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VALID FROM 01/10/2014

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Section 39

CROSS-BORDER PLACEMENTS

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VALID FROM 01/10/2014

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VALID FROM 01/10/2014

SCHEDULE 5 Section 96

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.....

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THE HEALTH RESEARCH AUTHORITY

PART 1

CONSTITUTION

VALID FROM 01/01/2015

Membership

1 (1) The HRA consists of—

- (a) a chair appointed by the Secretary of State,
- (b) at least three but no more than four other members appointed by the Secretary of State,
- (c) a chief executive appointed by the members appointed under paragraphs (a) and (b), and
- (d) at least two but no more than three other members appointed by the members appointed under paragraphs (a) and (b).

(2) The members appointed under sub-paragraph (1)(a) and (b)—

- (a) are not employees of the HRA, and
- (b) are referred to in this Schedule as the “non-executive members”.

(3) The members appointed under sub-paragraph (1)(c) and (d)—

- (a) are employees of the HRA, and

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(b) are referred to in this Schedule as the “executive members”.

(4) The number of non-executive members must exceed the number of executive members.

VALID FROM 01/01/2015

Non-executive members: terms of office

- 2
- (1) A person holds office as a non-executive member of the HRA on the terms of that person's appointment.
 - (2) A person may not be appointed as a non-executive member for a period of more than four years.
 - (3) A person who ceases to be a non-executive member is eligible for re-appointment.
 - (4) A person may resign from office as a non-executive member by giving notice to the Secretary of State.
 - (5) The Secretary of State may remove a person from office as a non-executive member on any of the following grounds—
 - (a) incapacity;
 - (b) misbehaviour;
 - (c) failure to carry out his or her duties as a non-executive member.
 - (6) The Secretary of State may suspend a person from office as a non-executive member if it appears to the Secretary of State that there are or may be grounds to remove that person from office under sub-paragraph (5).

VALID FROM 01/01/2015

Non-executive members: suspension from office

- 3
- (1) Having decided to suspend a person under paragraph 2(6), the Secretary of State must give notice of the decision to the person; and the suspension takes effect when the person receives the notice.
 - (2) The notice may be—
 - (a) delivered in person (in which case the person is taken to receive it when it is delivered), or
 - (b) sent by first class post to the person's last known address (in which case, the person is taken to receive it on the third day after the day on which it is posted).
 - (3) The initial period of suspension must not exceed six months.
 - (4) The Secretary of State may review the suspension.
 - (5) The Secretary of State—
 - (a) must review the suspension, if requested in writing by the person to do so, but

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- (b) need not review the suspension less than three months after the beginning of the initial period of suspension.
- (6) Following a review during a period of suspension, the Secretary of State may—
- (a) revoke the suspension, or
 - (b) suspend the person for a period of no more than six months from the expiry of the current period.
- (7) The Secretary of State must revoke the suspension if the Secretary of State—
- (a) decides that there are no grounds to remove the person from office under paragraph 2(5), or
 - (b) decides that there are grounds to do so but nonetheless decides not to do so.
- 4 (1) Where a person is suspended from office as the chair under paragraph 2(6), the Secretary of State may appoint a non-executive member as interim chair to exercise the chair's functions.
- (2) Appointment as interim chair is for a term not exceeding the shorter of—
- (a) the period ending with either—
 - (i) the appointment of a new chair, or
 - (ii) the revocation or expiry of the existing chair's suspension, and
 - (b) the remainder of the interim chair's term as a non-executive member.
- (3) A person who ceases to be the interim chair is eligible for re-appointment.

VALID FROM 01/01/2015

Non-executive members: pay

- 5 (1) The HRA must pay its non-executive members such remuneration as the Secretary of State may decide.
- (2) The HRA must pay, or provide for the payment of, such allowances or gratuities as the Secretary of State may decide to a person who is or has been a non-executive member of the HRA.

VALID FROM 01/01/2015

Employees: terms of office

- 6 (1) Each executive member of the HRA is appointed as an employee of the HRA on such terms as it decides.
- (2) A person may not be appointed as chief executive without the consent of the Secretary of State.
- (3) The HRA may appoint, on such terms as it decides, other persons as employees of the HRA (in addition to those appointed as executive members).

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VALID FROM 01/01/2015

Employees: pay

- 7
- (1) The HRA must pay its employees such remuneration as it decides.
 - (2) The HRA may pay, or provide for the payment of, such pensions, allowances or gratuities as it decides to or in respect of a person who is or has been an employee of the HRA.
 - (3) Before making a decision about pay under this paragraph, the HRA must obtain the approval of the Secretary of State to its policy on the matter.

Committees and sub-committees

VALID FROM 01/01/2015

- 8
- (1) The HRA must appoint a committee for the purpose of giving advice—
 - (a) to the HRA in connection with the exercise of the HRA's function under regulation 5(1)(a) of the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438) (approval for processing confidential patient information);
 - (b) to the Secretary of State in connection with the exercise of the Secretary of State's functions under regulations 2, 3(4) and 5 of those Regulations (processing of confidential patient information);
 - (c) to the Health and Social Care Information Centre in connection with—
 - (i) the exercise by the Centre of functions conferred in regulations under section 251 of the National Health Service Act 2006 (processing of patient information for medical purposes);
 - (ii) any publication or other dissemination by the Centre of information which is in a form which identifies an individual to whom the information relates or enables the identity of such an individual to be ascertained.
 - (2) The HRA may appoint other committees and sub-committees.
 - (3) The committee appointed under sub-paragraph (1) must consist of persons who are not members or employees of the HRA.
 - (4) Any other committee or sub-committee may consist of or include such persons.
 - (5) The HRA may pay such remuneration and allowances as it decides to a person who is a member of a committee or sub-committee, but is not an employee of the HRA, regardless of whether the person is a non-executive member of the HRA.
- 9
- Regulations may provide for the committee appointed under paragraph 8(1) to be required, in giving advice, to have regard to specified factors or matters.

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Commencement Information

II Sch. 7 para. 9 in force at 15.7.2014 for specified purposes by S.I. 2014/1714, art. 3(3)(b)

VALID FROM 01/01/2015

Procedure

- 10 (1) The HRA may regulate its own procedure.
- (2) A vacancy among the members of the HRA, or a defect in the appointment of a member, does not affect the validity of any act of the HRA.

VALID FROM 01/01/2015

Seal and evidence

- 11 (1) The application of the HRA's seal must be authenticated by the signature of a member of the HRA or a person who has been authorised (whether generally or specifically) for the purpose.
- (2) A document purporting to be duly executed under the HRA's seal or to be signed on its behalf must be received in evidence and, unless the contrary is proved, taken to be so executed or signed.
- (3) But this paragraph does not apply in relation to a document which is, or is to be, signed in accordance with the law of Scotland.

VALID FROM 01/01/2015

Status of the HRA

- 12 (1) The HRA is not to be regarded as a servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown.
- (2) The HRA's property is not to be regarded as property of, or property held on behalf of, the Crown.

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VALID FROM 01/01/2015

PART 2

FUNCTIONS

Exercise of functions

- 13
- (1) The HRA must exercise its functions effectively, efficiently and economically.
 - (2) The HRA may arrange for any of its committees, sub-committees or members or any other person (other than a devolved authority) to exercise any of its functions on its behalf.
 - (3) The HRA may arrange for any person to help it in the exercise of its functions (whether in a particular case or in cases of a particular description).
 - (4) Arrangements under sub-paragraph (2) or (3) may provide for the payment of remuneration and allowances to the persons with whom the HRA makes the arrangements.
 - (5) The HRA may do anything which appears to it to be necessary or desirable for the purposes of or in connection with the exercise of its functions.

Help or advice for other public authorities

- 14
- (1) The HRA may provide help or advice to another public authority for the purpose of the exercise by that authority of its functions.
 - (2) Help or advice under this paragraph may be provided on such terms as the HRA decides (including terms relating to payment of remuneration and allowances).
 - (3) “Public authority”—
 - (a) includes any person certain of whose functions are functions of a public nature, but
 - (b) does not include either House of Parliament or a person exercising functions in connection with proceedings in Parliament.
 - (4) A reference to a public authority—
 - (a) includes a public authority in the Channel Islands or the Isle of Man, but
 - (b) subject to that, does not include a reference to a public authority outside the United Kingdom.

Arrangements with devolved authorities

- 15
- (1) The HRA may arrange with a devolved authority for the HRA—
 - (a) to exercise on behalf of the devolved authority any function which corresponds to a function of the HRA;
 - (b) to provide services or facilities in so far as the devolved authority requires them in connection with the exercise of such a function.

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- (2) The terms and conditions on which arrangements under this paragraph may be made include provision for payment to the HRA in respect of its costs in giving effect to the arrangements.

Failure to exercise functions

- 16 (1) If the Secretary of State considers that the HRA is failing or has failed to exercise any of its functions, and that the failure is significant, the Secretary of State may direct the HRA to exercise such of its functions, in such manner and within such period, as the direction specifies.
- (2) If the HRA fails to comply with a direction under this paragraph, the Secretary of State may—
- (a) exercise the functions specified in the direction, or
 - (b) make arrangements for some other person to exercise them on the Secretary of State's behalf.
- (3) Where the Secretary of State exercises a power under sub-paragraph (1) or (2), the Secretary of State must publish the reasons for doing so.
- (4) The reference in sub-paragraph (1) to exercising a function includes a reference to exercising it properly.

VALID FROM 01/01/2015

PART 3

FINANCE AND REPORTS

Funding

- 17 The Secretary of State may, with the consent of the Treasury, make payments to the HRA at such times and on such conditions (if any) as the Secretary of State considers appropriate.

Fees and indemnities

- 18 (1) Regulations may require payment of a fee in relation to the exercise of a specified function of the HRA; and the amount of the fee is to be the amount specified in, or determined in accordance with, the regulations.
- (2) Where the amount of a fee is to be specified in regulations under this paragraph—
- (a) the Secretary of State must, before specifying the amount of the fee, have regard to the cost incurred in the exercise of the function to which the fee relates, and
 - (b) the HRA must provide the Secretary of State with such information, in such form, as the Secretary of State may request.
- (3) Regulations under this paragraph may require the HRA to determine the amount of a fee; and, where they do so, the regulations—

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- (a) must require the HRA, before determining the amount of the fee, to have regard to the cost incurred in the exercise of the function to which the fee relates, and
 - (b) must require the HRA to obtain the approval of the Secretary of State to the proposed amount of the fee.
- (4) Regulations under this paragraph which provide for the amount of a fee to be determined may specify factors in accordance with which it is to be determined.
- (5) Regulations under this paragraph may include provision—
- (a) for determining the time by which a fee is payable;
 - (b) for any unpaid balance to be recoverable as a debt due to the HRA (but for this not to affect any other method of recovery).
- (6) Before making regulations under this paragraph, the Secretary of State must consult such persons as the Secretary of State considers appropriate.
- (7) Section 265 of the Public Health Act 1875 (which relates to the protection of members and officers of certain authorities from personal liability) has effect as if there were included in the authorities referred to in that section a reference to the HRA.
- (8) In its application to the HRA as a result of sub-paragraph (7), section 265 of that Act has effect as if any reference in that section to that Act were a reference to this Act.
- (9) In section 71(2) of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc. of certain health service bodies), after paragraph (f) insert—
- “(fa) the Health Research Authority;”.

Accounts

- 19 (1) The HRA must keep accounts in such form as the Secretary of State may determine.
- (2) The HRA must prepare annual accounts in respect of each financial year in such form as the Secretary of State may determine.
- (3) The HRA must send copies of the annual accounts to—
- (a) the Secretary of State, and
 - (b) the Comptroller and Auditor General,
- within such period after the end of the financial year to which the accounts relate as the Secretary of State may determine.
- (4) The Comptroller and Auditor General must—
- (a) examine, certify and report on the annual accounts, and
 - (b) lay copies of them and the report on them before Parliament.
- (5) In this paragraph and paragraph 20, “financial year” includes the period—
- (a) beginning with the day on which the HRA is established, and
 - (b) ending with the following 31 March or, if the period ending with that date is 3 months or less, ending with the 31 March following that date.

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Annual report

- 20 (1) As soon as is feasible after the end of each financial year, the HRA must prepare an annual report on—
- (a) the activities it has undertaken during the year, and
 - (b) the activities it proposes to undertake during the current financial year.
- (2) The report must set out the steps the HRA has taken during the year to fulfil its main objective (see section 110(2)).
- (3) The HRA must—
- (a) lay a copy of the report before Parliament, and
 - (b) send a copy of it to the Secretary of State.
- (4) The HRA must provide the Secretary of State with such other reports and information relating to the exercise of its functions as the Secretary of State may request.

VALID FROM 01/01/2015

PART 4

CONSEQUENTIAL AMENDMENTS

Public Records Act 1958

- 21 In Part 2 of the Table in Schedule 1 to the Public Records Act 1958, at the appropriate place insert— “ Health Research Authority. ”

Public Bodies (Admission to Meetings) Act 1960

- 22 In the Schedule to the Public Bodies (Admission to Meetings) Act 1960, after paragraph (bm) (inserted by paragraph 30 of Schedule 5 to this Act) insert—
 “(bn) the Health Research Authority;”.

Parliamentary Commissioner Act 1967

- 23 In Schedule 2 to the Parliamentary Commissioner Act 1967, at the appropriate place insert— “ Health Research Authority. ”

House of Commons Disqualification Act 1975

- 24 In Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975, at the appropriate place insert— “ The Health Research Authority. ”

Copyright, Designs and Patents Act 1988

- 25 In section 48(6) of the Copyright, Designs and Patents Act 1988 (definition of “the Crown”), after “Health Education England” (inserted by paragraph 33 of Schedule 5 to this Act) insert “ , the Health Research Authority ”.

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Freedom of Information Act 2000

- 26 In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (other public bodies), at the appropriate place insert— “ The Health Research Authority. ”

Equality Act 2010

- 27 In Part 1 of Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty), in the group of entries under the heading “Health, social care and social security”, after the entry for Health Education England (inserted by paragraph 35 of Schedule 5 to this Act) insert— “ The Health Research Authority. ”

VALID FROM 01/01/2015

SCHEDULE 8

Section 113

RESEARCH ETHICS COMMITTEES: AMENDMENTS

Ionising Radiation (Medical Exposure) Regulations 2000 (S.I. 2000/1059)

- 1 In regulation 2(1) of the Ionising Radiation (Medical Exposure) Regulations 2000 (S.I. 2000/1059), in the definition of “ethics committee”—
- (a) omit paragraph (a), and
 - (b) for paragraph (c) substitute—
 - “(c) a research ethics committee recognised or established by or on behalf of the Health Research Authority under the Care Act 2014, or
 - (d) any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Welsh Ministers or the Scottish Ministers;”.

*Ionising Radiation (Medical Exposure) Regulations
(Northern Ireland) 2000 (S.R. 2000/194)*

- 2 In regulation 2(1) of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 (S.R. 2000/194), for the definition of “ethics committee” substitute—
- ““ethics committee” means a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Department;”.

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Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438)

- 3 In regulation 1(2) of the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438), for the definition of “research ethics committee” substitute—

““research ethics committee” means—

- (a) a research ethics committee recognised or established by or on behalf of the Health Research Authority under the Care Act 2014, or
- (b) any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Welsh Ministers.”

Nursing Homes Regulations (Northern Ireland) 2005 (S.R. 2005/160)

- 4 In regulation 2(1) of the Nursing Homes Regulations (Northern Ireland) 2005 (S.R. 2005/160), for the definition of “ethics committee” substitute—

““ethics committee” means a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Department of Health, Social Services and Public Safety;”.

Residential Care Homes Regulations (Northern Ireland) 2005 (S.R. 2005/161)

- 5 In regulation 2(1) of the Residential Care Homes Regulations (Northern Ireland) 2005 (S.R. 2005/161), for the definition of “ethics committee” substitute—

““ethics committee” means a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Department of Health, Social Services and Public Safety;”.

Independent Health Care Regulations (Northern Ireland) 2005 (S.R. 2005/174)

- 6 In regulation 2(1) of the Independent Health Care Regulations (Northern Ireland) 2005 (S.R. 2005/174), for the definition of “ethics committee” substitute—

““ethics committee” means a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Department of Health, Social Services and Public Safety;”.

Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Purposes) (Scotland) Order 2006 (S.S.I. 2006/310)

- 7 In article 1(2) of the Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Purposes) (Scotland) Order 2006 (S.S.I. 2006/310), for the definition of “appropriate Research Ethics Committee” substitute—

““appropriate Research Ethics Committee” means a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Scottish Ministers;”.

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Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 (S.I. 2006/1260)

8 In regulation 1(2) of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 (S.I. 2006/1260), for the definition of “research ethics authority” substitute—

““research ethics authority” means—

- (a) a research ethics committee recognised or established by or on behalf of the Health Research Authority under the Care Act 2014, or
- (b) any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Welsh Ministers or the Department of Health, Social Services and Public Safety in Northern Ireland.”

Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 (S.I. 2006/2810)

9 In regulation 2 of the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 (S.I. 2006/2810) (definition of “appropriate body”), for the words from “is a committee” to the end substitute “ is a research ethics committee recognised or established by or on behalf of the Health Research Authority under the Care Act 2014. ”

Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007 (S.I. 2007/833)

10 In regulation 2 of the Mental Capacity 2005 (Appropriate Body) (Wales) Regulations 2007 (S.I. 2007/833) (definition of “appropriate body”), for the words from “is a committee” to the end substitute “ is a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Welsh Ministers. ”

Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (S.I. 2010/995)

11 In regulation 2(1) of the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (S.I. 2010/995), for the definition of “research ethics committee” substitute—

““research ethics committee” means a research ethics committee recognised or established by or on behalf of the Health Research Authority under the Care Act 2014;”.

Independent Health Care (Wales) Regulations 2011 (S.I. 2011/734)

12 In regulation 25 of the Independent Health Care (Wales) Regulations 2011 (S.I. 2011/734) (research), in paragraph (2) for the words from “a research ethics committee” to the end substitute “ a group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by or on behalf of the Welsh Ministers. ”

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