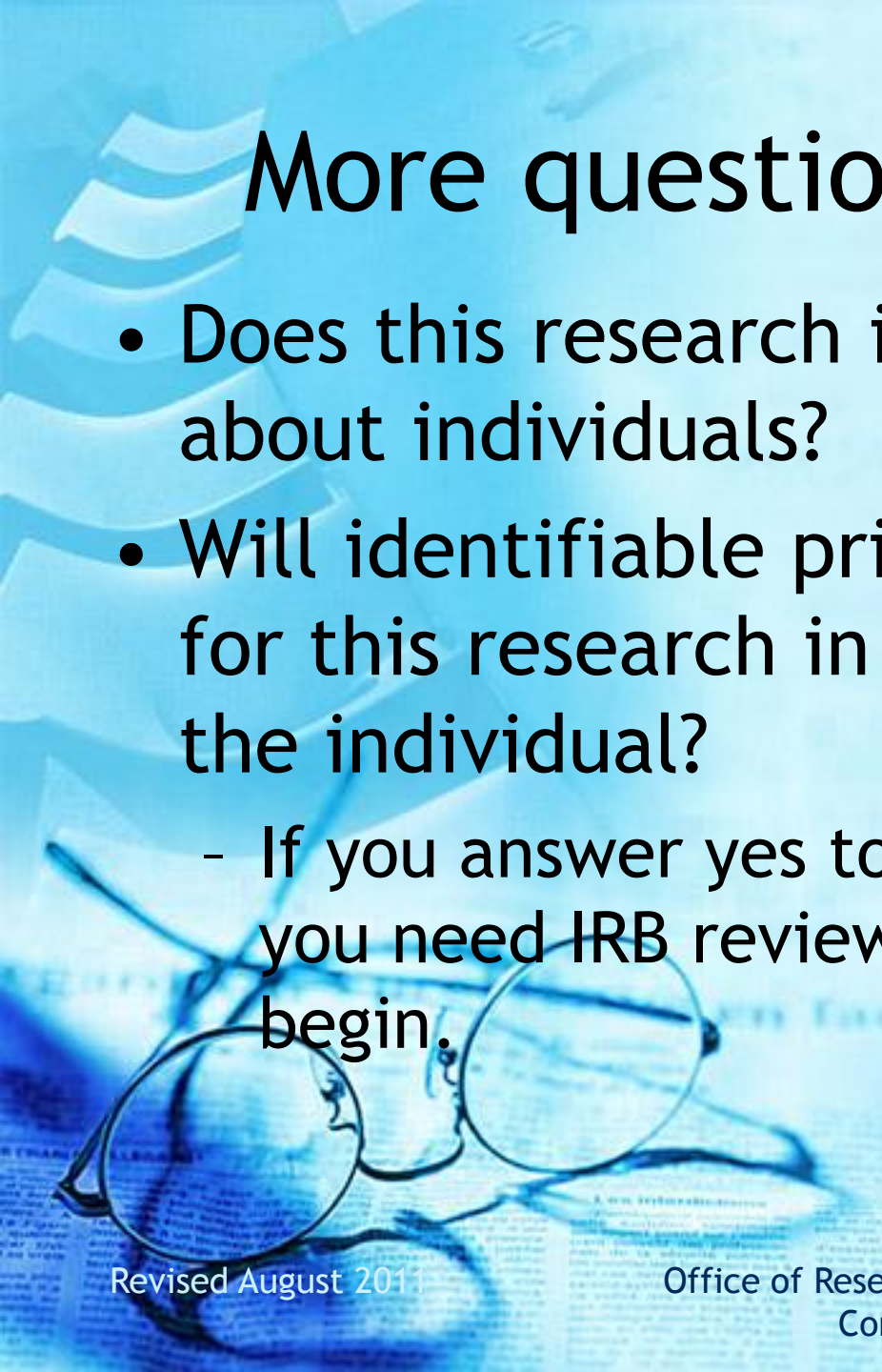
- A living individual about whom an investigator (whether professional or student) conducting research obtains:
  - data through intervention or interaction with the individual, or
  - identifiable private information

Questions to consider

- Does the research project involve an interaction with a living person (face-to-face, by mail, by phone, by email, etc.)?
- During this interaction, will you seek data about the person (i.e., behavior, beliefs, experiences, medical or economic status?

More questions to consider

- Does this research involve archival data about individuals?
- Will identifiable private data be obtained for this research in a form associable with the individual?
  - If you answer yes to any of these questions, you need IRB review and approval before you begin.



What about student research?

- Will the research be conducted outside the classroom or off campus?
- Do the results **have potential** to be published or presented outside the classroom or off campus?
- Is the activity **defined as a research project** with a research question or hypothesis?

Class-related Projects that require IRB approval

- All master's thesis and research projects involving human subjects
- All projects for which findings may be published or otherwise disseminated
- All class-related projects for which the data collected will be archived for any purposes other than administrative evaluations

Points to consider

- Since publication will require consent of the participants, it is prudent to seek IRB review of the consent form and other project materials in advance if there is *any* chance of publication later.
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Points to consider, continued

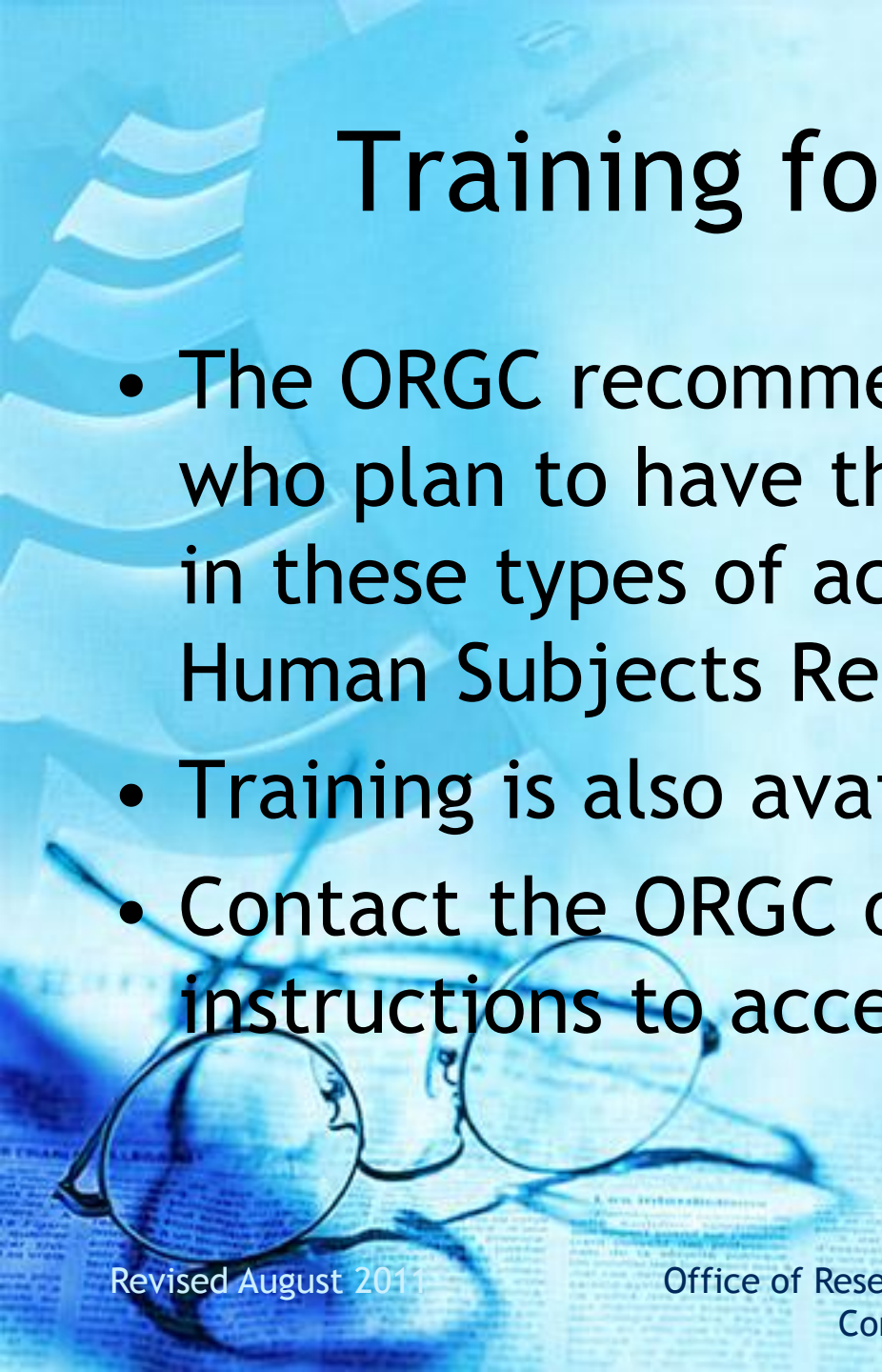
- If a student developed an exemplary research plan and collects data that is impressive enough that the instructor would like to use it as an example for subsequent projects, this would be archived and subject to IRB approval before it could be used.
- Without IRB approval, these data must be destroyed and cannot serve as an example.

Other classroom-related activities

- Course activities that involve human participants, but have no connection to research beyond the instructional function do not require IRB review.
- The collection of information from respondents for the purpose of class discussions or for the purpose of training in research or research methods **does not** require IRB review.
- In these situations, **instructors are responsible** for the protection of human subjects

Training for instructors

- The ORGC recommends that instructors who plan to have their students involved in these types of activities complete Human Subjects Research training.
- Training is also available for students.
- Contact the ORGC office (881-7015) for instructions to access to this training.



Student-involved research

- All student-involved research at UT Martin, involving human subjects, is classified as Expedited or Full Review.

Why do I need to file an IRB application?

- **Ethical research practices demand it.**
- **Federal regulations require it.**
- All human subjects research **must** have **prior** IRB approval.
- A "Federal-wide Assurance" binds UT Martin to uphold ethical and regulatory requirements in human subject research, regardless of funding.

Why?

- There have been instances in the past where researchers, some of whom had the best scientific intentions, did not protect their human subjects.
- Irrevocable harm and deaths resulted.

Some examples

- Nazi Medical Experiments of WWII
- Dr. Joseph Mengele and the Nuremburg Trials
- Japanese large scale human "experiments"
- Tuskegee Syphilis Study, 1932 – 1972
- Willowbrook State School, 1956 – 63
- San Antonio Birth Control Clinic, 1971

Additional examples

- Phocomelia birth defects, 1950's – 60's
- Milgram Experiments on Obedience to Authority, 1960's
- Jewish Chronic Disease Hospital, 1963
- Human Radiation Experiments, 1940's – 1970's

Remember

"Ethical lapses are almost never cases of bad people doing bad things, for no good reason. More often they are good people, doing bad things, for good reasons."

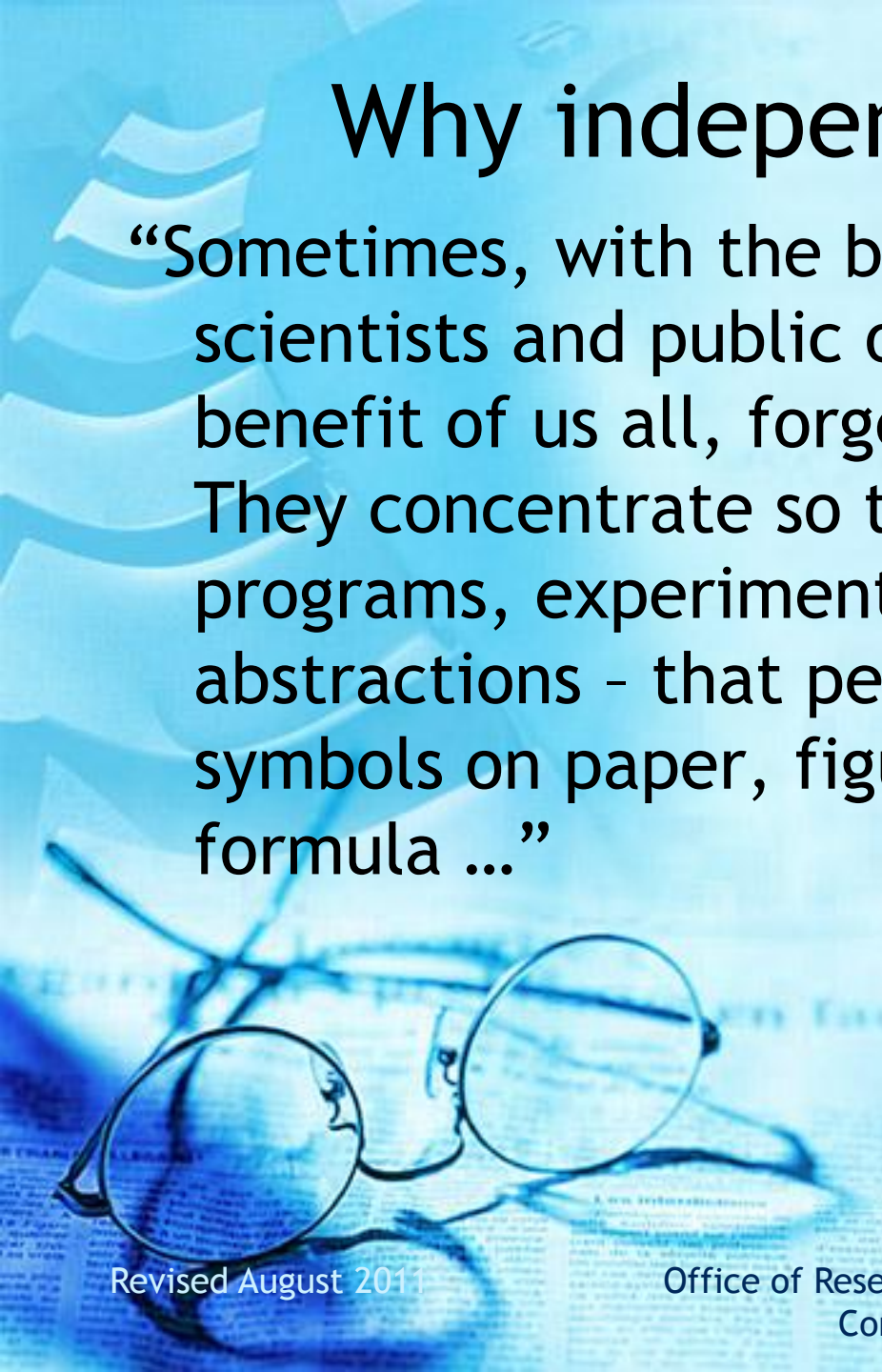
loosely quoting Marcia Angell, MD

(former) Editor-in-Chief, NEJM

Why independent review?

"Sometimes, with the best of intentions, scientists and public officials … working for the benefit of us all, forget that people are people. They concentrate so totally on plans and programs, experiments, statistics, - on abstractions – that people become objects, symbols on paper, figures in a mathematical formula …"

Atlanta Constitution, July 27, 1972



The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Respect for Persons

Beneficence

Justice

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979

Respect for Persons

- Treat individuals as autonomous agents.
- Don’t use people solely as a means to an end.
- Allow people to choose for themselves.
- Recognize a fundamental right to be left alone.
- Extra protections for vulnerable populations.
- **Practical applications:** informed consent and privacy protections.

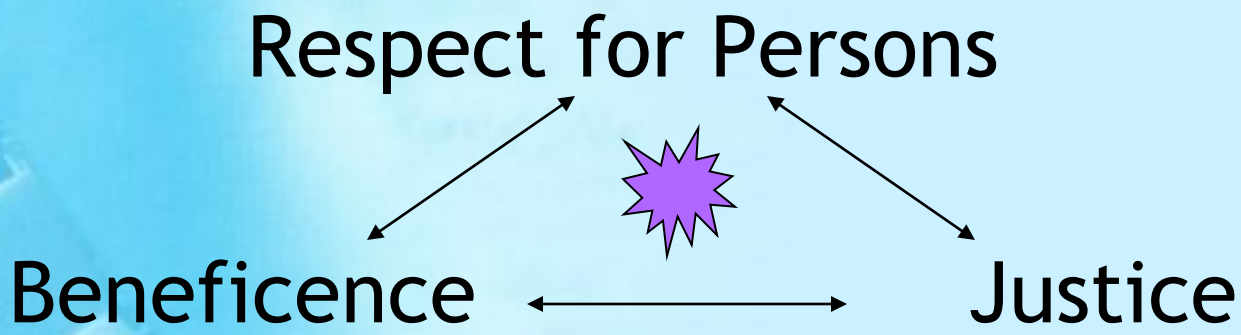
Beneficence

- Maximize benefits.
- Minimize risks.
- **Practical applications:** study design, risk-benefit analysis, competent investigators.

Justice

- Burdens and benefits of research should be distributed equitably.
- Treat people fairly.
- **Practical applications:** selection of subjects, recruitment, populations under study.

Conflict Among Ethical Principles



- Principles carry equal moral weight.
- Tension was anticipated and expected.
- Requires subjective judgment calls.
- Reasonable people will disagree.

"Common Rule"

- Federal policy for the Protection of Human Subjects
  - June 18, 1991
  - Adopted by 21 federal agencies
- Based on a system of assurances

Additional Protections for Vulnerable Populations 45 CFR 46

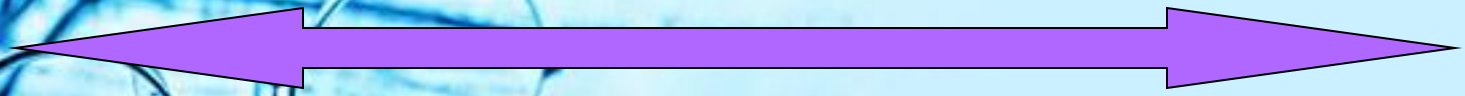
- Subpart B: (1975, 2002) Fetuses, pregnant women, and in vitro fertilization
- Subpart C: (1978) Prisoners
- Subpart D: (1983) Children
- Subpart E: (Proposed) Mentally disabled

Review Continuum

Level of risk determines
Route of Review

Exempt Expedited Full

Low Minimal Higher



Risk

Assessment of minimal risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Consider these risks

- Not just physical risk, but also
- Criminal/civil liability
- Financial risk
- Employment risk
- Stigmatization
- Insurability
- Embarrassment

Exempt

"If I think my research is exempt, then I don't have to do anything, right?"

Wrong!!!

Exempt does not mean "exempt from review." It means exempt from ***Full Review***.

“Exempt” Research

- Six categories, defined by 45 CFR 46 (32 CFR 219.010)
- Research must fall into one or more of the categories to be exempt.
- Researchers must fully explain their selection of category in their application.
- May still require consent and other safeguards.

Exemption Categories

1. Educational research
2. & 3. Tests, surveys, interviews or public observations
4. Research on existing public or anonymous data or specimens
5. Federal demonstration projects
6. Taste and food evaluations

Check the Handbook on the ORGC website for limitations and extra circumstances that may apply.

Some examples of Exempt

- Studies of normal educational practices in commonly accepted educational settings.
- Research involving educational tests or passive observation of public behavior that is anonymous or benign.
- Research involving surveys or interviews of adults that are anonymous or benign.

IRBs may still determine

- The study has more than minimal risk, so it cannot be exempt.
- State or local laws may prohibit an exemption.
- Exempt studies may still need consent.
- Exempt studies may have ethical concerns.

Expedited

"Okay, if my research is not exempt, the IRB can expedite it. This is quick, right?"

Not necessarily.

Expedited Review

- Expedited does not mean quicker.
- Rigor of review is the same as full review, number of reviewers is different.
- Review is carried out by IRB Chair and the IRB secretary.
- Both reviewers must agree to approve or the application will be sent to the full committee for review.

Initial Expedited Review

- Clinical studies where IND/IDE are **not** required
- Blood sample collection (small amounts, routine methods)
- Prospective collection of biological samples – noninvasive means
- Data collected through noninvasive means (routinely practiced in clinical settings)
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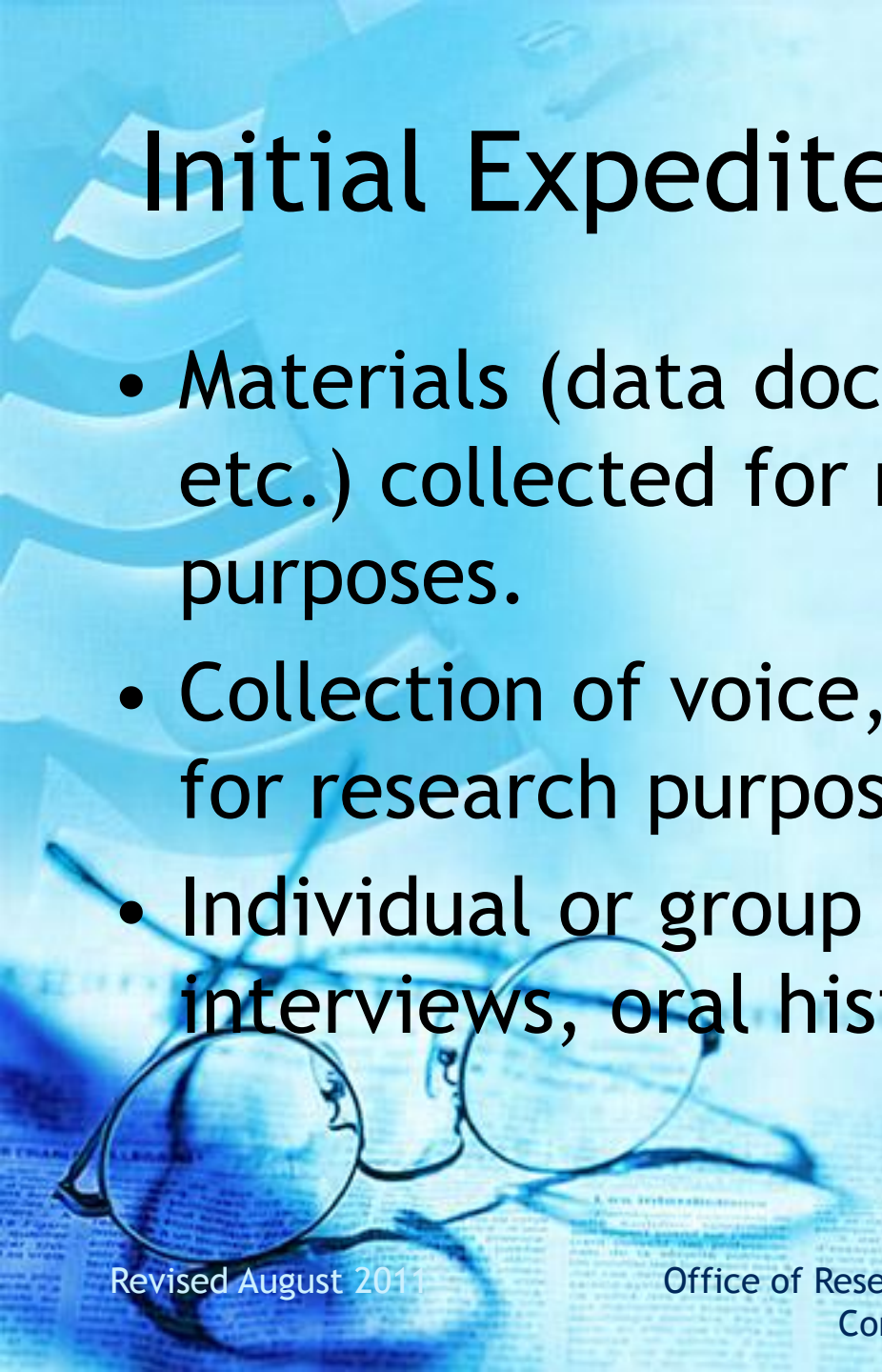
Initial Expedited Review, cont.

- Materials (data documents, specimens, etc.) collected for non-research purposes.
- Collection of voice, video, or digital data for research purposes
- Individual or group behavior, surveys, interviews, oral histories



Continuing Expedited Review

- Continuing review of research with no further direct subject participation
- Continuing review of minimal risk research (not under IND or IDE) where no additional risks have been identified.

Cautions

- Expedited does not mean cursory; documentation of substantial review is essential.
- If there are any questions, UT Martin will err on the side of full review.

Full Review means

- A full quorum is assembled (at least half of the members).
- All members participate in discussion and make comments (plenary review).
- Decision is rendered by a majority of the assembled quorum.
- No member with a conflict of interest participates in the decision.
- Numerical vote is taken and recorded.

Criteria for Approval
45 CFR 46.111

- Minimized risks (not eliminated)
- Reasonable risk/benefit assessment
- Equitable subject selection
- Informed consent process
- Informed consent documentation
- Data monitored for safety
- Confidentiality/privacy maintained
- Vulnerable populations protected.

What if I don't file an IRB application?

- Your ethics may be called into question.
- You may be subject to a Misconduct of Research and Service investigation.
- Your papers or presentations may be pulled from publication or program proceedings due to the absence of IRB approval.
- Grant funding may be denied.

Implications for UT Martin

- Failure to have and follow appropriate procedures for IRB review and approval can also result in federal investigations and sanctions for the university.

Other considerations that may apply

If you are involved in human subjects research

- with another university or organization or
- in an international venue,

there are additional considerations and/or procedures that may apply.

Contact the ORGC to discuss these.

Remember

- The Principal Investigator has ultimate responsibility for ethical conduct.
- Respect the time and process necessary for review. **IRB approvals are not retroactive.**

Also consider

- The IRB is there to assist by raising issues and asking questions that the PI may have overlooked or failed to consider.
- The researcher and the IRB should be considered collaborators.

Further information

Additional information can be accessed from the UT Martin Office of Research, Grants, and Contracts website: www.utm.edu/departments/rgc/irb.php

- Information concerning the UT Martin IRB,
- the UT Martin *Faculty, Staff, and Student Handbook for Studies Involving Human Participants*,
- definitions,
- the forms needed to file an IRB application,
- instructions for completing the application

Recommended Training

- UT Martin subscribes to an approved online training program regarding Human Subjects Research
- This online training is available at no cost to faculty, staff, and students of UT Martin
- Contact the UT Martin ORGC for information on access to this training