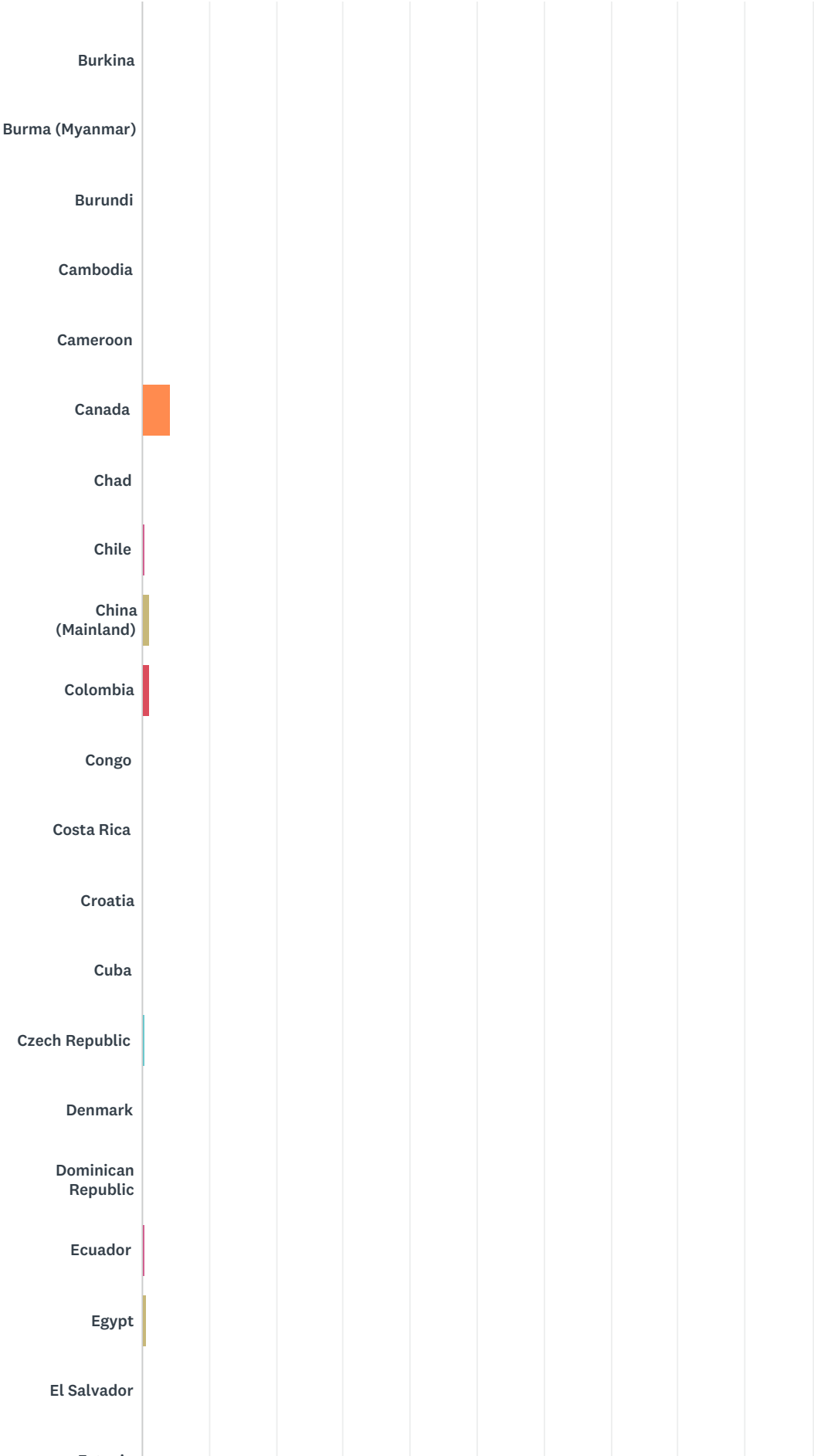


# Q1 Your country

Answered: 414    Skipped: 26





IRB/EC survey



IRB/EC survey

Iran										
Ireland										
Israel										
Italy										
Ivory Coast										
Jamaica										
Japan										
Jordan										
Kazakhstan										
Kenya										
Korea Peoples Republic										
Korea Republic Of										
Kosova										
Kyrgyzstan										
Laos										
Latvia										
Lebanon										
Lesotho										
Liberia										
Lithuania										
Luxembourg										

## IRB/EC survey

[illegible]

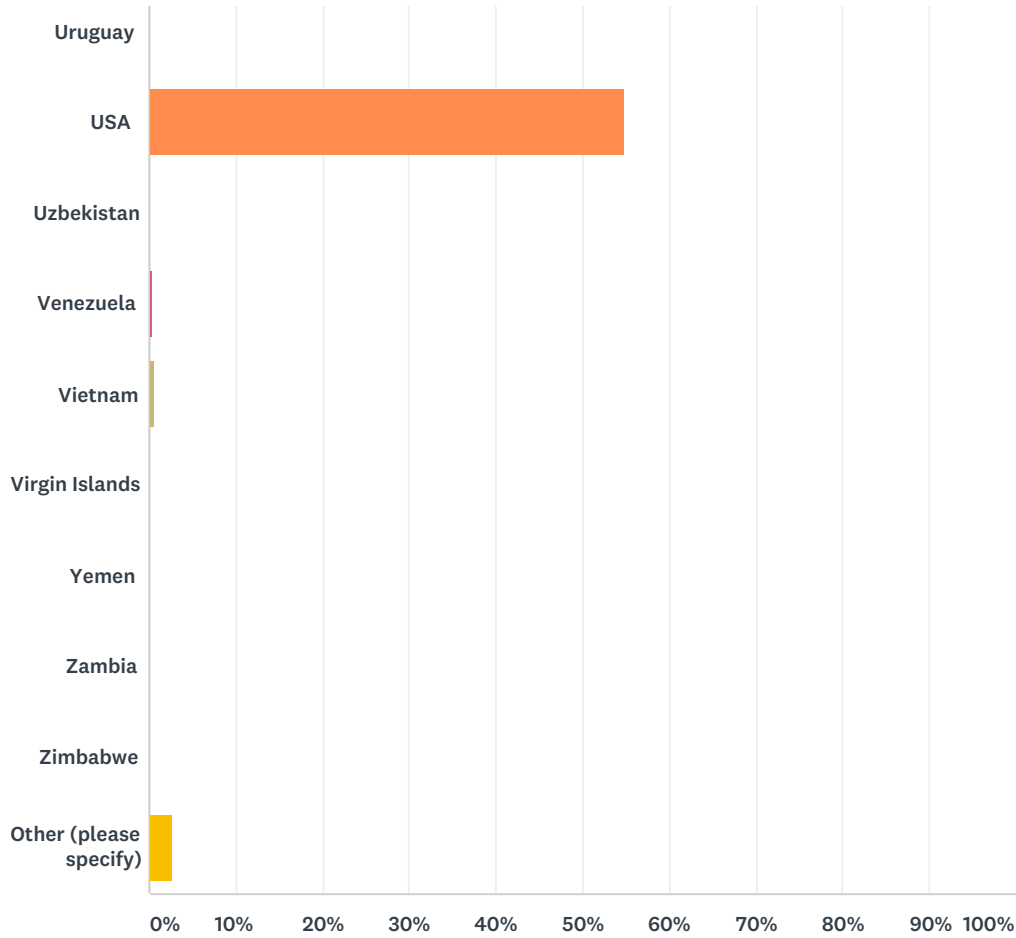
## IRB/EC survey

Pakistan
Palau
Panama
Papua N Guinea
Paraguay
Peru
Philippines
Poland
Portugal
Puerto Rico
Romania
Russia
Rwanda
Saint Lucia
Saudia Arabia
Senegal
Serbia And Montenegro
Seychelles
Sierra Leone
Singapore
Slovak

IRB/EC survey

Republic										
Slovenia										
South Africa										
Spain										
Sri Lanka										
Sudan										
Swaziland										
Sweden										
Switzerland										
Syria										
Taiwan										
Tajikistan										
Tanzania U Republic										
Thailand										
Trinidad/Tobago										
Tunisia										
Turkey										
Uganda										
Ukraine										
United Arab Emirates										
United Kingdom										

# IRB/EC survey



ANSWER CHOICES	RESPONSES	
Afghanistan	0.24%	1
American Samoa	0.24%	1
Angola	0.00%	0
Argentina	0.72%	3
Armenia	0.24%	1
Australia	3.62%	15
Austria	0.24%	1
Azerbaijan	0.00%	0
Bahamas	0.00%	0
Bangladesh	0.00%	0
Barbados	0.00%	0
Belarus	0.00%	0
Belgium	1.21%	5
Belize	0.00%	0
Benin	0.00%	0



## IRB/EC survey

Bolivia	0.24%	1
Botswana	0.00%	0
Brazil	2.66%	11
Bulgaria	0.24%	1
Burkina	0.00%	0
Burma (Myanmar)	0.00%	0
Burundi	0.00%	0
Cambodia	0.00%	0
Cameroon	0.00%	0
Canada	4.11%	17
Chad	0.00%	0
Chile	0.48%	2
China (Mainland)	0.97%	4
Colombia	0.97%	4
Congo	0.00%	0
Costa Rica	0.24%	1
Croatia	0.00%	0
Cuba	0.00%	0
Czech Republic	0.48%	2
Denmark	0.00%	0
Dominican Republic	0.24%	1
Ecuador	0.48%	2
Egypt	0.72%	3
El Salvador	0.24%	1
Estonia	0.00%	0
Ethiopia	0.24%	1
Faroe Islands	0.00%	0
Fiji	0.00%	0
Finland	0.48%	2
France	0.72%	3
French Polynesia	0.00%	0
Gabon	0.00%	0
Gambia	0.00%	0
Germany	1.69%	7
Ghana	0.00%	0

IRB/EC survey

Greece	0.00%	0
Guam	0.00%	0
Guatemala	0.24%	1
Guinea	0.00%	0
Haiti	0.24%	1
Honduras	0.00%	0
Hungary	0.48%	2
Iceland	0.00%	0
India	1.45%	6
Indonesia	0.24%	1
Iran	0.00%	0
Ireland	0.00%	0
Israel	0.24%	1
Italy	1.45%	6
Ivory Coast	0.00%	0
Jamaica	0.00%	0
Japan	0.24%	1
Jordan	0.24%	1
Kazakhstan	0.00%	0
Kenya	0.24%	1
Korea Peoples Republic	0.00%	0
Korea Republic Of	0.97%	4
Kosova	0.00%	0
Kyrgyzstan	0.24%	1
Laos	0.00%	0
Latvia	0.00%	0
Lebanon	0.24%	1
Lesotho	0.00%	0
Liberia	0.24%	1
Lithuania	0.00%	0
Luxembourg	0.00%	0
Macedonia	0.00%	0
Madagascar	0.00%	0
Malawi	0.00%	0

IRB/EC survey

Malaysia	0.00%	0
Maldives	0.00%	0
Mali	0.00%	0
Mauritius	0.00%	0
Mexico	0.97%	4
Moldova	0.00%	0
Monaco	0.00%	0
Mongolia	0.00%	0
Morocco	0.00%	0
Mozambique	0.24%	1
Namibia	0.00%	0
Nepal	0.00%	0
Netherlands	0.24%	1
New Zealand	0.00%	0
Nicaragua	0.00%	0
Nigeria	1.21%	5
Northern Mariana Islands	0.00%	0
Norway	0.48%	2
Pakistan	0.24%	1
Palau	0.00%	0
Panama	0.00%	0
Papua N Guinea	0.00%	0
Paraguay	0.00%	0
Peru	0.72%	3
Philippines	0.24%	1
Poland	0.00%	0
Portugal	0.00%	0
Puerto Rico	1.21%	5
Romania	0.24%	1
Russia	0.48%	2
Rwanda	0.00%	0
Saint Lucia	0.00%	0
Saudia Arabia	0.24%	1
Senegal	0.24%	1

# IRB/EC survey

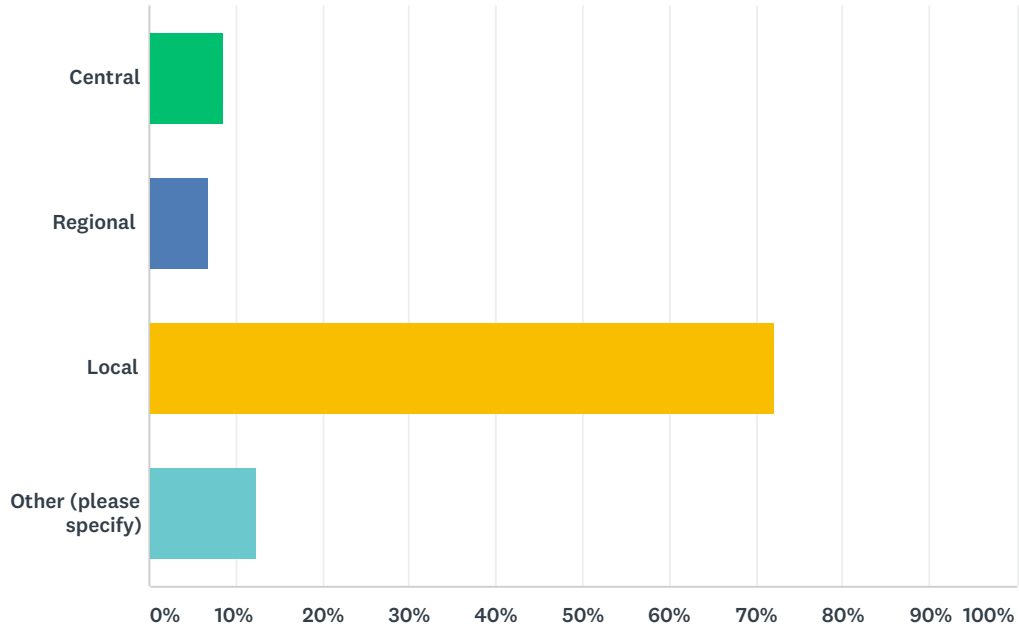
Serbia And Montenegro	0.24%	1
Seychelles	0.00%	0
Sierra Leone	0.24%	1
Singapore	0.00%	0
Slovak Republic	0.00%	0
Slovenia	0.24%	1
South Africa	0.24%	1
Spain	0.48%	2
Sri Lanka	0.00%	0
Sudan	0.00%	0
Swaziland	0.00%	0
Sweden	0.00%	0
Switzerland	0.24%	1
Syria	0.00%	0
Taiwan	0.72%	3
Tajikistan	0.00%	0
Tanzania U Republic	0.24%	1
Thailand	0.48%	2
Trinidad/Tobago	0.00%	0
Tunisia	0.00%	0
Turkey	0.00%	0
Uganda	0.48%	2
Ukraine	0.24%	1
United Arab Emirates	0.00%	0
United Kingdom	1.93%	8
Uruguay	0.24%	1
USA	54.83%	227
Uzbekistan	0.00%	0
Venezuela	0.48%	2
Vietnam	0.72%	3
Virgin Islands	0.00%	0
Yemen	0.00%	0
Zambia	0.00%	0
Zimbabwe	0.00%	0

# IRB/EC survey

Other (please specify)	2.66%	11
TOTAL		414

## Q2 Your IRB/EC is:

Answered: 410 Skipped: 30



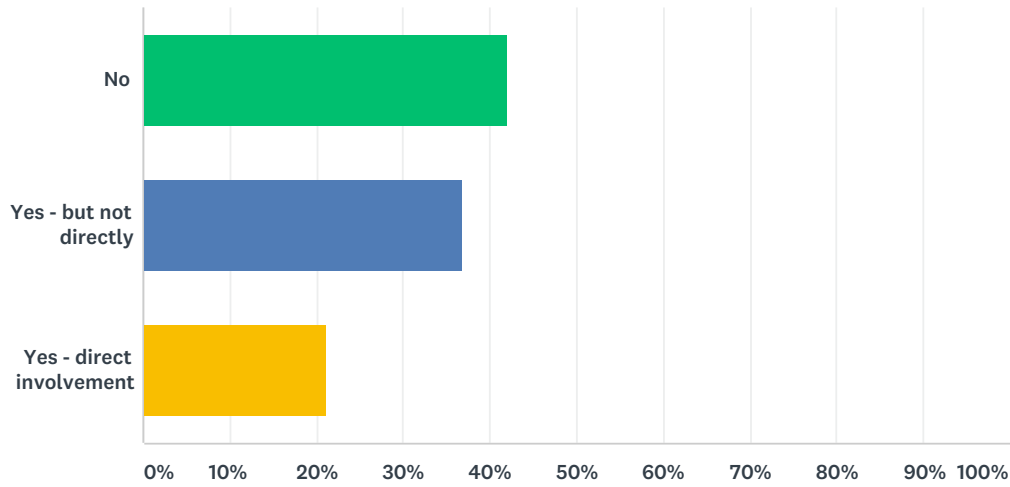
ANSWER CHOICES		RESPONSES	
Central		8.54%	35
Regional		6.83%	28
Local		72.20%	296
Other (please specify)		12.44%	51
TOTAL			410

Q3 Your IRB/EC site name (e.g. region, city or hospital name):

Answered: 371   Skipped: 69

## Q4 Do you yourself have previous experience with genetic studies?

Answered: 409 Skipped: 31

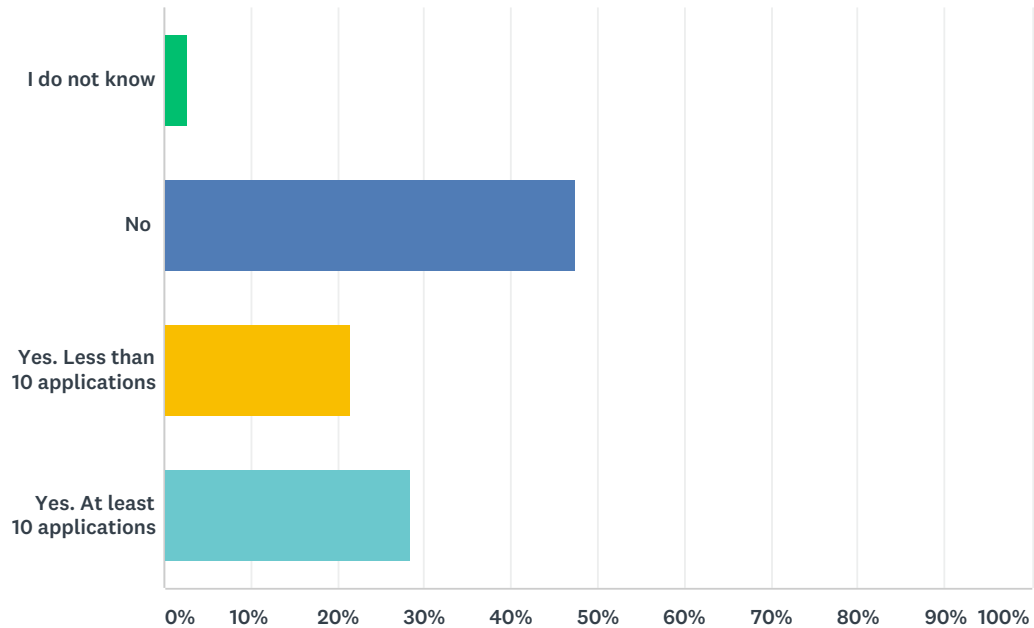


ANSWER CHOICES	RESPONSES	
No	42.05%	172
Yes - but not directly	36.92%	151
Yes - direct involvement	21.03%	86
TOTAL		409



## Q5 Has your Committee evaluated pharmacogenetic study applications?

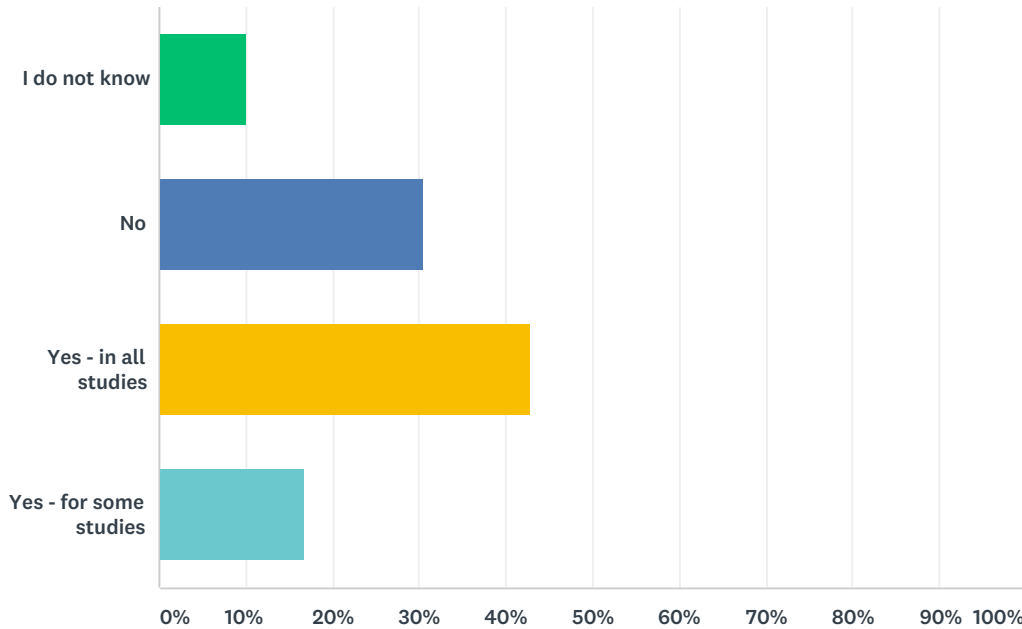
Answered: 409 Skipped: 31



ANSWER CHOICES	RESPONSES	
I do not know	2.69%	11
No	47.43%	194
Yes. Less than 10 applications	21.52%	88
Yes. At least 10 applications	28.36%	116
TOTAL		409

## Q6 Does your committee require a separate informed consent form for pharmacogenetic studies?

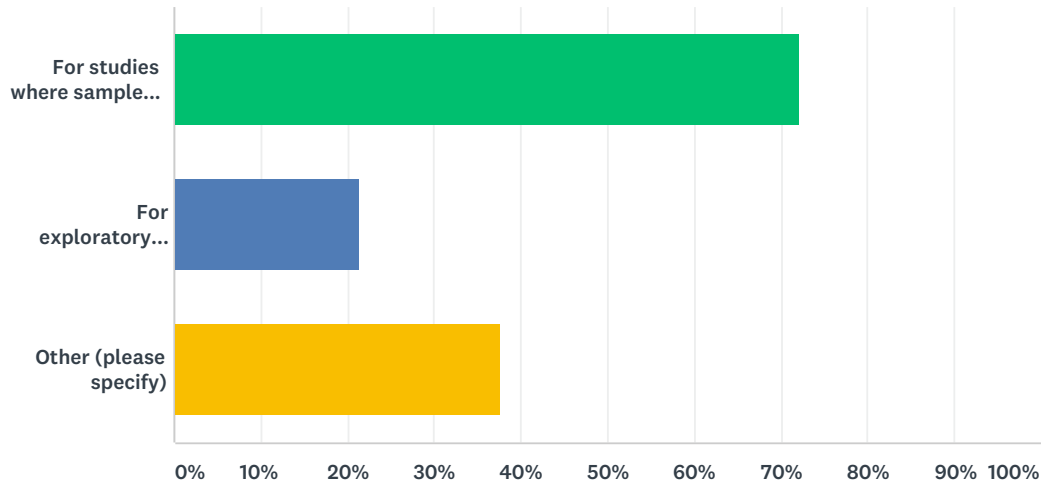
Answered: 390 Skipped: 50



ANSWER CHOICES	RESPONSES	
I do not know	10.00%	39
No	30.51%	119
Yes - in all studies	42.82%	167
Yes - for some studies	16.67%	65
TOTAL		390

## Q7 For what pharmacogenetic studies does your committee require a separate informed consent form?

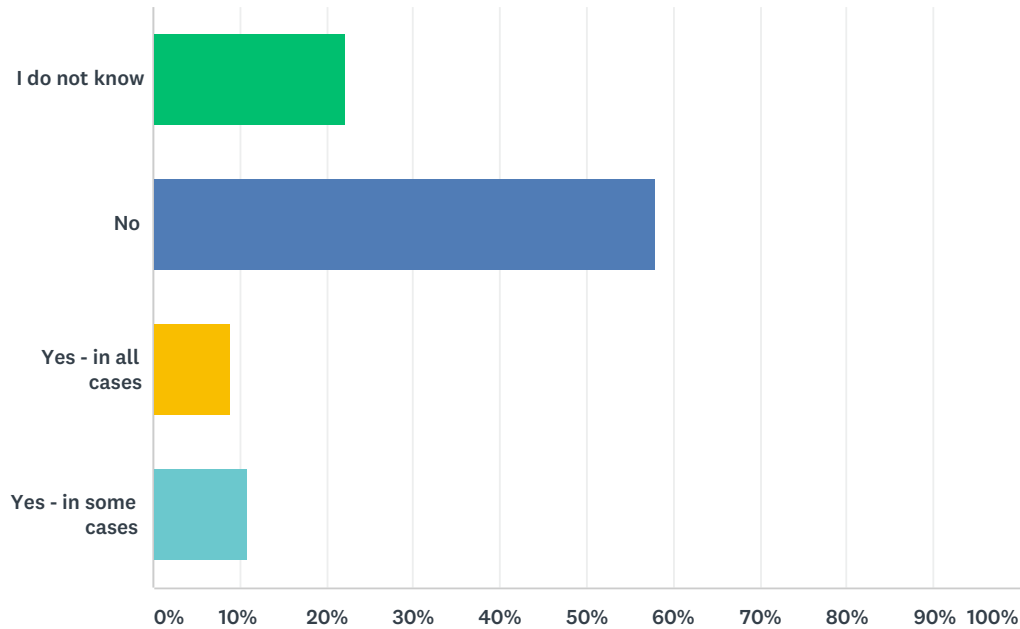
Answered: 61 Skipped: 379



ANSWER CHOICES	RESPONSES	
For studies where samples are collected for biobanking	72.13%	44
For exploratory studies	21.31%	13
Other (please specify)	37.70%	23
Total Respondents: 61		

## Q8 Does your committee require that individual genotypes are reported back?

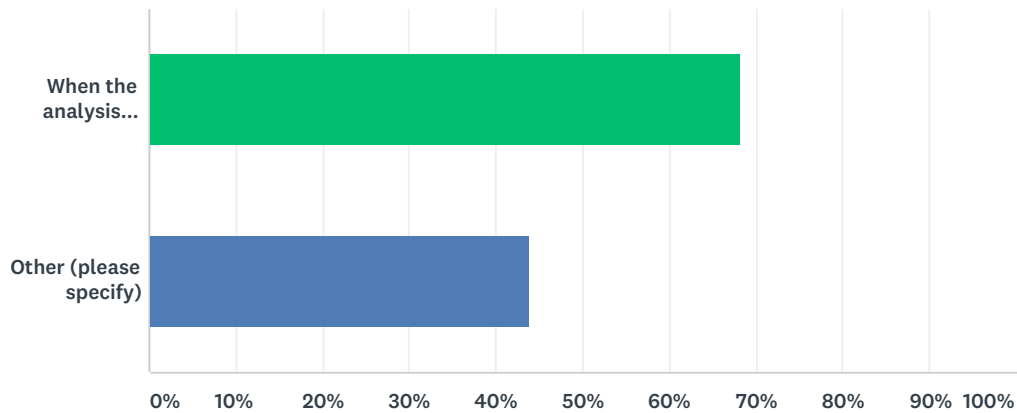
Answered: 378 Skipped: 62



ANSWER CHOICES	RESPONSES	
I do not know	22.22%	84
No	57.94%	219
Yes - in all cases	8.99%	34
Yes - in some cases	10.85%	41
TOTAL		378

Q9 In what cases does your committee require that individual genotype is reported back?

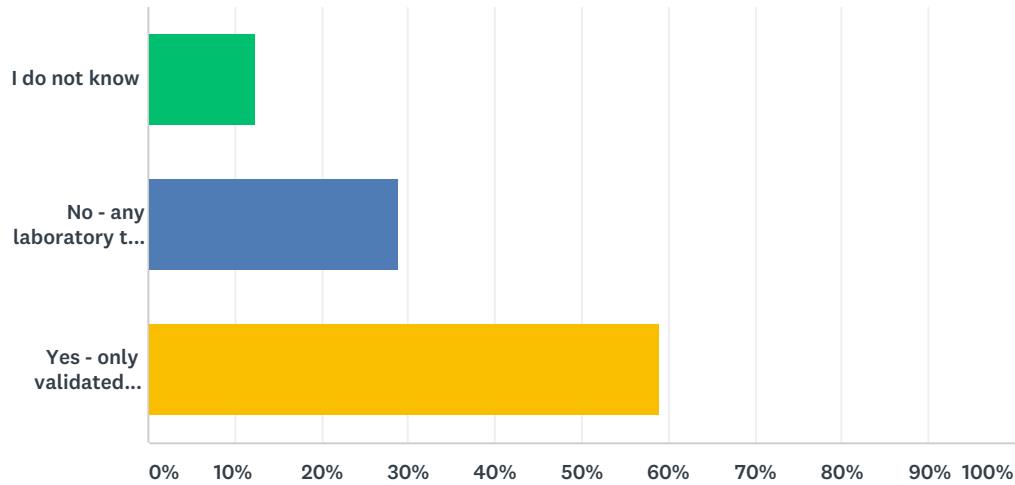
Answered: 41    Skipped: 399



ANSWER CHOICES		RESPONSES	
When the analysis concerns valid or probable valid biomarkers as defined by Regulatory Authorities		68.29%	28
Other (please specify)		43.90%	18
Total Respondents: 41			

## Q10 When genotype is reported back, does your committee require certain level of assay validation?

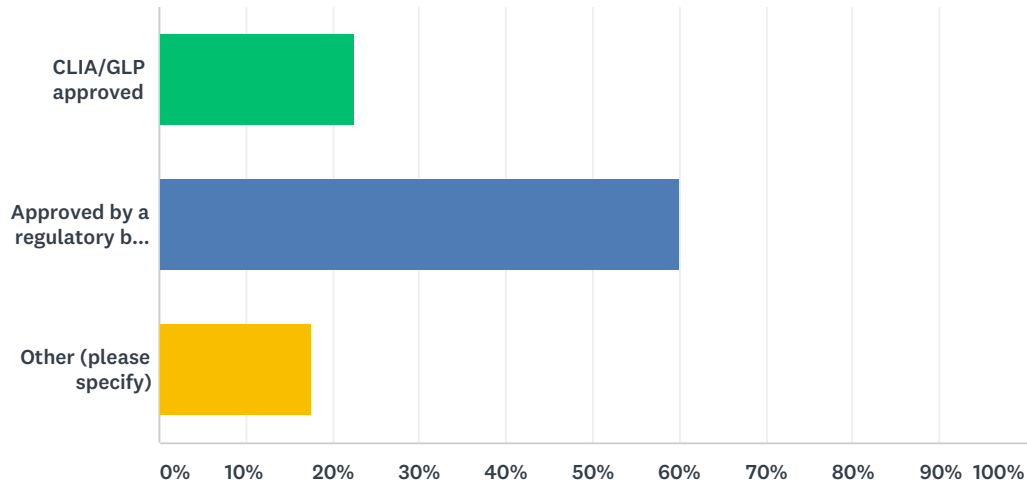
Answered: 73 Skipped: 367



ANSWER CHOICES		RESPONSES	
I do not know		12.33%	9
No - any laboratory test may be reported back		28.77%	21
Yes - only validated laboratory tests		58.90%	43
TOTAL			73

## Q11 Please specify level of validation that is required when genotype is reported back:

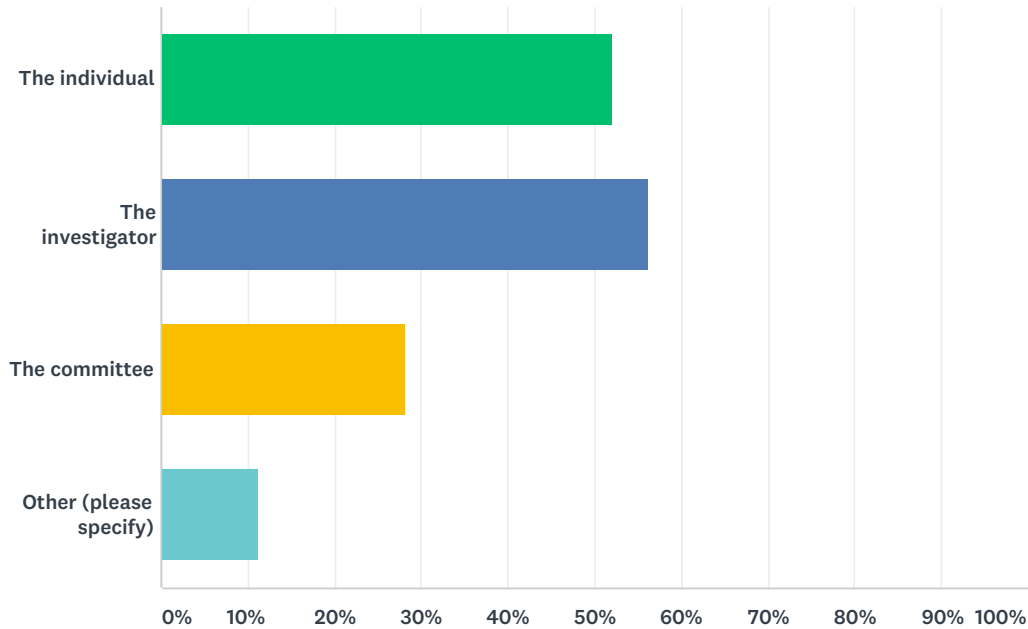
Answered: 40 Skipped: 400



ANSWER CHOICES	RESPONSES	
CLIA/GLP approved	22.50%	9
Approved by a regulatory body (e.g. FDA or EMEA)	60.00%	24
Other (please specify)	17.50%	7
TOTAL		40

## Q12 When genotypes are reported back, please select reported back to whom:

Answered: 71 Skipped: 369

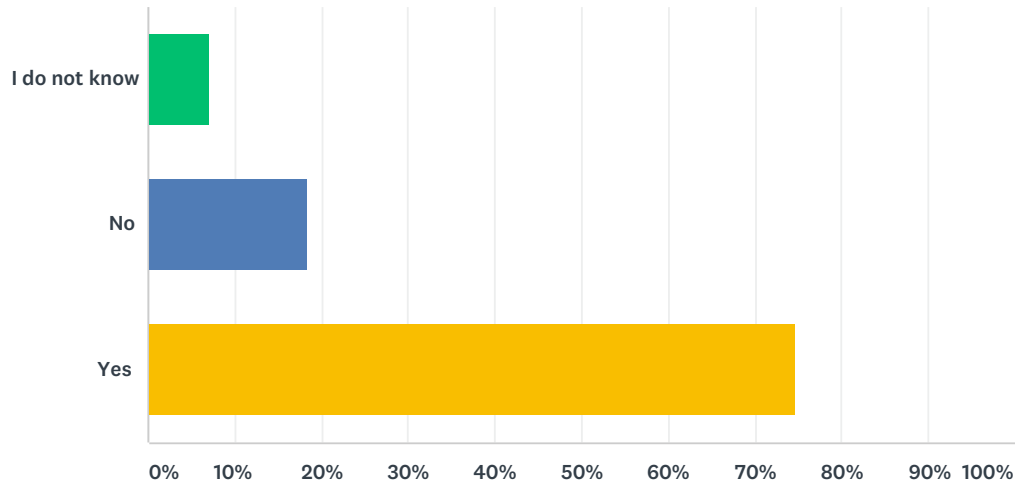


ANSWER CHOICES	RESPONSES	
The individual	52.11%	37
The investigator	56.34%	40
The committee	28.17%	20
Other (please specify)	11.27%	8
Total Respondents: 71		



# Q13 When genetic results are reported back to individuals, does your committee require genetic counseling?

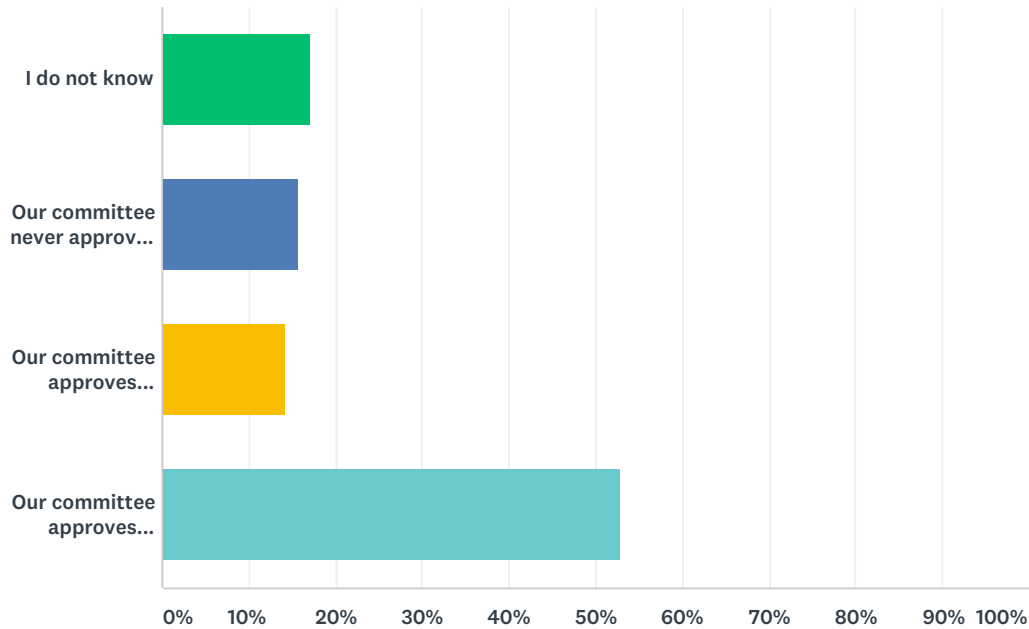
Answered: 71 Skipped: 369



ANSWER CHOICES	RESPONSES	
I do not know	7.04%	5
No	18.31%	13
Yes	74.65%	53
TOTAL		71

## Q14 What requirements are imposed by your committee to approve analysis of DNA?

Answered: 368 Skipped: 72



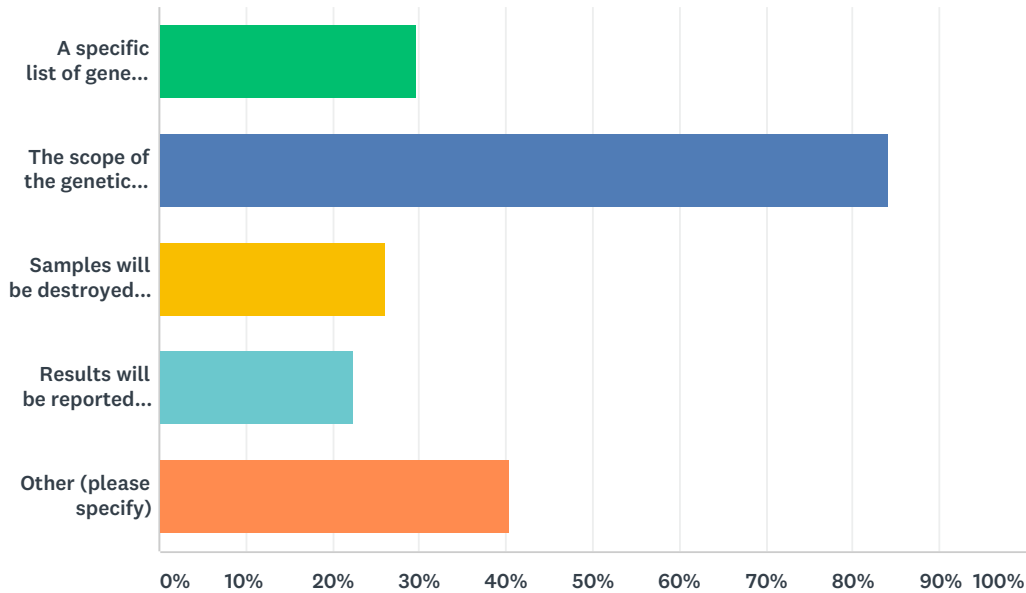
ANSWER CHOICES	RESPONSES	
I do not know	17.12%	63
Our committee never approves analysis of DNA	15.76%	58
Our committee approves analysis of DNA without imposed requirements	14.13%	52
Our committee approves analysis of DNA only under certain conditions	52.99%	195
TOTAL		368

## Q15 Please provide reason for the practice not to approve analysis of DNA

Answered: 50   Skipped: 390

## Q16 Our committee approves DNA analysis only if the following conditions are met:

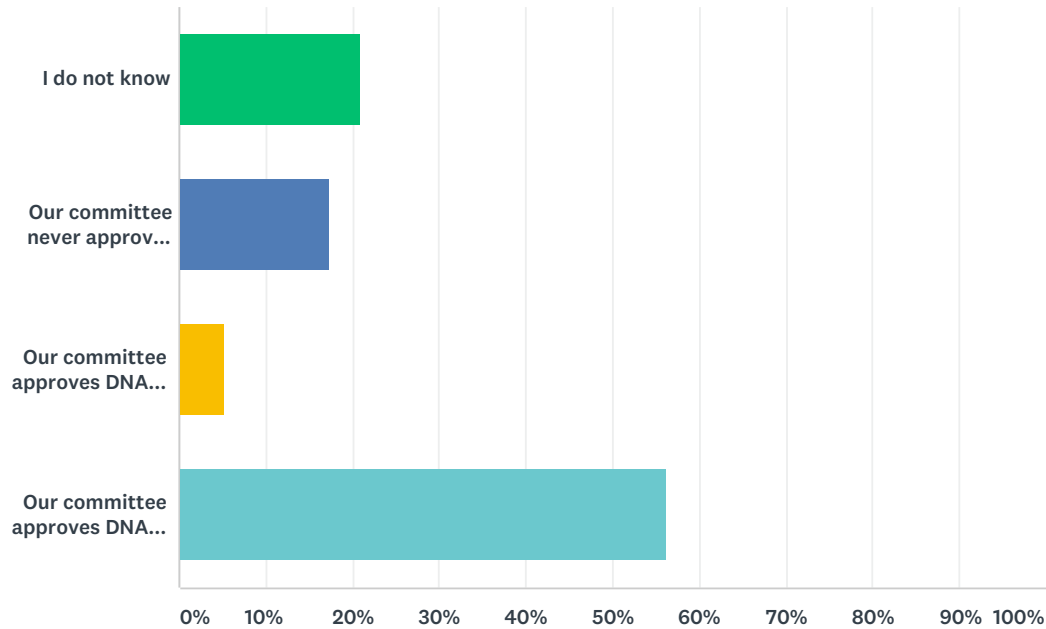
Answered: 188 Skipped: 252



ANSWER CHOICES	RESPONSES	
A specific list of genes is provided	29.79%	56
The scope of the genetic analysis is provided	84.04%	158
Samples will be destroyed following testing	26.06%	49
Results will be reported back to subjects	22.34%	42
Other (please specify)	40.43%	76
Total Respondents: 188		

## Q17 What requirements are imposed by your committee to approve DNA sample biobanking?

Answered: 357 Skipped: 83



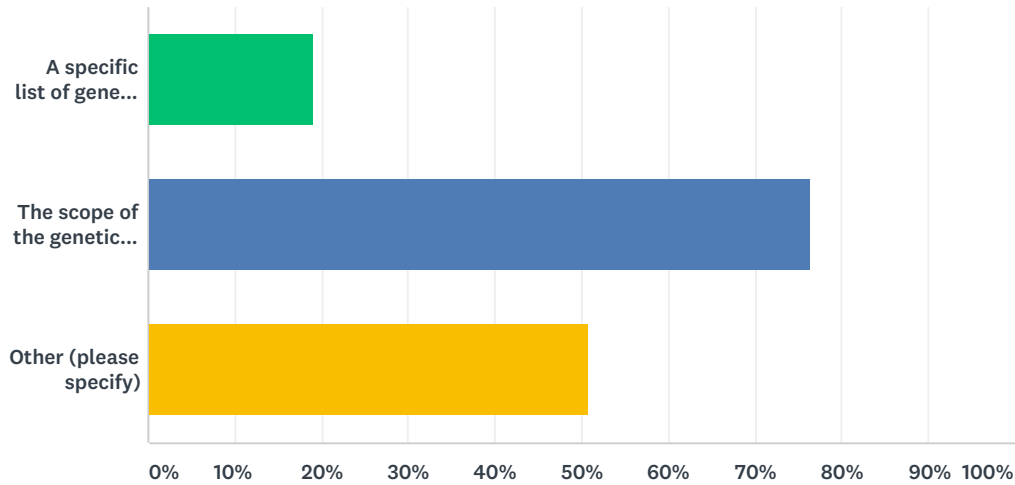
ANSWER CHOICES	RESPONSES	
I do not know	21.01%	75
Our committee never approves DNA biobanking	17.37%	62
Our committee approves DNA biobanking without imposed requirements	5.32%	19
Our committee approves DNA biobanking only if certain conditions are met	56.30%	201
TOTAL		357

**Q18 Please provide reason for the practice not to approve DNA biobanking.**

Answered: 52   Skipped: 388

## Q19 Our committee approves DNA sample biobanking only if the following conditions are met:

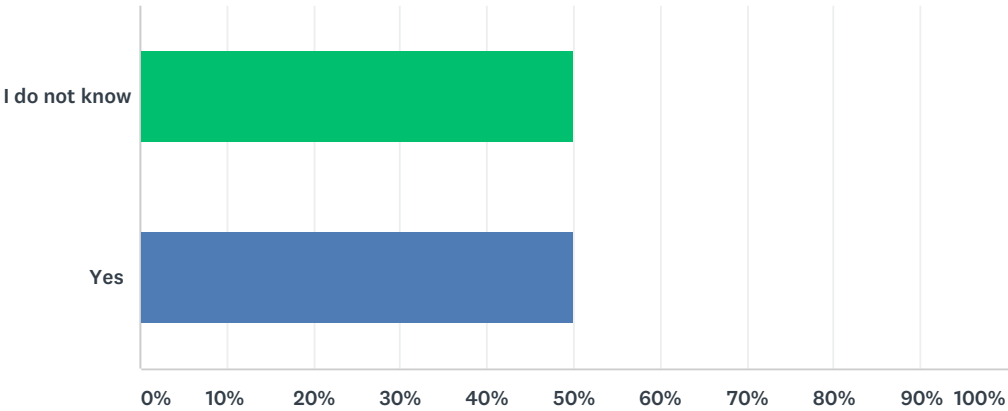
Answered: 199 Skipped: 241



ANSWER CHOICES	RESPONSES	
A specific list of genes is provided	19.10%	38
The scope of the genetic analysis is provided	76.38%	152
Other (please specify)	50.75%	101
Total Respondents: 199		

Q20 Does your committee require a certain coding categories for DNA sample biobanking? [You can find the coding definitions in the ICH Guideline (a PDF file will be opened in a new window)]

Answered: 212    Skipped: 228

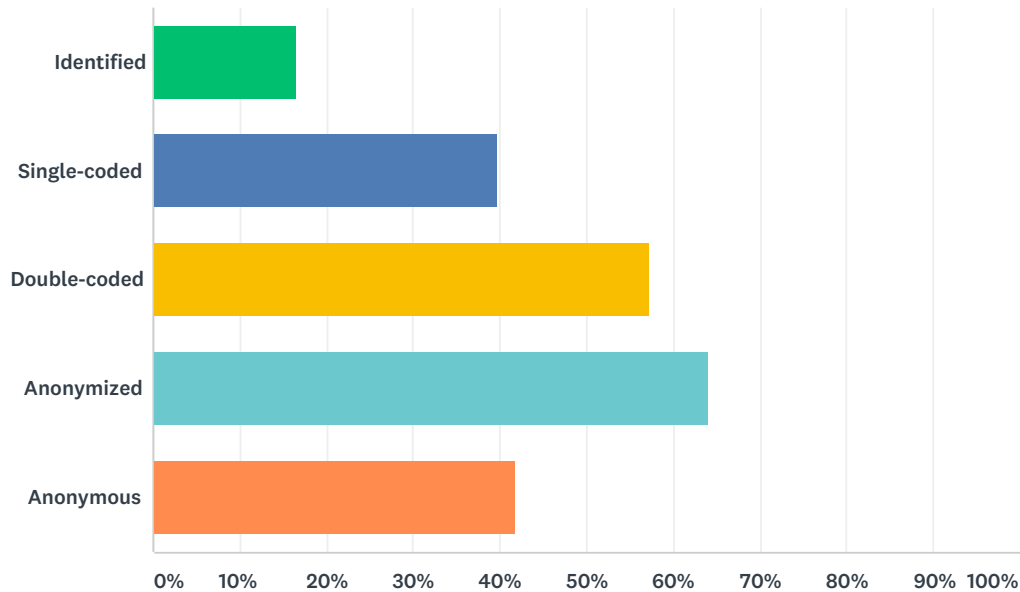


ANSWER CHOICES	RESPONSES	
I do not know	50.00%	106
Yes	50.00%	106
TOTAL		212



Q21 Our committee allows DNA biobanking if samples are: [You can find the coding definitions in the ICH Guideline (a PDF file will be opened in a new window)]

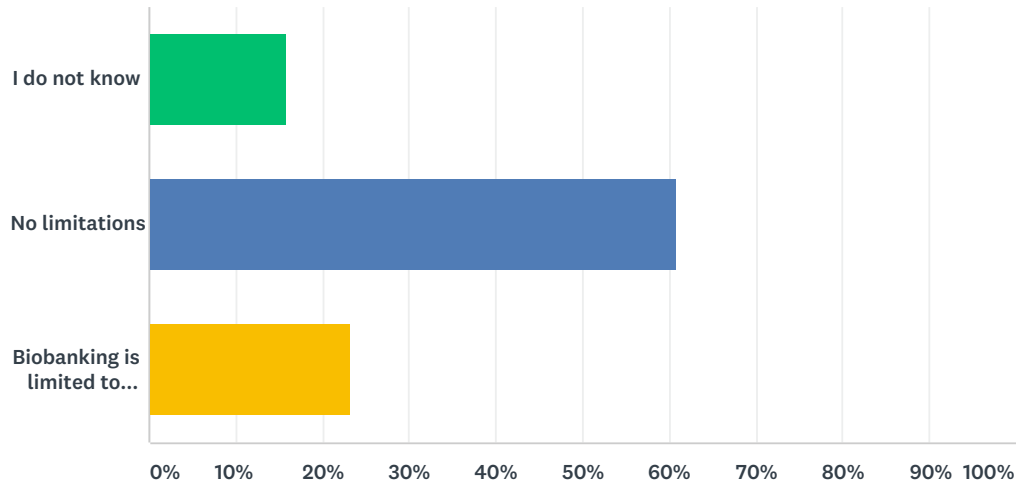
Answered: 103 Skipped: 337



ANSWER CHOICES	RESPONSES	
Identified	16.50%	17
Single-coded	39.81%	41
Double-coded	57.28%	59
Anonymized	64.08%	66
Anonymous	41.75%	43
Total Respondents: 103		

## Q22 Please indicate the geographical limitations specified by your committee for DNA biobanking:

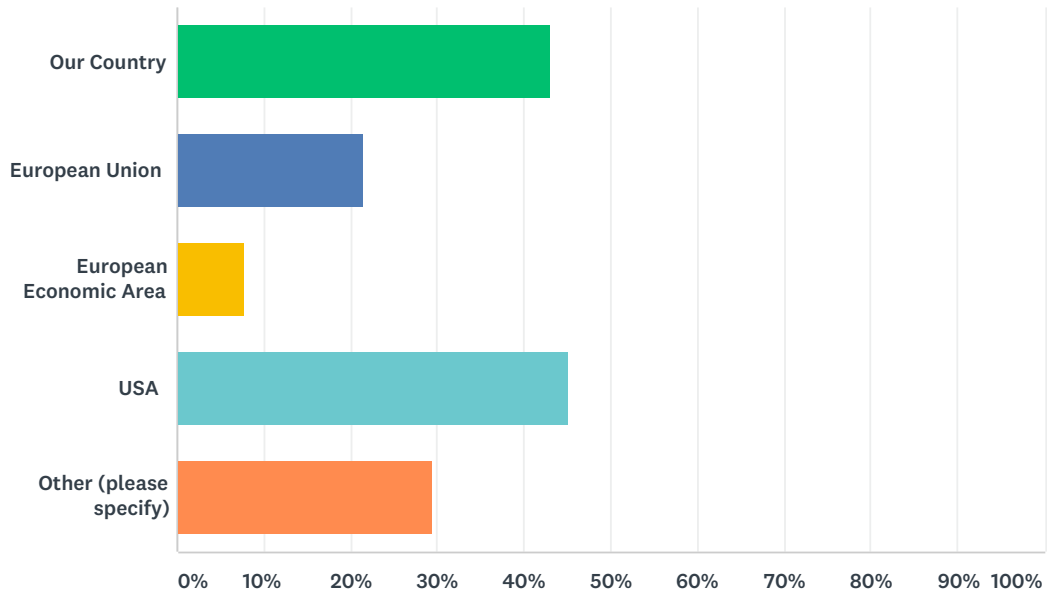
Answered: 215 Skipped: 225



ANSWER CHOICES	RESPONSES	
I do not know	15.81%	34
No limitations	60.93%	131
Biobanking is limited to certain locations	23.26%	50
TOTAL		215

## Q23 Biobanking is limited to locations within:

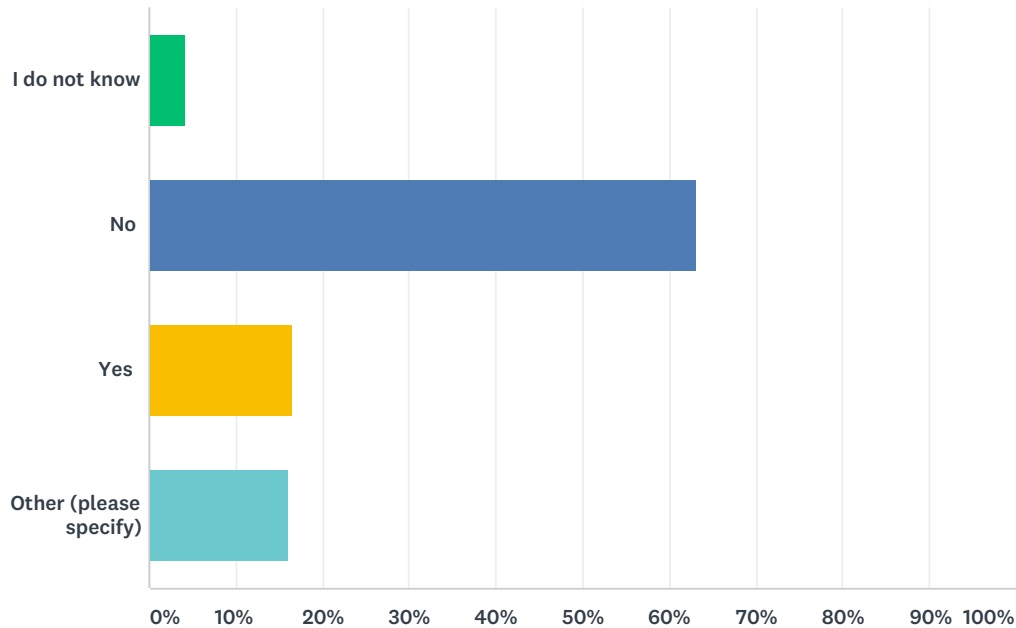
Answered: 51 Skipped: 389



ANSWER CHOICES	RESPONSES	
Our Country	43.14%	22
European Union	21.57%	11
European Economic Area	7.84%	4
USA	45.10%	23
Other (please specify)	29.41%	15
Total Respondents: 51		

## Q24 Does your committee limit the storage duration of DNA samples?

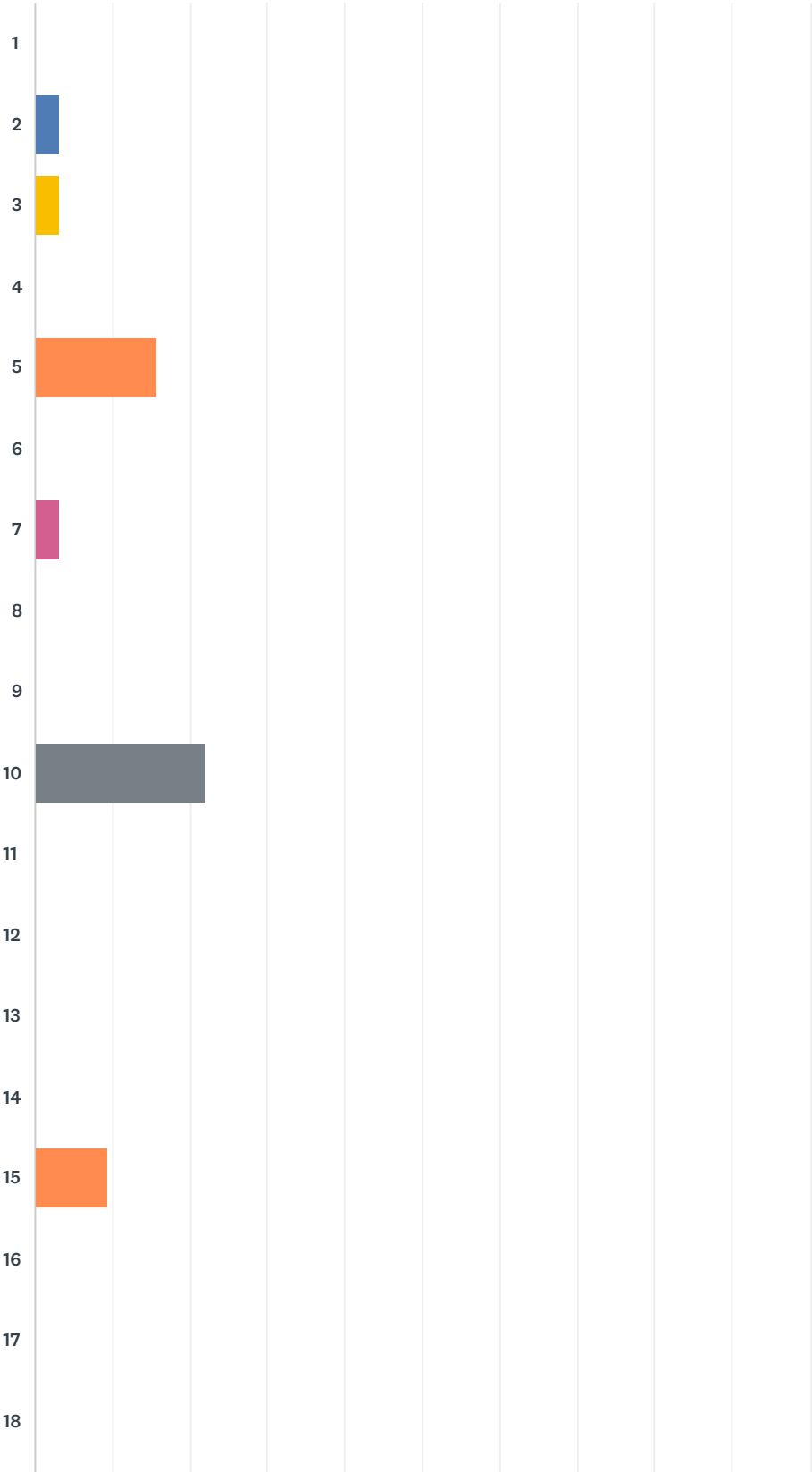
Answered: 217 Skipped: 223



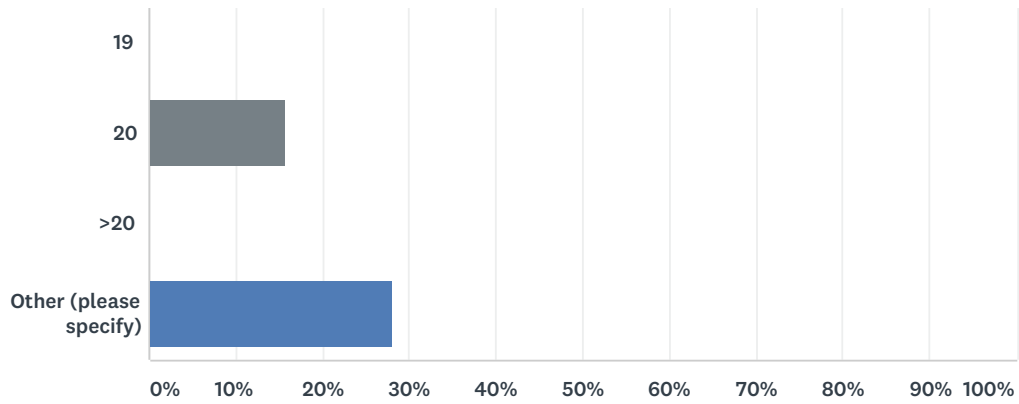
ANSWER CHOICES	RESPONSES	
I do not know	4.15%	9
No	63.13%	137
Yes	16.59%	36
Other (please specify)	16.13%	35
TOTAL		217

Q25 Your committee limits the storage duration of DNA samples for how many years?

Answered: 32    Skipped: 408



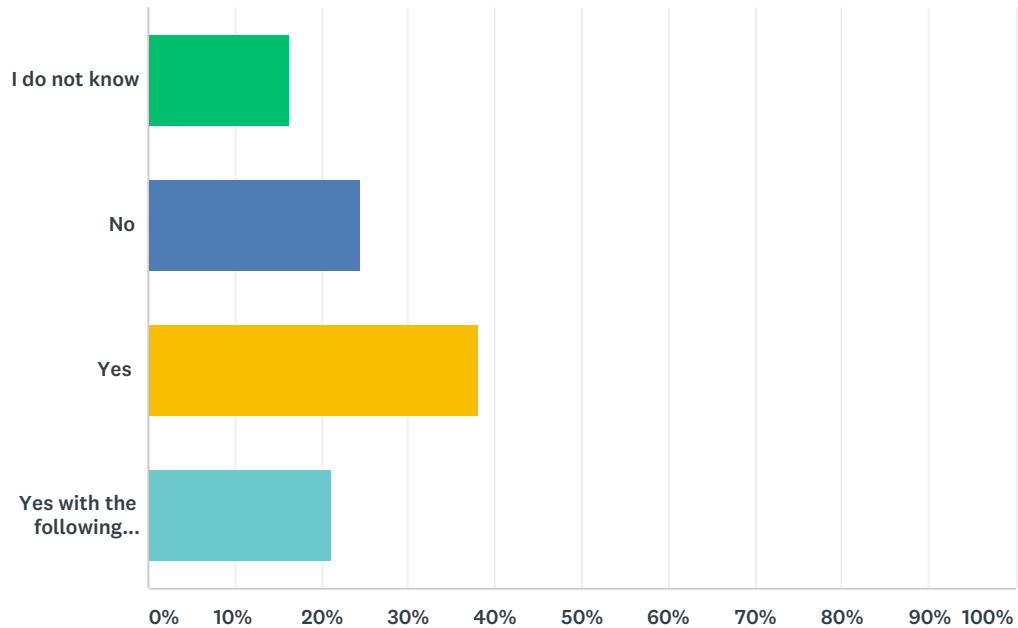
# IRB/EC survey



ANSWER CHOICES	RESPONSES	
1	0.00%	0
2	3.13%	1
3	3.13%	1
4	0.00%	0
5	15.63%	5
6	0.00%	0
7	3.13%	1
8	0.00%	0
9	0.00%	0
10	21.88%	7
11	0.00%	0
12	0.00%	0
13	0.00%	0
14	0.00%	0
15	9.38%	3
16	0.00%	0
17	0.00%	0
18	0.00%	0
19	0.00%	0
20	15.63%	5
>20	0.00%	0
Other (please specify)	28.13%	9
TOTAL		32

## Q26 Does your committee permit third-party research agreements?

Answered: 350 Skipped: 90



ANSWER CHOICES	RESPONSES	
I do not know	16.29%	57
No	24.57%	86
Yes	38.00%	133
Yes with the following restrictions:	21.14%	74
TOTAL		350

## Q27 Any additions or comments?

Answered: 80   Skipped: 360