

# An informed donor should be allowed to donate

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**Peter Reese, MD, MSCE**

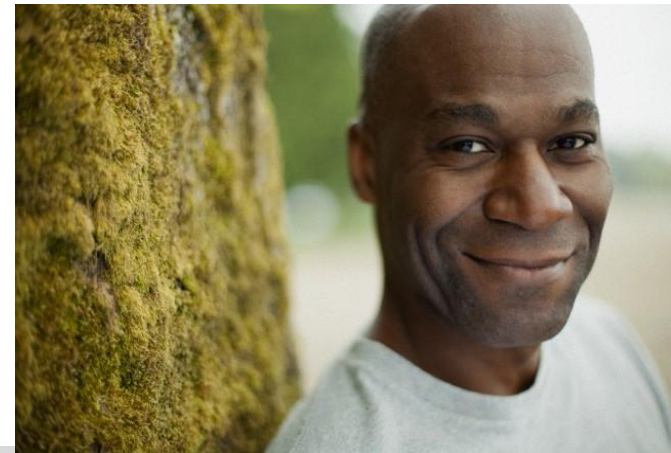
**Assistant Professor of Medicine & Epidemiology  
Chair, United Network for Organ Sharing  
Ethics Committee**



I have no conflicts of interest  
relevant to this talk

# Cases that keep me up at night

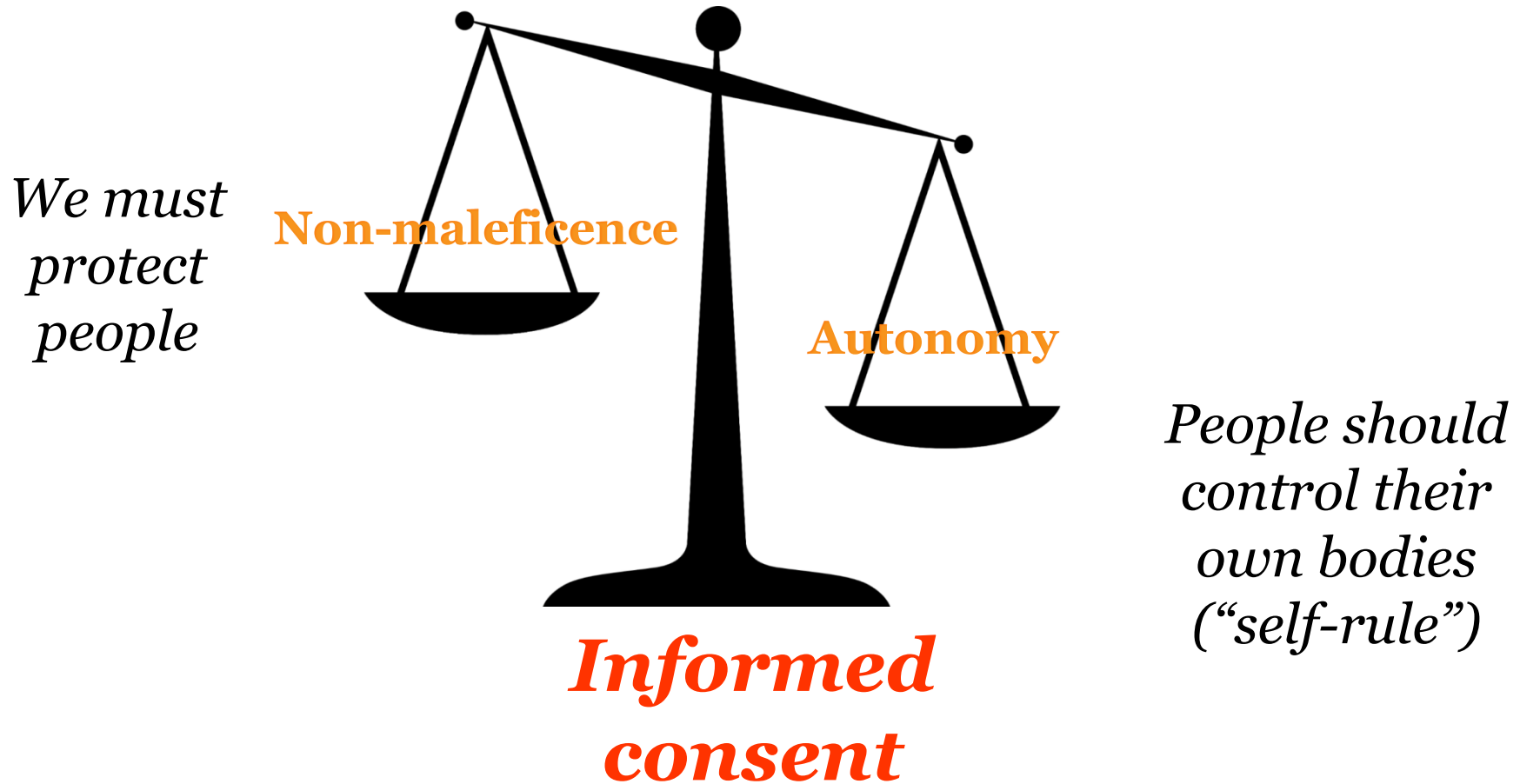
- James – a 46 year old Black man
  - Hoping to donate to his father with end-stage kidney disease due to diabetes
  - BMI of 38, but dieted/exercised to current BMI of 28
  - Other tests looked good
  - Educated, motivated



# Outline

- The health risks of kidney donation are reasonable
- Turning down an informed donor is paternalistic
- Exclusion criteria for kidney donation are arbitrary, inconsistent and reflect muddled thinking
- Kidney donation is a meaningful act for many people
  - Health professionals are in a poor position to judge how potential donors should assess risks vs non-medical benefits

# Conventional ethical principles in evaluating a potential kidney donor



Beauchamp TL, Childress JF. *Principles of biomedical ethics* (6th ed.). New York, NY: Oxford University Press.

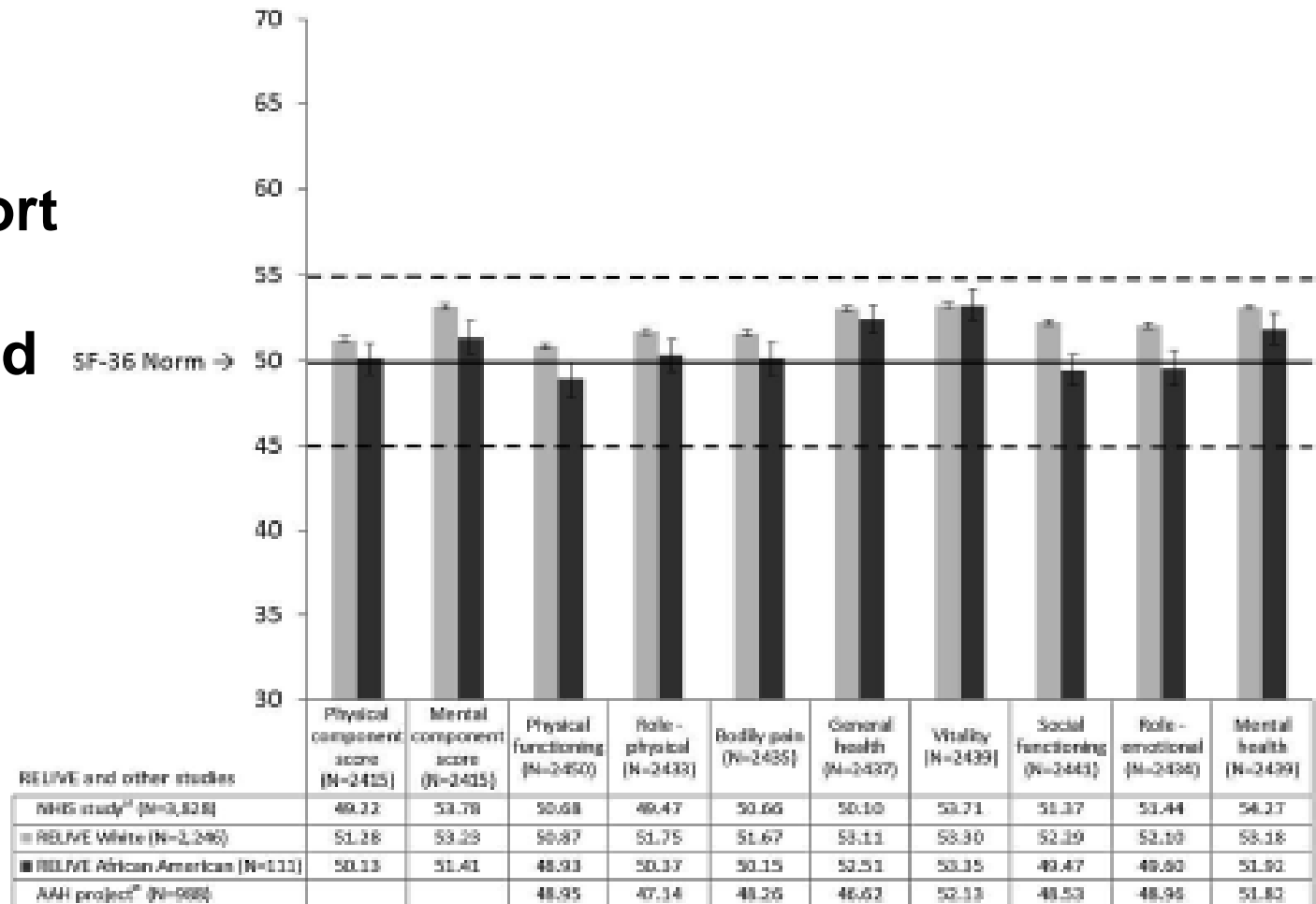


# Kidney Donation is Safe

- Similar rates of death and cardiac disease in the first 10 to 15 years after donation vs. healthy non-donors
  - Segev et al. *JAMA*
  - Garg et al. *BMJ*
  - Mjoen et al. *Kidney International*
  - Reese et al. *AJT*
- Higher relative risk of end-stage renal disease by 15 years of follow-up after donation
  - Low absolute risk at 15 years: < 1%
  - May be higher after that
    - Muzaale et al. *JAMA*
    - Mjoen et al. *Kidney International*
    - Grams et al. *NEJM*
- Small elevation in rate of pre-eclampsia after donation
  - Garg et al. *NEJM*
  - Reisaeter et al. *AJT*

# Donors report excellent quality of life and rarely regret the decision

- RELIVE cohort
- Well validated survey: SF-36



Gross et al. *American Journal of Transplantation*. 2013

# Exclusion criteria for donation are arbitrary, inconsistent and reflect muddled thinking

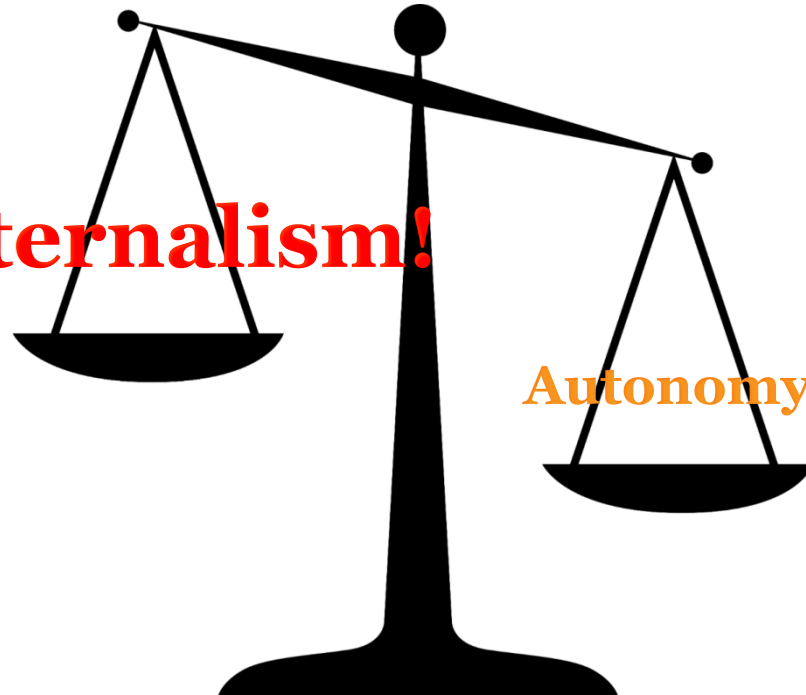
	UNOS guidelines (current) (8)	European Renal Best Practice Guidelines (2014) (9)	Amsterdam Forum (2005) (48)	UK donor evaluation guidelines (2011) (10)	Australia guidelines (2010) (49–54)
Hypertension	<i>Decline</i> <ul style="list-style-type: none"> <li>• “Uncontrollable” hypertension</li> <li>• Hypertension with end stage organ damage</li> </ul>	<i>Allow</i> <ul style="list-style-type: none"> <li>• Ambulatory blood pressure &lt;130/85 on a maximum of 2 medications</li> </ul> <i>Decline</i> <ul style="list-style-type: none"> <li>• Hypertensive end organ damage</li> </ul>	<i>Decline</i> <ul style="list-style-type: none"> <li>• Ambulatory blood pressure &gt;140/90</li> </ul> <i>Consider low-risk/acceptable</i> <ul style="list-style-type: none"> <li>• Hypertension is easily controlled and if &gt;50 years old, GFR &gt;80mL/min, urine albumin &lt;30 mg/24 h</li> </ul>	<i>Allow</i> <ul style="list-style-type: none"> <li>• Mild–moderate hypertension controlled with 1–2 medications if no significant end organ damage</li> </ul> <i>Relative contraindication</i> <ul style="list-style-type: none"> <li>• Hypertensive end-organ damage</li> <li>• Poorly controlled hypertension</li> <li>• Hypertension requiring &gt;2 medications for control</li> </ul>	<i>Decline</i> <ul style="list-style-type: none"> <li>• Hypertensive end-organ damage</li> <li>• Hypertension requiring &gt;2 medications</li> <li>• Hypertension with other cardiovascular risk factors</li> </ul>
Diabetes	<i>Decline</i> <ul style="list-style-type: none"> <li>• Diabetes</li> </ul>	<i>Decline</i> <ul style="list-style-type: none"> <li>• Diabetes, except in “exceptional circumstances”</li> </ul>	<i>Decline</i> <ul style="list-style-type: none"> <li>• Diabetes</li> <li>• Fasting glucose <math>\geq</math> 126 mg/dL on 2 occasions</li> </ul>	<i>Consider</i> <ul style="list-style-type: none"> <li>• Diabetes without end-organ damage and optimally managed cardiovascular risk factors</li> </ul>	<i>Decline</i> <ul style="list-style-type: none"> <li>• Diabetes</li> <li>• Past history of gestational diabetes</li> </ul>



# Actual ethical principles in evaluating a potential kidney donor

*We have failed to come to any consensus about how to protect people*

**Paternalism!**



**Autonomy**

*People should control their own bodies (“self-rule”)*

***Informed consent***

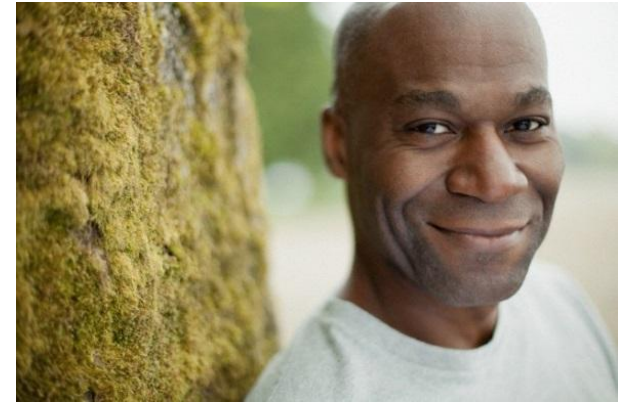
Beauchamp TL, Childress JF. *Principles of biomedical ethics* (6th ed.). New York, NY: Oxford University Press.

# A new concept of donor risk

- Do no harm is not the right standard
  - Instead: Avoid unreasonable risk
  - Let the donor's values define “unreasonable”
- We should remember the risks of not doing
  - The harms of inaction
  - Excluded donors can be harmed by watching the candidate suffer or die on dialysis
  - Think: mother to child, spouse to spouse
- Beneficence requires understanding and advocating for the donor's welfare and values

# What is the traditional basis for turning down a donor?

- Donor lacks autonomy
  - Coercion detected
- Failure of informed consent
  - Donor does not understand

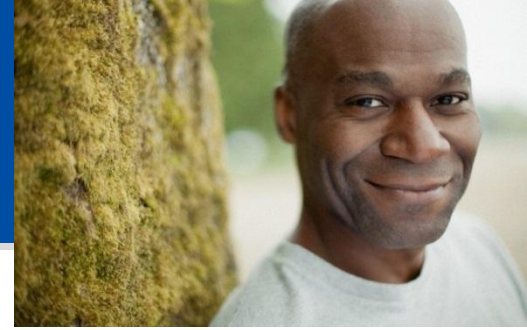


*Solutions: Assess for coercion and ignorance with multistep evaluation by interdisciplinary team*

- Potential harm to donor exceeds professional judgment of reasonable risk

*Solution: Admit that professional judgment is deeply flawed*

# We accepted James



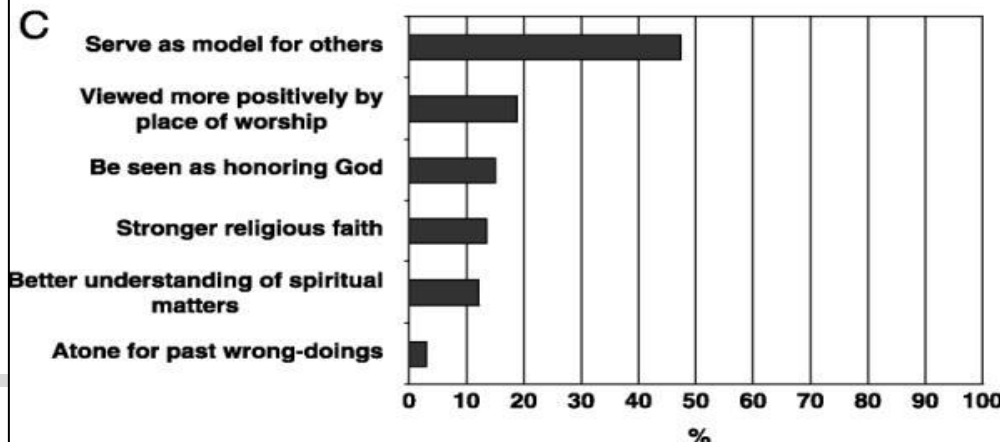
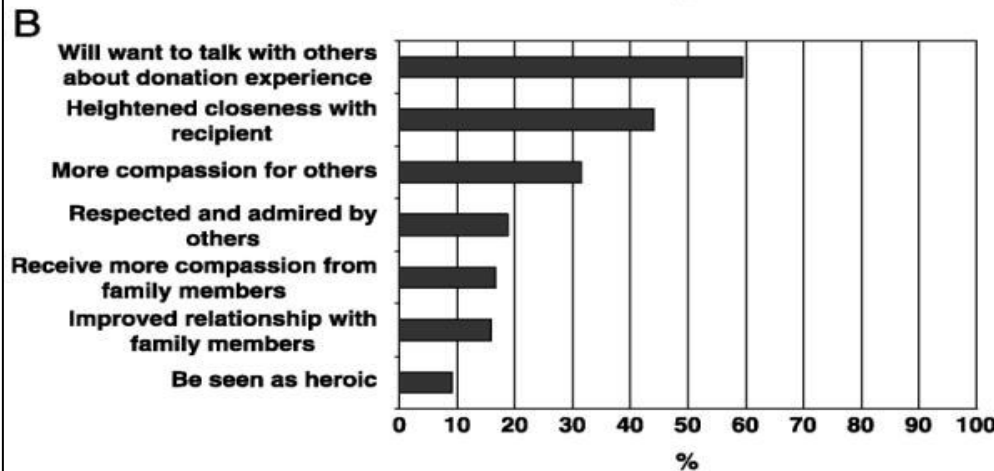
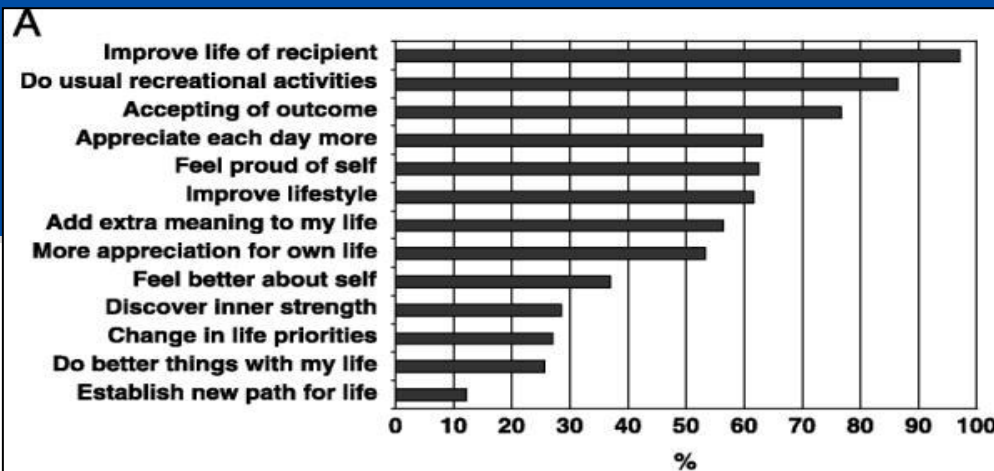
- He emphasized the importance of his relationship with his father
- He accepted a high level of uncertainty about long-term outcomes from donation
- We concluded that there is no right to donate a kidney. However, beneficence (balance of risk and benefit) concerns were acceptable to us and him.
- The decision was consistent with professional standards



# Beneficence Means Seeing the World through the Donor's Eyes

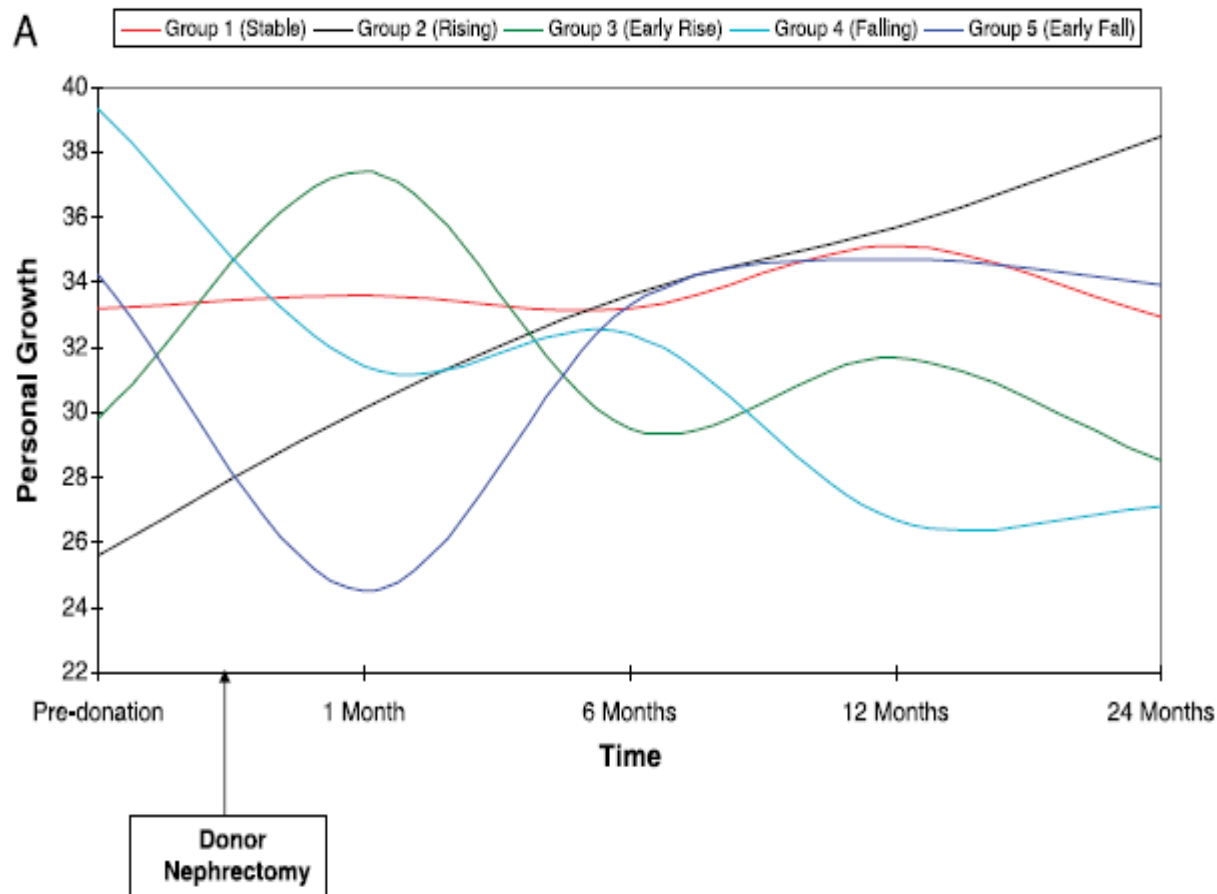
- To some donors, non-medical benefits of donation may be more important than medical risks
  - Sense of purpose and Well-being
    - What is the effect of not being able to carry out your role as you define it?
    - *e.g.*, Caring for a loved one
  - Quality of life
    - What is the effect of living with a very sick person or watching him or her die?
  - Financial stress
    - What is the effect on household income of a sick family member?





# Living donors expect to benefit

- Prospective cohort study among 133 live kidney donors at 3 centers
- Personal growth, interpersonal benefit and spiritual benefit



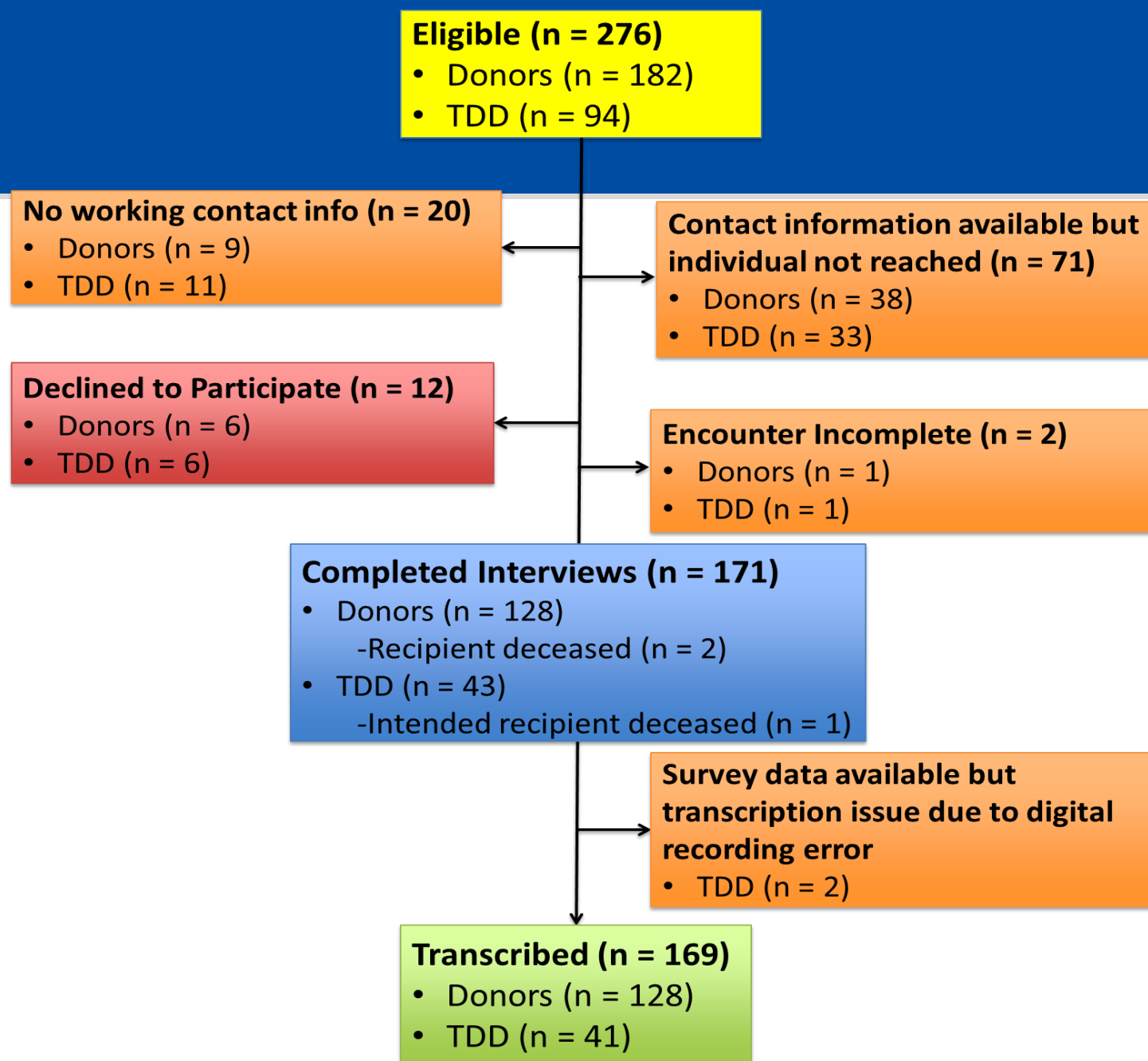
- Distinct patterns of personal growth and other domains
- Improvements often depended on how the recipient's transplant fared

- At 2 years:
  - 93% reported feeling good about improving recipient's life
  - 76% reported feeling proud of oneself
  - 58% reported increased appreciation for value of one's own life
  - 57% reported feeling better about self

# Can someone be harmed by refusal to allow donation?

- Single center retrospective cohort
  - Donors and turned down donors over past 3 years
  - Semi-structured interviews and questionnaires over the phone, digitally recorded
  - Exclusion criteria
    - Donor reluctance/opt-out of donation





## Characteristics of Individuals Turned Down for Kidney Donation and Kidney Donors

Characteristic	Turned Down Individuals n=43	Selected Donors, Matched on Category of Relationship to Recipient n=46	Donors n=128	P-value*
Median Age in years (IQR)	53 (35, 58)	45 (41, 50)	47 (41, 54)	0.06
Female (%)	23 (53)	34 (74)	84 (66)	0.16
Black race (%)	8 (19)	7 (15)	20 (16)	0.65
Relationship to intended recipient (%)				0.25
Parent	4 (9)	6 (13)	18 (14)	
Child	4 (9)	7 (15)	7 (5)	
Sibling	6 (14)	6 (13)	34 (27)	
Spouse/Partner	7 (16)	7 (15)	23 (18)	
Other	22 (51)	20 (43)	46 (35)	
Recipient transplanted (%)	22 (51)	46 (100)	128 (100)	

\* Comparison of Turned down individuals to entire cohort of donors (n=128)

## Quantitative Outcomes for Individuals Turned Down for Kidney Donation and Kidney Donors

<b>Instrument</b>	<b>Turned Down Individuals n=43</b>	<b>Selected Donors, Matched on Category of Relationship to Recipient n=46</b>	<b>Donors n=128</b>	<b>P-value*</b>
<b>Median PHQ-9 Depression scores (IQR)</b>	2 (0, 5)	1 (0, 3)	1 (0, 3)	0.06
<b>Median CARE (Provider empathy) scale (IQR)</b>	43 (34, 50)	48 (40, 50)	46 (40, 50)	0.10
<b>Median Financial stress (IQR)</b>	0 (0, 1)	1 (0, 3)	0 (0, 2)	0.29
<b>Median SF-12 Physical component score (IQR)</b>	57 (56, 59)	58 (56, 59)	57 (56, 59)	0.76
<b>Median SF-12 Mental component score (IQR)</b>	56 (50, 60)	57 (52, 60)	57 (54, 60)	0.33

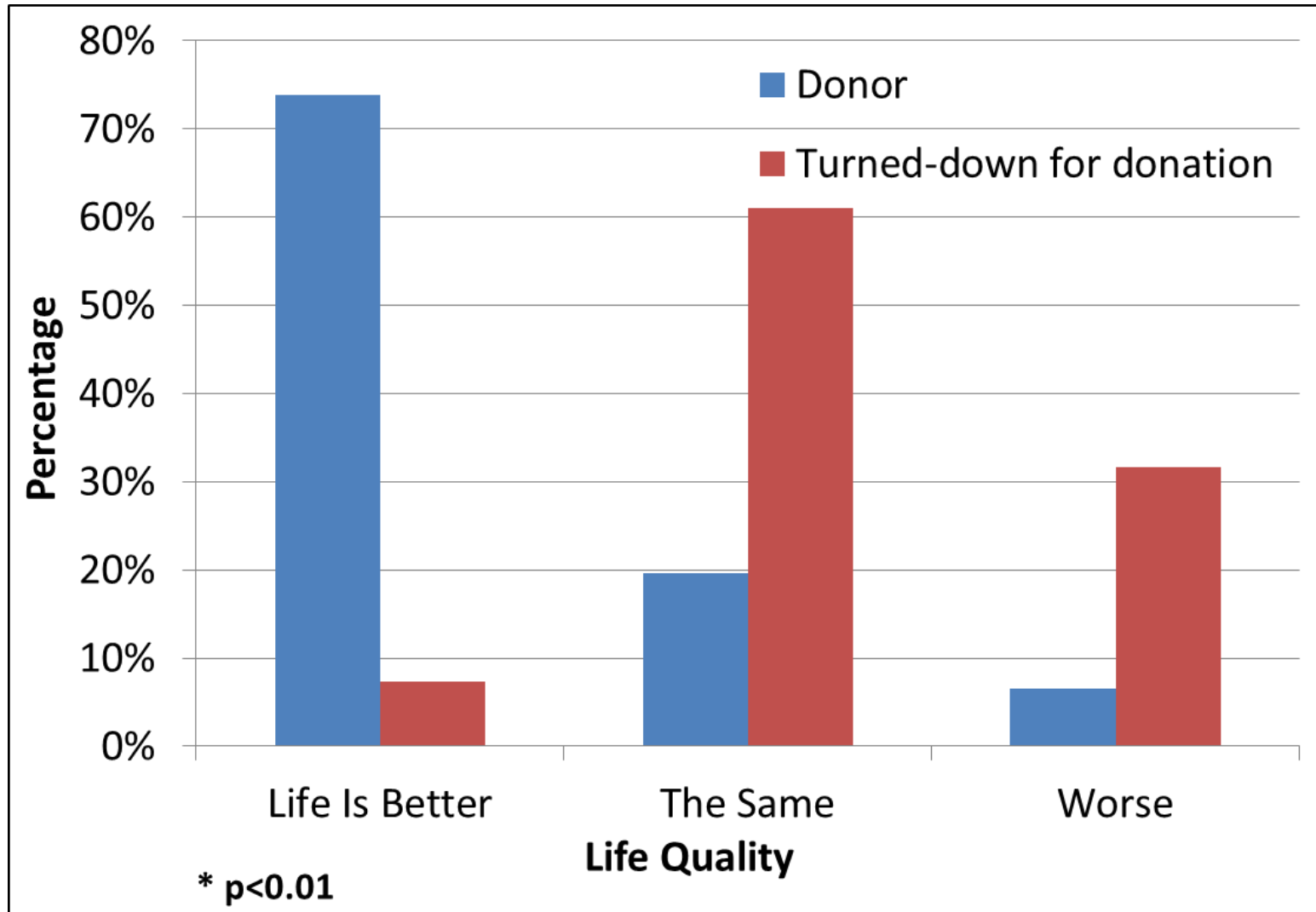
\* Comparison of Turned down individuals to entire cohort of donors (n=128)



# Qualitative data

- All donors responded to this statement
  - “My life is better than it would have been if I had not donated a kidney.”
- All non-donors responded to this statement
  - “My life is better than it would have been if I had donated a kidney.”
- Responses included agreement, neutral or disagreement, as well as open-ended responses
  - Data coded by trained personnel

# Assessments by donors and non-donors of how their lives were affected by the center's decision





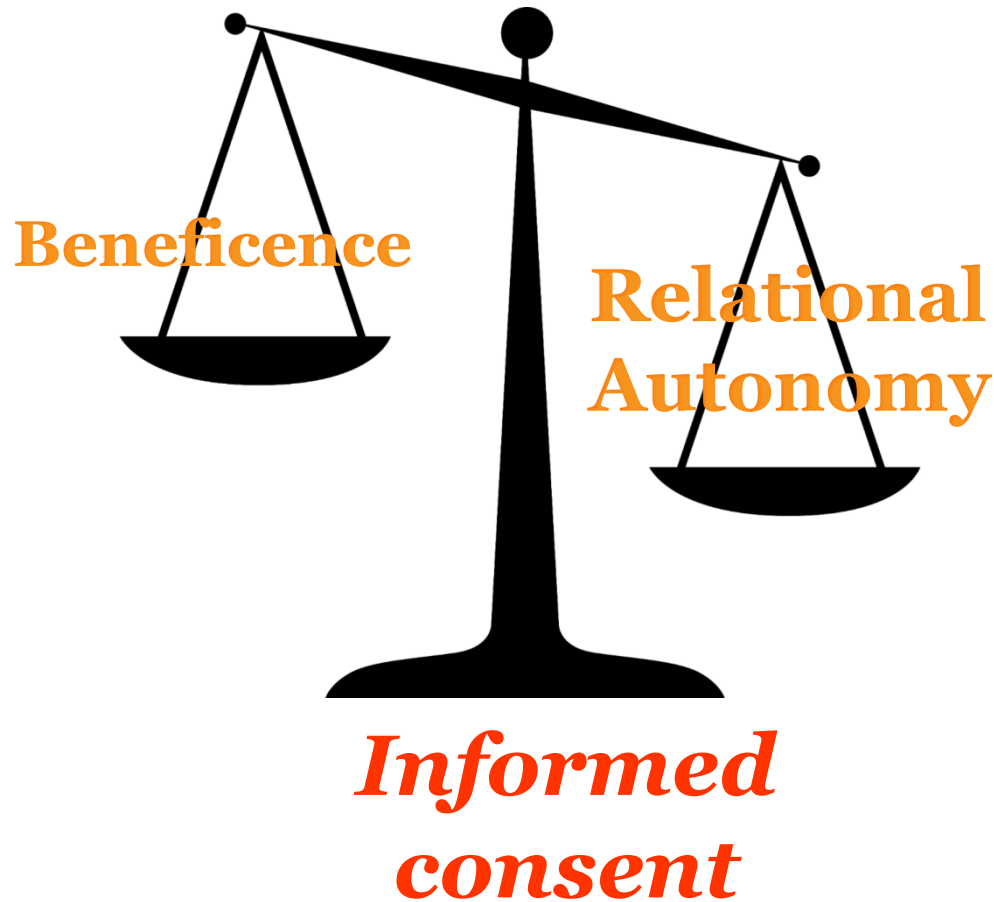
***Donor voices: Sue, talking  
about not being able to  
donate to her husband***

# Relational autonomy

- Highlights the social context within which all individuals exist
- Acknowledges the emotional and embodied aspects of decision-makers
- References the central role of others in decision-making
- From this perspective, clinicians should:
  - engage patients' and surrogates' emotional experiences

# A better model of principles in evaluating a potential kidney donor

*We must weigh risks and benefits and view them, where possible, through the patient's eyes*



*Well being depends on self-rule, as well as healthy relationships*

# We accepted James



- Taking care of his father was consistent with his core values
  - Relational autonomy
- He accepted the high level of uncertainty about long-term outcomes from donation
  - Informed consent was robust
- When considering risk and uncertainty, we took his perspective into account
  - Beneficence



# Take home messages

- Kidney donors who understand the risks should be allowed to donate, as long as risk is not extreme
- All decisions, including turning someone down for kidney donation, carry the potential for negative consequences
- A substantial minority of turned-down donors believe that:
  - The overall condition of their life is worse
  - They were prevented from doing something meaningful

# Thank you!

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