

HUMAN TISSUE AND ORGAN DONATION ACT

CODES OF PRACTICE AND SECONDARY LEGISLATION

SUMMARY OF RESPONSES TO THE PUBLIC CONSULTATION

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We asked

The consultation sought views on the Codes of Practice and Secondary Legislation required to implement the Human Tissue and Organ Donation Act 2021.

The purpose was to gather feedback on how various processes related to organ donation and human tissue management are handled on the Island, including the move to an opt-out system for organ donation. The consultation was focused on the following topics:

- Knowledge, understanding and opinions on the current process of organ donation, and the planned transition to an opt-out system
- Feedback on the procedures outlined in the draft Codes of Practice including;
 - The guiding fundamental principle of consent
 - Post-mortem examinations
 - Use of tissue for anatomical examination
 - The public display of human tissue
 - Research involving human tissue
 - Living and deceased organ donation, including for bone marrow and peripheral blood stem cells
- The operation of a licensing system for the regulation of human tissue on the Island, including licensing standards and exceptions
- How Public Health can best fulfil its duty to communicate with the public about organ donation
- Comments and feedback about the proposed Secondary Legislation

The consultation ran for four weeks from 31 March 2025 to 28 April 2025. Feedback was gathered through a combination of methods:

- **Online survey** hosted on the Government Consultation Hub
- **Public meetings:** held in the north, south, east, and west of the Isle of Man, with two sessions at each location
- **Focus groups:** with representatives from the funeral sector, medical staff in Manx Care, and individuals of different faiths.

Respondents answered a mix of closed yes/no questions and provided free-text comments.

You said

The Department received 124 submissions to this consultation, of which –

- 121 were via the online consultation survey;
- 2 were emailed;
- 1 was handwritten.

When examining who responded to the consultation

- 122 responses were from members of the public
- 1 was from a special health authority (NHSBT)
- 1 was from a public body (DHSC)

The responses set out in these submissions can be broadly categorised as –

- **Agreement with the Codes of Practice and Secondary Legislation**
 - Around three quarters of respondents agreed with the proposed contents of the Codes of Practice and Secondary Legislation, answering “Yes” to the main consultation questions.
 - Many expressed strong support for organ donation and welcomed the move to an opt-out system.
 - A common sentiment among these respondents was a desire for the opt-out system to be implemented quickly, ideally within six months or less.
- **Opposition against the move to an opt out system**
 - Around a fifth of respondents expressed concern about the transition from an opt-in to an opt-out system, preferring to retain the existing opt-in model to safeguard individual choice.
 - A recurring theme among these responses was the belief that presumed consent infringes upon personal autonomy and freedom of choice.
 - Concerns about trust were notable, with some respondents expressing a general lack of confidence in Government and healthcare organisations (such as Manx Care)

A detailed summary of the responses to each of the consultation questions is attached.

Additional themes identified include:

- **Clear communication**

Many respondents highlighted the need for comprehensive public awareness campaigns to explain how the opt-out system will work, the safeguards in place, and the implications for individuals and their families.
- **Safeguards and consent processes**

While the Codes of Practice set out detailed safeguards (particularly Code A on consent), respondents stressed that these protections must be clearly communicated, well understood, and strictly adhered to. Simplifying the consent process was a frequent suggestion.
- **Respect for individual autonomy**

Some participants emphasized the importance of respecting individual decisions about organ and tissue donation. Concerns were raised about the risk of families overriding a deceased person's recorded wishes, with many calling for clear processes that prioritise the individual's choice.
- **Role of families**

Others felt that family involvement is essential, particularly due to the sensitive and emotional nature of decisions following a death. There was a clear call for a balanced approach that considers both the individual's wishes and the family's circumstances.
- **Support for oversight and licensing**

Most respondents agreed with the need for strong regulation of human tissue use, including licensing arrangements. However, there were diverse views — some strong — about activities such as public display of human remains, particularly regarding when a licence should be required.
- **Whole body donation**

Public events and focus groups revealed considerable interest in the process of whole-body donation for medical education. Participants sought more transparency about how donations are handled, particularly regarding transfer to university hospitals and the respectful treatment of bodies.

We did

Having considered the consultation feedback, and following further engagement with key stakeholders, the following matters will be addressed before implementation of the Human Tissue and Organ Donation Act:

1. Timetable for Implementation

- The majority of respondents supported the introduction of the opt-out system within six months. In response, Public Health will aim to implement deemed consent from **January 2026**.

2. Clear and Sensitive Communication

- Effective communication about the opt-out system, consent process, and associated safeguards is critical.
- Public Health will develop a public awareness campaign that:
 - Clearly explains how the system will operate.
 - Addresses ethical, religious, and cultural considerations sensitively.
 - Emphasizes respect for individual autonomy while recognising the emotional impact on families during bereavement.
- Insights from the consultation will help shape communication methods, manage costs, and guide respectful advertising strategies.

3. Safeguards and Consent

- Feedback highlighted the importance of transparency around safeguards.
- Public Health will ensure that information about rights, decision-making processes, and family involvement is widely accessible and clearly explained.

4. Oversight and Licensing

- Consultation responses showed support for regulatory oversight but raised concerns about potential bureaucracy.
- Further work will be undertaken to refine the licensing requirements for scheduled purposes such as research and public display, balancing robust regulation with proportionality and efficiency.

5. Full Body Donation

- Public feedback identified a need for clearer information about whole body donation for medical education.
- Public Health will work to set clear expectations for potential donors and their families regarding the process, including how bodies are transferred, used, and treated with dignity and respect.

Next Steps

- The feedback has been used to finalise the Codes of Practice and Secondary Legislation as they move to the next stage. Any necessary amendments have been made based on the responses received.
- **Approval:** Between May and June 2025, the final versions will be submitted to the Cabinet Office Board and the Council of Ministers for approval, and preparations will be made for Tynwald's consideration in July 2025.
- **Public Awareness Campaign:** A comprehensive public awareness campaign will take place, aimed at helping people understand the new opt-out system and encouraging them to register their organ donation decision and share it with their next of kin.
- **Training and Regulatory Functions:** Public Health will begin its regulatory functions, including issuing licenses and ensuring compliance with the new laws. This will be supported by ongoing training for those involved, especially in Manx Care.

Timeline

- **July 2025:** Final approval of the Codes and Secondary Legislation by Tynwald.
- **1 January 2026:** Implementation of the opt-out system for organ donation.
- **July 2026:** First annual report to Tynwald, marking one year of the opt-out system in action.

6. Conclusion

Communicating the Impact

The responses to this consultation will be communicated through various channels, including:

- **Web updates:** on the Government website and the Consultation hub
- **Press release**
- **Social media**

We appreciate all who took the time to participate and share their views, and we are committed to ensuring the transparency for the process as we move forward with implementing the Human Tissue and Organ Donation Act.

Summary of responses to the Public Consultation on the Human Tissue and Organ Donation Act – Codes of Practice and Secondary Legislation

1. What is your name?

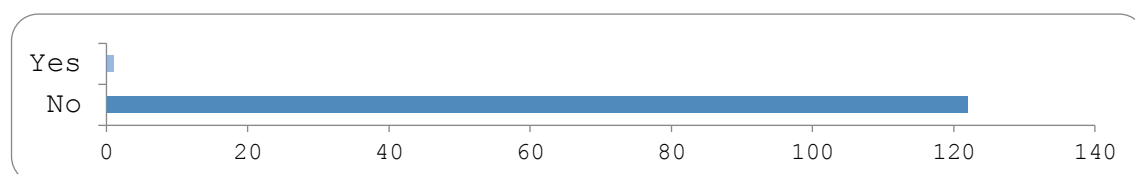
Name

There were 100 responses to this part of the question.

2. Are you responding on behalf of an organisation?

Organisation yes / no

There were 123 responses to this part of the question.



Option	Total	Percent
Yes	1	0.81%
No	122	99.19%
Not Answered	0	0.00%

Organisation name

There were 2 responses to this part of the question.

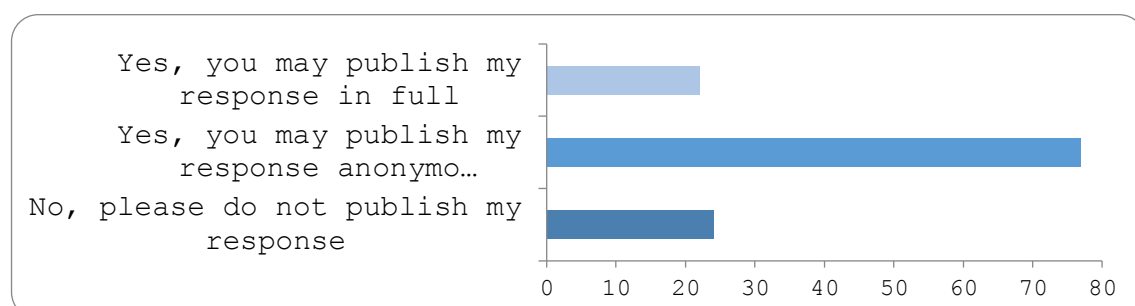
Your position within the organisation

There was 1 response to this part of the question.

3. May we publish your response?

Consent publishing

There were 123 responses to this part of the question.

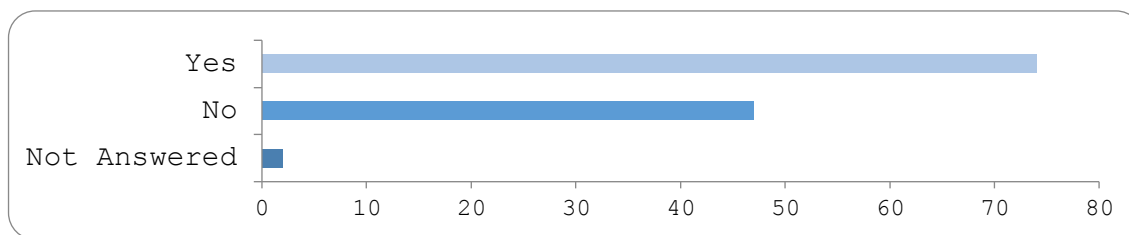


Option	Total	Percent
Yes, you may publish my response in full	22	17.89%
Yes, you may publish my response anonymously	77	62.60%
No, please do not publish my response	24	19.51%
Not Answered	0	0.00%

4. Do you know how and where to register your organ donation decision?

Yes/no

There were 121 responses to this part of the question.

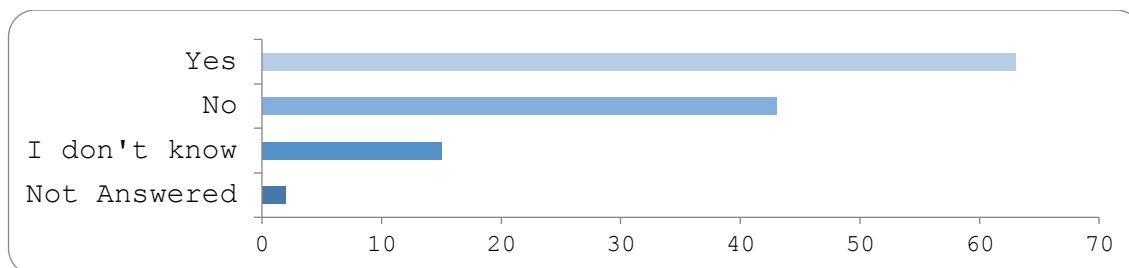


Option	Total	Percent
Yes	74	60.16%
No	47	38.21%
Not Answered	2	1.63%

5. Have you registered your decision already?

Yes/no

There were 121 responses to this part of the question.

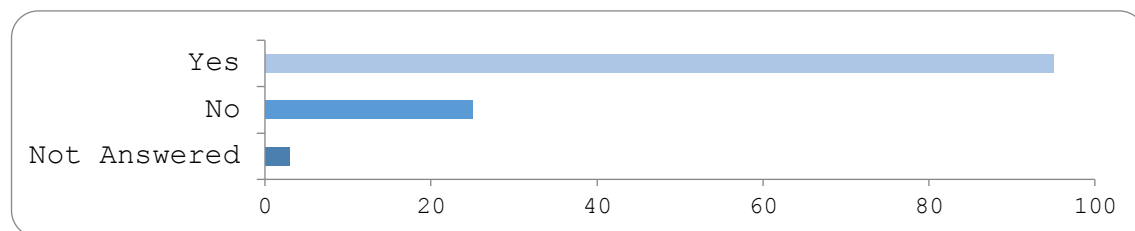


Option	Total	Percent
Yes	63	51.22%
No	43	34.96%
I don't know	15	12.20%
Not Answered	2	1.63%

6. Have you shared your decision with your family?

Yes/no

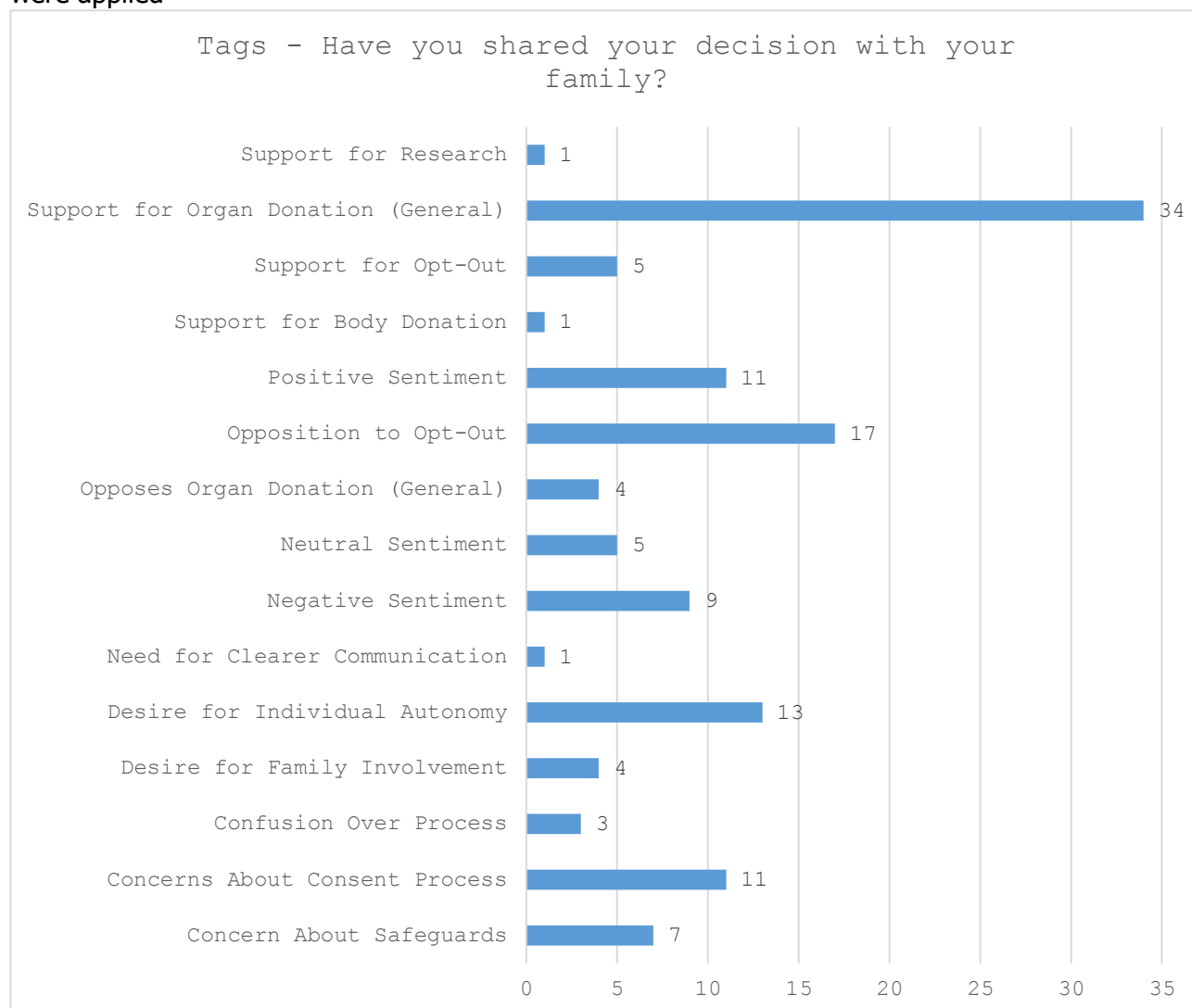
There were 120 responses to this part of the question.



Option	Total	Percent
Yes	95	77.24%
No	25	20.33%
Not Answered	3	2.44%

Comments box

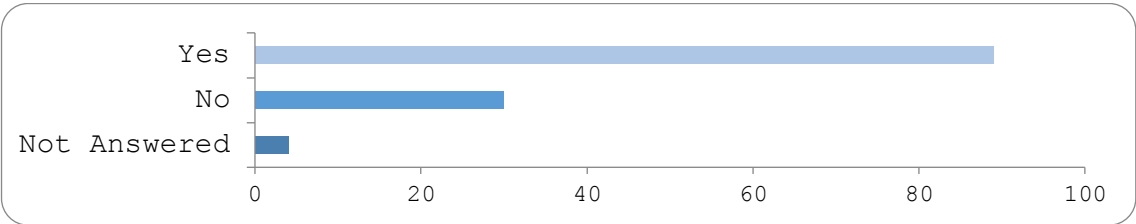
There were 68 responses to this part of the question. In analysing these responses the following tags were applied –



7. Do you agree that the current consent process is clear and easy to understand for individuals considering tissue and organ donation?

Yes/no

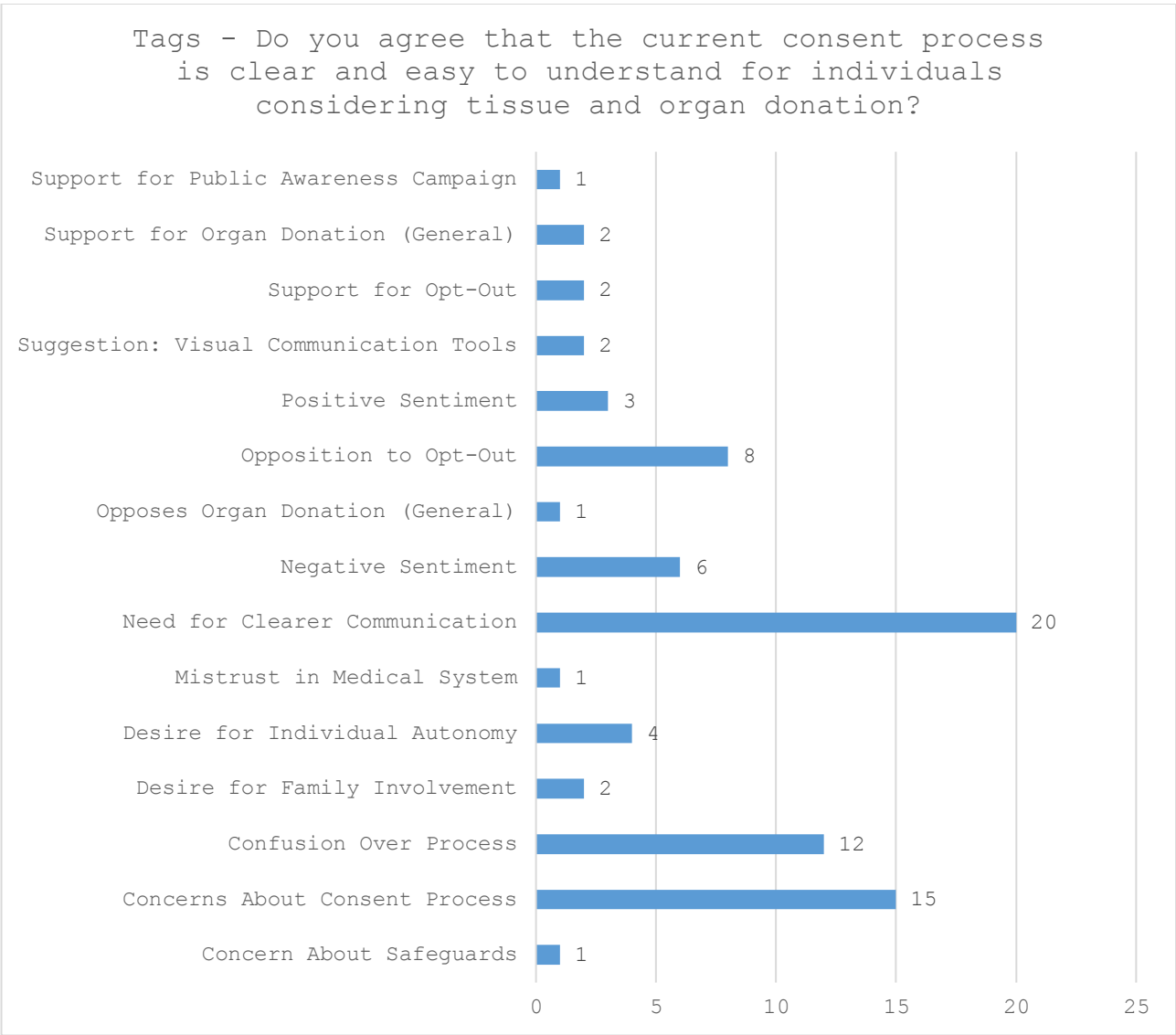
There were 119 responses to this part of the question.



Option	Total	Percent
Yes	89	72.36%
No	30	24.39%
Not Answered	4	3.25%

Comments box

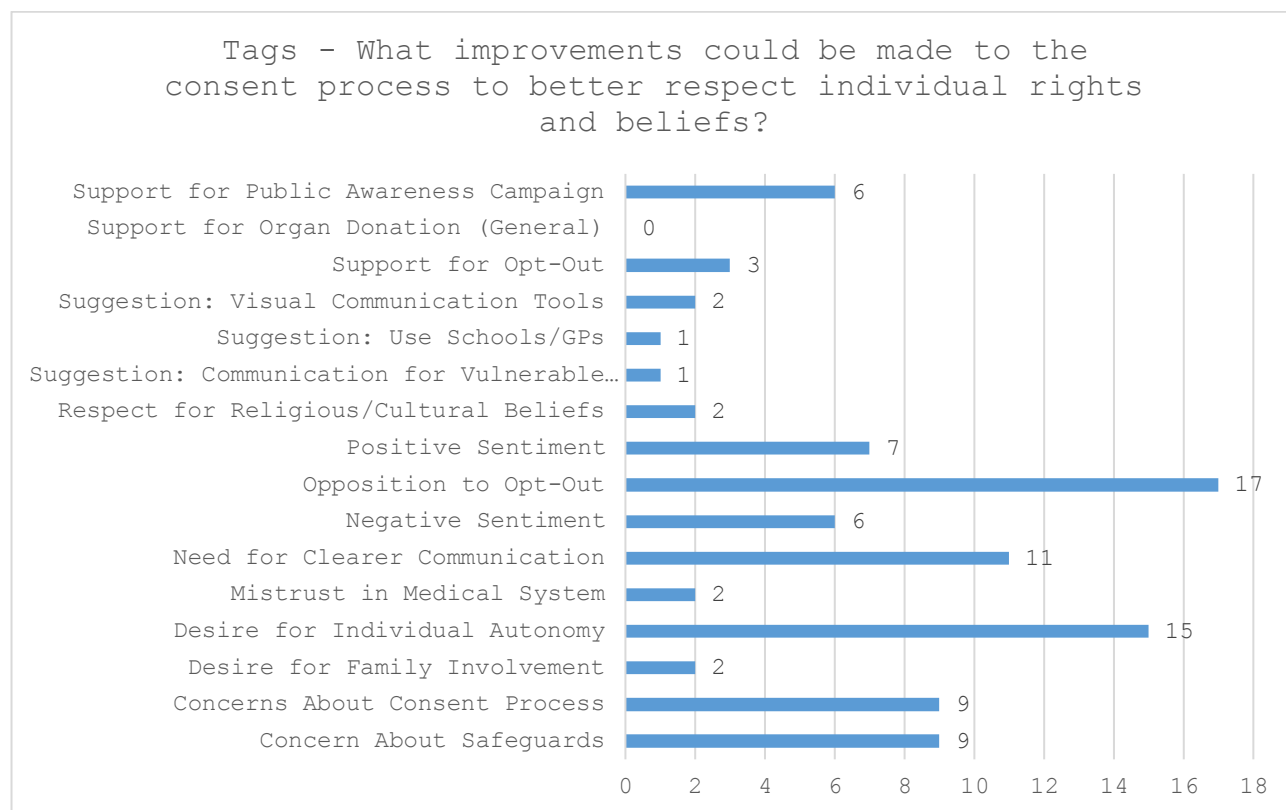
There were 37 responses to this part of the question. In analysing these responses the following tags were applied –



8. What improvements could be made to the consent process to better respect individual rights and beliefs?

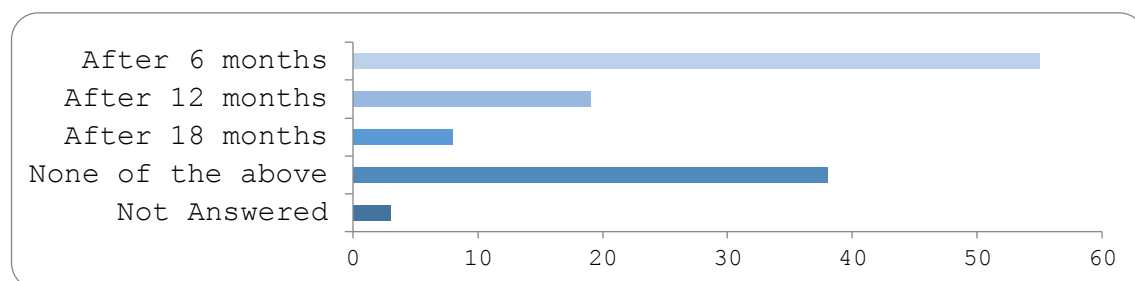
Comments box

There were 49 responses to this part of the question. In analysing these responses the following tags were applied –



9. Cabinet Office intends to bring the Codes of Practice and Secondary Legislation to Tynwald in July 2025. How long after this do you think the deemed consent ('opt out') process should commence?

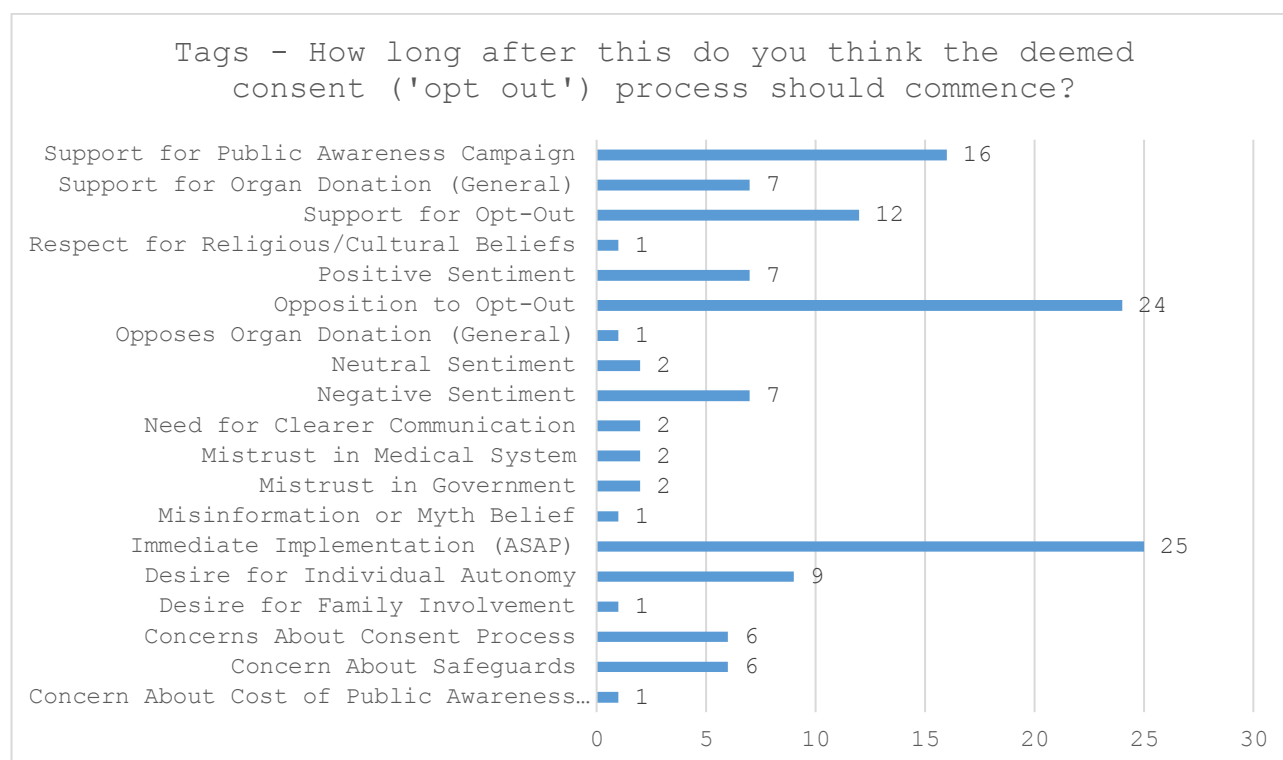
There were 120 responses to this part of the question.



Option	Total	Percent
After 6 months	55	44.72%
After 12 months	19	15.45%
After 18 months	8	6.50%
None of the above	38	30.89%
Not Answered	3	2.44%

Comments box

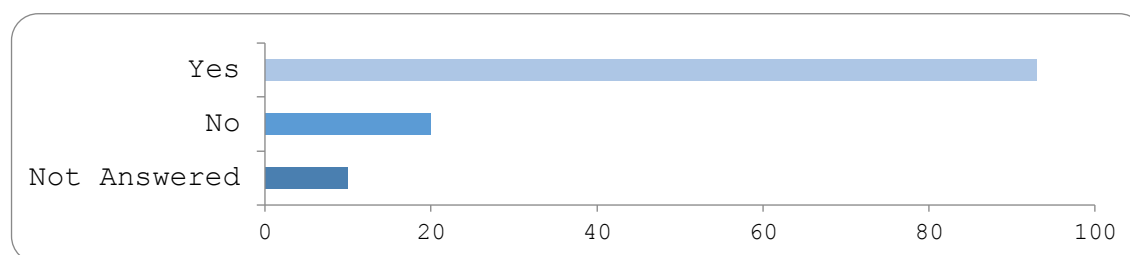
There were 73 responses to this part of the question. In analysing these responses the following tags were applied –



10. Do you agree with the proposed process of seeking consent for a hospital post-mortem?

Yes/no

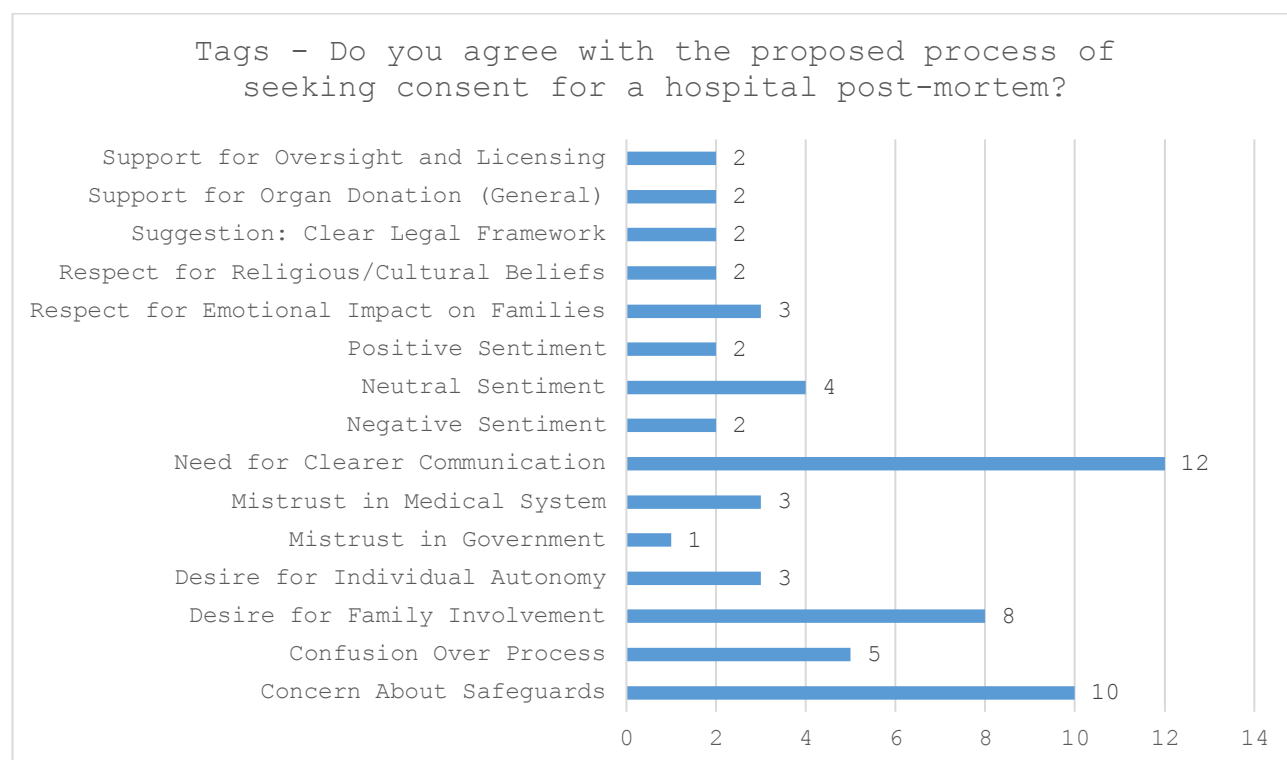
There were 113 responses to this part of the question.



Option	Total	Percent
Yes	93	75.61%
No	20	16.26%
Not Answered	10	8.13%

Comments box

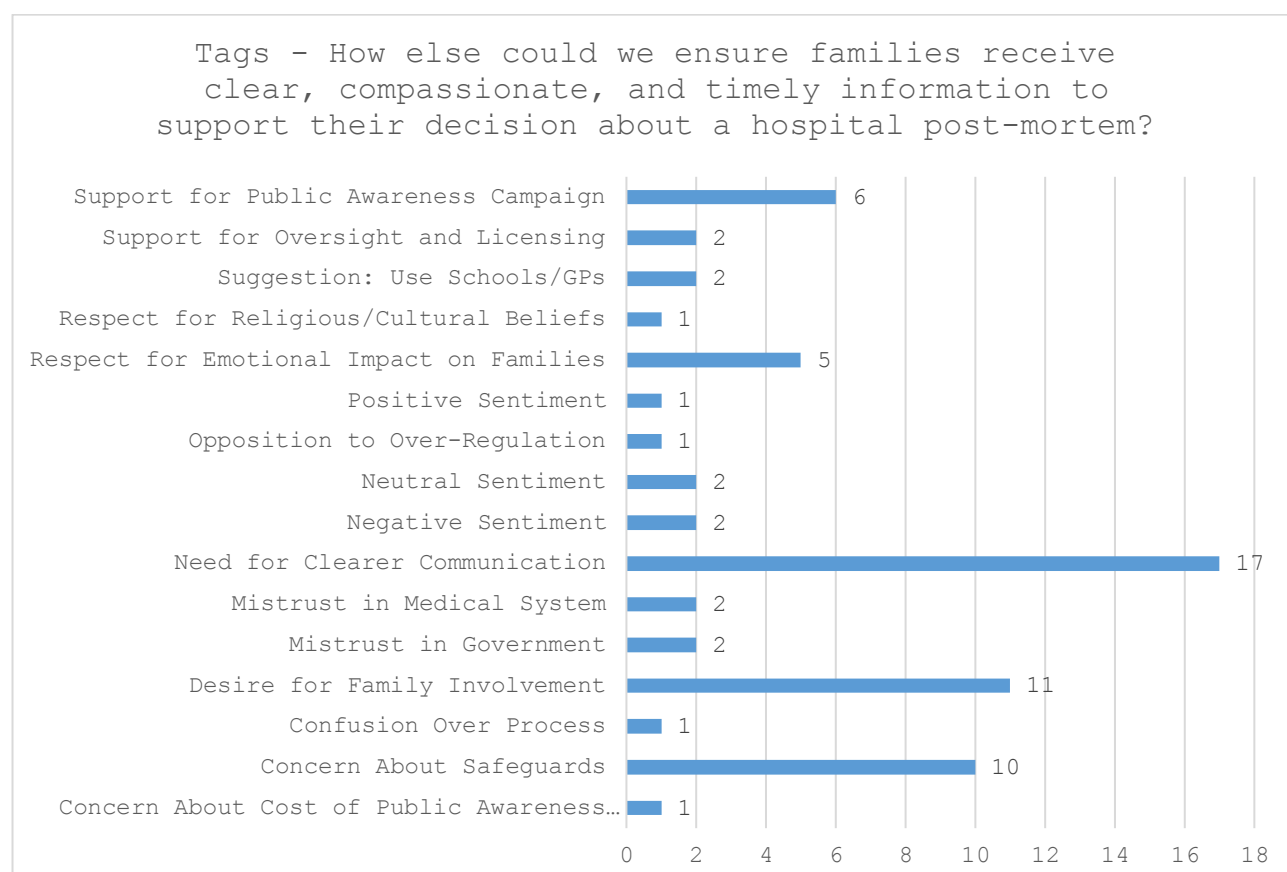
There were 25 responses to this part of the question. In analysing these responses the following tags were applied –



11. How else could we ensure families receive clear, compassionate, and timely information to support their decision about a hospital post-mortem?

Comments box

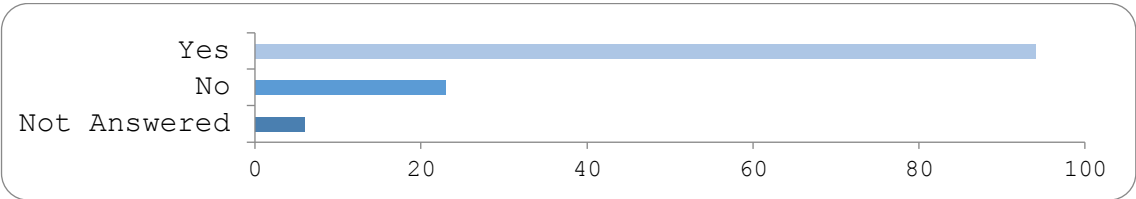
There were 30 responses to this part of the question. In analysing these responses the following tags were applied –



12. Do you agree with the proposed procedures for storing and disposing of tissue and organs after post-mortem examinations?

Yes/no

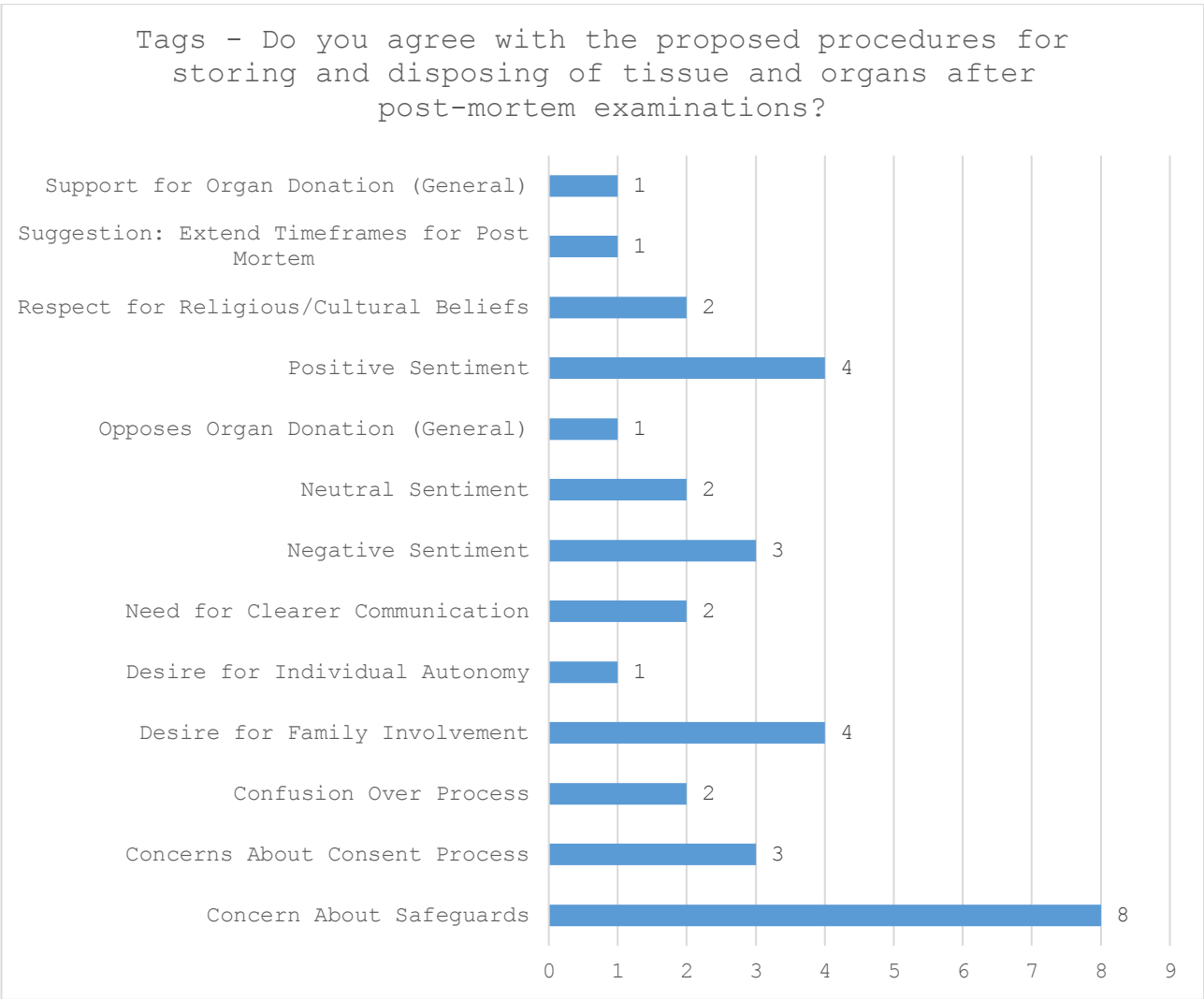
There were 117 responses to this part of the question.



Option	Total	Percent
Yes	94	76.42%
No	23	18.70%
Not Answered	6	4.88%

Comments box

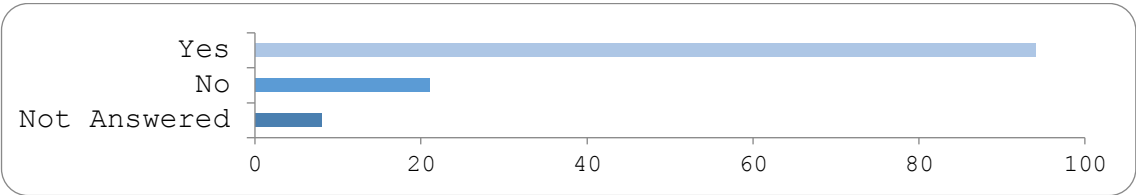
There were 23 responses to this part of the question. In analysing these responses the following tags were applied –



13. Do you agree with the proposed consent process for using bodies, tissues, and organs in anatomical examinations?

Yes/no

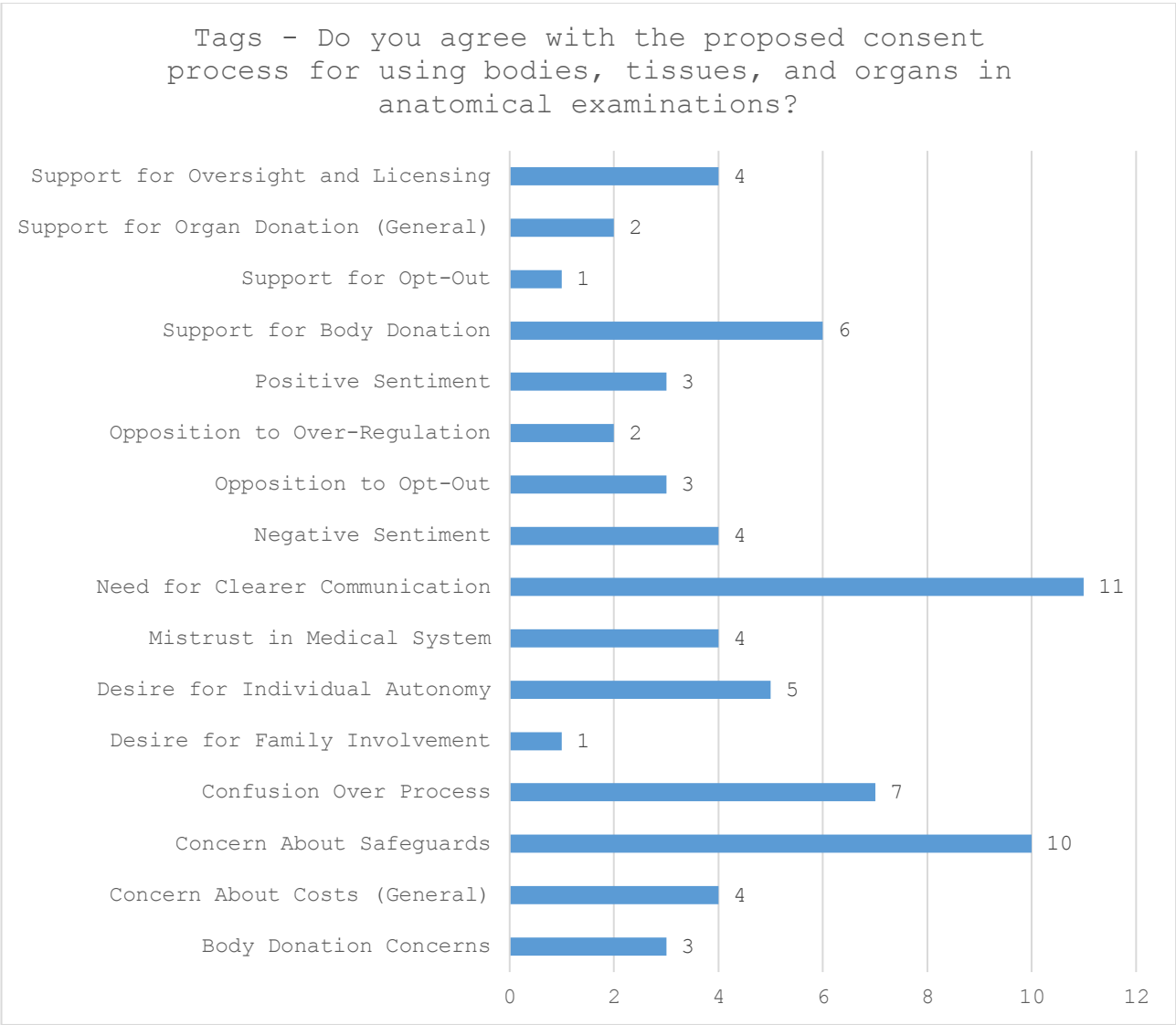
There were 115 responses to this part of the question.



Option	Total	Percent
Yes	94	76.42%
No	21	17.07%
Not Answered	8	6.50%

Comments box

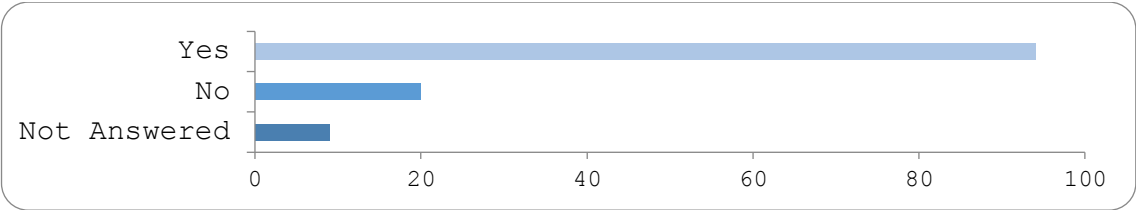
There were 30 responses to this part of the question. In analysing these responses the following tags were applied –



14. Do you agree with the proposed controls around the import/export of bodies, tissues and organs to be used for the purpose of anatomical examination?

Yes/no

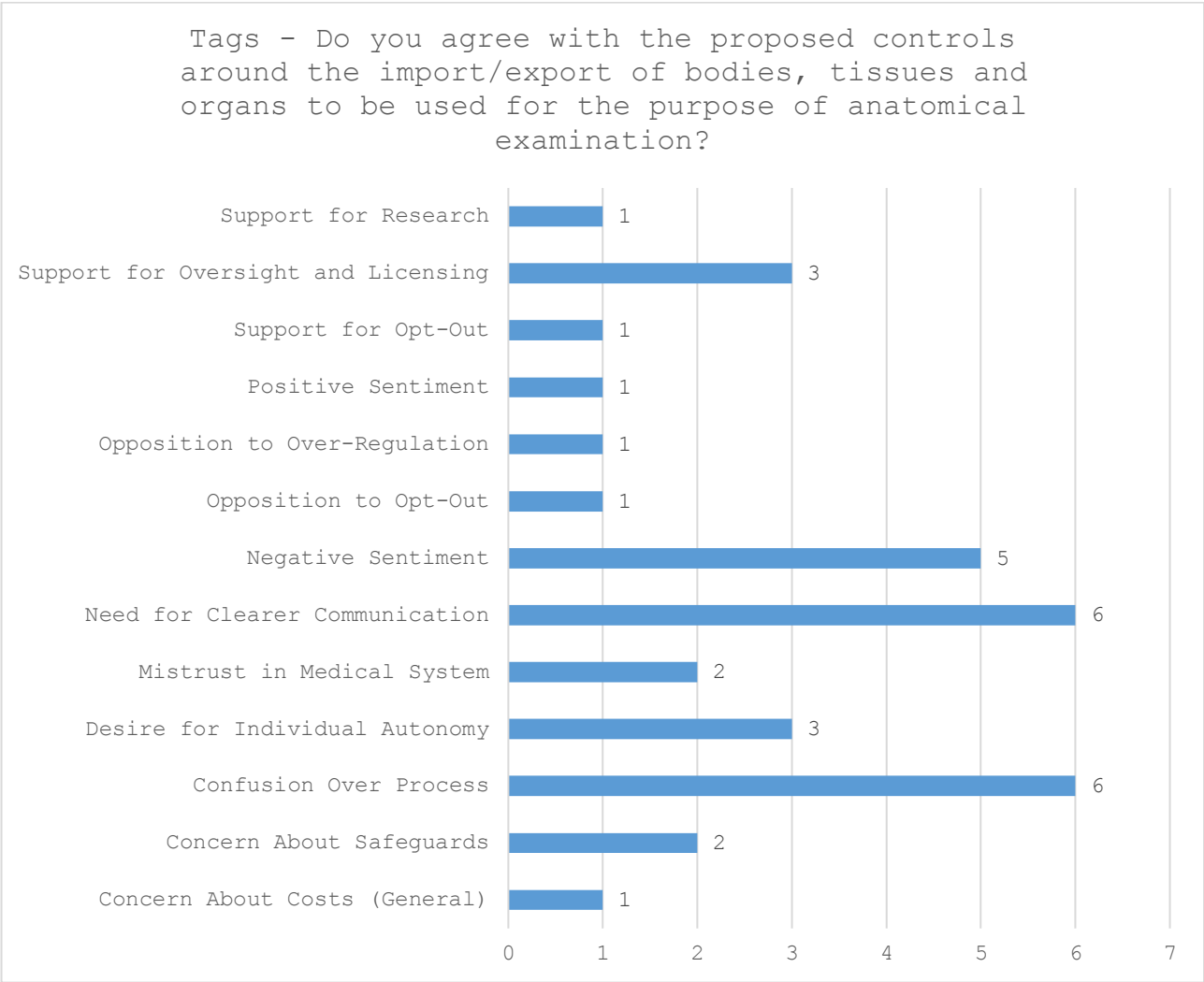
There were 114 responses to this part of the question.



Option	Total	Percent
Yes	94	76.42%
No	20	16.26%
Not Answered	9	7.32%

Comments box

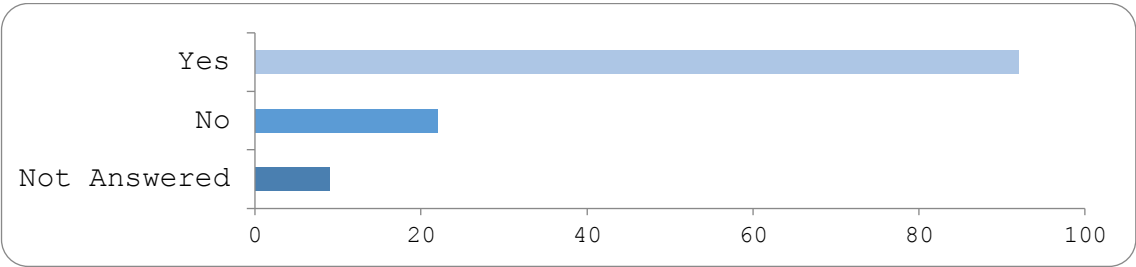
There were 18 responses to this part of the question. In analysing these responses the following tags were applied –



15. Do you agree that the storage and disposal arrangements for bodies, tissues and organs are appropriate?

Yes/no

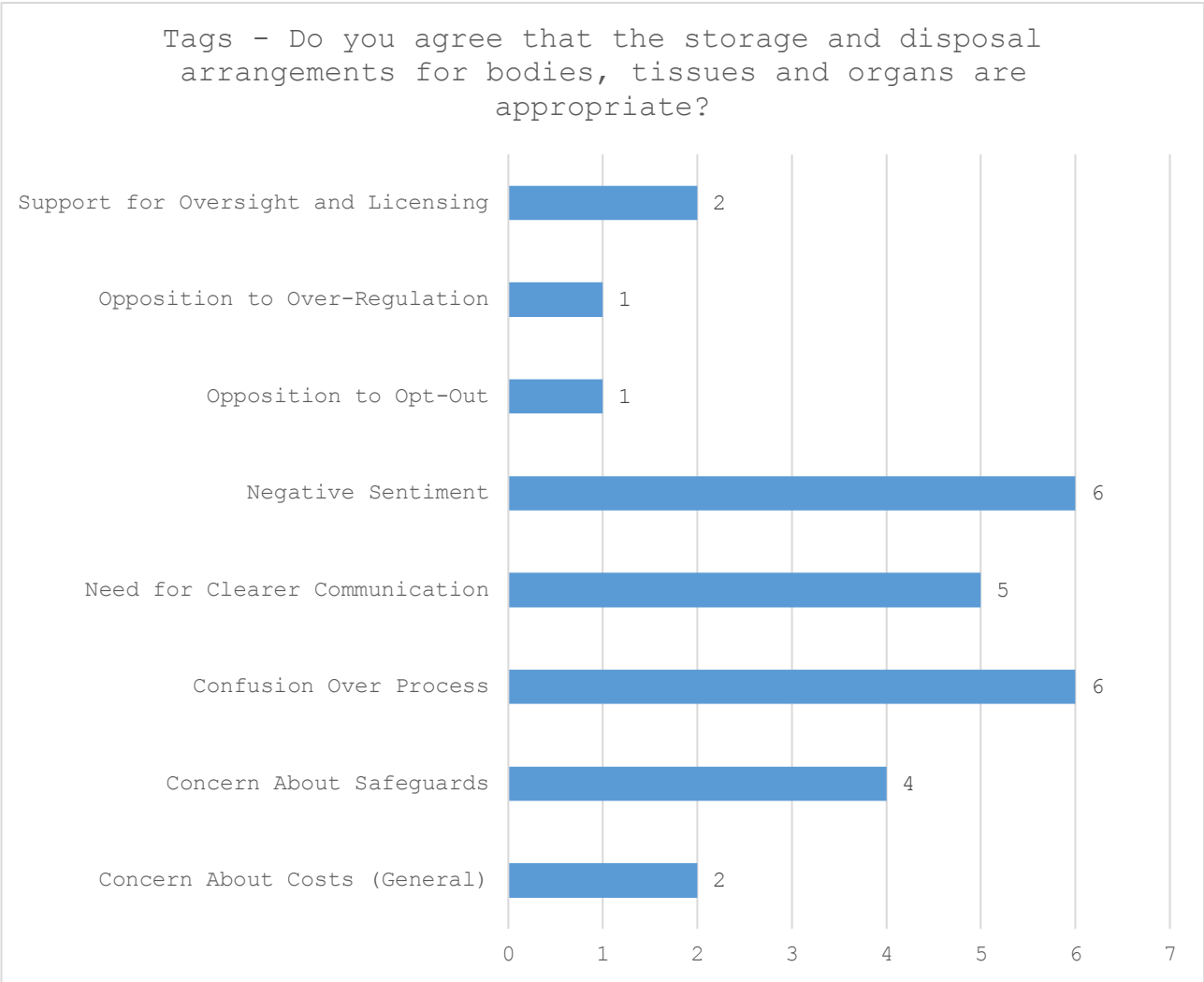
There were 114 responses to this part of the question.



Option	Total	Percent
Yes	92	74.80%
No	22	17.89%
Not Answered	9	7.32%

Comments box

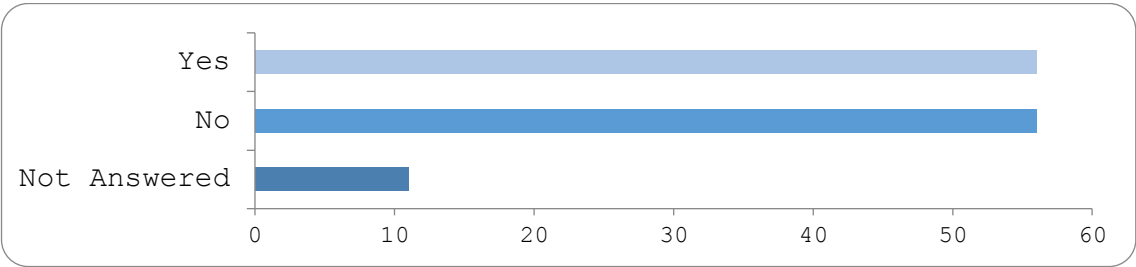
There were 16 responses to this part of the question. In analysing these responses the following tags were applied –



16. Do you agree that a license is not necessary for storing tissue with no plans for public display?

Yes/no

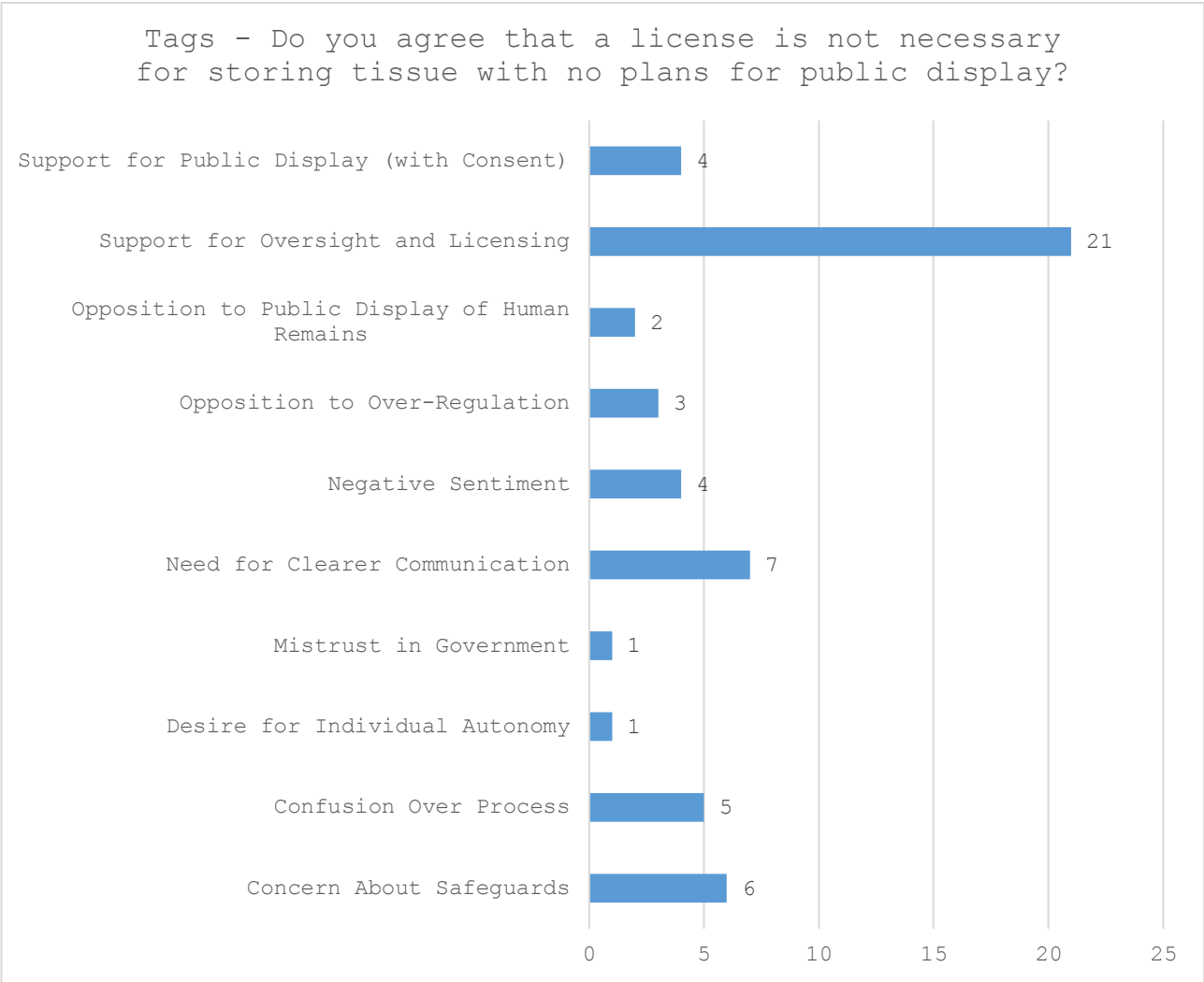
There were 112 responses to this part of the question.



Option	Total	Percent
Yes	56	45.53%
No	56	45.53%
Not Answered	11	8.94%

Comments box

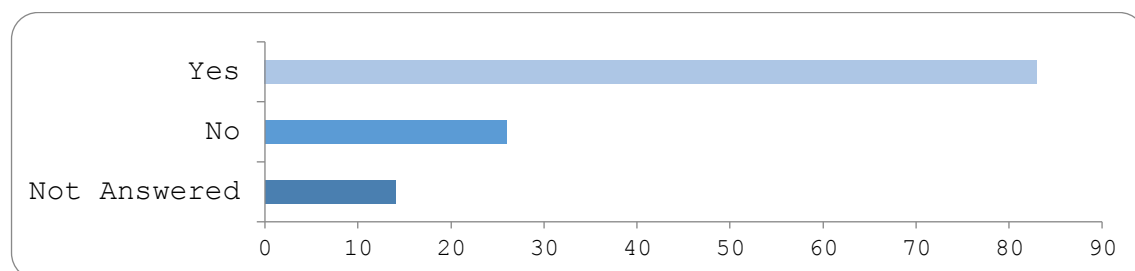
There were 34 responses to this part of the question. In analysing these responses the following tags were applied –



17. Do you agree with the proposed guidelines for the types of human tissue that may be displayed to the public?

Yes/no

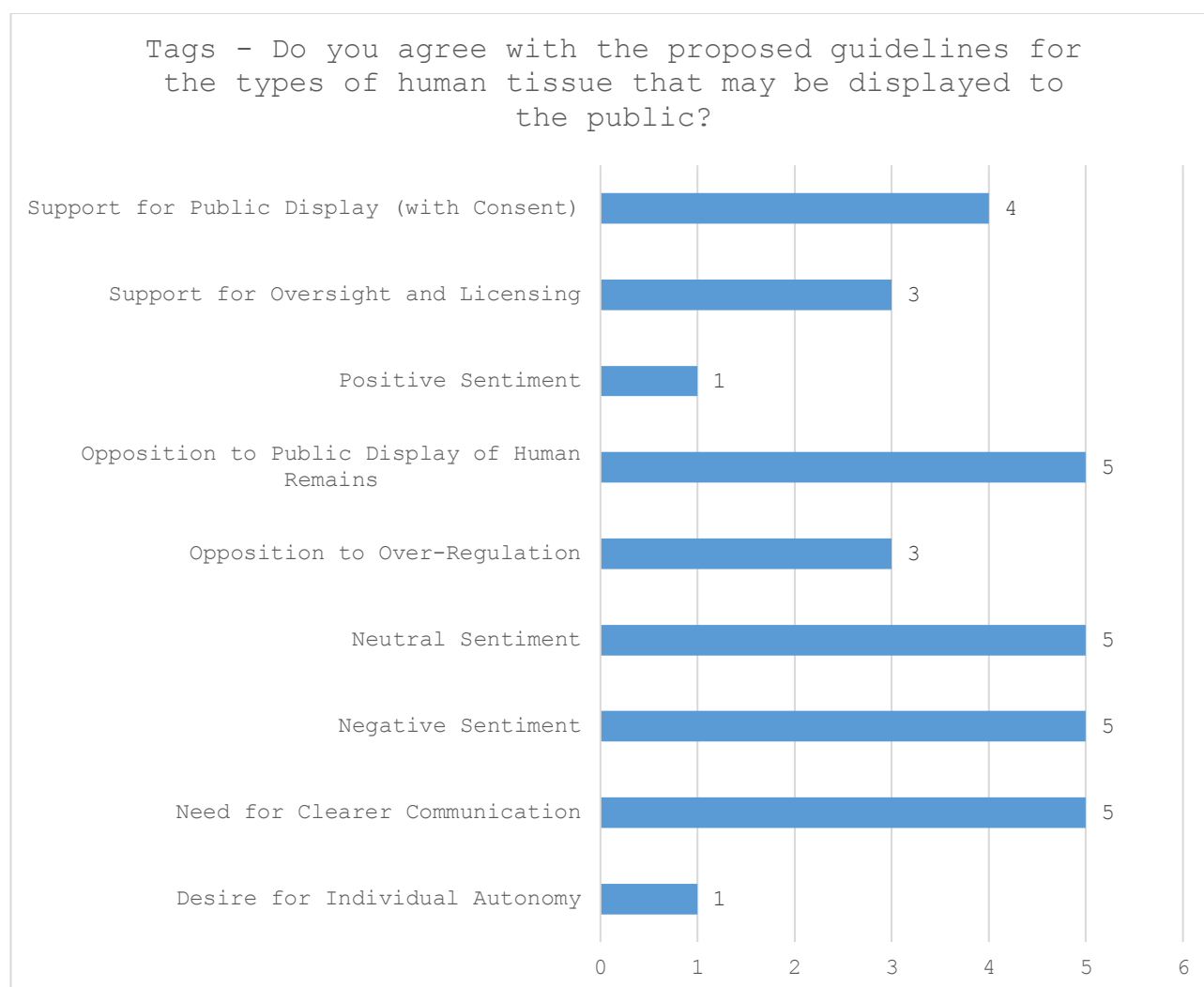
There were 109 responses to this part of the question.



Option	Total	Percent
Yes	83	67.48%
No	26	21.14%
Not Answered	14	11.38%

Comments box

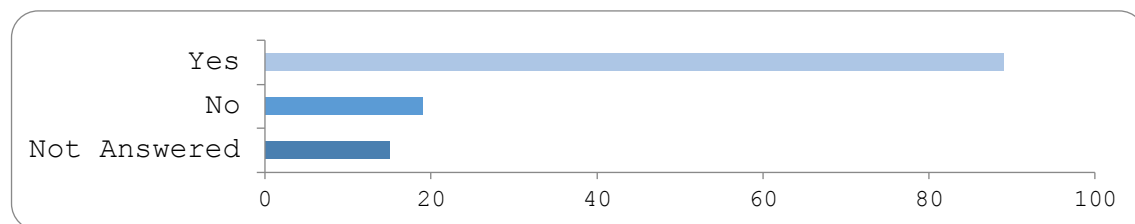
There were 23 responses to this part of the question. In analysing these responses the following tags were applied –



18. Do you agree with how 'research' is defined in the code (Page 7)?

Yes/no

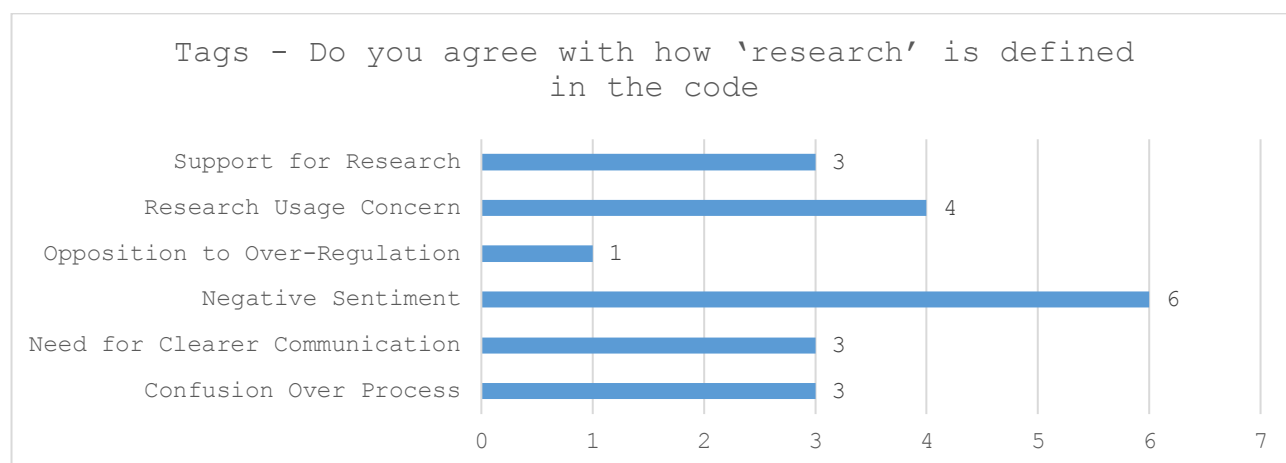
There were 108 responses to this part of the question.



Option	Total	Percent
Yes	89	72.36%
No	19	15.45%
Not Answered	15	12.20%

Comments box

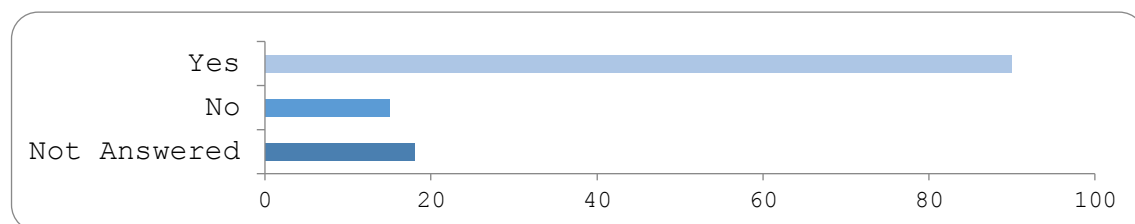
There were 14 responses to this part of the question. In analysing these responses the following tags were applied –



19. Do you agree that the proposed process for granting ethical approval for research is appropriate?

Yes/no

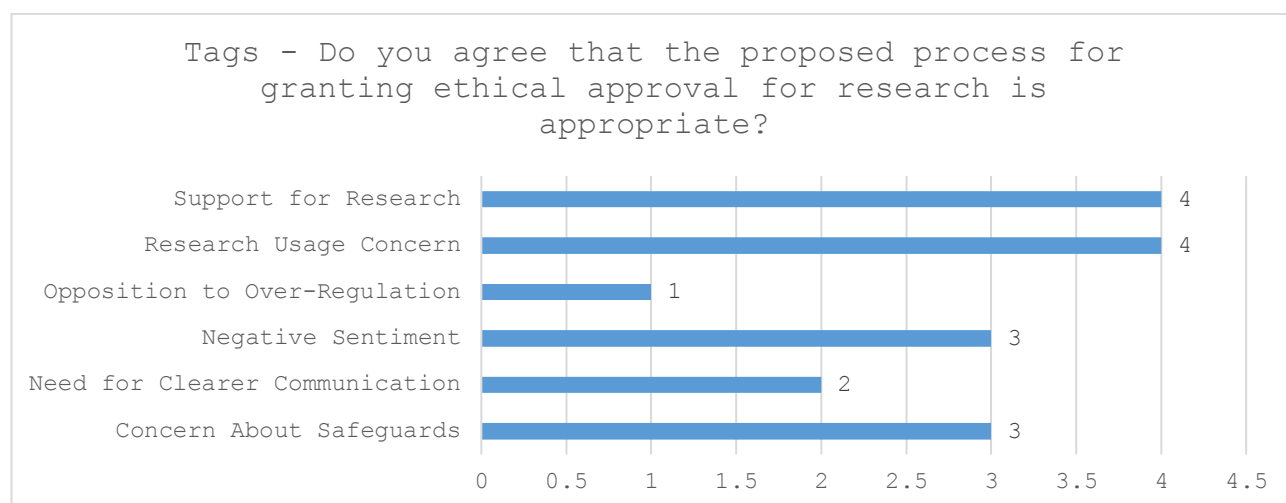
There were 105 responses to this part of the question.



Option	Total	Percent
Yes	90	73.17%
No	15	12.20%
Not Answered	18	14.63%

Comments box

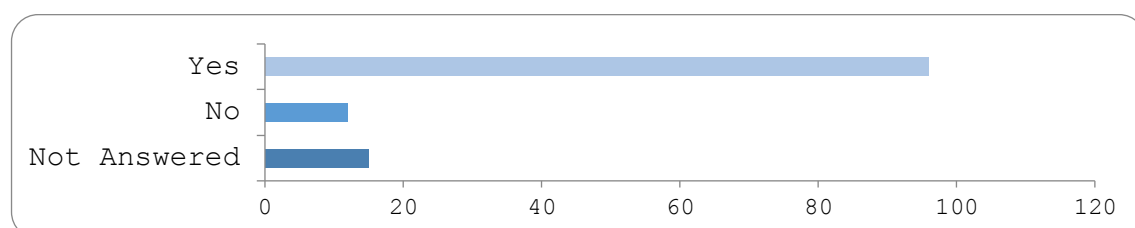
There were 12 responses to this part of the question. In analysing these responses the following tags were applied –



20. Do you think research using human tissue should be monitored after it has been approved?

Yes/no

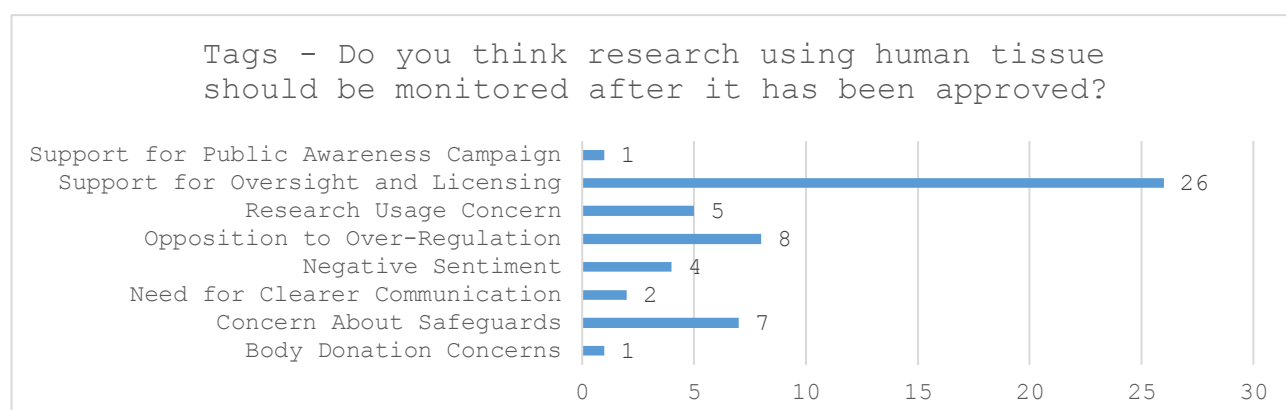
There were 108 responses to this part of the question.



Option	Total	Percent
Yes	96	78.05%
No	12	9.76%
Not Answered	15	12.20%

Comments box

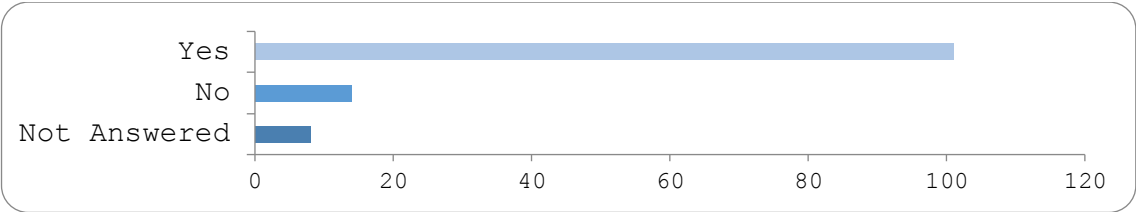
There were 39 responses to this part of the question. In analysing these responses the following tags were applied –



21. Do you agree that the code of practice clearly details the advice people should receive if they are travelling off island for living organ transplantation?

Yes/no

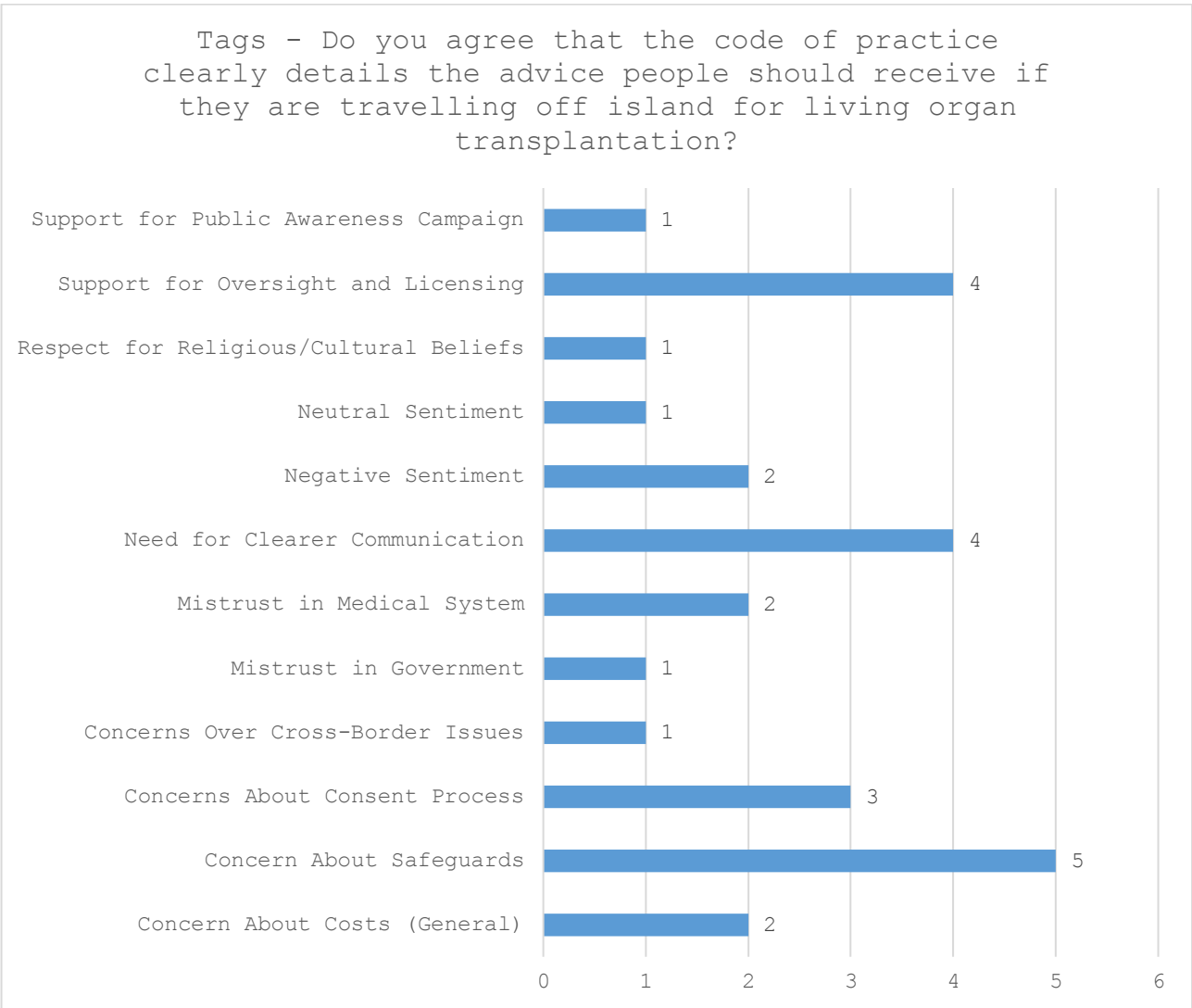
There were 115 responses to this part of the question.



Option	Total	Percent
Yes	101	82.11%
No	14	11.38%
Not Answered	8	6.50%

Comments box

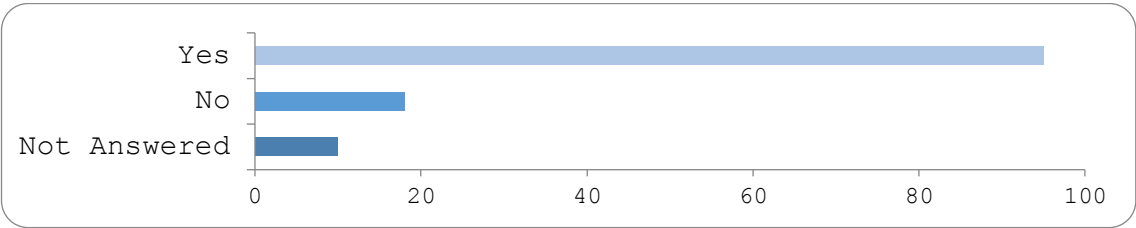
There were 14 responses to this part of the question. In analysing these responses the following tags were applied –



22. Do you agree with how 'resident' and 'ordinarily resident' are defined, particularly for students and prisoners (Pages 25 to 28)?

Yes/no

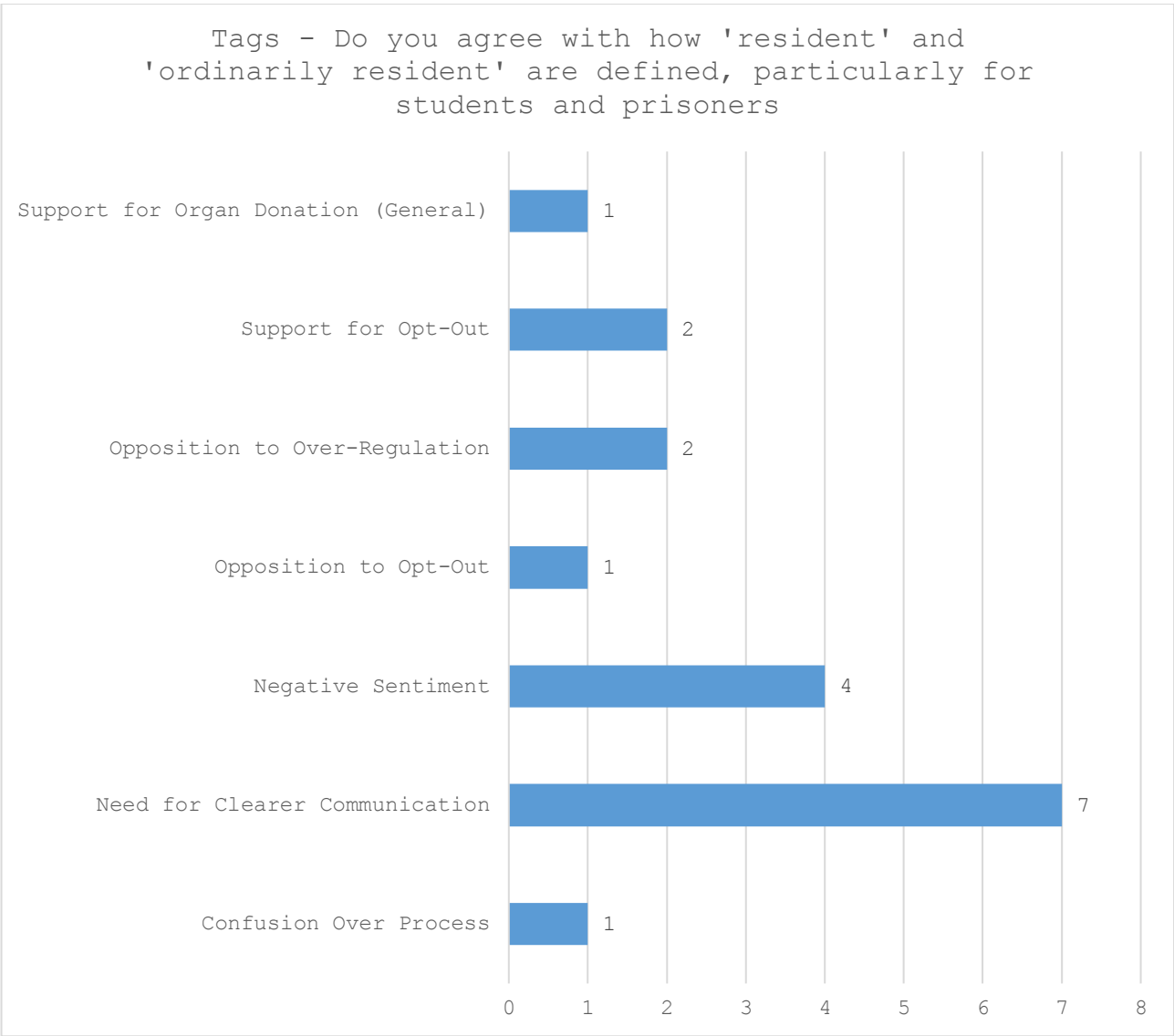
There were 113 responses to this part of the question.



Option	Total	Percent
Yes	95	77.24%
No	18	14.63%
Not Answered	10	8.13%

Comments box

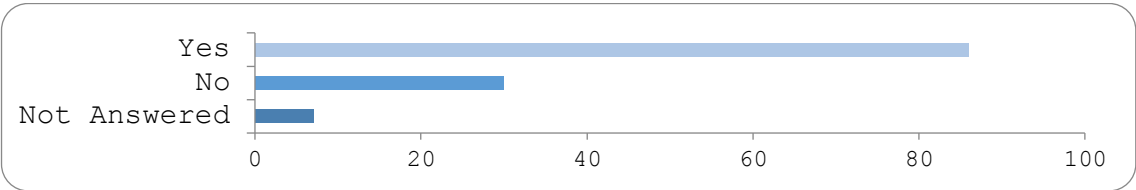
There were 13 responses to this part of the question. In analysing these responses the following tags were applied –



23. Do you agree that the proposed safeguards ensure organ donations align with the deceased’s wishes?

Yes/no

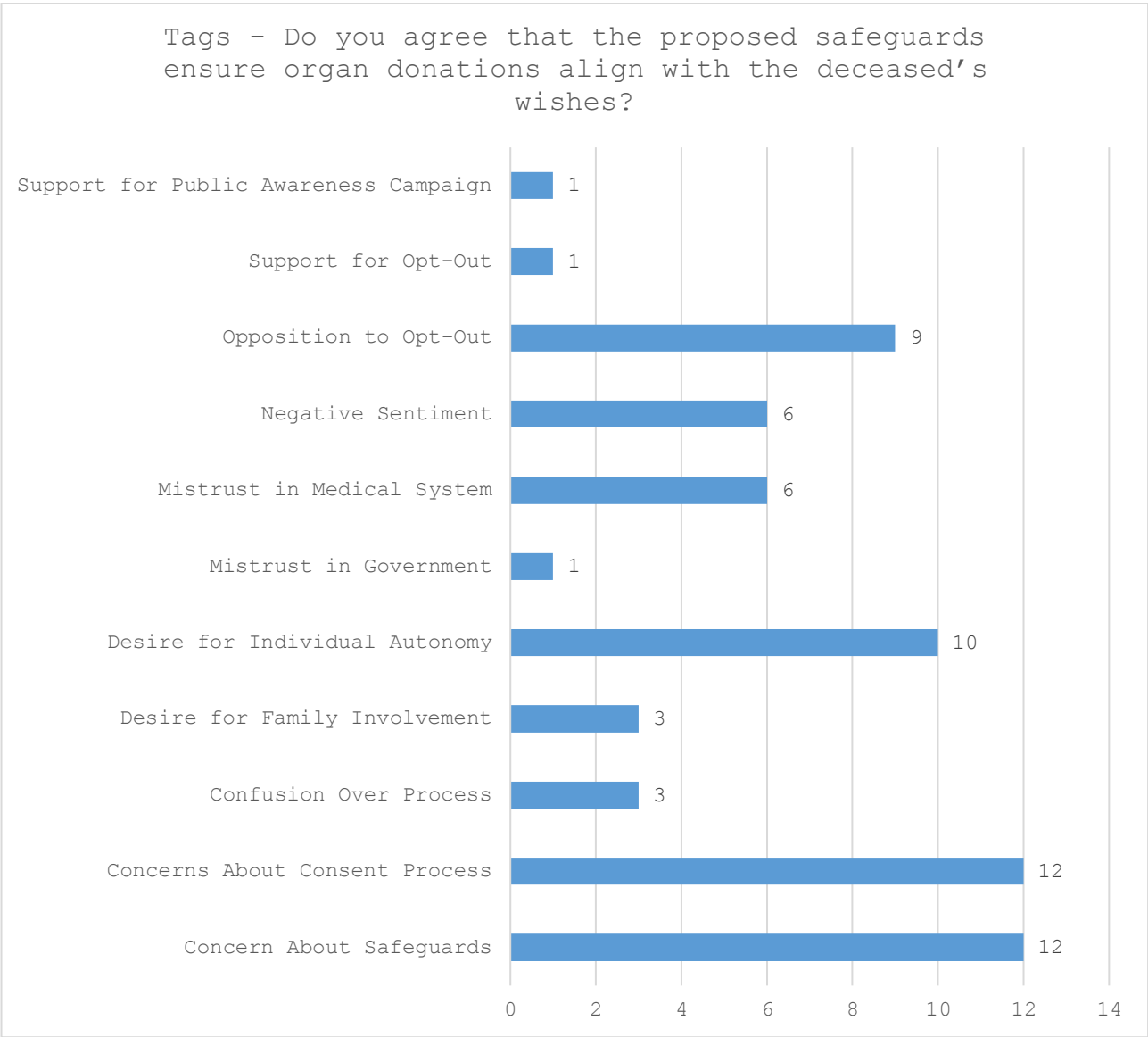
There were 116 responses to this part of the question.



Option	Total	Percent
Yes	86	69.92%
No	30	24.39%
Not Answered	7	5.69%

Comments box

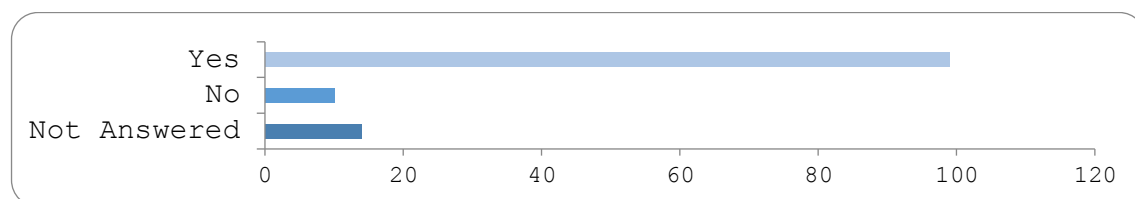
There were 26 responses to this part of the question. In analysing these responses the following tags were applied –



24. Do you agree that the code of practice clearly explains the advice given to people traveling off-island for bone marrow or PBSC donation?

Yes/no

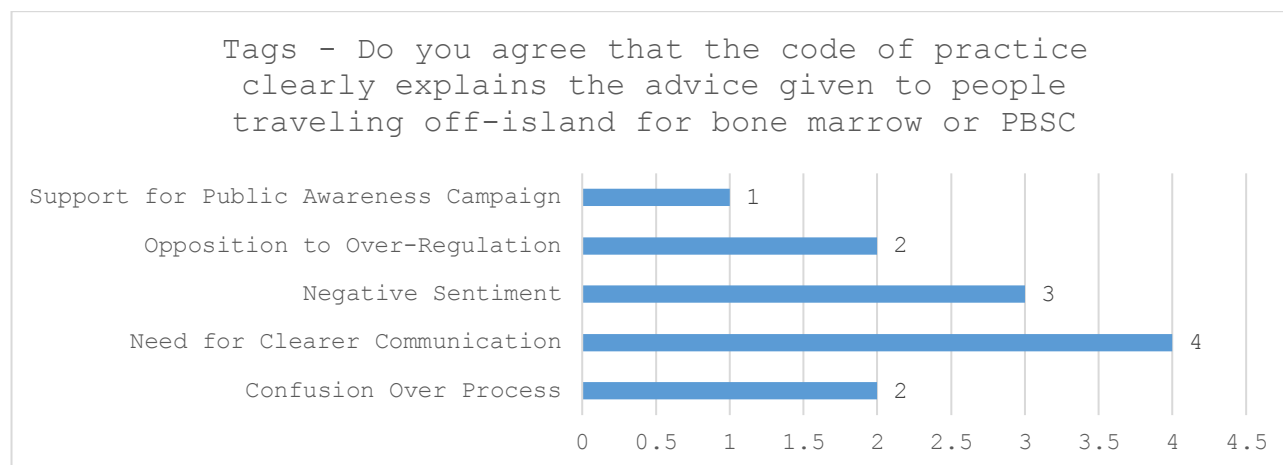
There were 109 responses to this part of the question.



Option	Total	Percent
Yes	99	80.49%
No	10	8.13%
Not Answered	14	11.38%

Comments box

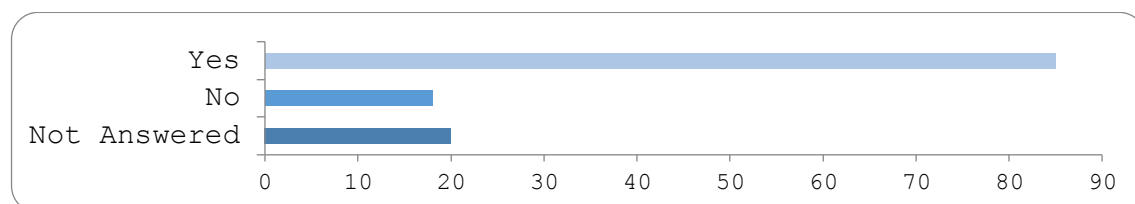
There were 10 responses to this part of the question. In analysing these responses the following tags were applied –



25. Do you agree with the proposed licensing standards?

Yes/no

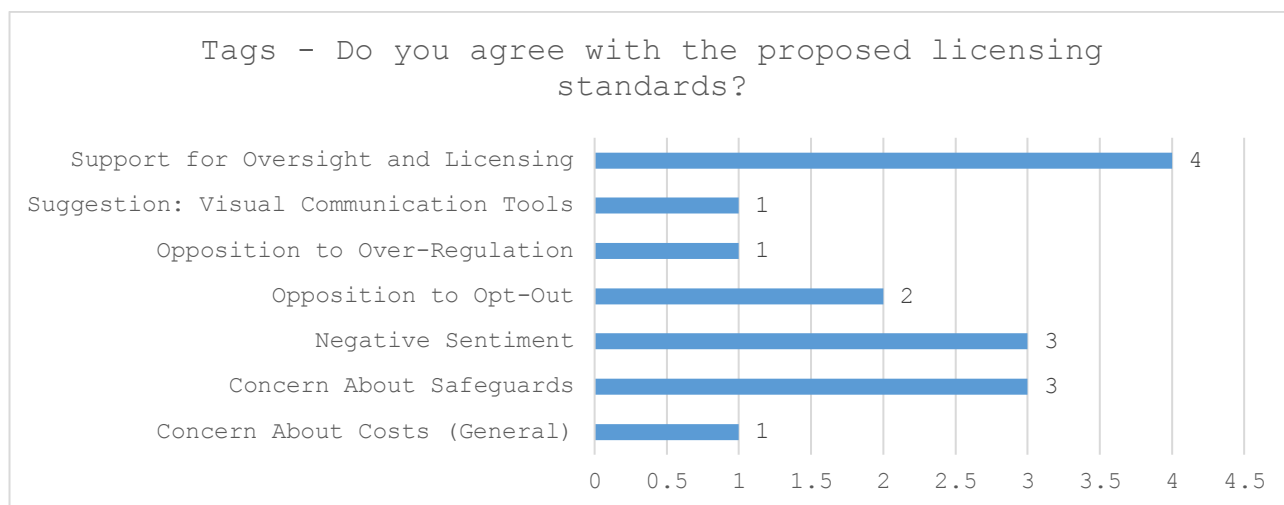
There were 103 responses to this part of the question.



Option	Total	Percent
Yes	85	69.11%
No	18	14.63%
Not Answered	20	16.26%

Comments box

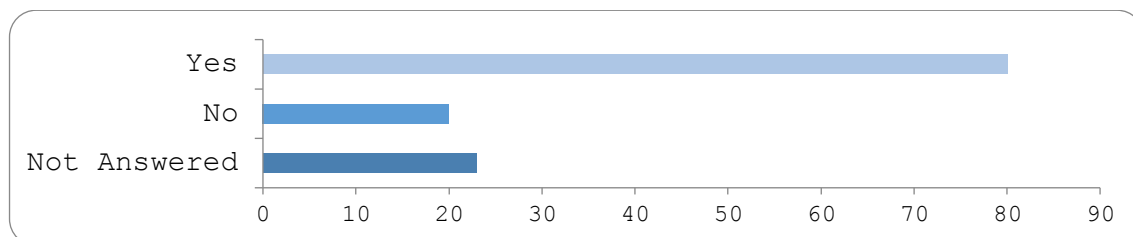
There were 12 responses to this part of the question. In analysing these responses the following tags were applied –



26. Do you agree with the proposed exceptions to licensing standards?

Yes/no

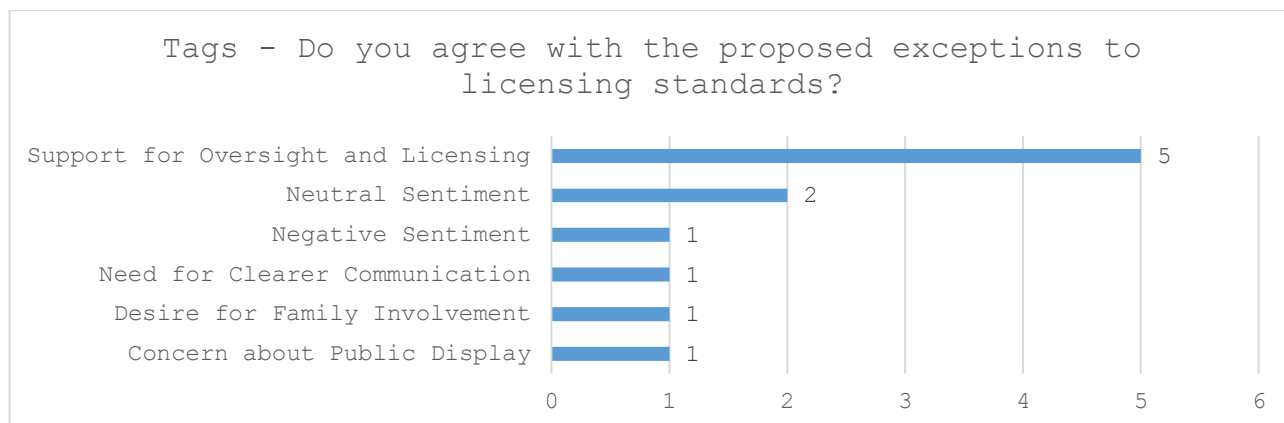
There were 100 responses to this part of the question.



Option	Total	Percent
Yes	80	65.04%
No	20	16.26%
Not Answered	23	18.70%

Comments box

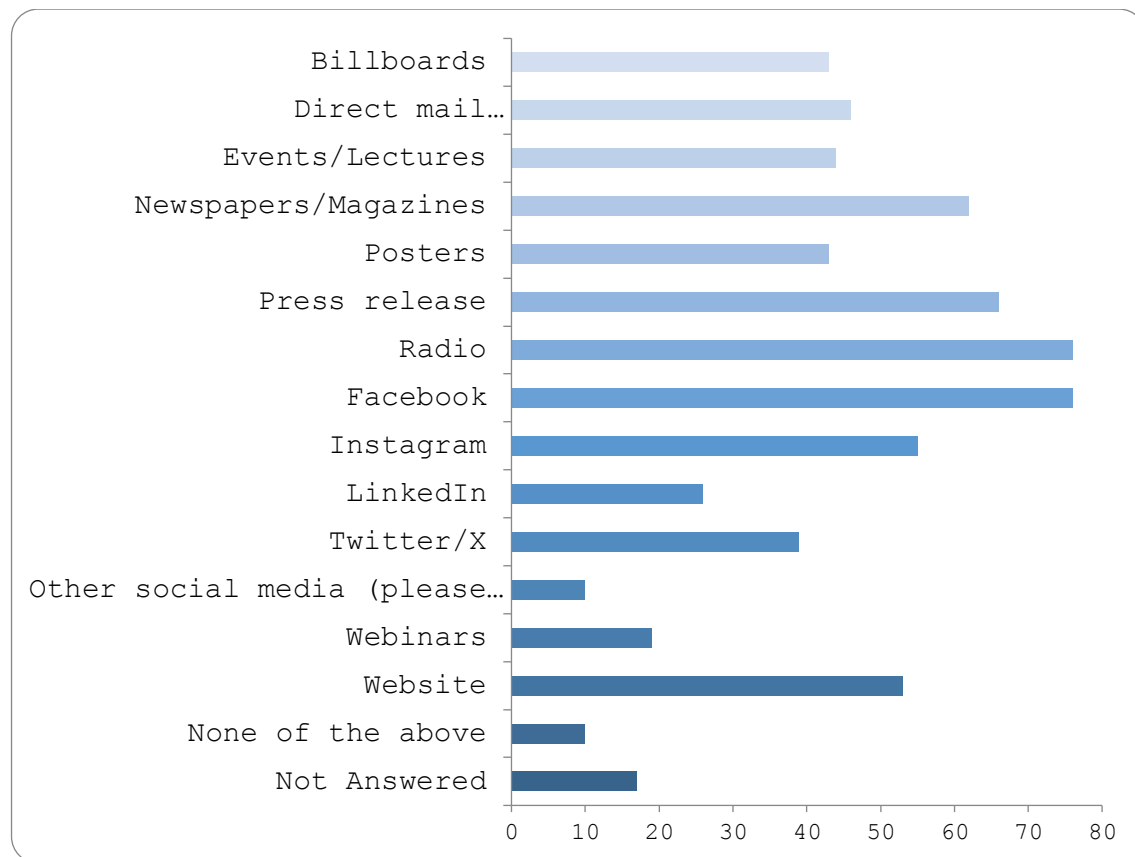
There were 10 responses to this part of the question. In analysing these responses the following tags were applied –



27. What communication methods do you believe would be most effective in encouraging people to consider organ and tissue donation?
Tick all that apply.

Select all that apply

There were 106 responses to this part of the question.



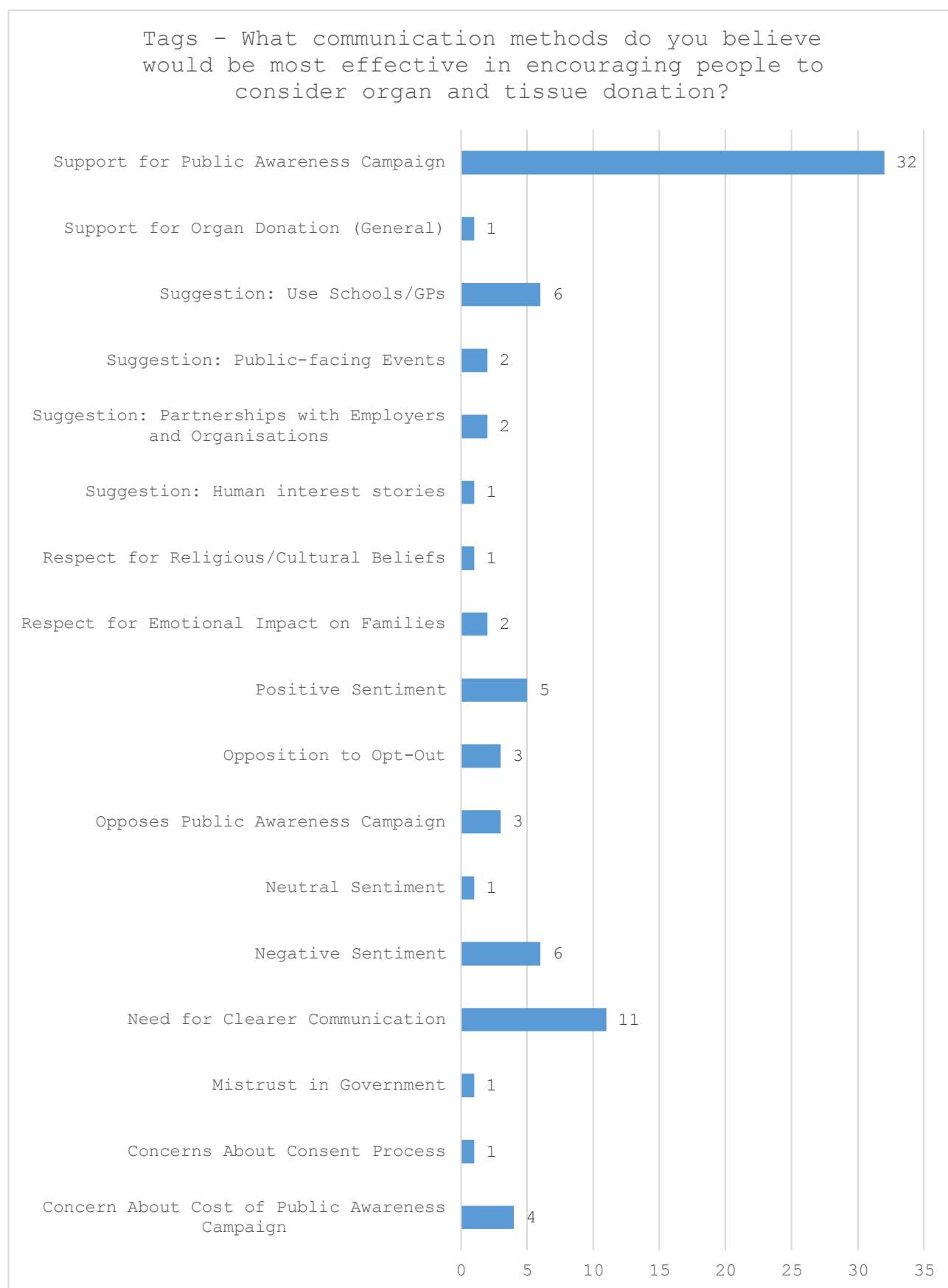
Option	Total	Percent
Billboards	43	34.96%
Direct mail (flyers/postcards)	46	37.40%
Events/Lectures	44	35.77%
Newspapers/Magazines	62	50.41%
Posters	43	34.96%
Press release	66	53.66%
Radio	76	61.79%
Facebook	76	61.79%
Instagram	55	44.72%
LinkedIn	26	21.14%
Twitter/X	39	31.71%
Other social media (please specify)	10	8.13%
Webinars	19	15.45%
Website	53	43.09%
None of the above	10	8.13%
Not Answered	17	13.82%

Other social media box

There were 6 responses to this part of the question.

Comments box

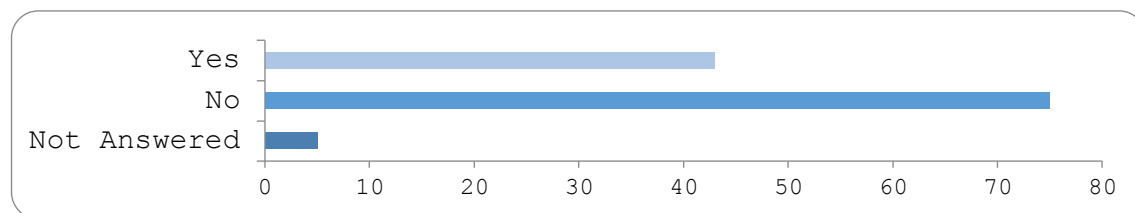
There were 42 responses to this part of the question. In analysing these responses the following tags were applied –



28. Do you have any concerns about organ donation?

Yes/no

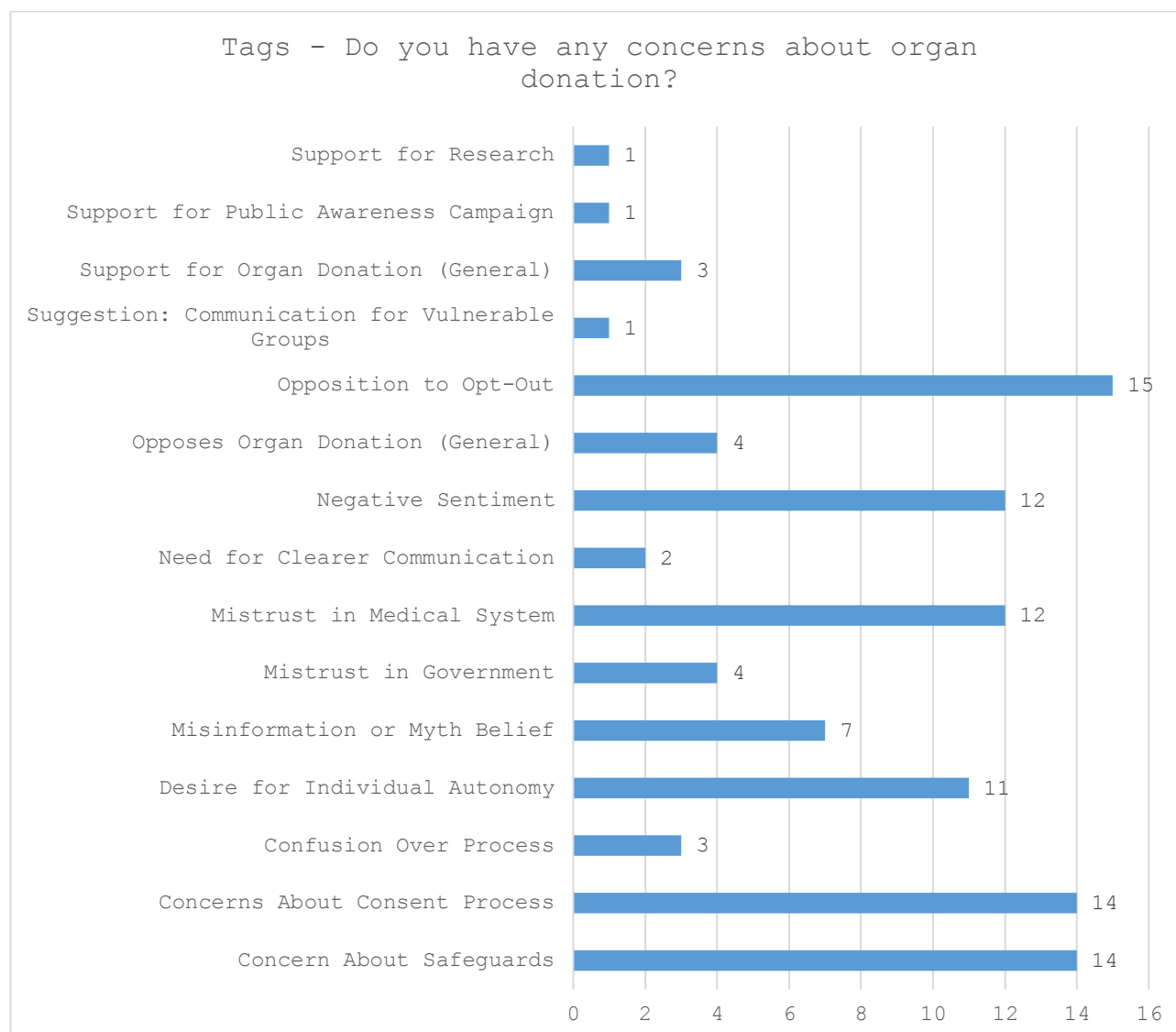
There were 118 responses to this part of the question.



Option	Total	Percent
Yes	43	34.96%
No	75	60.98%
Not Answered	5	4.07%

Comments box

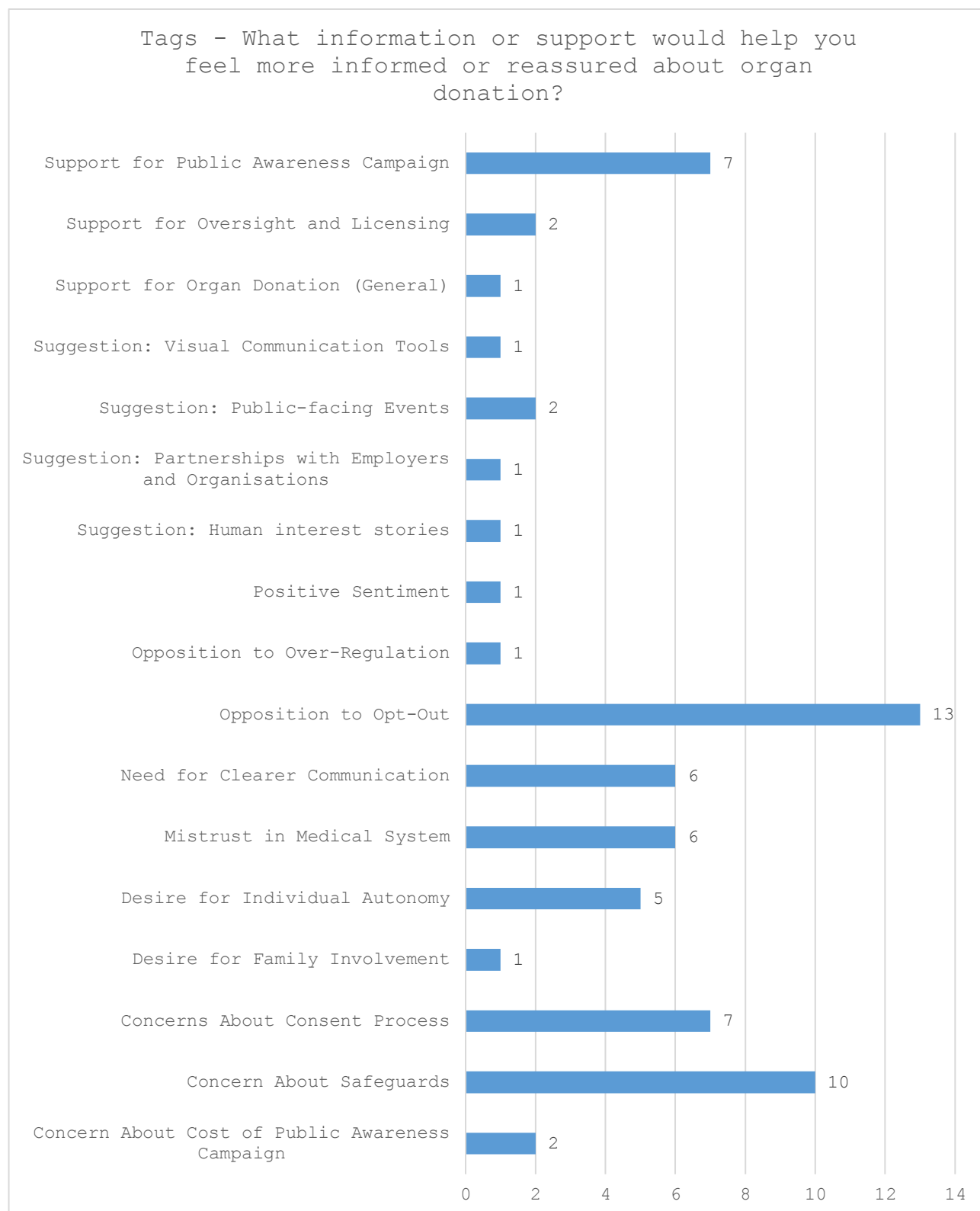
There were 37 responses to this part of the question. In analysing these responses the following tags were applied –



29. What information or support would help you feel more informed or reassured about organ donation?

Comments box

There were 33 responses to this part of the question. In analysing these responses the following tags were applied –



30. Do you have any other feedback on the codes of practice or proposed secondary legislation?

Comments box

There were 19 responses to this part of the question. In analysing these responses the following tags were applied –

