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16th July 2018

Dear Practice

GDPR – General Data Protection Regulations – Poster for General Practice

Further to our briefing on 7th June (attached for info) relating to the new Data Protection Act as it relates to research, we have now prepared a poster for your waiting area which you can use to inform patients that you are a research active practice and that their care team may look at their health records to check eligibility to take part in a research study, before inviting them to participate.

As described in our last briefing, this poster can be used in conjunction with information displayed on your website, literature for new patients and any other relevant media (e.g. screens in waiting area) to ensure the requirements of transparency in the new Data Protection Act are met as a research active practice.

May I also remind you that NHS organisations are also expected to publish information about the research projects they are involved in. Such records should include details of the Sponsor, allowing participants to access further transparency information provided by sponsors. We are happy to assist with this as necessary.

Additional guidance can be found on the HRA website, which will continue to be updated as more details are available, or at the MRC Regulatory Support Centre, however please do not hesitate to contact us if you have any queries.

Kind Regards

Clare Symms
Research Management and Finance Lead
Norfolk & Suffolk Primary and Community Care Research Office
CRN Eastern (Eastern Corridor), NCH&C and ECCH

Viv Shaw
R&D Manager, NHS Cambridgeshire and Peterborough CCG; CRN: Eastern RMG Manager
Primary and Community Care RMG Centre
Cambridgeshire Community Services, and Primary Care (Western corridor)

Appendix 1 - Poster

GP Poster FINAL.pdf

Appendix 2 – GDPR Briefing of 7th June 2018

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7th June 2018

Dear Practice

GDPR – General Data Protection Regulations – Briefing Note for General Practice

As you will be aware the General Data Protection Regulations came into effect on 25th May 2018. This briefing note is intended to advise you on key elements with respect to research in General Practice; guidance for research sites on GDPR requirements is also accessible on the HRA website - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

For individual studies the Sponsor will be responsible for ensuring they meet the requirements of GDPR for their study, and in the vast majority of cases participants will not need to be re-consented in order to comply with GDPR; Sponsors may need to provide additional information to patients on how their data is being used, and may ask practice staff to do this for example at the next face to face where practices see the participants. This is in order to meet transparency requirements and the research teams will act on this.

As a research active organisation you will also need to give information to your patients about your research activities to ensure the requirements of transparency are met. There are a number of ways in which you may wish to do this:

Via your practice website:

NHS organisations are expected to link from their webpages about research and about general use of patient information to this text on the HRA website (which provides information about transparency).

This explicitly states that *"People in your care team may look at your health records to check whether you are suitable to take part in a research study, before asking you whether you are interested or sending you a letter on behalf of the researcher."*

For GDPR purposes, contacting patients registered with you as a GP to invite them to take part in research comes within public interest, and meets the additional requirements of public interest for access to special category data as long as the studies have HRA Approval (including REC approval

were relevant) and are undertaken in accordance with the UK policy framework for Research in Health and Social Care.

In your new patient material:

We suggest you include a statement to be clear that:

- your practice is research active,
- you may be invited to take part in research and
- your patient records may be reviewed to check whether you are suitable to take part in a research study before asking you whether you are interested or sending you a letter on behalf of the researcher,

together with a link to the transparency information (as described above) on the HRA website which gives more information about how your information may be used in research. Some suggested wording is attached (Appendix 1).

Inclusion of a poster about research in a prominent area in your waiting / reception area:

We are working on developing a standard poster for practices but in the interim you can use the wording provided in appendix 1

Inclusion of a statement on your waiting area screens:

We suggest using similar wording to that above for new patient literature

NHS organisations are also expected to publish information about the research projects they are involved in. Such records should include details of the Sponsor, allowing participants to access further transparency information provided by sponsors. We will be able to support this by generating a global list of studies and Sponsors for reference, or an extract of practice relevant studies from Edge research database should one be needed.

Use of Docmail

We are aware that practices may use Docmail either as part of routine business or research purposes. The requirements in GDPR regarding transparency applies to all processing of personal data and is not exclusive to research. We therefore suggest that if you use docmail in any capacity you are clear in the transparency information you provide to patients about your data processing activities.

We hope this is helpful, the information on the HRA website will be updated as more details are available, however please do not hesitate to contact us if you have any queries.
Additional information on GDPR in relation to research can also be found at the MRC Regulatory Support Centre.

Kind Regards

Clare Symms
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Appendix 1 – suggested wording for new patient literature

Our practice is research active.

All NHS organisations are expected to participate and support health and care research.

Conducting high-quality clinical research helps us to keep improving NHS care by finding out which treatments work best.

If you are asked about taking part in research, usually someone in the care team looking after you will contact you. People in your care team may look at your health records to check whether you are suitable to take part in a research study, before asking you whether you are interested or sending you a letter on behalf of the researcher.

For more information about how your information may be used in research and your rights please visit https://www.hra.nhs.uk/information-about-patients/