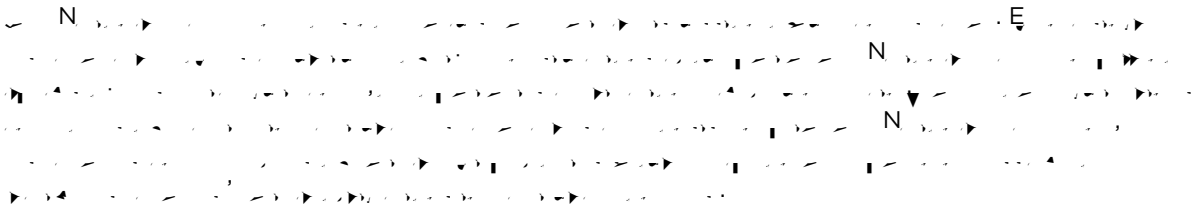
Na l R
an Research Coun

THE NATIONAL STATEMENT: A USER GUIDE

The National Statement on Ethical Conduct in Human Research (the National Statement):

- [illegible]
- [illegible]
- [illegible]
- [illegible]



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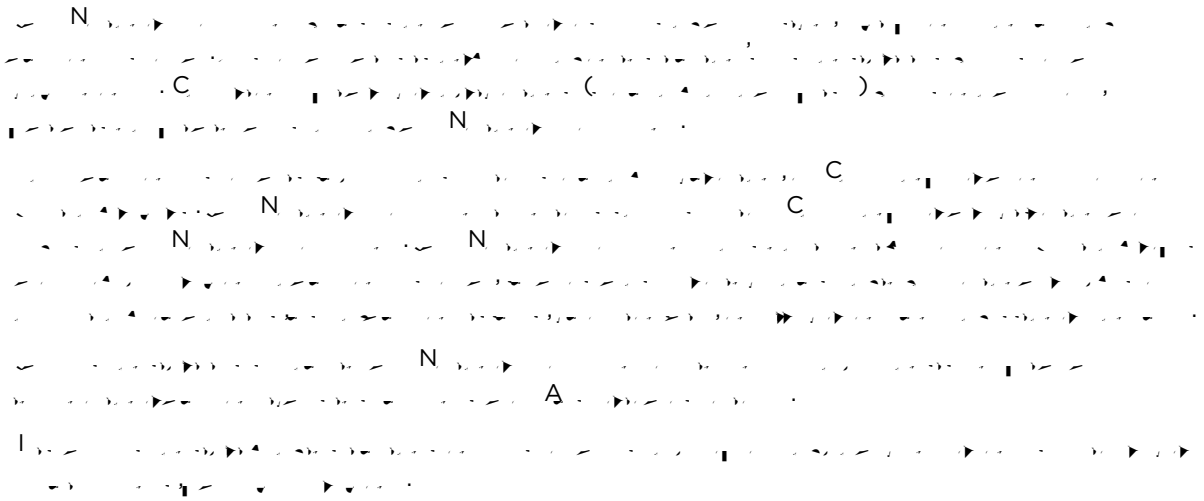

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Beneficence

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Risk of harm or discomfort

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Renegotiating consent

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Coercion and pressure

2.2.9 N

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Reimbursing participants

2.2.10 I

H

2.2.11 D

Where others need to be involved in participation decisions

2.2.12 ▼ [illegible]

CHAPTER 2.3 QUALIFYING OTHERWISE VALID CONSENT

Introduction

Consent

Legal / (), /

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Limited disclosure

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- (C 3.3)
- (C 3.).

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CHAPTER 3.1

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3.1.8

3.1.9

3.1.10

3.1.11

Element 2: Recruitment

3.1.12

3.1.13

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(2.2.2 2.2.).

3.1.26

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3.1.27

3.1.28

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3.1.31 /

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3.1.33

3.1.34 D

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' (2.2.1 2.2.1)

3.1.36

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3.1.38 F

(C 3.3 G).

Element 4: Collection, Use and Management of Data and Information

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What is data and what is information?

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Identifiability of information[5]

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3.1.39

Data management

3.1.43

3.1.44 F

1 7 001)-12. ( )-301 2-10. (13. ( )1.3 ( )- .2 ( )-2. (7 ( )-1

3.1.49

Secondary use of data or information

3.1.60 B

3.1.61

(.1.1).

Element 5: Communication of research findings or results to participants

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3.1.64 A C 3.2 3.3

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Disclosure to third parties of findings or results

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Element 6: Dissemination of project outputs and outcomes

Element 7: After the project

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3.1.72

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Ç 3.2 Ç 3.1 N

Prospective collection of human biospecimens for research

3.2.1 F [illegible] H EC [illegible]

Use of stored human biospecimens for research

3.2.2 e25 7.2 (e25 7.2 b1.8 (e) 16.6 (d 3 (c) 22.1 (t) (ß-s) E6 (c) 22..5 (b) 53 M-16.9 (b 60 (h) 40 ( ) 733 Tm [3] 21 (2) 5.8 (2)] TJ /p

Use of human biospecimens collected for clinical purposes

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(3.2.1)

Importation and exportation of human biospecimens for research

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Transition provisions for existing biospecimens

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Use of stored human biospecimens for research

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3.2.14

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H EC,
(C 2.3). I

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Element 5: Communication of research findings or results to participants

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H EC H EC

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(2.2.1)

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C 3.3 G

I

Element 3: Consent

3.3.10 I

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3.3.11 P

3.3.12 P

3.3.13 P

3.3.14 C

H EC

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3.3.15 A - (2.3.4),

3.3.16

Element 5: Communication of research findings or results to participants

3.3.26 I

3.3.27

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3.3.29 O

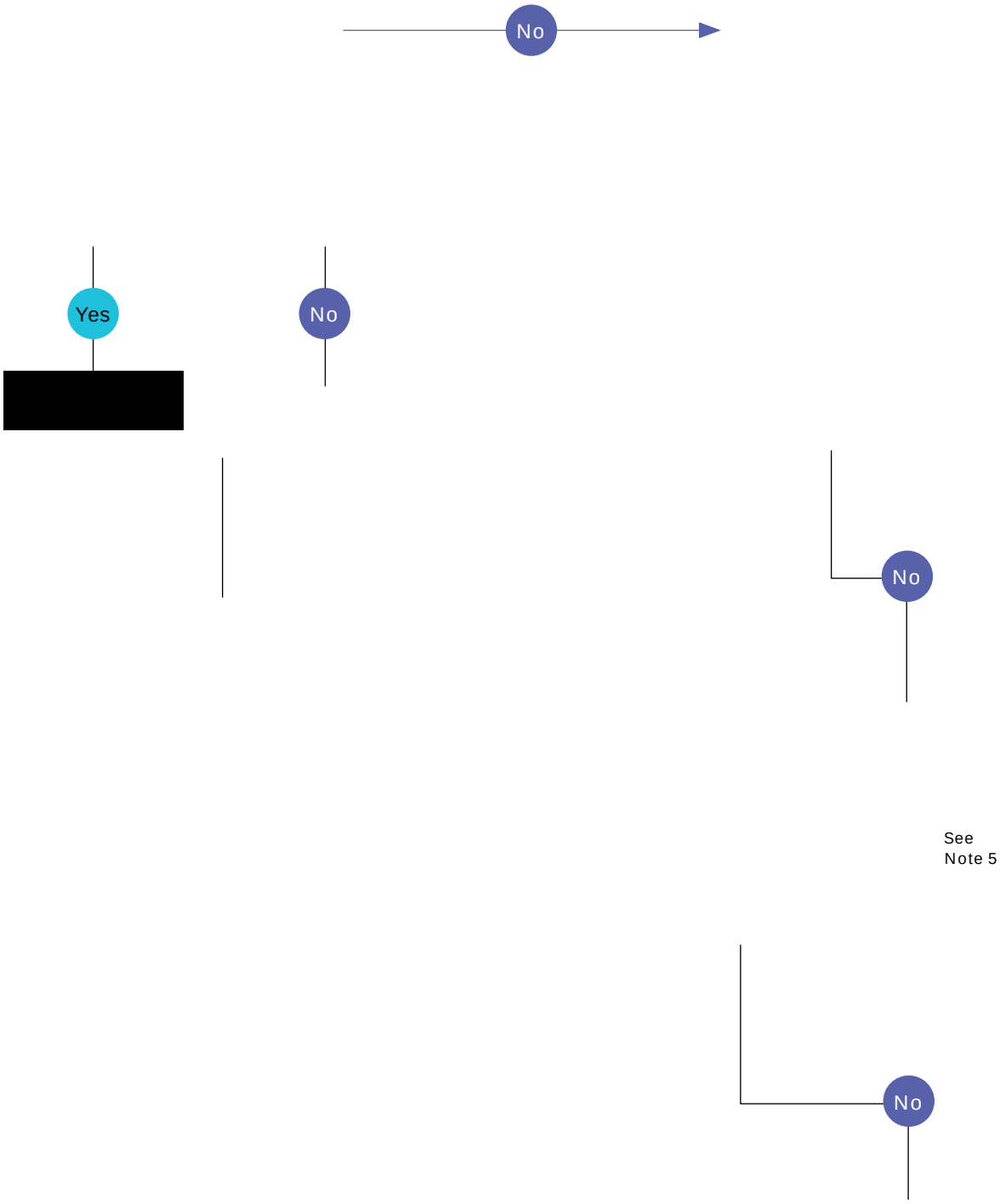
N A A (NA A)-

3.3.30

D

G D E

Decision tree for the management of findings in genomic research and health care



Note 1:

General Requirements

3.3.36 [illegible]

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3.3.42

3.3.43

3.3.44

Step 2: Validation and Assessment of Findings

3.3.45

3.3.46

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Step 3: Consent to Disclosure of Findings and Notification Requirements

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3.3.48

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3.3.49

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3.3.50

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3.3.51

( )-1 ( )-10. ( )-10.4 ( )-1 .1 ( )-1 .3 ( )-11.3 ( )-1 ( )-2. ( ) .2

Privacy Issues Specific to Genetic Information

3.3.58

3.3.59

3.3.60

3.3.61

C 3. A

I

3.4.1 HREC

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( ) (3.1.3)

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3.4.2

3.4.3 I HREC

3.4.4
HREC

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3.4.5 A
HREC. I
HREC

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Element 2: Recruitment

K

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(a)

3.4.8

(b)

(c)

(d)

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F a/

A C N

C 3.2 H

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E C (H EC)
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(.1.1).

1 2 N

G

The woman who is pregnant and the fetus *in utero*

4.1.1

4.1.2

C .2 C

4.1.3

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4.1.4

4.1.5

4.1.6 E

1 0.1 0. 1 /G 0 / 1 1 -0.01 0.0 /P L (-)/MCID 2 20

4.1.10

The human fetus, or fetal tissue, after separation

4.1.11

4.1.20 2.2.2 2.2.

C .2 C

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I . M

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Research merit and integrity

4.2.1

4.2.2

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4.2.3

Justice

4.2.4

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Beneficence

4.2.5

Justice

4.3.4

C P

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M

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Justice

4.4.2 P

Beneficence

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4.4.4

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Respect

4.4.5 P

4.4.6

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Justice

4.5.3 P

Beneficence

4.5.4 B

Respect

4.5.5 C

4.5.6

4.5.7

Justice

4.6.3

Beneficence

4.6.4 C

Respect

4.6.5

4.6.6 I

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4.6.7

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C A I P

I

A I P A I

D

Beneficence

4.7.7

4.7.8

4.7.9

Respect

4.7.10

4.7.11

4.7.12 N

4.8.7

4.8.8

4.8.9

4.8.10

Justice

4.8.11

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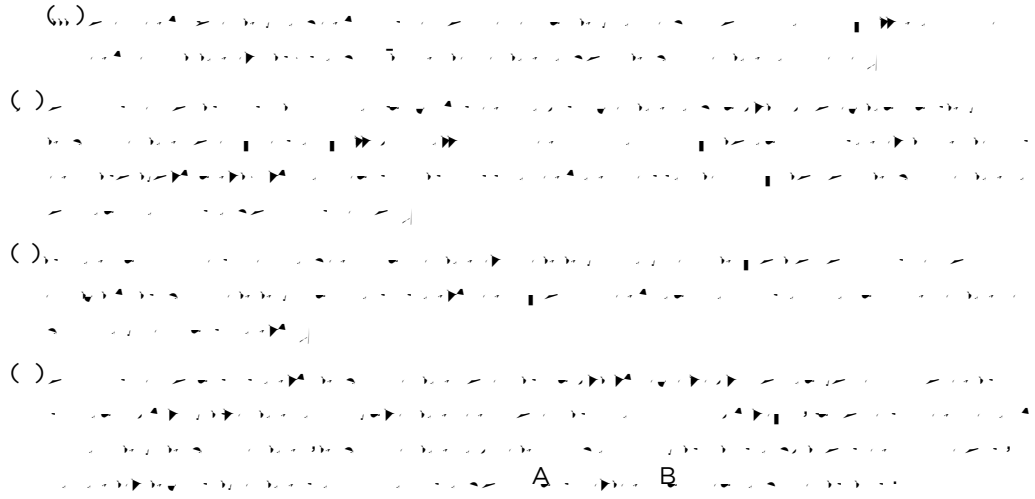
Respect

4.8.19

4.8.20 L

4.8.21 I



5.1.18

Oversight of ethics review

5.1.19

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Diversity and expertise

5.1.36 A H EC

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5.1.37 A

5.1.38

A

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5.1.39 H EC A I

A I P

.1.30( ).

A I

Appointment of HREC members

5.1.40 M H EC

I H EC

5.1.41 M

I

( ) H EC

H EC.

5.1.42 M

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Other responsibilities

5.1.44 A

5.1.45 I

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C .2 H EC

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A H EC

(C) .1 ( )-1 ( )-11 ( ) ( )-13 (2) ( )-2

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(. .2 ( )-22.BDC B . 3 ((.)-0. (2 210.3 2 2 0.3 .- .B 1)- (( )-

5.2.10 E

Communication with researchers and sponsors of research

5.2.11 G

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5.2.19 A

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5.3.7 A

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5.3.10 F C

Disclosure of interests

5.3.11 A (C A a/a C R C R a)

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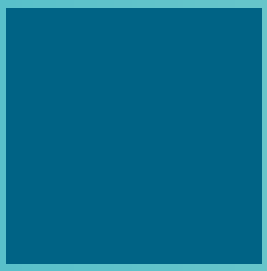

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