HRA Approval
• 400 face to face meetings with NHS/ LCRN/ HEI

• Emails to change contacts in every R&D office

• 60+ companies trained
Thank you!

• If you have been involved in readiness reviews
• If you have read the guidance and asked questions
• If you have trained colleagues
• If you have fed back what has gone well
• If you have fed back what could be better
HRA Approval applications

Median approval time in calendar days with no clock stop as at end April 2016

- Non-REC
- REC Proportionate Review
- REC Commercial
- REC non-Commercial

- time from REC decision to HRA Approval
- time to REC decision
Amendments Categorised

As at end April 2016

Category A 48%
Category B 19%
Category C 33%

Median time to categorisation 11 calendar days
Breakdown of Requests for HRA Approval up to 14th May

- Non-REC: 1%
- REC Proportionate Review: 9%
- REC Commercial: 19%
- REC non-Commercial: 71%
Median Time for HRA Approval for pre-HRA Approval studies

Median approval time in calendar days with no clock stop as at end April 2016

- Non-REC: 18
- REC Proportionate Review: 14
- REC Commercial: 14
- REC non-Commercial: 14
HRA Assessment Team

Assessment Manager

Nottingham: Senior Assessors, Assessors

Jarrow: Senior Assessors, Assessors

Manchester: Senior Assessors, Assessors

Bristol: Senior Assessors, Assessors

London: Senior Assessors, Assessors

Application Administrators and Amendment Co-ordinators
HRA Approval – Reflections

- Pre-HRA Approval studies
  - Use of SSI forms was very variable – and often just a metric trigger point
  - Some people getting in “just in case”
  - Not following instructions re listing and providing current document set
  - Everyone reads information differently
HRA Approval – Reflections

- New HRA Approval studies
  - NHS sites wanting to see studies coming through
  - Change enabled other local changes and to clear out non-moving studies
  - Some sites not yet aligned processes and issuing “permission”
  - Some sites taking assessment queries to sponsor not HRA
- Website has clear information, but difficult to find
High level process with HRA Approval

1. Applicant completes IRAS Form
   - Complete and submit other forms

2. Applicant submits IRAS pack to HRA
   - Applicant sends local package to site team

3. HRA issues outcome of initial assessment
   - Applicant adds initial HRA letter to local package

4. HRA issues HRA Approval to CI
   - Applicant sends HRA Approval to site

5. Organisation confirms capacity and capability

Site team = R&D team + research delivery team (PI, research nurses, etc) + LCRN team (for portfolio studies)
See www.rdforum.nhs.uk contacts

www.supportmystudy.nihr.ac.uk
Local set-up steps for sponsors
This diagram shows the process for setting up NHS participating organisations in England

1. Identify
   - Site identification
     • Starts before or after HRA application
     • Clinical Research Network support if needed

2. Assess
   - Assess capacity & capability
     • Send final protocol to research team and R&D/LCRN support
     • Official site selection
     • Sometimes assessment is not appropriate, e.g., staff research

3. Arrange
   - Practical arranging
     • Send local information pack to research team and R&D/LCRN support (includes HRA Initial Assessment Letter)
     • Sometimes no arranging is needed

4. Confirm
   - Exchange agreements
     • Send contract/agreement or Statement of Activities for signature
     • Site should be ready to recruit or start to agreed plan

5. Site Initiation
   - Sponsor initiates site
     • Send any supplies or medicinal products
     • Undertake any site initiation visit

Submit application to HRA

HRA initial Assessment letter issued
HRA Approval letter issued
Site ready to start/recruit
Applicant submits amendment to HRA

Sponsor sends amendment and categorisation to site cc R&D/ LCRN

35 days (Category A or B)

No objection from site

HRA confirms continuing HRA Approval

Sponsor sends letter to site cc R&D/ LCRN

HRA categorises amendment

Max 5 days

REC review

HRA confirms compliance with HRA assessment standards

MHRA approval

9 May 2016

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FAQs vs Q&A

• Timing of initial assessment letter – not a fixed date
• REC letter and versions vs Approval letter and versions – Approval is final
• HRA Approval for ‘historic’ studies – only for new sites
• Cross-border studies – follow nation-specific site process
Next stages for Technical Assurances
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9 May 2016
<table>
<thead>
<tr>
<th>Expert Advisors:</th>
<th>Reviewers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advise on development and delivery</td>
<td>Current professionals undertaking this work</td>
</tr>
<tr>
<td>Support Reviewers</td>
<td>Number of Reviewers recruited will relate to size of study roll-out phases</td>
</tr>
<tr>
<td>Train Reviewers and Technical Assurances Team</td>
<td>Application will be expression of interest with letter of support from line manager</td>
</tr>
<tr>
<td>Attend and provide input to conferences, update days, etc.</td>
<td>Undertake reviews of studies</td>
</tr>
<tr>
<td>Work with the Technical Assurances Manager to help with issues that arise during QC checks</td>
<td>Training and on-going support provided by TA team</td>
</tr>
</tbody>
</table>
Please let us know

- What is working well?
- What is working less well?
- Are there differences?
  - Secondary care, primary care, mental health, community care
  - Commercial, non-commercial
  - Study types
HRA Approval will continue to develop further

- Revisions to remaining model agreements
- Revisions to Research Passport guidance
- Develop REC – HRA assessment interaction
- Develop IRAS further
- Prepare for EU Clinical Trials Regulations
- Expand scope
HRA Approval is part of wider work

- Research transparency
- Timing of funding release
- Improving consistency of REC service
- Proportionate consent
- E-learning
Thank you

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www.hra.nhs.uk