

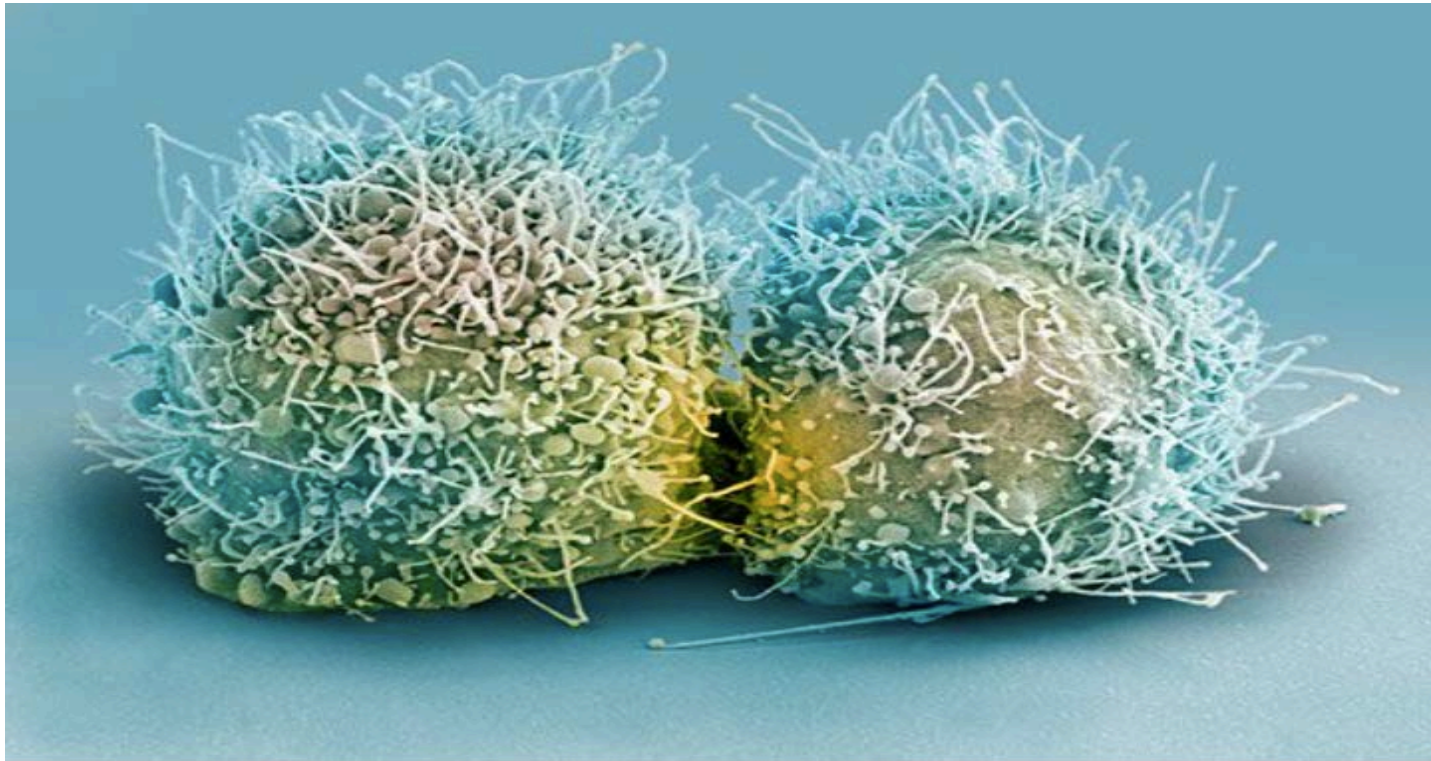
Inclusion of residual tissue in biobanks: opt-in or opt-out?

Noor Giesbertz

PhD medical ethics

Clinical geneticist in training

n.giesbertz@umcutrecht.nl



A HeLa cancer cell dividing. (© Dr. Thomas Deerinck / Visuals Unlimited / Corbis)



Rebecca
Skloot

THE
IMMORTAL
LIFE OF
HENRIETTA
LACKS



In 1951, a young woman from Baltimore died of cancer.
Her death changed medical science for ever.

Beskow. *Annu. Rev. Genom.
Hum. Genet.* 2016



Background (1)



- Opt-in or opt-out method to include residual tissue in biobanks?
- Biobanks: collection of human biological samples stored for biomedical research purposes
 - Also applicable to the samples stored in our diagnostic lab, if they are used for research
- Residual tissue: tissue that was taken in the course of clinical care and is leftover



Background (2)

- Informed consent: enable a person to make voluntary decision about participation in research with sufficient understanding
- Content and process
- Content: e.g. specific consent, broad consent
- Opt-in / opt-out: refers to the process of a consent procedure



Background (3)

- Opt-in: a person explicitly expresses consent
- Opt-out: inaction is treated as a signal of consent



Opt-out: scientific advantages

- Low refusal rates
 - include more samples
 - cost-efficient



Johnsson et al 2008 BMJ 337: a345; Rebers et al. 2016 PLOS ONE 11 (3)



Opt-out: grounded in a moral duty (1)

- Aim of biomedical research is to generate biomedical knowledge, which is beneficial to us all and may prevent serious harm
 - moral duty to participate in biomedical research
 - principles: beneficence, solidarity, reciprocity
- Residual tissue: low risks and burdens
- Inclusion the starting point

*Harris 2005 J Med Ethics 31; 242-248; van Diest 2002 BMJ325: 648-651;
Chadwick, Berg 2001 Nat Rev Genet 2: 318-321; Giesbertz et al. 2012 PLoS Biol 10(8)*



Concern (1) respect for autonomy

- Including samples from people without them knowing, and for some against their wishes
 - no respect for autonomy
 - harm people
- Depends on how the opt-out procedure shaped
 - sufficiently informed
 - make a choice whether they want to participate or not



Thick opt-out (opt-out plus)

1. Awareness is raised among people about inclusion of residual tissue as the default position
2. Adequate information is provided
3. A genuine possibility to object is presented and objections are adequately registered



To summarize

- Opt-out procedure
 - scientific advantages
 - justification in moral duty to participate primarily because of the low risks and burdens
- Respect for autonomy implies certain conditions



To summarize

- Opt-out procedure
 - scientific advantages
 - justification in moral duty to participate primarily because of the low risks and burdens
- Respect for autonomy implies **certain conditions**



Concern (2) low risks and burdens?

- Wide variety of research and diversity of samples
- Weaker moral duty
 - Higher risks and/or burdens, consider e.g. broad genetic testing WGS (unsolicited findings)
 - Sensitive tissue/cells/techniques, e.g. immortal cell-line
 - ...



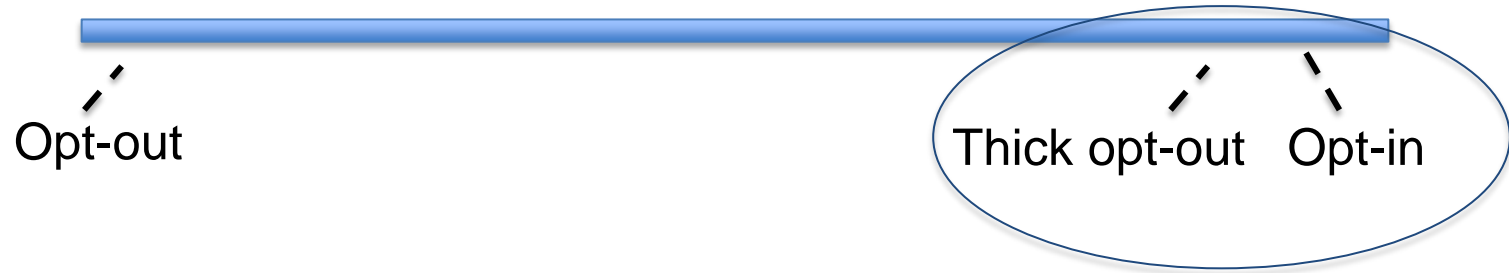
Concern (2) re consent

- Inclusion → storage → usage
- Sample included with thick opt-out broad consent
“your leftover tissue is used for biomedical research unless you object”
- Reconsent for specific higher risk study
“can we use your stored tissue for a WGS study...”



To conclude

- Opt-out procedure
 - Only when conditions are fulfilled



My opinion

