ACCEPTABLE PRACTICE TO IDENTIFY PATIENTS FOR PARTICIPATION IN CLINICAL RESEARCH TRIALS

The Privacy Rule describes how covered entities can implement patients' rights regarding use and disclosure of their Protected Health Information while maintaining the integrity of the research project. For activities involved in preparing for research, covered entities may use or disclose PHI to a researcher without an individual's authorization. However, the covered entity must obtain from the researcher representations that (1) the use or disclosure is requested solely to review PHI as necessary preparatory to research, (2) the PHI will not be removed from the covered entity in the course of review, and (3) the PHI for which use or access is requested is necessary for the research. The covered entity may permit the researcher to make these representations in written or oral form.

<u>According to HHS guidance on the Privacy Rule:</u>

> The preparatory to research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. However, the provision at 45 CFR 164.512(i)(1)(ii) does not permit the researcher to remove protected health information from the covered entity's site. *As such, a researcher who is an employee or a member of the covered entity's workforce could use protected health information to contact prospective research subjects*. The preparatory research provision would allow such a researcher to identify prospective research participants for purposes of seeking their Authorization to use or disclose protected health information for a research study.

Under the preparatory to research provision, a covered entity may permit a researcher who works for that covered entity to use PHI for purposes preparatory to research. A covered entity may also permit, as a disclosure of PHI, a researcher who is not a workforce member of that covered entity to review PHI (within that covered entity) for purposes preparatory to research. Within a hybrid entity, the situation is similar. A covered entity that is a hybrid entity may permit a researcher within its health care component to use, without an individual's Authorization, PHI for activities preparatory to research. A covered entity may also permit a researcher who is outside the hybrid entity's health care component to review PHI within that health care component without an individual's Authorization for purposes preparatory to research.

US Dept of Health and Human Services, National Institute of Health
HIPAA Privacy Rule Information for Researchers

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We believe participation in a research trial is an excellent opportunity to augment traditional therapy and we are hoping you will choose to offer your patients this alternative. If you make this decision to participate, although not required, there are several steps that can be taken to alert your patient population:

- Add an item to your Practice Privacy Statement that you will be participating in clinical research studies and that their charts may be reviewed for possible inclusion
- Post a notice in your waiting room stating the above
- Post a notice on your website stating the above
- Add an item to the paperwork each patient completes when they arrive for a visit notifying them of the above

If you choose to move forward, we will comply with whichever means you prefer to identify prospective study participants. However, we understand that this can be a time-consuming task and want to express our willingness to meet all of the obligations regarding protection of your patients' PHI while performing the review for you. The objective is to work together to provide an alternative treatment option for your patients while operating within the scope of the Privacy Rule.