


Health Authority – Abu Dhabi		هيئة الصحة - أبوظبي
HAAD External Policies Title: Licensing Requirements for Institutional Human Subjects Research		Reference Number: PHP/PHR/R02 Issue Date: February 2010 Next Review Date: February 2012

CHAPTER I. INTRODUCTION

1 Purpose

1.1 This Policy provides for the licensing of institutions engaged in Human Subjects Research in the Emirate of Abu Dhabi.

2 Background

2.1 The Health Authority Abu Dhabi (**HAAD**) is responsible for regulating all aspects of Human Subjects Research in the Emirate of Abu Dhabi.

2.2 HAAD has established a governance framework to ensure that Human Subjects Research is –

2.2.1 designed and conducted in accordance with the laws and regulations of the Emirate of Abu Dhabi,

2.2.2 consistent with HAAD Policies and Standards, and

2.2.3 subject to ethical review and monitoring.

2.3 The licensing of Human Subjects Research is the principal means by which HAAD fulfils its regulatory oversight and assures that effective compliance is achieved.

3 Scope

3.1 This Policy sets out the requirements for institutions to obtain and comply with the conditions of a licence to engage in and conduct Human Subjects Research.

3.2 This Policy applies in addition to other HAAD policies and standards relating to public health, and is without prejudice to the requirements of all other Federal and Abu Dhabi laws applicable to the activity of Human Subjects Research.

4 Related Policies

4.1 The following HAAD Policies are closely related to this one –

4.1.1 *“Policy Governing Research Involving Human Subjects”* (Ref PHP/PHR/R03).

4.1.2 *“Abu Dhabi Health Research Council”* (Ref PHP/PHR/R01).

5 **Interested Parties**

5.1 This Policy is of relevance to all individuals and institutions involved or wishing to engage in Human Subjects Research in the Emirate of Abu Dhabi.

CHAPTER II. LICENSING

6 The Licensing Requirement

- 6.1 No institution may carry out any Human Subjects Research unless –
 - 6.1.1 it holds an Institutional Research Licence granted by HAAD, and
 - 6.1.2 the Human Subjects Research carried out by it is within the description of research that it is permitted to carry out in accordance with the Licence.

7 The Institutional Research Licence

- 7.1 An Institutional Research Licence –
 - 7.1.1 will contain a condition describing the Human Subjects Research that is permitted to be carried out in accordance with the Licence, and
 - 7.1.2 may contain other conditions which -
 - (a) impose restrictions on the carrying out of Human Subjects Research,
 - (b) require that research to be carried out in a specified manner, or
 - (c) make provision for that research to be monitored, recorded, controlled or reviewed.
 - 7.2 HAAD may make an Institutional Research Licence subject to conditions at the time at which it is granted.
 - 7.3 HAAD may add to, remove or amend the conditions of an Institutional Research Licence at any time after it has been granted.
 - 7.4 Each Institutional Research Licence shall have effect for a period of two years from the date of its grant.
 - 7.5 At the end of this period, an Institutional Research Licence shall expire, and shall cease to be of any effect, unless HAAD determines that it is to be renewed.
 - 7.6 An Institutional Research Licence that is renewed shall have effect for a further two year period, at the end of which it shall expire unless HAAD determines that it is again to be renewed.
 - 7.7 There is no limit to the number of times a licence may be renewed by HAAD.
- ### **8 Licence Applications**
- 8.1 By following the application procedures described in Appendix A, an institution may apply for –

- 8.1.1 the grant of a new Institutional Research Licence,
 - 8.1.2 the renewal of its existing Institutional Research Licence, or
 - 8.1.3 the amendment of the condition of its Institutional Research Licence which describes the research that it is permitted to carry out in accordance with the Licence,
- 8.2 In any application the institution shall be required to demonstrate that -
- 8.2.1 it possesses the qualifications, experience and competence necessary to carry out the Human Subjects Research proposed in the application,
 - 8.2.2 there is scientific justification for each of the research activities proposed, and
 - 8.2.3 it will be able to comply with the requirements of this Policy and all other HAAD Policies applicable to the research activities proposed.
- 8.3 HAAD will reject an application if the institution fails to demonstrate to its satisfaction that these criteria are met.
- 8.4 An institution shall not make an application that contains any statements, or is accompanied by any documents or information, which are incomplete, inaccurate, false or misleading.
- 8.5 HAAD may reject any application that is in breach of requirements.

9 Duties of Licensed Research Institutions

- 9.1 A Licensed Research Institution must comply with the conditions of its Licence.
- 9.2 A Licensed Research Institution must carry out, monitor, record, control and review all Human Subjects Research in accordance with all applicable HAAD Policies, including in particular –
- 9.2.1 the *“Policy Governing Research Involving Human Subjects”* (Ref PHP/PHR/R03),
 - 9.2.2 Policies and standards relevant to document retention and information management; *“Medical Record / Health Information Retention and Disposal Policy”* (Ref PPR/HCP/0009/07).
- 9.3 A Licensed Research Institution must –
- 9.3.1 make available to HAAD, on request, its policies and procedures relating to the carrying out, monitoring, recording, controlling and reviewing of Human Subjects Research,
 - 9.3.2 actively monitor its compliance with this Policy and all other applicable HAAD Policies,
 - 9.3.3 provide to HAAD, on request, evidence to establish its compliance with this Policy and all other applicable HAAD Policies,
 - 9.3.4 at all times maintain appropriate indemnity insurance covering, in respect of its Human Subjects Research –

- (a) all adverse outcomes for individuals who are the subject of the research,
 - (b) all other potential liabilities of the Institution,
 - (c) all potential liabilities of individual clinicians and researchers employed by, or contracted to, the Institution,
- 9.3.5 report to HAAD, in advance, any proposal to publish or disseminate the findings of its Human Subjects Research,
- 9.3.6 provide to HAAD a copy of any publication that contains, or any other document that disseminates, those findings,
- 9.3.7 promptly report to HAAD any breach of the conditions of its Licence, of this or any other HAAD Policy, and of any breach of its internal policies and procedures.

10 The Abu Dhabi Health Research Council

- 10.1 HAAD may delegate to the Abu Dhabi Health Research Council any or all of the functions ascribed to HAAD in this Policy.
- 10.2 Where a function has been delegated to the Abu Dhabi Health Research Council, any exercise of that function by the Council shall have the same effect as if it had been made by HAAD.

CHAPTER III. COMPLIANCE, SANCTIONS, COMPLAINTS & APPEALS

11 Compliance

- 11.1 HAAD will monitor and audit compliance with this policy. All Licensed Research Institutions must comply with the [HAAD Policy on Licensing Requirements and Data Management].

12 Sanctions

- 12.1 HAAD may impose sanctions in relation to any breach of this Policy in accordance with the [HAAD Policy on Complaints, Grievances, Appeals, Sanctions and Suspensions].

13 Complaints

- 13.1 Complaints on the conduct of Human Subjects Research may be made to HAAD by any person or body with a legitimate interest in the research, and will be considered by HAAD in accordance with its Complaints Management Policy (www.haad.ae).

14 Appeals

- 14.1 A Licensed Research Institution, or an applicant for an Institutional Research Licence, may appeal against any decision of HAAD taken under this Policy, and the appeal shall be dealt with in accordance with the [HAAD Policy on Complaints, Grievances, Appeals, Sanctions and Suspensions].

CHAPTER IV. GLOSSARY OF TERMS

In this Policy the following terms shall have the meanings given to them below –

Abu Dhabi Health Research Council has the same meaning as in the Policy “*Abu Dhabi Health Research Council*” (Ref PHP/PHR/R01).

Human Subjects Research means any activity falling within one or more of the following categories -

- Studies of a physiological, biochemical, or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or in patients.
- Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalisable response to these measures against a background of individual biological variation.
- Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures.
- Studies concerning human health-related behaviour in a variety of circumstances and environments.

Institutional Research Licence means a licence granted by HAAD to an institution, in accordance with the provisions of this Policy, authorising the institution to engage in Human Subjects Research.

Licence means an Institutional Research Licence.

Licensed Research Institution means any institution holding an Institutional Research Licence.

APPENDIX A. LICENCE APPLICATIONS

- (1) Applications must be made to the Medical Research Section at HAAD for –
 - (a) the grant of a new Institutional Research Licence,
 - (b) the renewal of an existing Institutional Research Licence, or
 - (c) the amendment of the condition of a Institutional Research Licence which describes the research that is permitted to be carried out in accordance with the Licence.
- (2) The application must be made in the standard form which may be found on HAAD website at www.haad.ae.
- (3) At any time after receiving the application, HAAD may request such additional information or documents as it considers necessary for the purpose of assessing the application.
- (4) The institution making the application must provide any additional information or documents requested by HAAD, and must do so within any period of time specified in the request.
- (5) HAAD may from time to time set fees to be paid by an institution making an application, and the current level of fees may be found on HAAD website at www.haad.ae.
- (6) The institution making the application must provide payment of the appropriate fee at the same time as it makes the application.
- (7) HAAD may from time to time set timeframes for processing applications, and the specified timeframes may be found on the HAAD website at www.haad.ae.
- (8) An application for the renewal of an existing Institutional Research Licence should be made at least 60 days before the Licence is due to expire.