

## UFIRB 02 – Social & Behavioral Research

### Protocol Submission

**Title of Protocol:** Constructing the Subjects of Mental Illness: The Legal and Political Mediation of Health in Wales [version 2]

**Principal Investigator:** Andrew “Scott” Catey

**UFID #:** XXXX-XXXX

**Degree / Title:** Ph.D and Juris Doctor candidate

**Department:** University of Florida Department of Anthropology and Levin College of Law

**Mailing Address:** Department of Anthropology  
1112 Turlington  
Box 117305  
Gainesville, FL 32611-7305

**Email Address & Telephone Number:**

[catey@ufl.edu](mailto:catey@ufl.edu)

352.XXX.XXXX

**Co-Investigator(s):** N/A

**UFID#:** N/A

**Supervisor:** Dr. Faye Harrison

**UFID#:** XXXX-XXXX

**Degree / Title:** Ph.D. / Professor

**Department:** Anthropology

**Mailing Address:** Department of Anthropology  
1112 Turlington  
Box 117305  
Gainesville, FL 32611-7305

**Email Address & Telephone Number:**

email@ufl.edu

332.XXX.XXXX

**Date of Proposed Research:**

August 2008 – August 2009

**Source of Funding** (*A copy of the grant proposal must be submitted with this protocol if funding is involved*):

N/A.

**Scientific Purpose of the Study:**

The purpose of this study is to conduct an ethnographic investigation of recent constitutional reform in Great Britain and subsequent reform of the National Health Service (NHS) as it affects the experience and outcomes of health and illness in Cardiff, Wales. The organizing framework for the investigation centers on an analysis of the relatively newly developed National Assembly for Wales (NAW) and the ways in which its procedural changes, new professional norms, and bureaucratic demands affect the provision of and access to health care among a minority population in an urban environment.

The primary concern of this study is the ways in which law and policy shape human experience and behavior, and the PI's objective is to shift analysis of law and policy from a macro-social to micro-social and micro-political

scales that prioritize attention focused on interpersonal interactions and the interface of service users with political and service delivery infrastructures, including the National Assembly for Wales ministries and the civil service, local government, NHS organizations, the corporate and voluntary sectors, and community-based organizations. Specific attention will be paid to political, legal, and institutional changes that impact the provisioning of health care services, access to health care, and related effects on health outcomes among a minority population in Riverside neighborhood, in Cardiff. This population will provide critical data reflecting the diversity of Welsh society, including ethnicity, gender, language, age, socio-economic status, and nationality.

This project will append prior research in Riverside and similarly situated neighborhoods and communities in Wales and the UK through its ethnographic approach and the long-term proximity to participants and in-depth research process required by ethnographic immersion. Existing sources of evidence have been reviewed by the PI and integrated into the research proposal (approved by dissertation committee, April 2008) as framework and contextualizing material, and to highlight gaps in the extant data sets, results, and interpretations of health care service delivery and the experiences of users of the NHS infrastructure. The research process will integrate participants at all levels, and results will be reported in multiple formats to interested audiences, including the Riverside participants, their families and representatives, and policy makers in local government, NHS organization, and the NAW.

**Describe the Research Methodology in Non-Technical Language:** *(Explain what will be done with or to the research participant.)*

Constitutional change in Great Britain, termed 'devolution', includes a novel approach to regional policy-making in Wales, in which the new National Assembly is empowered to diverge from London's policy norms in order to shape the policy environment of Wales in ways most suited to its national needs. PI will use focus groups, surveys, interviews, and observation techniques to elicit data from study participants in Wales regarding the impact of such divergences. PI will emphasize semi-structured interviewing designed to elicit open-ended responses to questions regarding the experience of health care reform in Cardiff, Wales. Specific queries will also be used to gather information on the opinions of health care service users regarding the ways in which law and policy structure access, influence the ways in which users in Cardiff experience the health care system and recent changes within it, and how, if at all, health outcomes have changed in response to structural and institutional alterations. In addition, PI will interview or survey samples of NHS clinicians, workers, and administrators, as well as local government officials, in order to learn about professional and political perceptions of NHS reform, competitive political pressures in the newly developing polity, and the ways in which the macro-scale legal and constitutional transformation impacts regional and localized health care delivery and access.

It is common in ethnographic research to identify salient issues through open-ended ethnographic interviewing, and then to conduct surveys constructed in the context of judgment sampling. In this way, the survey instrument is culturally informed, and can account for relevant variables and their value, relative risks (if any), and representativeness. Interviews and other instruments will focus on gathering data relevant to understanding the mechanisms by which new national policy is created in Wales, as well as the ways in which it is implemented, evaluated, and reformed, and how these processes affect users' perceptions of, access to, and results from a differentiated NHS in Wales.

In addition to domestic legal and ethical requirements, PI has initiated development of instruments to conform with research governance protocols and ethical standards as required by the United Kingdom and the NAW. These include: (1) solicitation of information regarding specific requirements for ethnographic research in Wales, including research within NHS organizations; (2) seeking NHS approval and authorization to conduct research that will include patients and service users (however, no clinical research will be undertaken, and it is not anticipated that PI will interact with individuals in a way that will have direct bearing on the quality of their care); (3) conformity with the legislative and Assembly rules and requirements, as found in the NAW's Research Governance Framework for research on health and social care, including (a) clear mechanisms of responsibility, accountability, and transparency in the research process; (b) clear articulation of research instruments and objectives to participants in the research process; (c) dependable delivery of research results and conclusions at multiple scales; (d) ensuring the dignity, rights, safety, and well-being of research participants, and the protection of all data elicited from participants, especially the confidentiality of personal information; and (e) involvement of participants, their representatives, and their families in the conduct, analysis, interpretation, and reporting of

research data and results. Rules and requirements mandated by Wales, as well as professional responsibilities and best practices guidelines can be found on the websites of the Welsh Office of Research and Development (WORD), especially in the Research Governance Framework (<http://new.wales.gov.uk/dhss/research/word/publications/2181541/resgovframework.pdf?lang=en>) and the National Institute of Health Research, especially in its document entitled Research in the NHS – HR Good Practice Resource Pack (<http://www.nihr.ac.uk/files/passportdocs/5principles.pdf>).

Protocols and consent forms submitted and approved by UK and Welsh authorities will be available for review by UF IRB02 on demand. PI will make documents available as necessary.

**Describe Potential Benefits and Anticipated Risks:** *(If risk of physical, psychological or economic harm may be involved, describe the steps taken to protect participant.)*

No risks to participants in this study are anticipated. Potential benefits include generating a deeper understanding of the ways in which relationships are structured and power enacted in a newly-empowered and developing national governing environment.

**Describe How Participant(s) Will Be Recruited, the Number and AGE of the Participants, and Proposed Compensation:**

The Principal Investigator will intern or volunteer at the National Assembly for Wales, within the Health Ministry, which will enable him to interact with and elicit data from policymakers and their staff. In addition, PI will intern or volunteer with Hafal, a voluntary sector organization that provides assistance to NHS users for navigating the NHS bureaucracy and its administrative pathways. These institutional locations will enable PI to gain access to political and clinical professionals, various organizational staff, local government and NHS officials and civil servants, and NHS users through this institutional infrastructure. Participants will be recruited from these populations. These connections will facilitate PI's planned triple-pronged approach to data collection, focused on: national- and local level politicians, civil servants, and NHS professionals; corporate and voluntary organizations; and health care system users. All willing respondents will be interviewed and surveyed. The PI's planned activities are not foreseen to affect the type, quality, or extent of prevention, diagnosis, or treatment of illness, nor are these activities foreseen to cause injury or loss to patients or service users to whom the NHS has a duty of care.

PI will conduct interviews among participants at each of the three strata identified above. PI anticipates that interviews will be conducted among 20-25 members of the National Assembly; 20-25 members of local government; 30-40 members of the NHS in Cardiff; 20-25 members of voluntary sector organizations; and 40-50 NHS users. PI anticipates that subsequent surveys will be conducted with approximately 100 members of the National Assembly (including ministers and their staff); 100 participants in local government; 100 participants in NHS organizations; and approximately 200 NHS users, their families, carers, and representatives.

All participants will be 18 years of age or older. There will be no compensation.

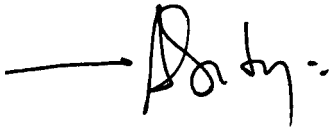
**Describe the Informed Consent Process. Include a Copy of the Informed Consent Document:**

Each potential participant will be given an informed consent form approved by UF IRB02 (see attached), and each will be asked to read and sign this document. Copies of this document will be provided to participants and

kept on file with the Principal Investigator.

PI will speak with each potential participant regarding the informed consent document, the participant's understanding of it, and the participant's ability to refuse to participate or to terminate participation without penalty. If a participant is interacted with on multiple occasions, PI will verify continued consent prior to each distinct interaction. Copies of the informed consent forms will be offered to each participant, and will be provided as desired.

**Principal Investigator(s) Signature:**

A handwritten signature in black ink, appearing to read "D. By:", with a horizontal line pointing to the start of the signature.

June 8, 2008

**Supervisor Signature:**

**Department Chair/Center Director Signature:**

**Date:**