Researcher Qualifications and Credentials – Judging appropriateness

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### Key terms for HREC / Secretariat to interpret

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Skill</strong></td>
<td>The learned ability to carry out a relevant task with pre-determined results within time/energy</td>
</tr>
<tr>
<td><strong>Experience</strong></td>
<td>The knowledge or mastery gained through involvement in or exposure</td>
</tr>
<tr>
<td><strong>Competency</strong></td>
<td>The ability to do something successfully or efficiently</td>
</tr>
<tr>
<td><strong>Qualification</strong></td>
<td>An official completion of a course that confers recognised status</td>
</tr>
<tr>
<td><strong>Credentialing</strong></td>
<td>An attestation issued by an authority of qualification, achievement, quality or aspect that indicates suitability</td>
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Regulatory Guidance - NEAF

• s2 “ … Summary of qualifications and relevant experience”

• Q6 “… any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research” and “describe and specify these …”

• Q7 “Do the researchers … require any additional training…”.
The NS (1.1, 5.1.1, 5.1.2, 5.7.3) references the Code in advising HRECs and institutions on their responsibilities to assess whether research is:

“(1.1a) justifiable by … skill and expertise of researchers”

“(1.1e) conducted or supervised … with experience, qualifications and competence that are appropriate for the research”
Regulatory Guidance - Code

• The Code requires the institution to

“(1.4) promote effective mentoring and supervision of researchers and research trainees”

“(3.1) ensure that each research trainee … has an appropriately qualified and trained supervisor”

• The Code requires researchers to

“(1.6) cite awards, degrees … publications accurately”
VMIA RGT: s4.4

“An institution may choose to delegate to its HREC Secretariat the …

(e) Assessment of qualifications of researchers”
“The CV provides a good check on whether the researchers have the skills to undertake the research. … If you feel that the CVs are inadequate check with the research team.”

“Check that a person is nominated as a back up if the principal investigator goes on holiday.”
Where did this lead us?

Review of NEAF s2, Q6 & 7 and CV is time consuming subjective and of limited value to justify appropriateness to conduct research

*Problem 1. Lack of consistent information from researchers*

*Problem 2. Lack of specific guidance by regulators*
Aim: To simplify this decision

Question: How do researchers interpret the requirements?

• Step 1: Audit of NEAF answers to s2 Q6 & 7
• Step 2: Audit of the CVs
Who are our researchers?

Results

11 NEAF audited = 62 researchers
Gender: 54% male to 46% female
What qualifications did our researchers state in the NEAF s2?
What research experience did our researchers state in the NEAF s2?

<table>
<thead>
<tr>
<th>Experience</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior experience</td>
<td>57%</td>
</tr>
<tr>
<td>No research experience</td>
<td>20%</td>
</tr>
<tr>
<td>Missing</td>
<td>8%</td>
</tr>
<tr>
<td>Principal Researcher</td>
<td>7%</td>
</tr>
<tr>
<td>Publication</td>
<td>7%</td>
</tr>
<tr>
<td>ICH GCP</td>
<td>2%</td>
</tr>
<tr>
<td>Grants success</td>
<td>0%</td>
</tr>
<tr>
<td>Researcher supervision</td>
<td>0%</td>
</tr>
</tbody>
</table>
Results from NEAF Audit

• Q6 “Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?”
  
  “No” = 100%

• Q7 “Do the researchers/investigators or others involved in any aspect of this research project require any additional training in order to undertake this research?”
  
  “No” = 79%
Results of CV audit

Researchers didn’t always provide a CV with their NEAF

- 24 (36%) CVs were received with 11 applications involving 67 investigators / researchers

Information was inconsistent and of little use to justify appropriateness to conduct research

- Generally clinical or job focused
- Little or no research focus
- Varying information provided
What can we do about it?

HREC Secretariat needs access to information to comply with the Code and justify each researcher’s appropriateness to conduct research.

Who has this information?

… the researchers!

… how can we get it now?
Let’s ask them to fill out a form!
‘Relevance’ – Researcher decides

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Research component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training (accredited courses)</td>
<td>ICH GCP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List previous positions /employment/experience (relevant to this project)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>List previous experience in research / clinical trials</td>
<td>Protocol design</td>
<td>Recruitment</td>
<td>Consent</td>
</tr>
<tr>
<td></td>
<td>Data collection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data management</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trial Procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>List current and past HREC project reference numbers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>List your publications that the topic or methods are relevant to this project</td>
<td></td>
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</tr>
</tbody>
</table>

Declaration I hereby declare that the information contained in this form is true and correct.

Name of Applicant
Signature of Applicant
Date

Local policy while we wait for the regulators

BHS Researcher Credentials Guideline

Principles

BHS staff that are named researchers or investigators on research projects will:

1. Be adequately experienced and qualified, or supervised, to conduct research.

2. Provide evidence to “justify their skill and expertise” (NS1.1a).
Conclusion

We want to comply with the Code and NS …

*Did some thinking, auditing,*
*Wrote some local policy*
*Made a tool*
*Test, trial and review … stay tuned until next update 2015😊*

Thank you

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