ADVICE FROM THE COLLEGE AND BAREC FOR ETHICS COMMITTEES / SPONSORS ON THE USE OF EXTERNAL PLATFORM FOR RECRUITMENT

History table		
Prepared by: BAREC & College Board Approved by : College Board Date of endorsement : 03/08/2026		
Previous version	Adopted version	Summary of changes
//	Version 1 (05/08/2026)	First version of the document

Abbreviations used

BAREC	Belgian Association of Research Ethics Committees
GCP	Good Clinical Practice
ICF	Informed Consent Form
GDPR	General Data Protection Regulation

Advice

▪ Certain external companies[1] serve as online platforms (“call centers”) that assist in the recruitment of participants for specific studies. These companies promote the study through various digital channels, including social media. Interested individuals - whether potential participants, their family members, or healthcare professionals - can reach out to these organizations to obtain more information about the trial. During this interaction, certain personal details may be collected to conduct an initial prescreening. Eligible candidates may then be referred to participating research sites, and/or their contact information may be shared directly with the relevant sites.

While the use of such call centers may provide certain advantages in terms of accessibility and workload management, the College and BAREC are concerned about the broader implications of this approach. The use of recruitment platforms raises several important issues that warrant attention. Below, the College and BAREC have listed some key concerns related to this type of outsourcing, together with their advice on how to cope with those key concerns:

[1] E.g Ionis Call Center, TrialTech, Tricals, Clariness, Pivotal’s Patient Journey, Autocruitment...

1. **Privacy**: When external companies are involved in the recruitment process, the privacy of potential participants may not always be guaranteed. In some cases, data such as the language and location of potential participants may be shared with the sponsor. According to GCP guidelines [1], the identity of the participant must remain protected from the sponsor at all times. Furthermore, data retention periods can vary, and collected data are not always destroyed immediately.

2. **Need for consent**: It is essential that potential participants are clearly informed (through a privacy policy e.g. included in the ICF) about the nature and purpose of such data collection and processing and provide their explicit consent. Additionally, participants should have the option to withdraw their consent at any time.

   However, some platforms do not perform actual prescreening (i.e. collecting basic information to test against inclusion/exclusion criteria). Instead, they function solely as intermediaries or communication hubs (mainly only providing information about the study), often focusing on recruitment for specific rare pathologies. A distinction can thus be made between ‘recruitment’ and ‘prescreening’ but in both cases, the consent of the potential participant is required because personal data is being processed. If study-specific data are already being collected, as is typically the case during prescreening, an ICF must be administered and signed. Moreover, even during simple recruitment processes, the external partner already collects personal data from the potential participant (in order to provide information), for which a consent is also required.

3. **Patient Perception, Trust and Patient Loss**: Patients may feel that they are not adequately followed up or that they have no personal contact after enrolling in a study When the initial contact and (part of) the follow-up are handled by an external party. This can undermine their trust in the care provided and in the medical teams. As a result, participants are likely to exhibit reduced compliance due to a lack of connection. There is also a risk that patients who sign up for a study through a call center may be referred to another site than the site where the patient receives treatment. This could not only be detrimental to the patient but also disrupt the continuity of care.

   It is therefore important to actively inform patients about the existence and potential risks of such call centers. Clinical trial sites working with a call center are strongly encouraged to advise patients against engaging through these external channels without consulting their treating physician first. In addition, on initial contact, the call center should ask whether the potential participant is already a patient in a hospital participating as site in the study. If so, this person should be referred to that hospital for participation.

4. **Training and Language Barriers**: Call center staff may lack the necessary medical training, raising concerns about their ability to provide accurate information. Additionally, the language of communication is sometimes limited to English, which could create communication challenges for non-English-speaking patients.

It is therefore recommended to only work with a call center that has sufficient personnel being able to communicate in the language(s) being spoken by the patients that would be contacted and to have personnel that has the necessary training.

5. **Implication of the study site**: Furthermore, each site should be consulted to determine whether they wish to work with the platform. The initiative to use a call center must originate from the principal investigator or study team and must comply with the conditions outlined in this advice. It is moreover strongly advised that clinical trials sites or sponsors engage an external call center only if the site can provide sufficient justification or demonstrate added value for doing so, for example in cases of specific recruitment challenges.

6. **Type of study population:** It is important to distinguish between the recruitment of patients *versus* the recruitment of healthy volunteers. In the case of healthy volunteers, the individuals concerned will not be already undergoing treatment or follow-up. Therefore, issues related to continuity of care do not apply. The primary concerns associated with these platforms generally do not apply to the recruitment of healthy volunteers, but issues like language and privacy may still pose problems in this target group and should therefore be adequately addressed as well. Moreover, for this specific target group, such websites might also be necessary in order to reach a sufficient number of people. This contrasts with patients with whom the researcher-treating physician has direct contact.

▪ It can be concluded that significant caution surrounds the use of recruitment by an external call center, and that its application is only allowed under specific circumstances.

<u>In brief, the College and BAREC strongly advise to respect the following conditions when using call centers or external platforms for recruitment:</u>

1. **Privacy, Data Protection and Informed Consent:** Privacy and data protection must be ensured by obtaining informed consent, limiting data collection to only essential contact information (excluding unnecessary sensitive health data), securely storing participant data with confidentiality and defined retention, complying with GDPR requirements, and restricting its use strictly to study recruitment purposes.
2. **Transparency**: Privacy policy and any documents that detail the operational procedure and the qualification of the staff collecting the information or contacting the potential participant must be included in the clinical trial application file. Any changes must be communicated via a modification of the clinical trial application file and follow the conditions present it this document.
3. **Added value**: The call center's role must be justified. The added value of the intermediary must be clear and aligned with the interest of the clinical site.
4. **Staff training**: Call center staff must have sufficient medical knowledge to provide accurate information and prevent misunderstandings.
5. **Respect for the clinical site's relationship with participants:** Recruitment through a call center or external platform must not circumvent the clinical practice or interfere with the established relationship between the participant and the clinical site. Appropriate procedures must be in place to verify whether a potential participant is already under the care of, or has an existing relationship with, a participating clinical

site. In such cases, recruitment and further communication should be coordinated with, or referred back to, that site and treating physician.

6. **Language proficiency**: Call center staff must speak the participant's language to ensure clear and accurate communication.

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[1] GCP 1.58 Trial Participant Identification Code: A unique identifier assigned to each trial participant to protect the participant's identity and used in lieu of the participant's name when the investigator reports adverse events and/or other trial-related data.