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Welcome to

Research Ethics in PPIE and Participatory Research

Presented by

Dr Steph Grohmann

Senior Program Manager Research Ethics and Inclusion

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Outline:

- What is research ethics and why do we need it?
- Some principles of research ethics
- Different understandings of research ethics
- Does PPIE/participatory research need ethics?
- Potential ethical pitfalls to consider in PPIE/participatory research
- Mini ethics checklist for PPIE/participatory research
- Where can I get support for my PPIE study/formal ethics review?
- Space for comments and questions

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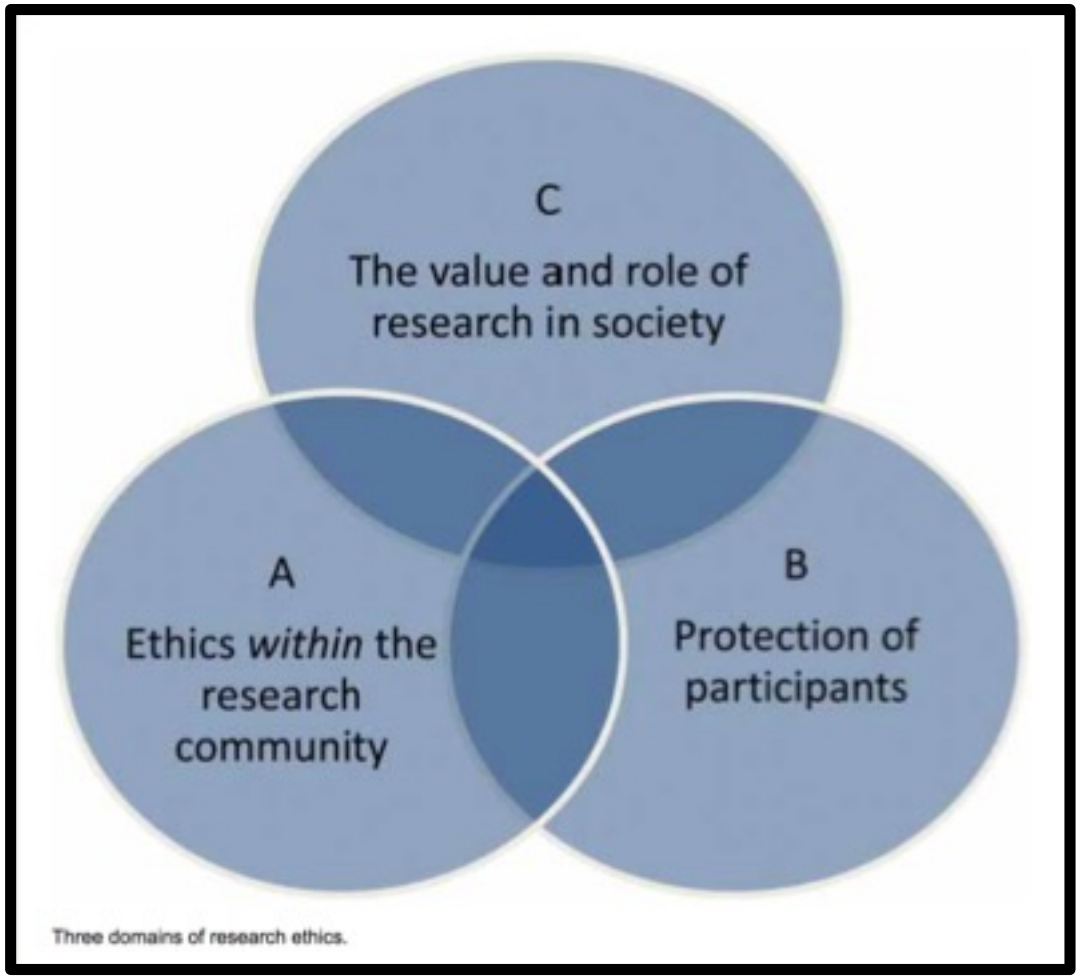
What is ‘research ethics’?

A) General conduct expected of scientists ‘re plagiarism, data falsification, conflict of interest… (a.k.a “research integrity”)

B) Ethics in research with human participants: how to not harm the people your research is about/for

C) The responsibility of science towards society: how to use public funds, make results applicable, avoid social harm



Three domains of research ethics.

Image credit: Reidun Tangen via Researchgate

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Why do we bother?

The history of (especially medical) research is a history of human rights abuses and the exploitation of vulnerable groups

Examples:

- Early vaccine studies
- Nazi experimentation
- Studies on enslaved people
- Racist science (e.g. Tuskegee study)
- Psychiatric interventions (e.g. lobotomies)
- Psychological experiments (Stanford Prison Study, Milgram Experiment…)

The Nuremberg doctor's trial, public domain

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.
   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the
   experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.]

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General principles…

- Informed Consent
- Beneficience and non-maleficience
- Respect for Persons
- Confidentiality and data protection
- Conflict of Interest
- Social Justice

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…and some not so general ones

- Reflexivity
- Epistemic/cultural/moral relativism
- Cultural and intellectual property
- Anonymity vs. Recognition
- Trauma-informed approaches
- Political economy considerations

…

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One ethics – or many?

In practice, ‘research ethics’ can refer to:

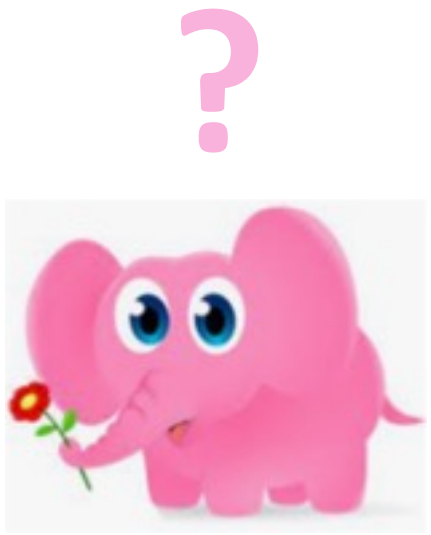
- **Institutional ethics procedures** (law-oriented, bureaucratic, ‘box-ticking’)
- **Professional ethics** systems in different disciplines (reflexive, qualitative, adaptive)
- **General ethics** (socio-culturally specific)

These levels **<u>can and do come into conflict</u>**!

Examples:

- Rigid bureaucratic procedures vs. the needs of culturally specific human subjects
- Legal liability vs. moral responsibility
- Managerial university governance vs. freedom of science

And: ‘for-profit’ science produces **inherent institutional conflicts of interest**



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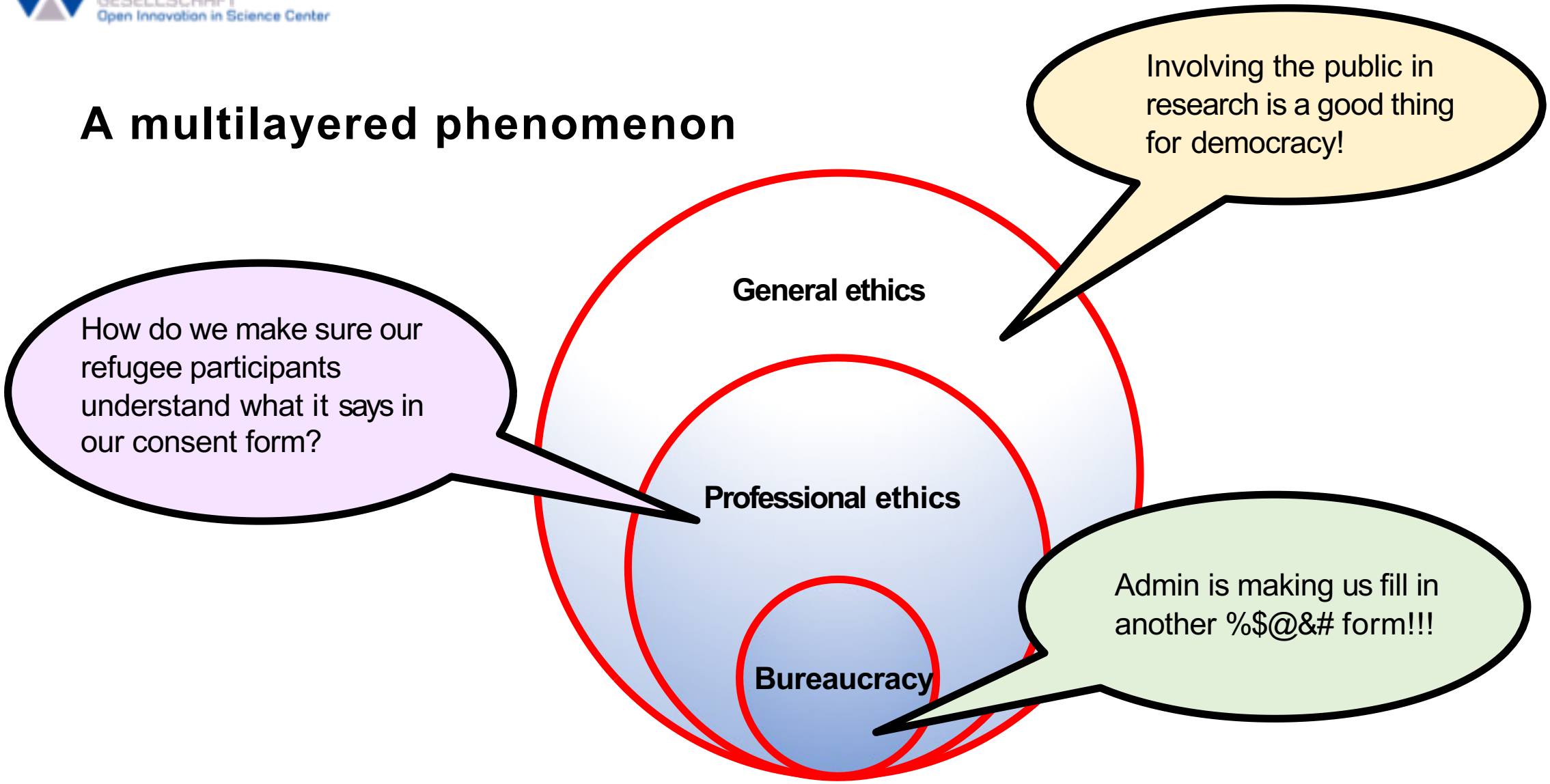
A multilayered phenomenon



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Is there an 'Ethics of PPIE'?

- "The rationale for PPI includes a moral/ethical dimension, based on the argument that those who have lived experience of the phenomenon being researched (eg., a health condition) should also have a voice in related research" (Kaisler et. al. 2021)

- "Currently, there is no requirement for formal ethical scrutiny of processes for engaging and collaborating in this way. This may leave researchers in a position where they unwittingly fail to consider in full the needs, capacity, level of involvement and required resources prior to approaching or working with PPIE
  members" (Troya 2019)

- "How, then, can we liberate from a disproportionate ethics regime this family of approaches to intervention design which have many goals and methods in common? How can we avoid constructing people as vulnerable participants rather than partners, with agency?" (Locock and Boaz 2019)

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Does PPIE need ethics review?

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Patient & Public / Resources for Researchers / Frequently Asked Questions / Do I need ethical approval to run an involvement activity?

Do I need ethical approval to run an involvement activity?

IN THIS SECTION

- Patient & Public
- What is Patient and Public Involvement and Public Engagement?
- Aims and Strategy
- Evidence

You do not need ethics to conduct an involvement activity. Patient and public involvement should inform research questions or research design with Public and Patient (and carer) opinions. If you are not sure if your activity counts as involvement or research, use the Health Research Authority tool.

If you are collecting opinions rather than study data, your activity is likely an involvement activity. For example, asking for feedback on a questionnaire counts as involvement as long as you do not ask for or record the public contributor's responses to the questions, but their opinions on the suitability/wording of the questions.

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So…does PPIE need ethics review?

- In Austria, only **experimental medical studies have a legal requirement** for ethics review
- Medical ethics committees often **decline review for non-experimental methodologies** as this is not their area of expertise
- **Timeline collisions:** involvement often starts at the design stage, but ethics review comes later
- Guidance from many internationally **leading institutions** in health research exempts PPIE from ethics review

But:

- There is **mounting criticism** about PPIE/participatory research being an ethical 'Wild West'
- **Publishers and funders** increasingly want to see proof of ethics review for ALL activities involving human participants

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Challenges for ethics practice in PPIE research

- **Different understandings** of what we mean by 'ethics' lead to conflicts
- Different **institutional and research cultures** don't always translate between international contexts
- Institutional **timeframes and remits** do not map well onto PPIE contexts
- Lack of **clear guidance**: what to look out for in PPIE research?
- Some **ethical pitfalls** are specific to PPIE research

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Potential pitfalls

1) Participation becoming a ‘fig leaf’ to avoid bureaucracy
2) Lack of oversight over ethical treatment of co-creators
3) Lack of redress for participants in case of complaints
4) Potentially less care ‘re data protection/anonymity
5) Blindness to socio-cultural power differentials
6) Lack of reflection on potential harms through involvement (e.g. trauma)
7) Lack of reflection on economic aspects of collaboration (‘yay, free labor!’)
8) Lack of reflection about participant’s own perspective

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How not to ethics 1:

‘The Noble Savage’…

- 19th century colonial idea that indigenous people are ‘**pure, good and child-like’**, unlike Westerners
- Jean-Jacques **Rousseau**: only the “uncorrupted savage” can be truly virtuous
- Famous example: **Robinson Crusoe** and ‘Friday’
- But: **Positive stereotypes are still stereotypes**
- **Othering and homogenizing** ANY community is the first step towards dehumanizing them

Illustration for ‘Robinson Crusoe’, public domain

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…to 'The Noble Patient'?

"Patients/participants are always pure and good and have only the best interests of science/society in mind. Any patient is as good as any other, so I'll just go with the low hanging fruit to save time".

But:

- Patients/participants **do not all think and feel alike**. Sometimes they disagree profoundly among each other. Some patient communities are in an ongoing state of conflict (e.g. various disability communities over 'cure vs. acceptance' debates).

- Patients/participants are individuals, **subject to bias, personal preference and prejudice** – just like us.

'Respect for persons' also means resisting the temptation to 'other' and/or homogenize participants

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How not to ethics 2:

‘Goodbye and thanks for all the scientific capital!’

Thanks to neoliberalism, scientific careers demand the accumulation of social capital in form of publications, citations, and other ‘performance indicators’. Our participants are helping us to do this. They contribute:

- **social capital**: contacts, community access, credibility
- **knowledge capital**: data, skills, experience
- **cultural capital**: insights into the life-worlds of research consumers/beneficiaries
- **ethical capital**: their participation makes us look better to funders and publishers

We owe it to them to consider what constitutes fair compensation for this investment in our work. This can include material rewards as well as public recognition.

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How not to ethics 3:

‘How were we supposed to know this would upset them?’

- All participatory research, but especially research involving patients, poses a **risk for distressing or traumatic material** to surface
- This is even more likely when working with **marginalized or vulnerable groups** and their loved ones
- We cannot know in advance what exactly may cause distress to our participants, but we can **think about what is likely to,** especially in terms of responses to illness and suffering
- We should be prepared for the eventuality of a crisis by having a **trauma response plan**, e.g. including a process to refer participants to psychosocial emergency services

Participatory research on illness and other distressing topics needs to be trauma-informed and have a risk-mitigation strategy in place

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How not to ethics 4:

‘…but we did everything the ethics committee asked for!’

In the early 1900s, **Walter Reed** (USA) conducted experiments to determine the cause of yellow fever.

He exposed Spanish immigrant workers in Cuba to the disease. Participants were promised **$100 (ca. $3500 today)**, twice that if they developed symptoms.

Six participants died, including **two researcher-volunteers** (Reed himself declined to self-experiment).

The participants **all signed consent forms**, some translated into Spanish. Reed’s study today counts as the first use of consent forms in medical history.

Image: public domain

Bureaucracy does not replace a conscience

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Our support services

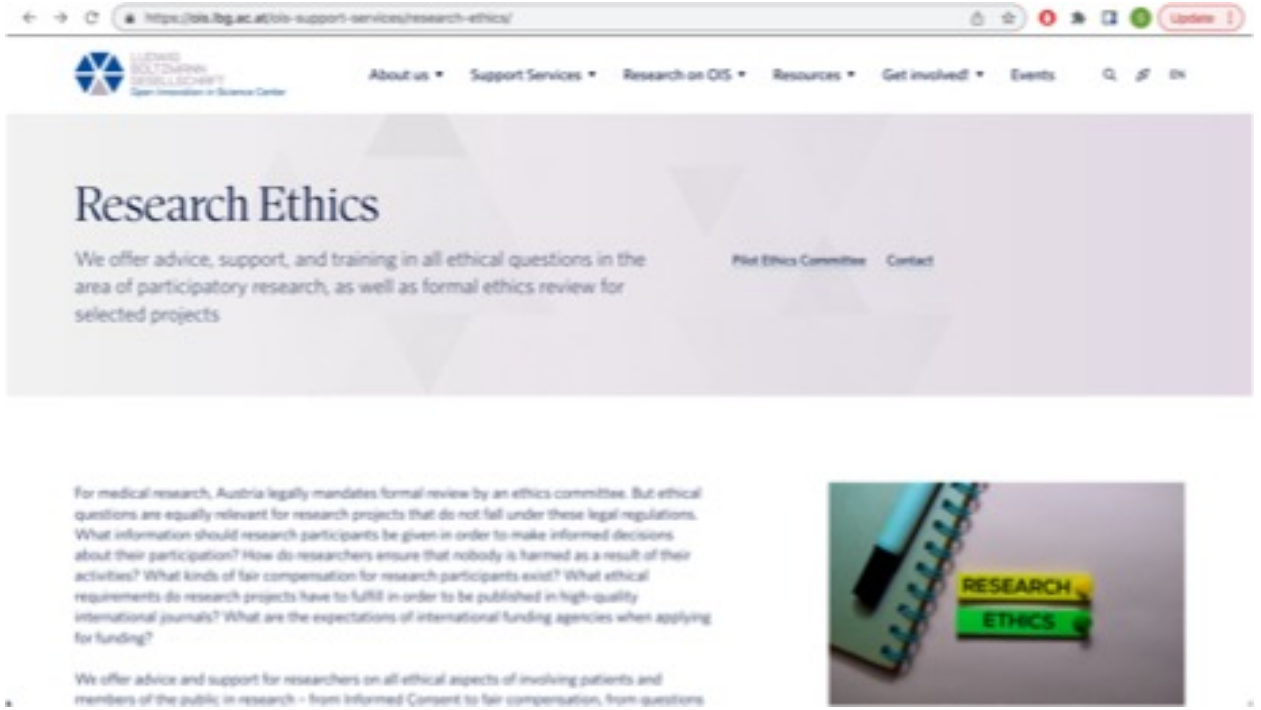
The LBG OIS Center offers **advice, support and training** on all things research ethics

Troubleshooting available any time

We’re always happy to answer your questions:

ethics@lbg.ac.at

steph.grohmann@lbg.ac.at



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Key takeaways:

- Research ethics is a **multidimensional and contested** set of practices
- PPIE/participatory research is **not an ethics-free zone**
- ‘Patients/participants’ are **individual persons**, not a homogenous mass
- Participation is a **contribution to our livelihood** and should be honored as such
- Participatory research must be **trauma-informed and risk-aware**
- **Bureaucracy** can help to monitor ethics but it **does not replace a moral compass**
- The **LBG OIS Center** is here to help!

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Thank you!!!

"These new regulations will fundamentally change the way we get around them."